EVALUATION OF THE CHRONIC PAIN MEDSCHECK TRIAL

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The technical information in this document is used by the Medical Services Advisory Committee (MSAC) to inform its deliberations. MSAC is an independent committee which has been established to provide advice to the Minister for Health on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost effectiveness. This advice will help to inform government decisions about which medical services should attract funding under Medicare.

MSAC's advice does not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

This report was prepared by HealthConsult. An Expert Panel was established by the Pharmacy Guild of Australia to oversee the trial and evaluation design as well as the trial implementation. The evaluation report was commissioned by the Pharmacy Guild of Australia as a requirement of the Sixth Community Pharmacy Agreement (6CPA) Pharmacy Trial Program (PTP) with funding provided by the Australian Government Department of Health.

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EXECUTIVE SUMMARY

This document is the Final Report of the Evaluation of the Chronic Pain MedsCheck (CPMC) Trial.

Chronic Pain MedsCheck Trial

The CPMC Trial was funded by the Australian Government Department of Health (the Department) as part of the Sixth Community Pharmacy Agreement (6CPA) Pharmacy Trial Program (PTP). The 6CPA PTP was established to trial new and expanded community pharmacy programs that seek to improve clinical outcomes for participants by progressing the role of community pharmacies in the delivery of primary healthcare services.

The Pharmacy Guild of Australia (the Guild) entered into a Grant Agreement with the Department to undertake this trial, and the Guild contracted HealthConsult to design and evaluate the effectiveness of the Trial. An Expert Panel was established by the Pharmacy Guild of Australia to oversee the Trial and evaluation design as well as the Trial implementation.

The primary objectives of the evaluation of the CPMC Trial were to determine:

- the efficacy of the CPMC intervention in preventing incorrect use and/or overuse of pain medication, increasing participant's pain medication health literacy, improving their ability to self-manage their chronic pain and improving their overall quality of life
- the acceptance of, and satisfaction with, the CPMC intervention by pharmacists, participants and referred providers
- the cost-effectiveness/utility of the CPMC intervention.

The CPMC intervention was an in-pharmacy, patient-centred service that focused on reviewing participant's medications and providing education and information to improve participant's self-management of chronic pain. The CPMC Trial was undertaken from November 2018 (commencement of patient recruitment) to February 2020 (last follow-up services conducted).

The CPMC Trial had two arms referred to as Group A and Group B:

- **Group A** pharmacies offered two face-to-face consultations with consenting eligible participants – an initial consultation and a follow-up consultation three months later.
- **Group B** offered two face-to-face consultations with consenting eligible participants – an initial consultation and a follow-up consultation three months later – in addition, a third contact point was at six weeks after the initial consultation, where a follow-up consultation was conducted by telephone.

The additional contact point was included in the CMPC Trial design based on expert advice which stated that patients with chronic pain are complex and require frequent contact with health professionals in order to enact change. This hypothesis was tested in a community pharmacy setting by the inclusion of Group B (three contact points) compared to Group A (two contact points).

Pharmacy recruitment to participate in the CPMC Trial occurred through an expression of interest (EOI) process issued by the Guild. All community pharmacies were invited to participate in the CPMC Trial, as per the Minister of Health's announcement.

All pharmacies that expressed an interest to participate were randomised to either Group A or Group B on a ratio of 1:1 (i.e. equal number of pharmacies randomised to Group A and Group B). In addition, a subgroup of community pharmacies was then selected at random from Group A and Group B to be "evaluation trial" sites instead of "main trial" sites. There was no difference in the intervention conducted by "main trial" or "evaluation trial" sites. However, three additional measures were required to be collected from the evaluation trial site participants (quality of life, health literacy and self-management) to inform the evaluation.

SUMMARY OF THE PICO

The Population, Intervention, Comparator and Outcomes (PICO) that guided the evaluation of the CPMC Trial is presented in Table 1. The PICO was considered and accepted by the Expert Panel.

Table 1 Criteria for guiding the evaluation of the CPMC Trial in participants with chronic pain

Component	Subgroup	Description
Population	Groups A and Group B	Individuals who: attended a community pharmacy; suffered from chronic pain for three months or longer; had not had a Home Medicines Review, MedsCheck, Diabetes MedsCheck or CPMC within the previous 12 months; were taking medication (prescription or over the counter) for their pain; were identified by a community pharmacists as either experiencing self-management or dependency issues; and were not active clients of a recognised Pain Management Service (to ensure the CPMC service did not duplicate existing services received by the trial participant).
Intervention	Group A	An initial in-pharmacy face-to-face consultation between the pharmacist and the trial participant which involves: a review and assessment of the trial participant's chronic pain experience and medication usage, including analgesics; provision of information, education and/or referrals; development of a written action plan with a focus on medication management education (including medication safety and efficacy), and self-management strategies to reduce reliance on medication alone for pain management. **A follow-up** in-pharmacy face-to-face consultation approximately **three months** after the initial consultation which involves a review and assessment against the written

Component	Subgroup	Description
		action plan, updating the action plan (if required) and providing follow-up support and referral as required.
	Group B	Same intervention as for Group A above, with additional **follow-up consultation** via telephone approximately 6 weeks after the initial consultation. The intervention carried out during the 6-week consultation was the same as the 3-month follow-up described for Group A.
Comparator/s	Group A (post-intervention)	The comparator groups for the Group A intervention are: • no service, with data collected on Group A participants prior to commencing the CPMC intervention and compared to data collected on Group A participants at the end of the CPMC intervention. • the Group B intervention, with data collected from Group A participants post-intervention compared to data collected from Group B participants post-intervention.
	Group B (post-intervention)	The comparator groups for the Group B intervention are: • no service, with data collected from Group B participants prior to commencing the CPMC intervention and compared to data collected from Group B participants at the end of the CPMC intervention. • the Group A intervention, with data collected from Group B participants post-intervention compared to data collected from Group A participant's post-intervention.
Outcomes	Groups A and B	**Patient relevant outcomes** • Decrease in pain severityα • Decrease in pain interferenceα • Decrease in psychological distress, depression and/or anxietyα • Improvements in quality of life* • Reduction in average daily morphine equivalent dose for participants taking opioid medicationα • Improvements in self-management of pain* • Improvements in health literacy* • Patient acceptance/satisfaction with the service* • Adherence to action plan*

Component	Subgroup	Description
		Cost-effectiveness outcomes • Cost per participant involved in the CPMC Trial • Cost per unit change in pain severity • Cost per unit change in pain interference • Cost per unit change in pain self-efficacy • Cost per unit change in self-management* **Cost-utility outcome** • Cost per Quality Adjust Life Years (QALY)* **Healthcare system outcomes** • Pharmacist/Pharmacy acceptance/satisfaction • Health care resource use (e.g., emergency department visits and/or admissions due to pain€, PBS utilisation)

[α] included in mini ePPOC (all sites) € Derived from self-reported data collected in mini-ePPOC (all sites) and linked MBS/PBS data for participants that provided consent from evaluation sites only *evaluation trial sites only

PHARMACY NUMBERS AND CHARACTERISTICS

From October 2018 to December 2019, 1,630 pharmacies registered for the CPMC Trial. Of these, 1,042 (63.9%) completed the training. Only 550 (33.7%) had at least one participant commence the CPMC Trial and complete their initial consultation. In total, 1,080 pharmacies (66.3%) either withdrew and provided notification, were lost to follow up, or did not have anyone commence the CPMC intervention and complete their initial consultation.

Pharmacy characteristic data including the type of pharmacy, location and dispensing model was collected from the 550 participating pharmacies, with participation defined as pharmacies that had at least one individual start the CPMC Trial and complete their initial consultation.

Overall, pharmacies in all States and Territories were represented in the CPMC Trial with the exception of Northern Territory. Most of the pharmacies were located in major cities (64.1%), with around a third located in inner and outer regional areas (32.8%) and only a very small proportion of pharmacies located in remote and very remote areas (3.1%).

In total, 453 (82.2%) of the participating pharmacies were main trial sites and 98 (17.8%) were evaluation trial sites. Group A and Group B had similar proportions of main and evaluation sites and spread of pharmacies across the different Pharmacy Accessibility and Remoteness Index for Australia (PhARIA) categories. The PhARIA was used to determine the accessibility of participating pharmacies. Most of the participating pharmacies were highly accessible (86.2%). Much smaller proportions of participating pharmacies were accessible (9.3%), moderately accessible (2.2%), remote (1.1%) and very remote (1.3%).

PARTICIPANT NUMBERS AND CHARACTERISTICS

A total of 8,239 individuals (termed 'participants') enrolled in the CPMC Trial and completed their initial consultation. Around two thirds of them participated in the trial at a main trial site (68.5%) and almost a third participated in the trial at an evaluation trial site (31.5%). Table 2 presents the number of participants that completed their initial, midpoint (Group B only) and follow-up consultations. In summary:

- Group A had a total of 4,316 participants (52% of the total number of participants) commence the CPMC Trial. Of these, 2,853 (66%) completed their follow-up consultation.
- Group B had 3,923 participants (48% of the total number of participants) commence the CPMC Trial. Over half of these participants (60%) completed their midpoint consultation and around a third (39%) completed their follow-up consultation.

Table 2 Number of CPMC Trial participants who completed initial, midpoint and follow-up consultations

Group	Consultation		
	Initial	Midpoint	Follow-up
Group A	4,316	-	2,853
Group B	3,923	2,335	1,521
TOTAL	8,239	2,335	4,374

Source: Participant data collected using Trial GuildLink software

There was no follow-up data for 3,865 of the 8,239 participants that commenced the Trial and completed their initial consultation. These participants represent 46.9% of the total initial sample and are considered to be lost to follow up.

The distribution of participants across the different age groups was comparable between the main trial and evaluation trial sites, with largest proportion of participants in the 70-74 year age range in both types of trial sites.

Across all pharmacies, 62.6% of participants were female and 37.4% of participants were male. There were similar differences in gender between participants at main and evaluation sites and between participants in Group A and Group B. The gender characteristics of participants across all trial sites were similar at the initial and follow-up timepoints.

To be eligible for the CPMC Trial, participants needed to have been experiencing pain for more than three months. Around half of them (47% in Group A and 50% in Group B) had experienced pain for more than five years, and most (85% in Group A and 82% in Group B) had experienced pain for over 12 months.

The most common reason pharmacists invited individuals to participate in the CPMC Trial across all pharmacies was suboptimal chronic pain management (26.9%), followed by taking analgesics including non-prescription and complementary medicines (20.0%), difficulties in maintaining activities of daily living due to pain (10.8%), and taking opioids (<50 OME) (10.8%).

The number of pain sites reported by participants at their initial consultation was similar between Groups A and B, with the largest proportion of participants experiencing pain at 2-3 sites. The site of pain most commonly reported by participants at their initial consultation across all pharmacies was the back (24.6%), followed by leg (11.1%), knee (10.4%) and arm/shoulder (10.3%).

Prior to commencement of the CPMC intervention, around three quarters of the participants in both Group A and Group B reported experiencing pain all the time, either at varying levels of intensity or the pain was always present at the same intensity. Participants were also asked to rate the severity of their pain in the past week. At the start of the intervention, 22% reported experiencing mild pain, 31% reported experiencing moderate pain and 47% reported experiencing severe pain.

The key characteristics of participants who were lost to follow-up were comparable to those of participants that completed their follow-up consultation, except participants that attended their follow-up consultation had slightly higher proportions belonging in the older age categories, defined as 65 years and above, and living in a major city. The frequency and severity of the pain experienced by participants prior to commencing the intervention were also comparable between those that completed their follow-up consultation and those who were lost to follow-up.

IMPACT ON PARTICIPANT OUTCOMES

Overall, the CPMC intervention delivered by both Group A and Group B pharmacies has been shown to be effective in improving a number of participant health outcomes, including pain severity, pain interference and overall level of psychological distress. Participation in the CPMC intervention also helped individuals improve their pain self-efficacy and self-management, which suggests they are better equipped to manage their chronic pain and are more confident in performing daily activities despite their pain. Group B demonstrated greater improvements, in terms of the effect size, in most of these participant outcomes from initial to follow-up compared to Group A. Table 3 provides a summary of the changes in key participant outcomes by Group A and Group B sites.

Table 3 Summary of the changes in the key outcomes from initial to follow-up in Groups A and B

	Initial measure			**Follow-up measure**			**Change from initial to follow-up**			
	n	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**Mean**	**95% CI**		**P value**
								Upper	**Lower**	
Pain severity										
Group A	4,316	6.09 (2.08)	6	2,853	5.20 (2.24)	5	-0.89	-0.79	-0.99	0.00
Group B	3,923	6.15 (2.20)	6	1,521	4.60 (2.54)	5	-1.55	-1.41	-1.69	0.00
Pain interference (general activities)										
Group A	4,316	5.72 (2.62)	6	2,853	4.81 (2.58)	5	-0.91	-0.78	-1.03	0.00

	Initial measure			Follow-up measure			Change from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value
								Upper	Lower	
Group B	3,923	5.80 (2.73)	6	1,521	4.15 (2.79)	4	-1.65	-1.49	-1.82	0.00
Pain interference (sleep)										
Group A	4,316	5.27 (3.04)	6	2,853	4.38 (2.86)	5	-0.88	-0.74	-1.03	0.00
Group B	3,923	5.25 (3.15)	5	1,521	3.56 (2.91)	3	-1.69	-1.51	-1.88	0.00
Psychological distress										
Group A	4,316	3.35 (3.38)	2	2,853	2.62 (2.96)	2	-0.73	-0.58	-0.88	0.00
Group B	3,923	3.47 (3.60)	2	1,521	2.33 (3.20)	1	-1.13	-0.93	-1.34	0.00
Pain self-efficacy										
Group A	4,316	7.37 (3.08)	8	2,853	8.14 (2.80)	8	0.77	0.91	0.63	0.00
Group B	3,923	7.22 (3.31)	7	1,521	8.60 (3.19)	9	1.38	1.57	1.18	0.00
Self-management total score										
Group A	1,452	71.08 (14.35)	72	725	76.69 (13.41)	78	5.61	6.86	4.36	0.00
Group B	565	72.82 (15.71)	76	239	73.98 (15.00)	76	1.16	3.51	1.18	0.00
AQoL utility score										
Group A	1,443	0.58 (0.26)	0.61	725	0.63 (0.25)	0.68	0.05	0.07	0.03	0.00
Group B	562	0.53 (0.28)	0.54	234	0.70 (0.24)	0.75	0.17	0.21	0.13	0.00
Average morphine equivalent dose										
Group A	2,161	50.84 (63.90)	30	1,359	49.87 (62.35)	30	-0.97	3.33	-5.26	0.07
Group B	1,809	47.74 (54.30)	30	700	47.82 (54.52)	30	0.08	4.82	-4.67	0.60
Healthy literacy total score										
Group A	1,450	39.05 (11.3)	39	725	45.71 (9.52)	46	6.66	7.63	5.71	0.00

	Initial measure			Follow-up measure			Change from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value
								Upper	Lower	
Group B	565	44.11 (12.27)	46	238	44.60 (12.01)	47	0.49	2.34	1.36	0.60
ED presentations										
Group A	4,316	0.16 (0.65)	0	2,853	0.15 (0.62)	0	-0.01	0.01	-0.04	0.67
Group B	3,923	0.16 (0.69)	0	1,521	0.14 (0.65)	0	-0.02	0.01	-0.03	0.40
Hospital admissions										
Group A	4,316	0.10 (0.47)	0	2,853	0.09 (0.48)	0	-0.00	0.00	-0.01	0.26
Group B	3,923	0.10 (0.43)	0	1,521	0.09 (0.46)	0	-0.00	0.00	-0.01	0.50
Vegetable intake										
Group A	4,316	2.51 (1.36)	2	2,853	2.74 (1.30)	3	0.23	0.17	0.29	0.00
Group B	3,923	2.63 (1.43)	2	1,521	3.31 (1.35)	3	0.68	0.59	0.76	0.00

Abbreviations: AQOL, The Assessment of quality of life instrument; CI, Confidence interval; ED, Emergency department; SD, Standard deviation

There were improvements in the severity of pain experienced by participants from initial to follow-up in both Groups and these changes were statistically significant. On average, Group B participants demonstrated a greater improvement in their pain severity over time from initial to follow-up compared to Group A participants.

There were also improvements in the degree of interference the participant's pain had on both their general activities and sleep from initial to follow-up in both Groups, and these changes were also statistically significant. On average, Group B participants demonstrated greater improvements in the degree of pain interference compared to Group A participants from initial to follow-up on both their general activities and sleep from initial to follow-up.

The average level of psychological distress experienced by participants at the initial consultation were similar in Groups A and B and both Groups demonstrated statistically significant improvements from initial to follow-up.

Pain self-efficacy scores were similar in Groups A and B at the start of the intervention. There were improvements in the participant's levels of self-efficacy from initial to follow-up in both Groups A and B, and these changes were statistically significant. On average, Group B participants demonstrated a

greater improvement in their self-efficacy in managing their pain from initial to follow-up compared to Group A participants.

Group A participants improved their average self-management and health literacy total scores from initial to follow-up and both increases were statistically significant. Group B participants also had a statistically significantly higher average self-management score at follow-up compared to initial but the increase in their average health literacy total score was not statistically significant.

There was a statistically significant improvement in the average AQoL utility score from initial to follow-up in Group A participants that was almost clinically important (i.e. change of 0.06 units or more).[1] Group B participants also demonstrated a statistically significant improvement in their average AQoL utility score from initial to follow-up and this change was clinically important.

There was no change in the average daily morphine equivalent dose in Group A or Group B participants from initial to follow-up. Given the intervention was only over a three month period, advice from Expert Panel membership suggests this is not unexpected in the short timeframe.

Less than 10% of participants in both Groups reported at the initial and follow-up timepoints that they had visited the hospital, either as a presentation to an Emergency Department (ED) or hospital admission, in the last month as a result of their pain. On average, participants in both Group A and Group B reported fewer ED presentations due to their chronic pain at follow-up compared to the initial timepoint (0.15 c.f. 0.16 times in Group A and 0.14 c.f. 0.16 times in Group B) but these changes were not statistically significant. Participants also reported fewer hospital admissions because of their pain, on average, at follow-up compared to the initial timepoint. Again, this change was not statistically significant.

Participants were asked two questions on vegetable intake and consumption of sugar sweetened drinks because it was hypothesised by members of the Australian Pain Society, that optimising diet with healthy food allows gut bacteria to thrive, which results in a reduction in inflammation and pain. Vegetable intake and consumption of sugar sweetened drinks were similar in Groups A and B at the start of the intervention and there were statistically significant improvements in both measures from initial to follow-up in both Groups. On average, Group B participants demonstrated greater improvements in these two nutritional measures.

At the start of the intervention, 22% of participants (n=1,813) reported experiencing mild pain, 31% (n=2,591) reported experiencing moderate pain and 47% (n=3,835) reported experiencing severe pain. Subgroup analyses using data combined from both Groups A and B showed that, on average, participants' pain severity (Table 4) decreased from initial to follow-up regardless of whether their pain was mild (3.02 to 2.82), moderate (5.55 to 4.71) or severe (7.97 to 6.23) prior to commencing the intervention. However, participants that had moderate or severe pain at the initial timepoint benefited more from the intervention, demonstrating significantly larger improvements to their average pain severity scores, with reductions of 15.3% and 21.5% respectively, compared to those that had mild pain, with a reduction of 8.3%, from the start of the intervention.

Table 4 Changes to average pain severity scores for different categories of pain severity

	Pain severity score at initial			Pain severity score at follow-up			Change in pain severity score from initial to follow-up (using only matched data)			
Pain severity experienced at initial	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value***
Mild pain	1,813	3.02 (1.03)	3	961	2.82 (1.77)	3	961	-0.25 (1.69)	-8.28	N/A#
Moderate pain	2,591	5.55 (0.50)	6	1,407	4.71 (1.81)	5	1,407	-0.85 (1.81)	-15.3	0.00
Severe pain	3,835	7.97 (1.00)	8	2,006	6.23 (2.13)	7	2,006	-1.71 (2.09)	-21.5	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Mild pain category was used the comparison group in this regression modelling

Similarly, subgroup analyses using data combined from both Groups A and B showed that, on average, participants' pain interference to general activities (**Error! Reference source not found.**) also decreased from initial to follow-up regardless of whether their pain was mild (3.17 to 2.58), moderate (5.33 to 4.33) or severe (7.30 to 5.72) prior to commencing the intervention. However, participants who had moderate or severe pain at the initial timepoint benefited more from the intervention, demonstrating statistically significantly larger improvements to their average pain interference scores, with reductions of 17.6% and 21.8% respectively, compared to those that had mild pain, with a reduction of 16.7%, at the start of the intervention.

Table 5 Changes to pain interference (to general activities) levels for different categories of pain severity

	Pain interference score at initial			Pain interference score at follow-up			Change in pain interference score from initial to follow-up (using only matched data)			
Pain severity experienced at initial	**N**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value***
Mild pain	1,813	3.17 (2.10)	3	961	2.58 (2.07)	2	961	-0.53 (1.85)	-16.72	N/A#
Moderate pain	2,591	5.33 (2.06)	5	1,407	4.33 (2.29)	5	1,407	-0.94 (2.14)	-17.64	0.00
Severe pain	3,835	7.30 (2.16)	8	2,006	5.72 (2.57)	6	2,006	-1.59 (2.35)	-21.78	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Mild pain category was used the comparison group in this regression modelling

Further subgroup analyses using data combined from Group A and B Group showed the average AQoL utility scores increased the most for participants whose pain severity and pain interference to general activities improved and, conversely, became worse for participants whose pain severity and interference became worse (Table 6). There were also slight improvements in the average AQoL utility score, pain self-efficacy and self-management for participants whose pain severity and pain interference to general activities were unchanged from initial to follow-up. This suggests those that were more confident and able to manage their pain and perform their daily activities despite their ongoing chronic pain experienced improved quality of life.

Table 6 Average change in AQoL utility scores depending on whether participants' pain severity and interference (to general activities) changed from initial to follow-up

	AQoL utility score at initial			**AQoL utility score at follow-up**			**Change in AQoL utility score from initial to follow-up (using only matched data)**			
	n	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value***
Changes in pain severity from initial to follow-up										
Pain severity improved	755	0.57 (0.26)	0.60	560	0.70 (0.24)	0.75	382	0.10 (0.22)	0.27	0.00
Pain severity unchanged	313	0.52 (0.29)	0.56	239	0.58 (0.26)	0.62	155	0.03 (0.26)	0.10	N/A#
Pain severity became worse	194	0.59 (0.25)	0.64	160	0.57 (0.24)	0.56	109	-0.02 (0.24)	-0.07	0.22
Changes in pain interference (general activities) from initial to follow-up										
Interference improved	703	0.56 (0.26)	0.59	537	0.70 (0.23)	0.75	366	0.10 (0.22)	0.24	0.00
Interference unchanged	362	0.55 (0.28)	0.59	275	0.60 (0.27)	0.65	176	0.04 (0.25)	0.10	N/A#
Interference became worse	197	0.59 (0.25)	0.64	147	0.54 (0.25)	0.55	104	-0.04 (0.26)	-0.10	0.05

Source: Evaluation data collected via Survey Monkey at the initial (n=1,443) and follow-up (n=565) timepoints, and participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

Note: AQoL questionnaire was administered only at the evaluation sites during the initial and follow-up consultations. Not all participants who responded to questions about their pain severity and interference completed the AQoL questionnaire.

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Unchanged pain severity and pain interference categories were used as the comparison groups in this regression modelling

TRANSLATION ISSUES

The economic model used CPMC Trial intervention data, CPMC evaluation data which included linked MBS and PBS data. The key translation issues are summarised below in Table 7.

Table 7 Translation issues

Type	Issue	Comments
Applicability	Generalisability of the evidence • Comparability of trial population vs. general Australian population ○ Baseline characteristic • Determination of the cost of the pharmacy intervention by trial arm	In general, the population in the CPMC Trial was comparable to the Australian population with chronic pain. HealthConsult conducted an activity-based costing study to determine costs of the interventions. However, to align with standard practice for MSAC assessment, the trial fees and not the representative cost of the interventions have been used in the economic model.
Extrapolation	• Time horizon of the model	The time horizon in the model was considered conservative as the condition does not lead to a reduction in survival. A pre vs post model was used with results after six months before and after trial initiation evaluated.
Transformation	• Derivation of reduction in PBS and MBS services and hospital costs data • Utilities applied in the economic evaluation • Application of participant reported outcomes using an unvalidated questionnaire in this population • Morphine equivalent units	Analysis on the reduction in PBS and MBS services undertaken from data requested from Services Australia. Self-reported emergency department presentation and hospitalisation data used. The utilities were calculated directly from the trial utilities The use of the mini-ePPOC tool and analysis of morphine units is discussed in Section C

Abbreviations: CPMC, Chronic pain MedsCheck; MBS, Medicare Benefits Schedule; mini-ePPOC, mini- electronic Persistent Pain Outcomes Collaboration; MSAC, Medical services advisory committee; PBS, Pharmaceutical Benefits Schedule

Pre-modelling studies are included in Section C to address these issues. A summary of the findings of each pre-modelling study and its implications to the economic evaluation is presented in Table 83.

ECONOMIC EVALUATION

A stepped economic evaluation of the CPMC Trial was not possible. Instead, a pragmatic pre vs post analysis was undertaken. Costs and outcomes at baseline were assumed to be reflective of Treatment-As-Usual (TAU). Results at the 3-month follow up were analysed to determine whether the interventions were effective in providing benefits to CPMC Trial participants. A summary of the key characteristics of the economic evaluation is provided in Table 8. A total of 24 analyses were conducted.

Table 8 Summary of the economic evaluation

Perspective	**Healthcare system**
Comparator	Treatment-As-Usual (TAU)
Type of economic evaluation	Cost utility analysis (CUA) and cost effectiveness analysis (CEA)
Sources of evidence	CPMC Trial
Time horizon	Six months
Outcomes	**Primary outcome:** Cost per QALY **Secondary Outcomes:** Cost per unit reduction in pain interference measured using the BPI as part of the mini-ePPOC Cost per unit reduction in pain severity measured using the BPI as part of the mini-ePPOC Cost per unit reduction in pain self-efficacy measured using the PSEQ-2 as part of the mini-ePPOC Cost per unit increase in self-management measured using the PIH Cost per unit reduction in morphine equivalent units Cost per PBS script reduction Cost per MBS service reduction
Methods used to generate results	Trial based. A quasi-experiment of pre vs post intervention
Discount rate	Not applicable as the model duration is less than one year
Software packages used	Microsoft Excel 2016

Abbreviations: BPI: Brief pain inventory; CPMC, Chronic Pain MedsCheck; MBS, Medicare benefits schedule; mini-ePPOC, The miniature electronic persistent pain outcomes collaboration questionnaire; PBS, Pharmaceutical benefits scheme; PIH, The Partners in health scale; PSEQ-2, Pain self-efficacy questionnaire

Key structural assumption of the model are: analyses assume that baseline results obtained prior to (or at the start of) the initial intervention are indicative of TAU.

The overall costs and outcomes, and incremental costs and outcomes as calculated for the intervention and comparative intervention in the model, and using the base case assumptions, are shown by groups analysed (Group A and Group B in Table 9 and Table 10, respectively). For the primary analysis, ICERs showed that Groups A and B are dominant to TAU (i.e. lower costs and greater outcomes). For morphine units, pain interference, pain severity, MBS services and PBS scripts – lower outcome values are more desirable. For calculation purposes, the incremental gain in outcomes was inversed. Group B has a cost saving ICER of $2,578.43 per unit of morphine lost.

Table 9 Results of the economic evaluation: Group A

Incremental cost per QALY

	CPMC intervention	**TAU**	**Increment**
Costs	$1,378.46	$1,513.57	-$135.11
QALYs	0.63	0.58	0.05
Cost per QALY	DOMINANT		

Incremental cost per unit change for self-management assessed using the PIH scale

	CPMC intervention	**TAU**	**Increment**
Costs	$1,378.46	$1,513.57	-$135.11
Units	76.69	71.08	5.61
Cost per unit change	DOMINANT		

Incremental cost per unit change in morphine equivalent units

	CPMC intervention	**TAU**	**Increment**
Costs	$1,378.46	$1,513.57	-$135.11
Units	49.87	50.84	0.97
Cost per unit change	DOMINANT		

Incremental cost per reduction change in moderate-severe pain interference in participants assessed using the BPI

	CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11
Proportion moderate-severe	0.65	0.79	0.14
Cost per reduction in moderate-severe participants	DOMINANT		

Incremental cost per reduction change in moderate-severe pain severity in participants assessed using the BPI

	CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11
Proportion moderate-severe	0.58	0.70	0.11*
Cost per reduction in moderate-severe participants	DOMINANT		

Incremental cost per unit change in participants achieving meaningful functional outcomes assessed using the PSEQ-2

	CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11
Change	0.65	0.53	0.12
Cost per unit change	DOMINANT		

Incremental cost per unit change in PBS script usage

	CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11
Units	8.10	9.78	1.68

	CPMC intervention	TAU	Increment
Cost per unit change	DOMINANT		

Incremental cost per unit change in MBS service usage

	CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11
Units	7.85	10.49	2.64
Cost per unit change	DOMINANT		

Abbreviations: BPI: Brief pain inventory; CPMC, Chronic Pain MedsCheck; MBS, Medicare benefits schedule; QALY, Quality adjusted life years; PBS, Pharmaceutical benefits scheme; PIH, Partners in health scale; PSEQ-2, Pain self-efficacy questionnaire; TAU, Treatment as usual

Note: For morphine units, pain interference, pain severity, MBS services and PBS scripts – lower outcome values are more desirable. For calculation purposes, the incremental gain in outcomes were inversed.

Note * rounding error

Table 10 Results of the economic evaluation: Group B

Incremental cost per QALY

	CPMC intervention	TAU	Increment
Costs	$1,180.00	$1,386.27	-$206.27
QALYs	0.70	0.53	0.17
Cost per QALY	DOMINANT		

Incremental cost per unit change for self-management assessed using the PIH scale

	CPMC intervention	TAU	Increment
Costs	$1,180.00	$1,386.27	-$206.27
Units	73.98	72.82	1.16
Cost per unit change	DOMINANT		

Incremental cost per unit change in morphine equivalent units

	CPMC intervention	**TAU**	**Increment**
Costs	$1,180.00	$1,386.27	-$206.27
Units	47.82	47.74	-0.08
Cost per unit change	$2,578.43		

Incremental cost per reduction change in moderate-severe pain interference in participants assessed using the BPI

	CPMC intervention	**TAU**	**Increment**
Costs	$1,180.00	$1,386.27	-$206.27
Proportion moderate-severe	0.52	0.77	0.26
Cost per reduction in moderate-severe participants	DOMINANT		

Incremental cost per reduction change in moderate-severe pain severity in participants assessed using the BPI

	CPMC intervention	**TAU**	**Increment**
Costs	$1,180.00	$1,386.27	-$206.27
Proportion moderate-severe	0.58	0.69	0.11
Cost per reduction in moderate-severe participants	DOMINANT		

Incremental cost per unit change in participants achieving meaningful functional outcomes assessed using the PSEQ-2

	CPMC intervention	**TAU**	**Increment**
Costs	$1,180.00	$1,386.27	-$206.27

	CPMC intervention	TAU	Increment
Change	0.62	0.50	0.13
Cost per unit change	DOMINANT		

Incremental cost per unit change in PBS script usage

	CPMC intervention	TAU	Increment
Costs	$1,180.00	$1,386.27	-$206.27
Units	5.69	7.84	2.15
Cost per unit change	DOMINANT		

Incremental cost per change in MBS service usage

	CPMC intervention	TAU	Increment
Costs	$1,180.00	$1,386.27	-$206.27
Units	5.88	10.33	4.44
Cost per unit change	DOMINANT		

Abbreviations: BPI: Brief pain inventory; CPMC, Chronic Pain MedsCheck; MBS, Medicare benefits schedule; QALY, Quality adjusted life years; PBS, Pharmaceutical benefits scheme; PIH, Partners in health scale; PSEQ-2, Pain self-efficacy questionnaire; TAU, Treatment as usual

Note: For morphine units, pain interference, pain severity, MBS services and PBS scripts – lower outcome values are more desirable. For calculation purposes, the incremental gain in outcomes were inversed.

Group B is dominant to Group A, for the primary outcome of cost/QALY. When comparing results for three secondary outcomes (pain self-management, morphine equivalence and pain severity) for Group B vs A, cost saving ICERs per unit lost were obtained (~$45, ~189 and ~$99,000 per outcome, respectively, Table 11).[2] As there are no published willingness to pay thresholds for these outcomes, it is difficult to determine if these cost savings are acceptable. Group B is dominant (i.e. lower costs and greater outcomes) to Group A in other analyses. For the pain-severity analysis, three decimal places have intentionally been shown to provide clarity behind the ICER presented.

Table 11 Results of the economic evaluation: Group B vs A

Incremental cost per QALY

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental QALYs	0.17	0.05	0.12
Cost per QALY	DOMINANT		

Incremental cost per unit change for self-management assessed using the PIH scale

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental units	1.16	5.61	-4.45
Cost per unit change	$44.57		

Incremental cost per unit change in morphine equivalent units

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental units	-0.08	0.97	-1.05
Cost per unit change	$189.42		

Incremental cost per reduction change in moderate-severe pain interference in participants assessed using the BPI

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental change in proportion moderate-severe	0.26	0.14	0.12
Cost per reduction in moderate-severe participants	DOMINANT		

Incremental cost per reduction change in moderate-severe pain severity in participants assessed using the BPI

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental change in proportion moderate-severe	0.109*	0.111*	-0.002*
Cost per reduction in moderate-severe participants	$99,231.13		

Incremental cost per unit change in participants achieving meaningful functional outcomes assessed using the PSEQ-2

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental change	0.13	0.12	0.01
Cost per unit change	DOMINANT		

Incremental cost per unit change in PBS script usage

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental units	3.40	2.56	0.84
Cost per unit change	DOMINANT		

Incremental cost per unit change in MBS service usage

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental units	4.44	2.64	1.80
Cost per unit change	DOMINANT		

Abbreviations: BPI: Brief pain inventory; CPMC, Chronic Pain MedsCheck; MBS, Medicare benefits schedule; PBS, Pharmaceutical benefits scheme; QALY, Quality adjusted life years; PIH, Partners in health scale; PSEQ-2, Pain self-efficacy questionnaire; TAU, Treatment as usual

Note: For morphine units, pain interference, pain severity, MBS services and PBS scripts – lower outcome values are more desirable. For calculation purposes, the incremental gain in outcomes were inversed.

* Three decimal places shown to demonstrate the difference between both groups

For brevity, results of the primary analysis (cost/QALY) are presented in Table 12. Modelled results were most sensitive to hospitalisation and MBS costs in Groups A and B as well as B vs A. As with Groups A and B vs TAU, in all sensitivity analyses Group B is dominant (i.e. greater outcomes and lower costs) over Group A for cost per QALY. Consequently, individual ICERs calculated for each sensitivity analysis was not produced in Table 12.

Table 12 Key drivers of the economic model

Description	**ICER**
Group A	
Base case	DOMINANT
Intervention hospitalisation costs increased from $438.16 to $514.40 (Upper bound of 95% CI)	DOMINANT
Intervention hospitalisation costs decreased from $438.16 to $361.93 (Lower bound of 95% CI)	DOMINANT
Intervention emergency department presentation costs from $109.15 to $125.92 (Upper bound of 95% CI)	DOMINANT
Intervention emergency department presentation costs from $109.15 to $92.39 (Lower bound of 95% CI)	DOMINANT
Intervention CPMC Trial costs increased from $131.22 to $157.46 (20% relative increase)	DOMINANT
Intervention CPMC Trial costs decreased from $131.22 to $104.98 (20% relative decrease)	DOMINANT
Intervention PBS costs increased from $250.91 to $279.04 (Upper bound of 95% CI)	DOMINANT
Intervention PBS costs decreased from $250.91 to $222.77 (Lower bound of 95% CI)	DOMINANT
Intervention MBS costs increased from $449.01 to $515.29 (Upper bound of 95% CI)	DOMINANT
Intervention MBS costs decreased from $449.01 to $382.73 (Lower bound of 95% CI)	DOMINANT
Intervention QALYs increased from 0.63 to 0.65 (Upper bound of 95% CI)	DOMINANT
Intervention QALYs decreased from 0.65 to 0.61 (Lower bound of 95% CI)	DOMINANT
TAU hospitalisation costs increased from $498.13 to $565.98 (Upper bound of 95% CI)	DOMINANT
TAU hospitalisation costs decreased from $498.13 to $430.29 (Lower bound of 95% CI)	DOMINANT
TAU emergency department presentation costs from $114.43 to $128.55 (Upper bound of 95% CI)	DOMINANT
TAU emergency department presentation costs from $114.43 to $100.30 (Lower bound of 95% CI)	DOMINANT

Description	ICER
TAU PBS costs increased from $310.94 to $345.80 (Upper bound of 95% CI)	DOMINANT
TAU PBS costs decreased from $310.94 to $276.07 (Lower bound of 95% CI)	DOMINANT
TAU MBS costs increased from $590.07 to $631.78 (Upper bound of 95% CI)	DOMINANT
TAU MBS costs decreased from $590.07 to $548.36 (Lower bound of 95% CI)	DOMINANT
TAU QALYs increased from 0.59 to 0.60 (Upper bound of 95% CI)	DOMINANT
TAU QALYs decreased from 0.59 to 0.57 (Lower bound of 95% CI)	DOMINANT
Group B	
Base case	DOMINANT
Intervention hospitalisation costs increased from $457.31 to $568.78 (Upper bound of 95% CI)	DOMINANT
Intervention hospitalisation costs decreased from $457.31 to $345.84 (Lower bound of 95% CI)	DOMINANT
Intervention emergency department presentation costs from $101.65 to $125.67 (Upper bound of 95% CI)	DOMINANT
Intervention emergency department presentation costs from $101.65 to $77.63 (Lower bound of 95% CI)	DOMINANT
Intervention CPMC Trial costs increased from $164.03 to $196.84 (20% relative increase)	DOMINANT
Intervention CPMC Trial costs decreased from $164.03 to $131.22 (20% relative decrease)	DOMINANT
Intervention PBS costs increased from $145.94 to $172.42 (Upper bound of 95% CI)	DOMINANT
Intervention PBS costs decreased from $145.94 to $119.45 (Lower bound of 95% CI)	DOMINANT
Intervention MBS costs increased from $311.07 to $367.11 (Upper bound of 95% CI)	DOMINANT
Intervention MBS costs decreased from $311.07 to $255.03 (Lower bound of 95% CI)	DOMINANT
Intervention CPMC Trial QALYs increased from 0.70 to 0.73 (Upper bound of 95% CI)	DOMINANT
Intervention CPMC Trial QALYs decreased from 0.70 to 0.67 (Lower bound of 95% CI)	DOMINANT
TAU hospitalisation costs increased from $495.91 to $568.47 (Upper bound of 95% CI)	DOMINANT
TAU hospitalisation costs decreased from $495.91 to $423.35 (Lower bound of 95% CI)	DOMINANT
TAU emergency department presentation costs from $101.87 to $125.94 (Upper bound of 95% CI)	DOMINANT
TAU emergency department presentation costs from $101.87 to $77.79 (Lower bound of 95% CI)	DOMINANT
TAU PBS costs increased from $216.92 to $256.28 (Upper bound of 95% CI)	DOMINANT

Description	ICER
TAU PBS costs decreased from $216.92 to $177.55 (Lower bound of 95% CI)	DOMINANT
TAU MBS costs increased from $560.16 to $599.89 (Upper bound of 95% CI)	DOMINANT
TAU MBS costs decreased from $560.16 to $520.44 (Lower bound of 95% CI)	DOMINANT
TAU QALYs increased from 0.53 to 0.55 (Upper bound of 95% CI)	DOMINANT
TAU QALYs decreased from 0.53 to 0.51 (Lower bound of 95% CI)	DOMINANT
Group B vs A	
Base case	DOMINANT
Group B hospitalisation costs increased from $457.31 to $568.78 (Upper bound of 95% CI)	DOMINANT
Group B hospitalisation costs decreased from $457.31 to $345.84 (Lower bound of 95% CI)	DOMINANT
Group B emergency department presentation costs from $101.65 to $125.67 (Upper bound of 95% CI)	DOMINANT
Group B emergency department presentation costs from $101.65 to $77.63 (Lower bound of 95% CI)	DOMINANT
Group B CPMC Trial costs increased from $164.03 to $196.84 (20% relative increase)	DOMINANT
Group B CPMC Trial costs decreased from $164.03 to $131.22 (20% relative decrease)	DOMINANT
Group B PBS costs increased from $145.94 to $172.42 (Upper bound of 95% CI)	DOMINANT
Group B PBS costs decreased from $145.94 to $119.45 (Lower bound of 95% CI)	DOMINANT
Group B MBS costs increased from $311.07 to $367.11 (Upper bound of 95% CI)	DOMINANT
Group B MBS costs decreased from $311.07 to $255.03 (Lower bound of 95% CI)	DOMINANT
Group B trial incremental QALYs increased from 0.17 to 0.20 (Arbitrary 20% increase)	DOMINANT
Group B CPMC Trial QALYs decreased from 0.17 to 0.14 (Arbitrary 20% decrease)	DOMINANT
Group A hospitalisation costs increased from $438.16 to $514.40 (Upper bound of 95% CI)	DOMINANT
Group A hospitalisation costs decreased from $438.16 to $361.93 (Lower bound of 95% CI)	DOMINANT
Group A emergency department presentation costs from $109.15 to $125.92 (Upper bound of 95% CI)	DOMINANT
Group A emergency department presentation costs from $109.15 to $92.39 (Lower bound of 95% CI)	DOMINANT
Group A CPMC Trial costs increased from $131.22 to $157.46 (20% relative increase)	DOMINANT
Group A CPMC Trial costs decreased from $131.22 to $104.98 (20% relative decrease)	DOMINANT
Group A PBS costs increased from $250.91 to $279.04 (Upper bound of 95% CI)	DOMINANT

Description	ICER
Group A PBS costs decreased from $250.91 to $222.77 (Lower bound of 95% CI)	DOMINANT
Group A MBS costs increased from $449.01 to $515.29 (Upper bound of 95% CI)	DOMINANT
Group A MBS costs decreased from $449.01 to $382.73 (Lower bound of 95% CI)	DOMINANT
Group A CPMC Trial QALYs increased from 0.05 to 0.06 (arbitrary 20% increase)	DOMINANT
Group A CPMC Trial QALYs decreased from 0.05 to 0.04 (arbitrary 20% decrease)	DOMINANT

Abbreviations: CI, confidence intervals; ICER, Incremental cost effectiveness ratio; MBS, Medicare benefits schedule; PBS, Pharmaceutical benefits scheme QALY, Quality adjusted life year.

There is a strong association between chronic pain and mental health conditions such as depression, anxiety or mental health problems in general. Pain is also associated with sleep disorders.3 Consequently, additional codes analysed under system groups N03, N05 and N06 were included in the analysis (originally codes for N02A N02B, N02C, M01A and M02A were analysed which cover for opioids, anti-neuropathic, migraine medications and NSAIDs). These additional codes cover for anticonvulsants, benzodiazepines and antidepressants, respectively. When analysing results by system groups, every group (excluding NSAIDs) saw a decrease in scripts per patient in both Groups A and B. NSAID usage slightly increased by an average of 0.09 and 0.08 scripts per patient in Group A and B, respectively, but this gain was not statistically significant.

An increase in Allied Health usage was observed in Group A (8.2% increase, 0.21 services), while service usage significantly declined in Group B (31.3% decrease, 0.76 services). This could be due to the additional contact with the pharmacist but smaller participant numbers in Group B at follow up may have meant any increase in service usage were unable to be detected.

ESTIMATED EXTENT OF USE AND FINANCIAL IMPLICATIONS

An epidemiological approach was used to estimate the financial implications of the introduction of the CPMC intervention for chronic pain. The ongoing inclusion of the CPMC intervention is expected to result in a decrease in the average number of PBS scripts and MBS services, hospitalisations and ED presentations for participants.

The financial implications to the Governments resulting from the continuation of the CPMC intervention are summarised in Table 13 by results from Group A, B, and B vs A. From these results and assuming all eligible participants (28,814 individuals in 2021, increasing to 30,695 in 2025) partake in the intervention, cost savings to the Commonwealth government and State and Territories health departments are expected. If all eligible participants undertook the Group A or Group B intervention a saving of $49.74 million and $160.51 million, is estimated, respectively over the five-year period indicated in Table 13. Group B resulted in greater cost savings than Group A due to a greater number of MBS services averted. When comparing Group B to A, a cost to States and Territories is calculated. This is due to a greater number of hospitalisations avoided in Group A compared to Group B, which results in greater savings to States and Territories.

Table 13 Total costs to State and Territory governments with the pharmacist led pain intervention

	2021	2022	2023	2024	2025
Group A					
Cost of intervention	$3,780,972	$3,843,487	$3,905,703	$3,967,104	$4,027,749
MBS costs to Government	-$10,730,475	-$10,907,894	-$11,084,465	-$11,258,723	-$11,430,834
PBS costs to Government	-$810,027	-$823,420	-$836,749	-$849,903	-$862,896
Total cost to Commonwealth Government	-$7,759,530	-$7,887,827	-$8,015,511	-$8,141,522	-$8,265,981
Cost to States and Territories	-$1,871,883	-$1,902,832	-$1,933,634	-$1,964,033	-$1,994,057
Total cost of CPMC program	-$9,631,413	-$9,790,659	-$9,949,145	-$10,105,555	-$10,260,038
Group B					
Cost of intervention	$4,726,359	$4,804,505	$4,882,277	$4,959,031	$5,034,839
MBS costs to Government	-$31,894,760	-$32,422,110	-$32,946,942	-$33,464,899	-$33,976,473
PBS costs to Government	-$2,433,895	-$2,474,137	-$2,514,187	-$2,553,713	-$2,592,751
Total cost to Commonwealth Government	-$29,602,296	-$30,091,743	-$30,578,852	-$31,059,580	-$31,534,384
Cost to States and Territories	-$1,480,166	-$1,504,639	-$1,528,996	-$1,553,033	-$1,576,774
Total cost of CPMC program	-$31,082,463	-$31,596,382	-$32,107,848	-$32,612,613	-$33,111,159
Difference between Group B and A					
Cost of intervention	$945,387	$961,018	$976,575	$991,927	$1,007,091
MBS costs to Government	-$21,164,284	-$21,514,216	-$21,862,477	-$22,206,176	-$22,545,639
PBS costs to Government	-$1,623,868	-$1,650,718	-$1,677,438	-$1,703,809	-$1,729,855

	2021	2022	2023	2024	2025
Total cost to Commonwealth Government	-$21,842,766	-$22,203,916	-$22,563,341	-$22,918,058	-$23,268,404
Cost to States and Territories	$391,716	$398,193	$404,639	$411,000	$417,283
Total cost of CPMC program	**-$21,451,050**	**-$21,805,723**	**-$22,158,702**	**-$22,507,058**	**-$22,851,121**

Abbreviations: CPMC, Chronic pain MedsCheck; MBS, Medicare benefits schedule; PBS, Pharmaceutical benefits scheme

Note: Total Cost to Commonwealth Government calculated by adding Cost of intervention with MBS and PBS costs to Government.

CONSUMER IMPACT SUMMARY

In a participant survey, undertaken as part of the evaluation, that had a total of 186 completed responses, participants were asked at the conclusion of their CPMC intervention to reflect on whether they felt their knowledge and understanding of their chronic pain medications had changed as a result of the intervention. A large majority of the participants (81.7%) responded that they felt their overall knowledge and understanding of their chronic pain medication had improved as a result of the intervention and around a fifth reported noticing a definite improvement that has made a real and worthwhile difference.

Overall, participants described the CPMC intervention as “great”, “worthwhile” and “an excellent opportunity”. Other qualitative feedback obtained from participants indicated that participating in the CPMC Trial had helped improved their knowledge about the causes of their chronic pain, medications they were taking and their effects, pain management techniques other than medication, and the importance of a healthy diet and regular physical activity.

OTHER RELEVANT CONSIDERATIONS

The pharmacist’s experience of providing CPMC services was examined via a Pharmacist Satisfaction Survey, which had a low response rate of 43 completed responses. This explored the impact of completing training, assessing the consistency of service delivery and by determining pharmacists’ perception of the ease and usefulness of the CPMC Trial resources. In summary:

- Only just over half of the participants (n=24) reported that the CPMC Trial had a moderate to very high impact on improving their job satisfaction.
- The perceived ease of the CPMC Trial was mixed. ‘Following the intervention protocol’ and ‘using the mini-ePPOC tool’ were rated to be the easiest tools to use, and ‘developing an action plan’ was rated as being harder to perform.
- Nearly two thirds of pharmacists reported that the participant education resources were useful (26 of 43, or 60%).

- Pharmacists reported that the most substantial perceived benefits as a result of the CPMC Trial were seen in participants with mild to moderate pain and with mild depression, anxiety, or stress. They perceived that participants with severe pain and mild to severe depression, anxiety or stress were less likely to experience any benefits from this service.

Pharmacists were interviewed as part of the 24 case studies that were randomly selected from all pharmacies enrolled in the CPMC Trial. These pharmacists reported that the intervention changed their scope of practice in a mostly rewarding way. The intervention and its associated renumeration encouraged more in-depth patient assessments resulting in holistic treatment and care, and provided pharmacists with the opportunity to delve deeper into the various aspects of chronic pain (quality of life, pain severity, diet, exercise) which they felt helped them provide better advice to their patients.

CONCLUSION

The CPMC intervention was shown to be effective in improving a number of participant health outcomes, including pain severity, pain interference and overall level of psychological distress. Participation in the CPMC intervention also helped individuals improve their pain self-efficacy and management, which means they were better equipped to manage their chronic pain and were more confident in performing daily activities despite their pain.

The Group B intervention (i.e. three consultations) showed greater improvements in most of the participant health outcomes from initial to follow-up compared to Group A (i.e. two consultations).

The value of the midpoint telephone consultation in the Group B intervention was highlighted by pharmacists who were interviewed as part of the case studies as it provided them with an earlier opportunity to assess compliance to recommendations made during the initial consultation, reinforce key information and address any questions or issues the participants had. The usefulness of telephone follow-up of patients as part of pharmacy interventions has also been demonstrated in the literature, providing further support that the telephone consultation provided at midpoint may have been key to the achievement of the greater outcomes experienced by Group B participants.

Overall, participants that experienced all levels of pain severity and interference to general activities (mild, moderate or severe) at the start of the intervention benefited from completing the CPMC intervention. However, participants with moderate or severe pain or experienced moderate or severe pain interference at the initial timepoint appeared to have benefited more from the intervention.

For the primary analysis, Groups A and B are dominant to TAU (i.e. lower cost and greater outcomes). When comparing Group B to Group A, three secondary outcomes (morphine equivalence, self-management and pain severity scores) for Group B vs A, cost saving ICERs per unit lost were obtained (~$45 and ~$189 and ~$99,000 per outcome, respectively).[4] As there are no published willingness to pay values for these outcomes, it is difficult to determine whether these ICERs are acceptable. Group B is dominant to Group A in other analyses.

Overall, the CPMC intervention was deemed to provide greater value for money for those with moderate and severe levels of pain at the start of the intervention.

RECOMMENDATIONS

The Group B intervention is the recommended intervention model (i.e. face-to-face initial consultation and follow-up consultation with a telephone consultation at midpoint) if CPMC is to be implemented as an ongoing program. This is due to the Group B intervention resulting in greater improvements in most of the participant health outcomes at three months and was shown to be more cost-effective compared to Group A.

A number of aspects of the intervention have shown to be particularly effective in improving health outcomes, and in any future iterations of the intervention the recommendation is to continue the following:

- focus on improving the participants' pain self-efficacy levels and enabling them to manage their own pain effectively regardless of their pain severity and interference at the initial consultation
- motivate participants to adhere to the action plan provided as much as possible, and
- provide written referrals for participants to bring to their GP and/or an allied health professional where appropriate.

A number of changes are suggested, based on the feedback received during the CPMC Trial, to further improve participants' and pharmacists' experiences of the CPMC intervention if CPMC is implemented as a future program.

1. While the action plans were tailored for the individual based on their responses to the initial assessment questions, in the CPMC Trial they included all the recommended actions which was found to be overwhelming for the participants. Although it is important to allow individuals flexibility in which action/s to implement, it may be more helpful if a 'staged approach' is adopted where the pharmacist outlines the overall plan but works with the participant on implementing a few agreed actions. Progress should continue to be reviewed at each contact point and once the participant feels they are able to implement another action, it is added progressively to the action plan. Individuals' attempts to implement the recommended actions could also be better supported in between consultations through automated prompts and advice provided via email or SMS.
2. Additional work is needed to further improve pharmacists' use of technology to facilitate the delivery of the CPMC intervention. Pharmacists involved in the CPMC Trial found it challenging to work with the trial software including the assessment tools they needed to administer with the participant. The software was developed specifically for the CPMC Trial within a very short timeframe. A number of fixes were made during the CPMC Trial period but further enhancements are still required. The initial focus should be on automating the patient's results from their assessment and tailoring of the action plan, streamlining how the medication record

is populated and reviewed by the pharmacist whilst with the patient, and facilitating the GP and/or allied health professional referral process.

3. More targeted training and professional development opportunities may be helpful in supporting an ongoing high quality of care provided to participants as well as maintaining or increasing the pharmacists' motivation to deliver the CPMC intervention particularly during periods of less activity.
4. Pharmacists valued the patient assessments conducted at the consultations, as they provided them with an understanding of the participant's health and pain experience and were useful prompts for considering the key factors impacting on their pain and quality of life. A number of the outcome measures were, however, collected for the purposes of the evaluation only (i.e. assessment of QoL (AQoL-4D), PIH Scale and the health literacy questions) and are not required as part of an ongoing future delivery of the CPMC intervention. It is recommended that a monitoring process is set up if the CPMC program is delivered as part of routine practice and the intervention is evaluated periodically. Monitoring should involve the use of the mini ePPOC as a tool for pharmacists to assess the participants, guide treatment options and measure their outcomes. Future evaluations will benefit from the use of the AQoL-4D and PIH Scale but it is not recommended that the health literacy tool is used as it is not validated (no suitable tool was identified for the CPMC Trial and so an unvalidated one was used) and may therefore add to the participate burden unnecessarily.
5. Given the short duration of the CPMC Trial (i.e. three months), it would benefit from some additional research to understand participants' experiences of the service and the longer-term effectiveness (i.e. post three months) of the CPMC intervention. One potential way to do this would be to follow up with participants six months after they complete the CPMC intervention to assess whether any behavioural changes and outcomes are sustained and gain insight into the key enabling factors. Future research efforts may also include interviewing or surveying individuals who do not continue with the service and pharmacists who are unable to recruit individuals to further improve the intervention delivery. In addition, because some positive outcomes of the CPMC Trial were demonstrated at the midpoint consultation, it may be worthwhile conducting more evaluation activities for a subgroup of participants at that timepoint, such as administering the additional evaluation questions at the midpoint consultation, to explore this further.

ACRONYMS AND ABBREVIATIONS

Acronym/abbreviation	Meaning
6CPA	Sixth Community Pharmacy Agreement
AIHW	Australian Institute of Health and Welfare
ARTG	Australian Register of Therapeutic Goods
CI	confidence interval
CNS	central nervous system
CPA	community pharmacy agreement
CTCAE	common terminology criteria for adverse events
DALY	disability adjusted life year
FPM ANZCA	Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists
HESP	Health Expert Standing Panel
HRQoL	health-related quality of life
HTA	health technology assessment
ICER	incremental cost-effectiveness ratio
ITT	Intention to treat
MBS	Medicare Benefits Schedule
MD	mean difference
MSAC	Medical Services Advisory Committee
NHMRC	National Health and Medical Research Council
PASC	PICO Confirmation Advisory Sub-Committee of the MSAC
PBS	Pharmaceutical Benefits Scheme
PRO	Patient reported outcome
PTP	Pharmacy Trial Program
QALY	Quality adjusted life year
QoL	Quality of life
SD	Standard deviation
SEIFA	Socio-Economic Indexes for Areas
TAU	Treatment As Usual
TGA	Therapeutic Goods Administration

SECTION A CONTEXT

This report on the evaluation of the CPMC Trial is intended for review by the MSAC. MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Schedule (MBS) as well as other funding sources (e.g. community pharmacy agreements, CPA) in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

The CPMC Trial was funded by the Australian Government Department of Health (the Department) as part of the 6CPA PTP. The 6CPA PTP was established to trial new and expanded community pharmacy programs that seek to improve clinical outcomes for participants and by progressing the role of community pharmacies in the delivery of primary healthcare services.

The Pharmacy Guild of Australia (the Guild) entered into a Grant Agreement with the Department to undertake this trial, and the Guild contracted HealthConsult to design the Trial and evaluate the effectiveness of the Trial. This evaluation has been undertaken as part of the Grant Agreement requirements and may inform the Departments decision-making regarding whether the proposed intervention should be publicly funded under future CPAs.

Appendix A provides a list of the people involved in the Expert Panel that was established by the Guild to oversee the trial design and implementation (as required by the Department).

The proposed CPMC trial service was outlined in a Trial Protocol that was reviewed, considered and accepted by the Expert Panel. It was not considered and/or presented to the PICO Confirmation Advisory Sub-Committee (PASC).

This report has been prepared according to the Technical Guidelines for preparing assessment reports for the MSAC – Service Type: Investigative, using the standard template. It is important to note, however, that this template is not fit for purpose for a program evaluation report; therefore, any irrelevant sections are marked as "N/A" and some of the headings used in the standard MSAC template have been modified to make the report suitable for a program evaluation report.

An overview of the information provided in this report is provided below:

- **Section A**: Describes the Trial, including the target population and the intervention. It also provides an overview of the outcomes examined and the comparator groups utilised to evaluate the effectiveness of the Trial.
- **Section B:** Describes the evaluation methodology (including the data collection and analysis methods) and the results of the participant outcomes.
- **Section C**: Describes how the outcomes data presented in Section B have been translated for use in the economic model presented in Section D.
- **Section D**: Presents the economic evaluation of the Trial.

- **Section E**: Presents the financial implications of the CPMC service.
- **Section F**: Presents other findings identified by the evaluation of the CPMC service.

A.1. Items in the agreed PICO Confirmation

The evaluation of the CPMC Trial addresses all of the PICO elements that were pre-specified in the Trial Protocol that was presented to the Expert Panel.

A.2. Proposed Service – description of the CPMC

The CPMC intervention, is an in-pharmacy, patient-centred service that focused on reviewing participants' medications and providing education to improve participants' self-management of chronic pain. The trial design commenced in February 2018, and pharmacy recruitment began in September 2018 with participant recruitment beginning in November 2018.

The CPMC trial had two arms referred to as Group A and Group B. In summary:

- **Group A** pharmacies offered two face-to-face consultations with consenting eligible participants – an initial consultation and another three months later.
- **Group B** offered two face-to-face consultations with consenting eligible participants – an initial consultation and another three months later – the additional contact point was at six weeks after the initial consultation where a follow-up consultation was conducted by telephone.

Pharmacy recruitment to participate in the Trial occurred through an expression of interest (EOI) process issued by the Guild. The EOI included a description of the Trial as well as a description of the difference between participating as a Group A or Group B pharmacy. All community pharmacies were invited to participate in the trial, as per the Minister of Health's announcement at the time.

To be eligible to take part in the CPMC trial, pharmacies must have:

- been approved to dispense pharmaceutical benefits as part of the Pharmaceutical Benefits Scheme (PBS) defined in Section 90 of the National Health Act 1953 (Cth) (Section 90 pharmacy)
- been able to ensure that services are delivered by a Registered Pharmacist face-to-face with the participant in the community pharmacy or over the telephone (midpoint consultation only for Group B)
- provided evidence, if required, that there was an area of the community pharmacy that is physically separated from the retail trading floor so that privacy and confidentiality of the participant is protected
- been appropriately furnished with facilities (including a having a computer in the consultation room with the trial software loaded) to allow the participant and the pharmacist to sit down together
- been able to allow the participant and pharmacist to talk at normal speaking volumes without being overheard by any other person (including pharmacy staff)
- been able to obtain written participant consent in accordance with the Australian Privacy Principles (APP 3, APP5, APP6, APP 11 and APP 12)

- been accredited by an approved Pharmacy Accreditation Program
- followed the trial protocol (e.g. used the outputs of the mini-ePPOC tool (which was the data collection process built into the trial software) and the associated flow charts which detail the type of education, information and/or referrals to provide to the participant and guide the information included in their written action plan); and
- agreed to providing the data collected to HealthConsult Pty Ltd for the purpose of evaluation.

All pharmacies that expressed an interest to participate in the CPMC Trial were randomised to either Group A or Group B on a ratio of 1:1 (i.e. equal number of pharmacies randomised to Group A and Group B). After completing the required continuing professional development (CPD) accredited online training, pharmacists in each group recruited participants that met the inclusion/exclusion criteria (see section A.4 for further information). Pharmacists then provided their designated Group services according to the Trial protocol.

Of note, the CPMC service model for Group A was largely based on the Diabetes MedsCheck service model delivered by community pharmacies under the 6CPA. Hence, the Group A intervention included two consultations. The Group B intervention built on literature and expert advice which suggested participants suffering from chronic pain are complex participants who need additional support.[1,4,8] Therefore, an additional consultation was added. The initial consultation and final consultation for Group A and B were identical. The only difference between Group A and Group B was the additional consultation which occurred at midpoint of the intervention (i.e. six weeks after the initial consultation).

MARKETING STATUS OF DEVICE / TECHNOLOGY

Not applicable

OTHER INDICATIONS

Not applicable

CURRENT FUNDING ARRANGEMENTS

The Federal Department of Health funded the CPMC Trial under Tranche 3 of the PTP. The value of the grant was $20 million. The funding commenced in October 2018 and is due to expire at the end of June 2020.

A.3. Proposal for Public Funding

To be considered for funding under future CPAs.

A.4. Proposed population

The population eligible for the Trial were participants who:

- attended a community pharmacy
- over the age of 18
- holder of a valid Medicare card and/or DVA card

- living at home in a community setting
- suffered from chronic pain for three months or longer
- had not had a Home Medicines Review, MedsCheck, Diabetes MedsCheck or Chronic Pain MedsCheck within the previous 12 months
- had been taking medication (prescription or over the counter) for their pain
- were identified by a community pharmacist as either experiencing self-management or dependency issues, and
- not a current client of a recognised Pain Management Service.

A.5. Comparator Details

The comparator for the Trial was baseline data collected at the initial consultation (i.e. pre trial design). Participants who received the intervention from Group A pharmacies also served as comparators for participants who received the intervention from Group B pharmacies, and vice versa. See Table 14 for a summary.

Table 14 Summary of comparators to the CPMC intervention(s)

Intervention (data collection timepoint)	Comparator (Group and data collection timepoint)
Group A (three months post initial consultation)	Group A (baseline data collected at initial consultation)
Group B (three months post initial consultation)	Group B (baseline data collected at initial consultation)
Group A (change at three months post initial consultation)	Group B (change at three months post initial consultation)

A.6. Clinical management Algorithm(s)

Figure 1 presents the clinical management algorithm of the CPMC services offered by Group A compared to Group B pharmacies.

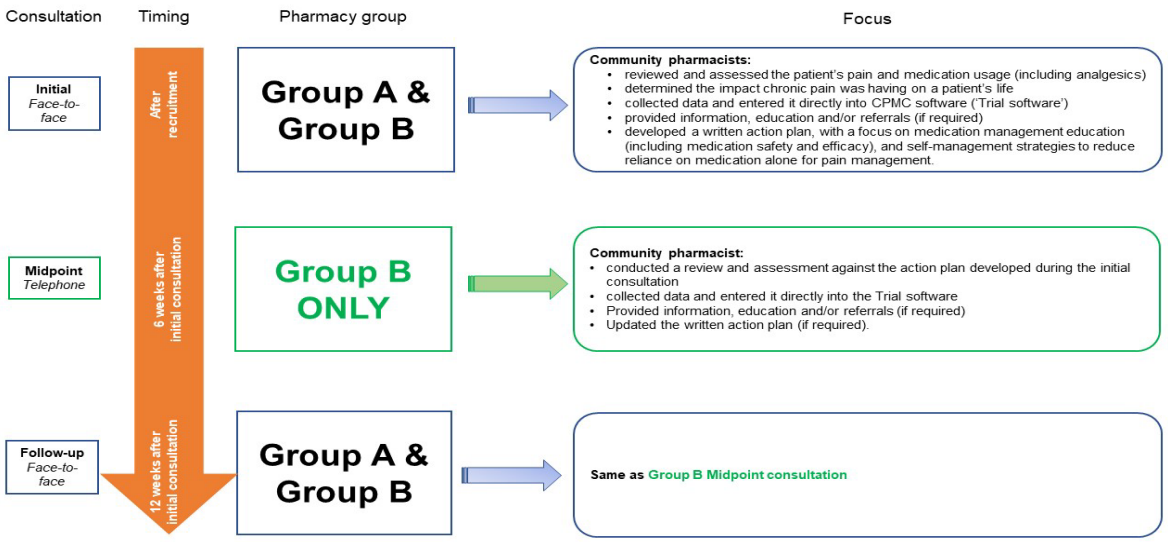


Figure 1 Overview of CPMC services offered by Group A and Group B pharmacies

Additional details about the intervention implemented at Group A and Group B pharmacies are provided in Figure 2 and Figure 3, respectively.

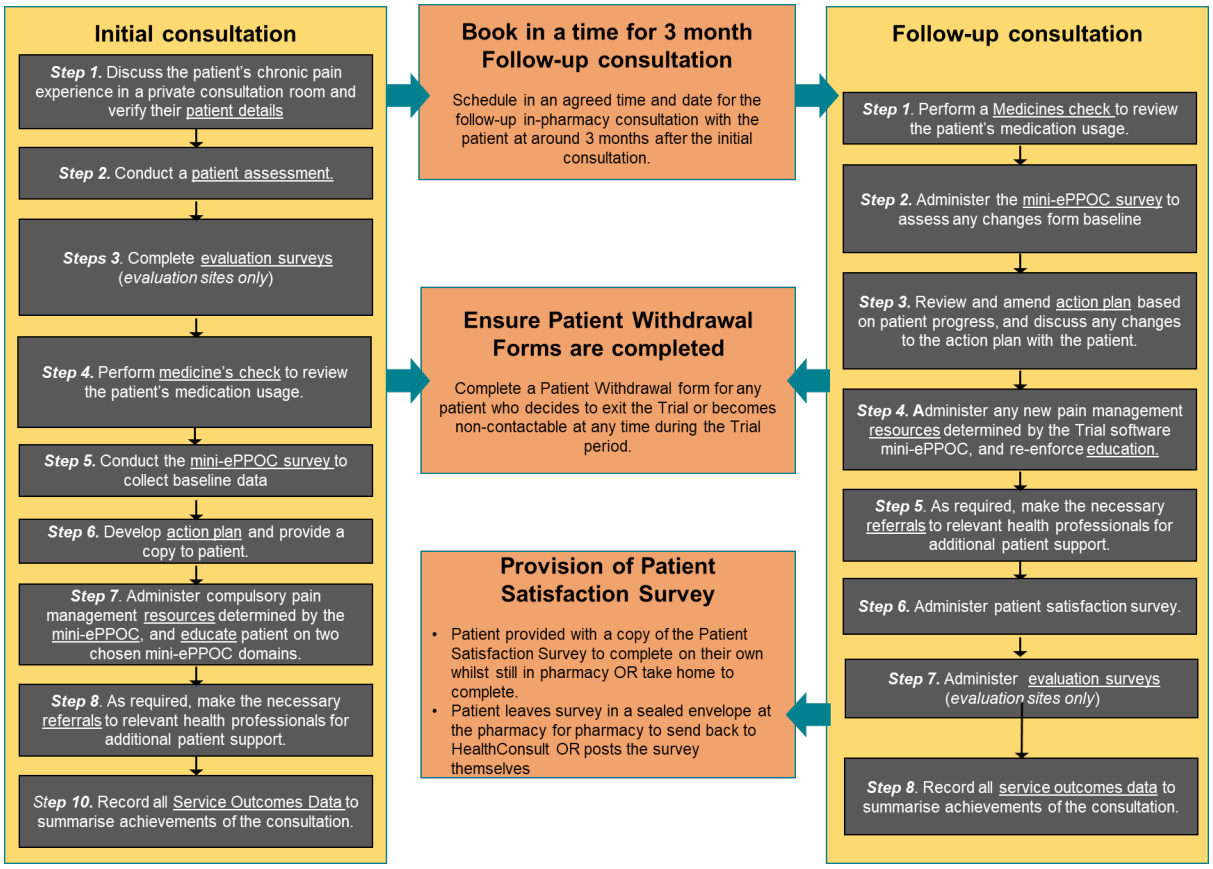


Figure 2 Detailed overview of the intervention implemented at Group A pharmacies

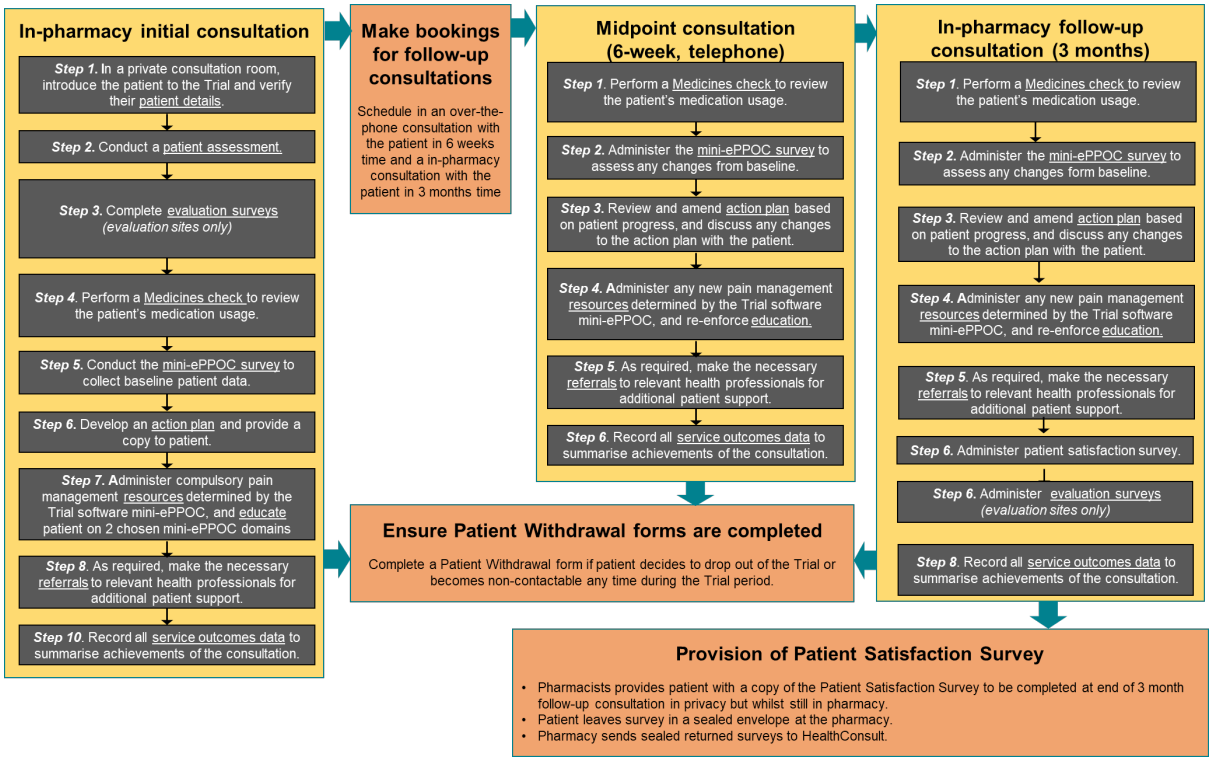


Figure 3 Detailed overview of the intervention implemented at Group B pharmacies

A.7. Key Differences in the Delivery of the Proposed Medical Service and the Main Comparator

The main comparator in the trial design is the trial participant's baseline data (i.e. baseline data collected at initial consultation) compared to the follow-up data (i.e. follow-up data collected at the three month follow-up). The trial participant endpoint data was also compared when analysing Group B versus A (i.e. data collected at the three month consultation). This is a classical pre and post trial/evaluation design. Group B was also compared to Group A, to assess whether having the additional contact point with the participant has any significant effect on their outcomes. The additional contact point was included in the trial design based on expert advice which stated that patients with chronic pain are complex and require frequent contact with health professionals in order to enact change. Hence this hypothesis was tested in a community pharmacy setting by the inclusion of Group B (three contact points) compared to Group A (two contact points).

A.8. Clinical Claim

Approximately one in five Australians are affected by chronic pain. This increases over the age of 65 where the number of people affected by chronic pain rises to one in three.[5,6] The prevalence of chronic pain is projected to increase as Australia's population ages.[7] It has been reported that 27% of chronic pain sufferers are classified as either Grade Chronic Pain III or IV which means that the pain was moderately to severely limiting.[8]

A summary of findings in relation to the impact of chronic pain includes:

- The total financial cost of chronic pain in Australia in 2018, was estimated to be $73.2 billion, comprising $12.2 billion in health system costs, 48.3 billion in productivity losses and $12.7 billion in other financial costs (such as informal care, aids and modifications and deadweight losses).[9]
- Over 40% of people living with chronic pain experience depression or anxiety[10] and a higher suicide rate compared to the general population.[11]
- People suffering with chronic pain experience greater limitations to daily activities such as social activities and physical tasks, than those without chronic pain.[12]
- Older adults with chronic pain have a higher risk of falls, worsening mobility and disability.[13]
- Chronic pain is the leading cause of early retirement and reduced level of workforce participation.[14]
- Chronic pain significantly deteriorates people's quality of life as it affects all dimensions of health-related quality of life, in particular, the physical and mental components. People with chronic pain also frequently experience sleep disturbances.[15]
- GP visits relating to chronic pain increased by 67% between 2006-2007 and 2015-2016, representing approximately 400,000 more encounters. Participants with chronic pain are also more likely to have longer hospital stays than those without chronic pain.[10]

As stated in the National Pain Strategy (2010)[16] "there is a key role for pharmacists in pain management, both in the hospital setting and in the community. Pharmacists support participants in getting the most out of their medicines. They are also ideally placed for monitoring chronic pain and triaging acute pain. Pharmacists monitor and advise on prescription medicines; they also assess and advise on supplementary use of non-prescription medicines, complementary medicines and potentially, non-pharmaceutical interventions. For chronic pain, the pharmacist plays an important role in supporting ongoing self-management".

Also aligned to the time of the announcement of trial funding was the introduction of all codeine-containing medicines becoming Prescription Only Medicines (includes combination analgesics and codeine-containing cough, cold and flu products). This presented an opportunity to further utilise the accessibility of community pharmacy as a screening agency with appropriate 'referral' for participants with poorly controlled chronic pain.

Pharmacists are experts in medicines and are the most accessible community healthcare professional for many individuals. Pharmacists already offer (in addition to their core dispensing role) competencies and services relevant to the needs of people living with and receiving treatments for pain. There are over 5,700 community pharmacies spread across metropolitan, regional and rural areas of Australia. The coverage and accessibility of community pharmacies means they are ideally placed for identifying participants with chronic pain.

The hypothesis was that community pharmacists could use their skills to identify chronic pain suffers, review their pain medication and then through the provision of a clinical consultation understand their chronic pain issues and advise them how to better manage their pain using pharmacological (e.g. non-prescription (including complimentary medicine) and/or lower dose pain medication) and/or or non-pharmacological participant education and/or information (e.g. self-management techniques or suggesting a referral to a local doctor or other health professionals for support).

In addition, there is often a lack of access to appropriate advice and support on chronic pain in the community, and it is difficult for participants to access effective treatment that is timely and affordable. Community pharmacists see participants on a regular basis without the need for an appointment. As such, pharmacists are ideally placed to provide a patient-based solutions to support participants who are suffering from chronic pain. The CPMC service was expected to fill a gap in pain management services.

A.9. Summary of the PICO

The Population, Intervention, Comparator and Outcomes (PICO) that guided the evaluation of the CPMC Trial are presented in Table 15. The PICO was considered and accepted by the Expert Panel.

Table 15 Criteria for guiding the evaluation of the CPMC Trial in participants with chronic pain

Component	Subgroup	Description
Population	Groups A and B	Individuals who: attended a community pharmacy; suffered from chronic pain for three months or longer; had not had a Home Medicines Review, MedsCheck, Diabetes MedsCheck or Chronic Pain MedsCheck within the previous 12 months; were taking medication (prescription or over the counter) for their pain; were identified by a community pharmacists as either experiencing self-management or dependency issues; and were not active clients of a recognised Pain Management Service (to ensure the Chronic Pain MedsCheck service did not duplicate existing services received by the participant).
Intervention	Group A	An initial in-pharmacy face-to-face consultation between the pharmacist and the participant which involves: a review and assessment of the participant's chronic pain experience and medication usage, including analgesics; provision of information, education and/or referrals; development of a written action plan with a focus on medication management education (including medication safety and efficacy), and self-management strategies to reduce reliance on medication alone for pain management. A 3-month follow-up in-pharmacy face-to-face consultation approximately three months after the initial consultation which involves a review and assessment against the written action plan, updating the action plan (if required) and providing follow-up support and referral as required.
	Group B	Same intervention as for Group A above, with additional 6-week follow-up via telephone approximately 6 weeks after the initial consultation. The intervention carried out during the 6-week consultation is the same as the 3-month follow-up described for Group A.
Comparator/s	Group A (post-intervention)	The comparator groups for the Group A intervention are: • no service, with data collected on Group A participants prior to commencing the CPMC intervention and compared to data collected on Group A participants at the end of the CPMC intervention. • the Group B intervention, with data collected on Group A participants post-intervention compared to data collected on Group B participants post-intervention.

Component	Subgroup	Description
	Group B (post-intervention)	The comparator groups for the Group B intervention are: no service, with data collected on Group B participants prior to commencing the CPMC intervention and compared to data collected on Group B participants at the end of CPMC intervention. the Group A intervention, with data collected on Group B participants post-intervention compared to data collected on Group A participants post-intervention.
Outcomes	Groups A and B	**Participant relevant outcomes** • Participant acceptance/satisfaction with the service* • Decrease in pain severityα • Decrease in pain interferenceα • Decrease in psychological distress, depression and/or anxietyα • Change in utilisation of pharmacological and/or non-pharmacological services or reduction in average daily morphine equivalent dose for participants taking opioid medication*α • Improvements in quality of life* • Improvements in health literacy* • Improvements in self-management of pain* • Adherence to action plan* **Cost-effectiveness outcomes** • Cost per participant involved in the trial • Cost per unit change in pain severity • Cost per unit change in pain interference • Cost per unit change in pain self-efficacy • Cost per unit change in self-management **Cost-utility outcome** • Cost per Quality Adjust Life Years (QALY) **Healthcare system outcomes** • Pharmacist/Pharmacy acceptance/satisfaction • Health care resource use (e.g. (emergency department visits and/or admissions due to pain€, PBS utilisation)

[α] included in mini ePPOC€ Derived from self-reported data collected in mini-ePPOC (all sites) and linked MBS/PBS data for participants that provided consent from evaluation sites only) *evaluation trial sites only

A.10. Consumer impact summary

In a trial participant survey for those who attended community pharmacies, undertaken as part of the evaluation, that had a total of 186 completed responses, participants were asked at the conclusion of their CPMC intervention to reflect on whether they felt their knowledge and understanding of their chronic pain medications had changed as a result of the intervention. A large majority of the participants responded that they felt their overall knowledge and understanding of their chronic pain medication had improved as a result of the intervention and around a fifth reported noticing a definite improvement that has made a real and worthwhile difference.

Overall, participants described the CPMC intervention as “great”, “worthwhile” and “an excellent opportunity”. Other qualitative feedback obtained from participants indicated that participating in the Trial had helped improved their knowledge about the causes of their chronic pain, medications they were taking and their effects, pain management techniques other than medication, and the importance of a healthy diet and regular physical activity.

SECTION B CLINICAL EVALUATION

B.1. Evaluation methodology

The primary objectives of the evaluation of the CPMC Trial were to determine:

- the efficacy of the CPMC in preventing incorrect use and/or overuse of pain medication, increasing participants' pain medication health literacy, improving their ability to self-manage their chronic pain and improve their overall quality of life
- the acceptance of, and satisfaction with the CPMC by pharmacists, participants and referred providers
- the cost-effectiveness/utility of the CPMC.

All pharmacies that expressed an interest to participate in the CPMC Trial were randomised to either Group A or Group B on a ratio of 1:1 (i.e. equal number of pharmacies randomised to Group A and Group B). In addition, initially 50 community pharmacies were selected at random from Group A and Group B (total of 100 pharmacies) to be "evaluation trial" sites as opposed to the "main trial" sites. Due to insufficient participant recruitment numbers at the evaluation sites and some of these sites withdrawing from the trial, the number of evaluation sites increased to 120 per group in June 2019, with 70 Group A main trial sites selected at random to become Group A evaluation trial sites and 70 Group B main trial sites selected at random to become to Group B evaluation trial sites. Consequently, the results of these additional evaluation sites were used for the economic evaluation.

There was no difference in the intervention conducted by "main trial" sites or "evaluation trial" sites. However, three additional outcome measures were required to be collected from the evaluation trial sites (quality of life, health literacy and self-management) and not by the main trial sites to inform the evaluation. Note the power of the trial was based on the evaluation trial sites which were a subset of the overall trial.

Figure 4 describes the timeline from Trial design/development to completion of data collection. As described in Section A, pharmacies that responded to the Guild's EOI were assessed for eligibility and randomised into Group A or Group B at a ratio of 1:1. Once they were allocated, 240 pharmacies were selected at random (120 from Group A and 120 from Group B) to be evaluation trial sites. Pharmacies that were *not* randomised as being an evaluation trial site are referred to as 'main' sites, and the evaluation trial sites are referred to as 'evaluation' sites.

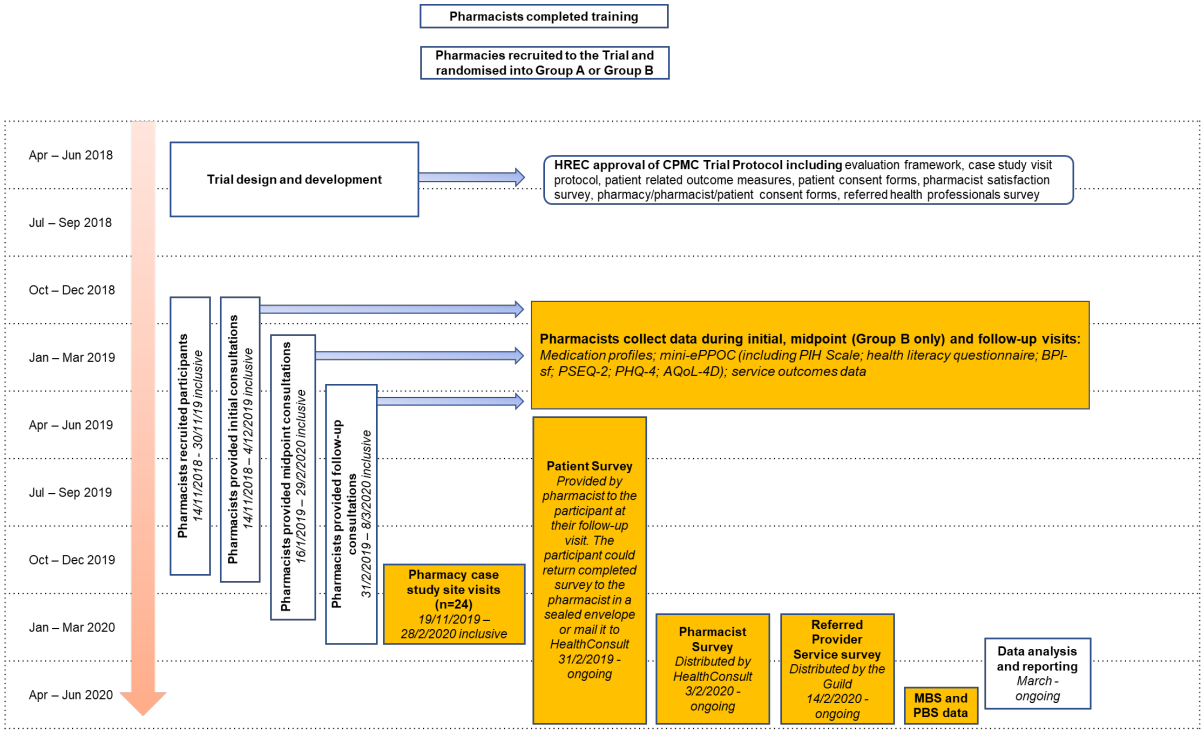


Figure 4 Description of the CPMC Trial evaluation

An evaluation framework was developed that guided the evaluation (see Appendix E). Ethics approval was provided by Bellberry Human Research Ethics Council (Protocol Number 2018-05-369).

The evaluation of the Trial involved collecting data from five main sources:

- Data collected on trial participants by pharmacists at the time of consultation and entered into pharmacy Trial software.
- Pharmacy case study site visits (qualitative data was gathered from 24 (12 from Group A and 12 from Group B) randomly selected pharmacies)
- Pharmacist Satisfaction Survey
- Referred Provider Satisfaction Survey
- Linked PBS and MBS data (from consenting individuals).

Further detail on the timing of data collection is provided in Section B.4.

B.2. Results of Literature Search

Not applicable

B.3. Risk of Bias Assessment

Not applicable

B.4. Characteristics of the evidence base

PHARMACY CHARACTERISTICS

According to data provided by the Guild, from October 2018 to December 2019, 1,630 pharmacies registered for the trial and were provided access to the mandatory training. A small proportion

(5.3%) of these pharmacies withdrew from the Trial shortly afterwards. A total of 1,042 (63.9%) completed the training and commenced participant recruitment and 550 (33.7%) had at least one participant commence the Trial and complete their initial consultation. In total, 1,080 pharmacies (66.3%) either withdrew and provided notification, were lost to follow up, or did not have anyone commence the CPMC intervention and complete their initial consultation (Figure 5).

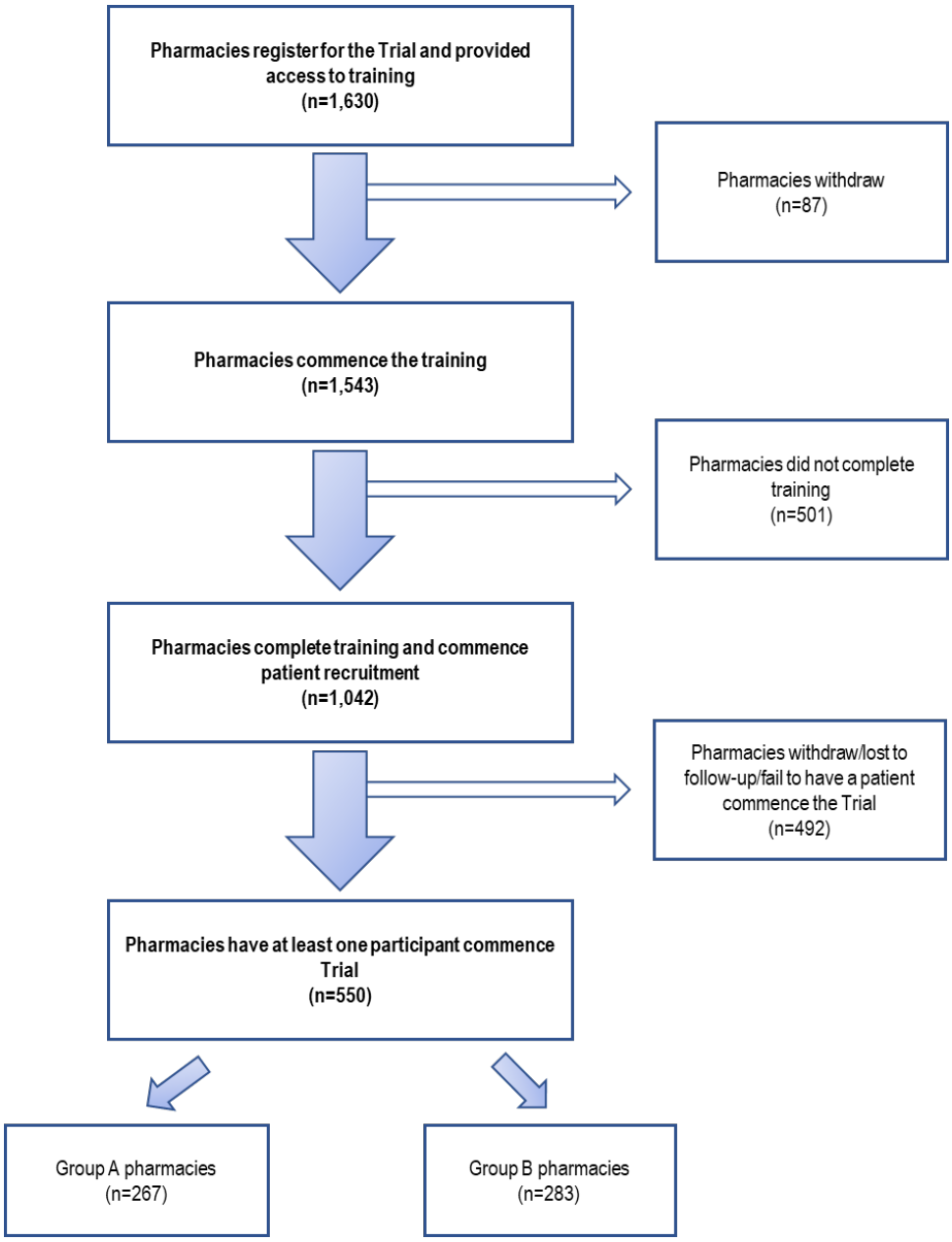


Figure 5 Flowchart of the number of pharmacies through the Trial

Data was collected on the type of pharmacy, location and dispensing model. This section presents the data reported by the 550 participating pharmacies, with participation defined as pharmacies that had at least one individual start the trial and complete their initial consultation.

Table 16 summarises the geographical locations[17] of the participating pharmacies. All pharmacies across Australia were invited to participate. All States and Territories were represented in the Trial

with the exception of Northern Territory (NT). The reason why no pharmacy from the NT participated in the Trial was not further investigated.

Most of the pharmacies were located in major cities (64%), with around a third located in inner and outer regional areas (33%) and only a very small proportion of pharmacies located in remote and very remote areas (3%).

Table 16 Number of participating pharmacies by state/territory and geographical location

State/Territory	Geographical location of pharmacy			Total
	Major city	Regional	Remote	
ACT	16	1	0	17
NSW	106	55	1	162
QLD	63	44	9	116
SA	57	13	1	71
TAS	0	20	1	21
VIC	45	27	0	72
WA	66	20	5	91
NT	0	0	0	0
Total	**353 (64.1%)**	**180 (32.8%)**	**17 (3.1%)**	**550 (100%)**

Source: Pharmacy Registration Survey, n = 549 at the initial timepoint

Abbreviations: ACT, Australian Capital Territory; NSW, New South Wales, QLD, Queensland; SA, South Australia; TAS, Tasmania; VIC, Victoria; WA, Western Australia; NT, Northern Territory

The Pharmacy Accessibility and Remoteness Index for Australia (PhARIA) was used to determine the accessibility of participating pharmacies. PhARIA is a composite index that incorporates measurements of geographic remoteness[18] with a professional isolation component represented by the road distance to the five closest pharmacies.

The index results, ranging from 0 (high accessibility) to 12 (high remoteness), have been divided into six categories as shown in Table 17.

Table 17 PhARIA categories

Category	Index	Accessibility/Remoteness
Category 1	0 - 1	Highly Accessible
Category 2*	>1 - 2	Accessible (Group A)
Category 3*	>2 - 4	Accessible (Group B)
Category 4	>4 - 6	Moderately Accessible
Category 5	>6 - 9	Remote
Category 6	>9 - 12	Very Remote

Source: https://www.adelaide.edu.au/hugo-centre/services/pharia#pharmacy-aria-categories

* Categories 2 and 3 were both classified as "Accessible" for this report

The locations and accessibility of all pharmacies that participated in the trial are shown in Table 18.

Table 18 Number of participating pharmacies by state/territory and accessibility

State/Territory	Accessibility of pharmacy (based on PhARIA)					Total
	Highly accessible	Accessible	Moderately accessible	Remote	Very remote	
ACT	17	0	0	0	0	17
NSW	138	17	5	2	0	162
QLD	97	11	4	2	2	116
SA	64	4	2	0	1	71
TAS	16	5	0	0	0	21
VIC	63	8	0	1	0	72
WA	79	6	1	1	4	91
NT	0	0	0	0	0	0
Total	**474 (86.2%)**	**51 (9.3%)**	**12 (2.2%)**	**6 (1.1%)**	**7 (1.3%)**	**550 (100%)**

Source: Pharmacy Registration Survey, n = 550 at the initial timepoint

Abbreviations: ACT, Australian Capital Territory; NSW, New South Wales, QLD, Queensland; SA, South Australia; TAS, Tasmania; VIC, Victoria; WA, Western Australia; NT, Northern Territory

As stated, pharmacies were recruited into the Trial through an EOI process. Of the 550 participating pharmacies, 267 (49%) were allocated to Group A and 283 (52%) were allocated to Group B.

In total, 452 (82%) of the participating pharmacies were main sites and 98 (18%) were evaluation sites. Group A (Table 19) and Group B (Table 20) had similar proportions of main and evaluation sites and spread of pharmacies across the different PhARIA categories.

Table 19 Number of main and evaluation sites by accessibility in Group A

Site	Accessibility of pharmacy (based on PhARIA)					Total
	Highly accessible	Accessible	Moderately accessible	Remote	Very remote	
Main	187	15	7	4	3	216 (80.9%)
Evaluation	45	6	0	0	0	51 (19.1%)
Total	**232 (86.9%)**	**21 (7.9%)**	**7 (2.6%)**	**4 (1.5%)**	**3 (1.1%)**	**267 100%)**

Source: Pharmacy Registration Survey, n = 267 at the initial timepoint

Table 20 Number of main and evaluation sites by accessibility in Group B

Site	Accessibility of pharmacy (based on PhARIA)					Total
	Highly accessible	Accessible	Moderately accessible	Remote	Very remote	
Main	200	25	5	2	4	236 (83.4%)
Evaluation	42	5	0	0	0	47 (16.6%)

Site	Accessibility of pharmacy (based on PhARIA)					Total
	Highly accessible	Accessible	Moderately accessible	Remote	Very remote	
Total	**242 (85.5%)**	**30 (10.6%)**	**5 (1.8%)**	**2 (0.7%)**	**4 (1.4%)**	**283 (100%)**

Source: Pharmacy Registration Survey, n = 283 at the initial timepoint

Almost half of the participating pharmacies belonged to a franchise banner group (47%) and around a quarter were independent pharmacies (28%). The remaining participating pharmacies belonged to either a private banner group (17%), buying group (3.9%), friendly society group (3.9%), or were a community (0.2%) or shopping centre (0.2%) pharmacy. Figure 6 shows the proportions of participating pharmacies in each pharmacy type.

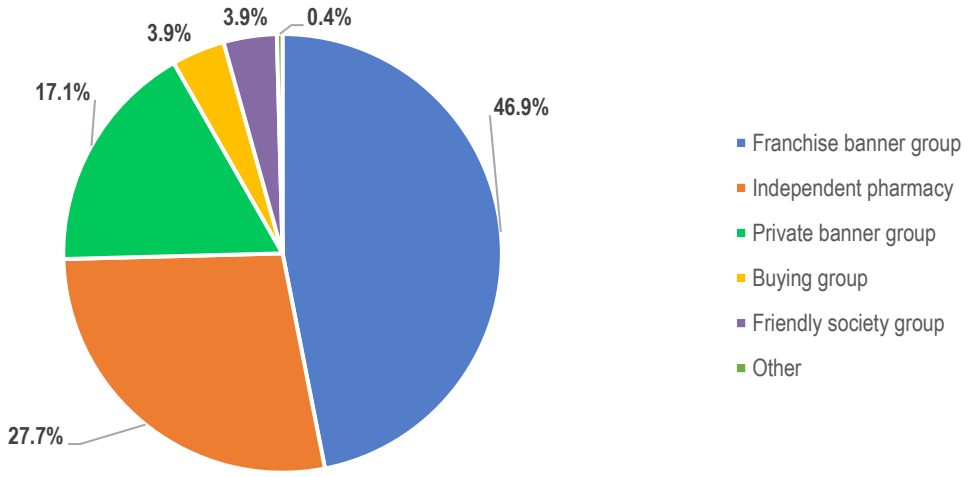


Figure 6 Proportion of pharmacies participating in the trial by ownership type

Source: Pharmacy Registration Survey at the initial timepoint (n=484*)

*There were 66 pharmacies that did not provide any information about the type of pharmacy or dispensing model

Franchise banner group is a group of retail pharmacies that operate like franchises to franchise groups. Examples include Amcal, Guardian, Chemworld; Soul Pattinson; Pharmacist Advice; API Health Care, Chemmart, Terry White, Healthsense, Synergy. Independent pharmacies are owned by pharmacists who are generally in charge of the business as a whole as well as working as a pharmacist. An example is Laird's Pharmacy (in Elwood, Melbourne) Private banner group is a group of retail pharmacies that are formed for mutual support and allow joint advertising and promotion. Examples include Full Life, My Chemist. Buying groups are formed by individual pharmacists whose aim is to act collectively in purchasing, and in doing so, obtain cheaper prices than would be possible if they were acting individually. Examples include Barretts (Vic), Chemplus (SA).

Friendly society groups are mutual organisations where all the assets belong to their members and profits are reinvested in the organisations. Examples include National Pharmacies, UFS Pharmacies.

In terms of the dispensing model, most of the participating pharmacies were semi-forward pharmacies (60%) and around a third were forward pharmacies (34%) (Figure 7). The rest of the pharmacies were divided into traditional pharmacies (5.8%) and other (0.6%).

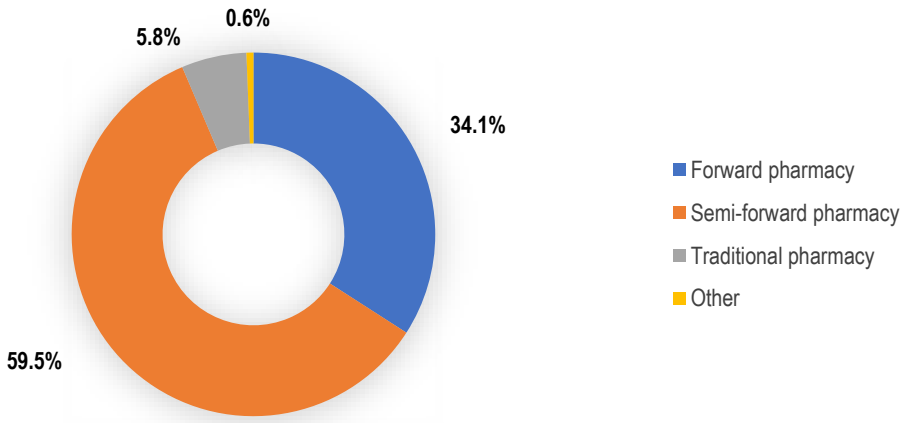


Figure 7 Proportion of pharmacies participating in the trial by dispensing model type

Source: Pharmacy Registration Survey at the initial timepoint (n=484*)

*There were 66 pharmacies that did not provide any information about the type of pharmacy or dispensing model

[1] Forward pharmacy is where a participant with a prescription deals directly with the pharmacist.

[2] Semi-forward pharmacy is a combination of forward and traditional pharmacy.

[3] Traditional pharmacy is where pharmacy assistants interact with participants and the pharmacist only speaks with a patient if necessary or requested.

PARTICIPANT CHARACTERISTICS

A total of 8,239 individuals enrolled in the CPMC trial and completed their initial consultation in Groups A or B pharmacies. Around two thirds of them participated in the trial at a main site (69%) and almost a third participated in the trial at an evaluation site (31%).

Table 21 presents an outline of the number of participants that completed their initial, midpoint (Group B only) and follow-up consultations. In summary:

- Group A had a total of 4,316 participants (52% of the total number of participants) at the start of the trial. Of these, 2,853 (66%) completed their follow-up consultation.
- Group B had 3,923 participants (48% of the total number of participants) commence the trial. Over half of these participants (60%) completed their midpoint consultation and around a third (39%) completed their follow-up consultation.

Table 21 Number of trial participants who completed initial, midpoint and follow-up consultations

Group	Consultation		
	Initial	Midpoint	Follow-up
Group A	4,316	-	2,853
Group B	3,923	2,335	1,521
TOTAL	**8,239**	**2,335**	**4,374**

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

Figure 8 provides an outline of participant flow through the Trial. There was no follow-up data for 3,866 of the 8,239 participants that commenced the Trial and completed their initial consultation. These participants represent 47% of the total initial sample and are considered to be lost to follow

up. The proportion of participants that were lost to follow up is slightly higher than the lost to follow up rate of 40% that was expected when the Trial was designed and on which the sample size calculations were based. There was no formal follow up of participants that dropped out of the Trial. Informal feedback received from pharmacists suggested a lack of time and competing priorities were key reasons for non-completion.

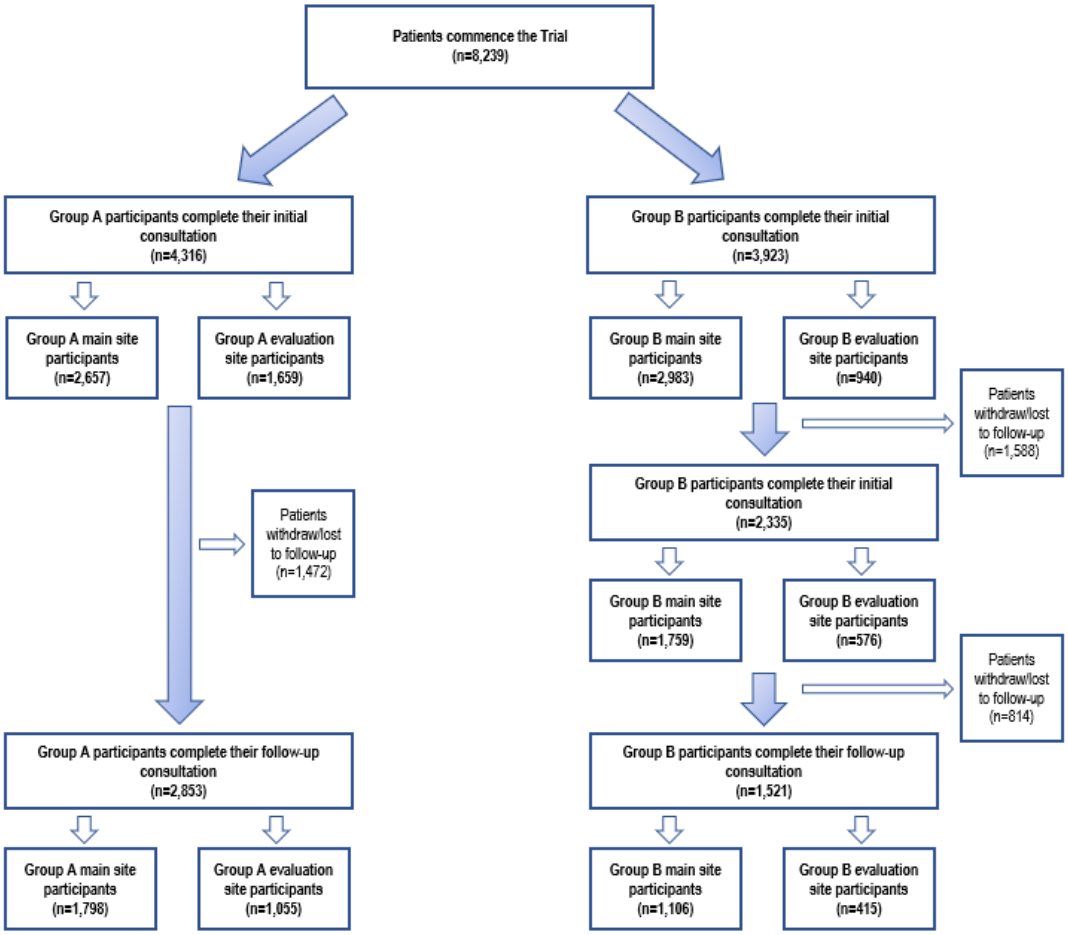


Figure 8 Flowchart of the number of participants through the Trial

Participants that completed their follow-up consultation were on average slightly older than those who were lost to follow up (60.7 years c.f. 57.0 years, $P < 0.01$). There were no differences in the other participant characteristics including gender and location. There was also no difference in the pain severity or pain interference (both general activities and sleep) experienced at the initial timepoint between participants that completed their follow-up consultation and those that were lost to follow up.

Group B had a higher proportion of participants who were lost to follow-up compared to Group A (61.2% c.f. 33.9%). Pharmacists suggested a lack of time and competing priorities were key reasons for non-completion and loss to follow-up, which may have resulted in fewer midpoint consultations at six weeks being completed.

Age characteristics

The distribution of participants across the different age groups was comparable between the main and evaluation sites (Figure 9), with largest proportion of participants in the 70–74-year age range in both types of site.

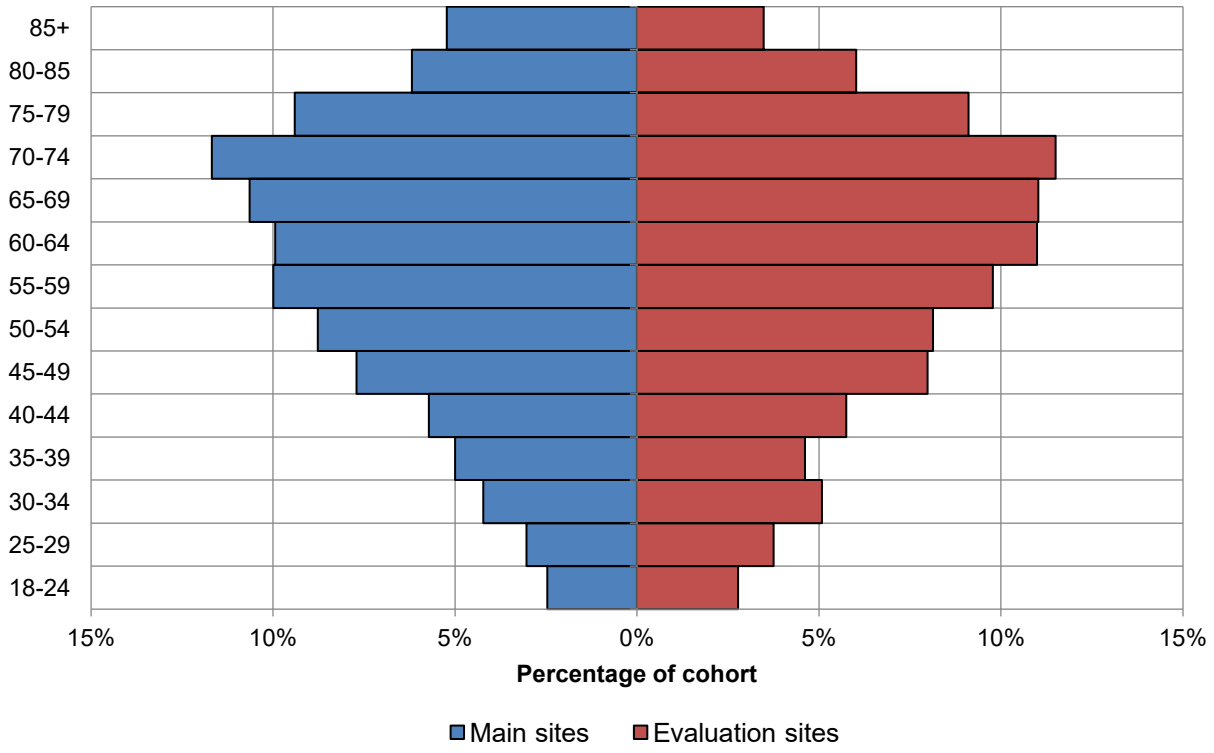


Figure 9 Comparison of age characteristics between the main and evaluation trial sites

Source: Participant data collected using GuildLink at the initial timepoint (n=8,120*)

*There were 119 participants for whom we currently have an incorrect the date of birth which is under investigation by the Guild and HealthConsult

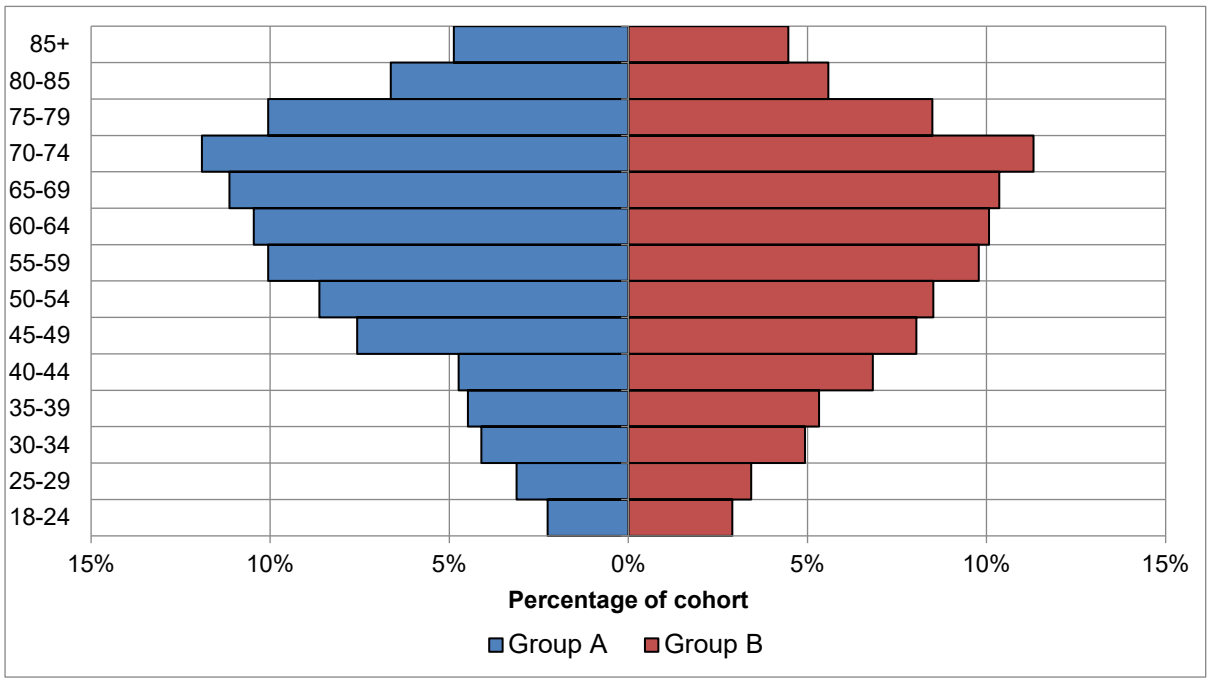


Figure 10 Comparison of age characteristics between Group A and Group B

Source: Participant data collected using GuildLink at the initial timepoint (n=8,120*)

*There were 119 participants for whom we currently have an incorrect the date of birth which is under investigation by the Guild and HealthConsult

Gender characteristics

Overall, across all pharmacies, 63% of participants were female and 37% of participants were male. There were similar differences in gender between participants at main and evaluation sites (**Error! Reference source not found.**) and between participants in Group A and Group B (Table 22). The gender characteristics of participants across all trial sites were similar at the initial and follow-up timepoints.

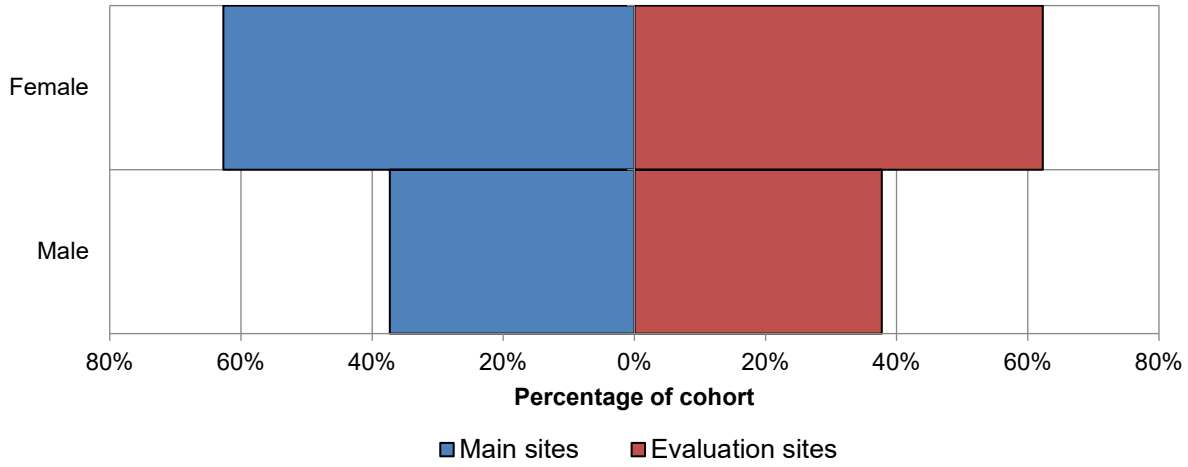


Figure 11 Proportion of females and males in the trial participants

Source: Participant data collected using GuildLink at the initial timepoint (n=7,938*)

*There were 301 participants who did not disclose their gender

Table 22 Proportions of male and female participants by site in each Group

	Gender			Total
	Male	Female	Undisclosed	
Group A				
Main	922	1,608	127	2,657
Evaluation	563	1,014	82	1,659
Total (% Group)	1,485 (34.4)	2,622 (60.8)	209 (4.8)	4,316 (100.0)
Group B				
Main	1,108	1,805	70	2,983
Evaluation	378	540	22	940
Total	1,486 (37.9)	2,345 (59.8)	92 2.3)	3,923 (100.0)

Source: Participant data collecting using GuildLink at the initial timepoint (n=8,239)

Location

As shown in Table 23, almost half (45%) of all participants resided in NSW. Around 16% lived in QLD and SA, 12% in VIC, and the remaining participants were from WA, TAS and the ACT. None of the trial participants were recruited from NT which is consistent with no pharmacies in NT participating in the

trial. The distribution of participants across the different States and Territories was similar between Group A and Group B, and between the main and evaluation sites.

Table 23 Proportions of participants by site and State/Territory in each Group

State/Territory	Group A		Group B		All Sites N (%)
	Main	Evaluation	Main	Evaluation	
ACT	30	12	115	1	158b (1.92)
NSW	871	1,144	1,004	651	3,670 (44.54)
QLD	567	184	518	50	1,319 (16.01)
SA	484	90	600	105	1,279 (15.52)
TAS	97	21	41	15	174 (2.11)
VIC	359	102	477	76	1,014 (12.31)
WA	249	106	228	42	625 (7.59)
NT	-	-	-	-	-
TOTAL	**2,657**	**1,659**	**2,983**	**940**	**8,239 (100)**

Source: Participant data collected using GuildLink at the initial timepoint (n=8,239)

Abbreviations: ACT, Australian Capital Territory; NSW, New South Wales, QLD, Queensland; SA, South Australia; TAS, Tasmania; VIC, Victoria; WA, Western Australia; NT, Northern Territory

Regionality

Participants were categorised as living in a major city, regional (inner and outer regional) and rural (remote and very remote) area based on the postcode of the pharmacy at which they participated in the CPMC Trial. Almost three-quarters (71.3%) of all participants lived in a major city, around a quarter (24.6%) lived in a regional area and a small proportion (4.1%) lived in a rural area of Australia.

Table 24 Proportions of participants by site and regionality in each Group

State/Territory	Group A		Group B		All Sites N (%)
	Main	Evaluation	Main	Evaluation	
Major city	1,711	1,517	1,936	708	5,872 (71.3)
Regional	777	121	913	218	2,029 (24.6)
Rural	169	21	134	14	338 (4.1)
TOTAL	**2,657**	**1,659**	**2,983**	**940**	**8,239 (100)**

Source: Participant data collected using GuildLink at the initial timepoint (n=8,239)

Note: 'Regional' includes inner regional and outer regional areas of Australia, and 'rural' includes remote and very remote areas of Australia

Socioeconomic status

Socioeconomic status was determined using the Socio-Economic Indexes for Areas (SEIFA), based on participants' postcodes.[19] All areas were ordered from lowest to highest score, with a lower score indicating that an area is relatively disadvantaged compared to an area with a higher score. The

lowest 10% of areas are given a decile number of 1, the next lowest 10% of areas are given a decile number 2 and so on, up to the highest 10% of areas which are given a decile number of 10.

Table 25 shows that participants were spread relatively evenly across all the deciles, with around half (54%) living in areas with decile numbers 1-5 and the other half (48%) living in areas with decile numbers 6-10. A few of the pharmacies located in the more disadvantaged areas were evaluation sites recruited large numbers of participants into the Trial which was why Deciles 2 and 5 had the highest proportions of participants (Figure 12).

Table 25 Proportions of participants by site and SEIFA decile in each Group

Decile	Group A		Group B		All Sites N (%)
	Main	Evaluation	Main	Evaluation	
1	306	83	67	35	491 (5.96)
2	307	406	530	446	1,689 (20.50)
3	258	31	177	25	491 (5.96)
4	143	22	423	21	609 (7.39)
5	259	433	380	66	1,138 (13.81)
6	180	70	487	214	951 (11.54)
7	267	87	184	10	548 (6.65)
8	371	311	259	63	1,004 (12.19)
9	292	113	324	48	777 (9.43)
10	274	103	152	12	541 (6.57)
TOTAL	**2,657**	**1,659**	**2,983**	**940**	**8,239 (100)**

Source: Participant data collected using GuildLink at the initial timepoint (n=8,239)

Abbreviations: ACT, Australian Capital Territory; NSW, New South Wales, QLD, Queensland; SA, South Australia; TAS, Tasmania; VIC, Victoria; WA, Western Australia; NT, Northern Territory

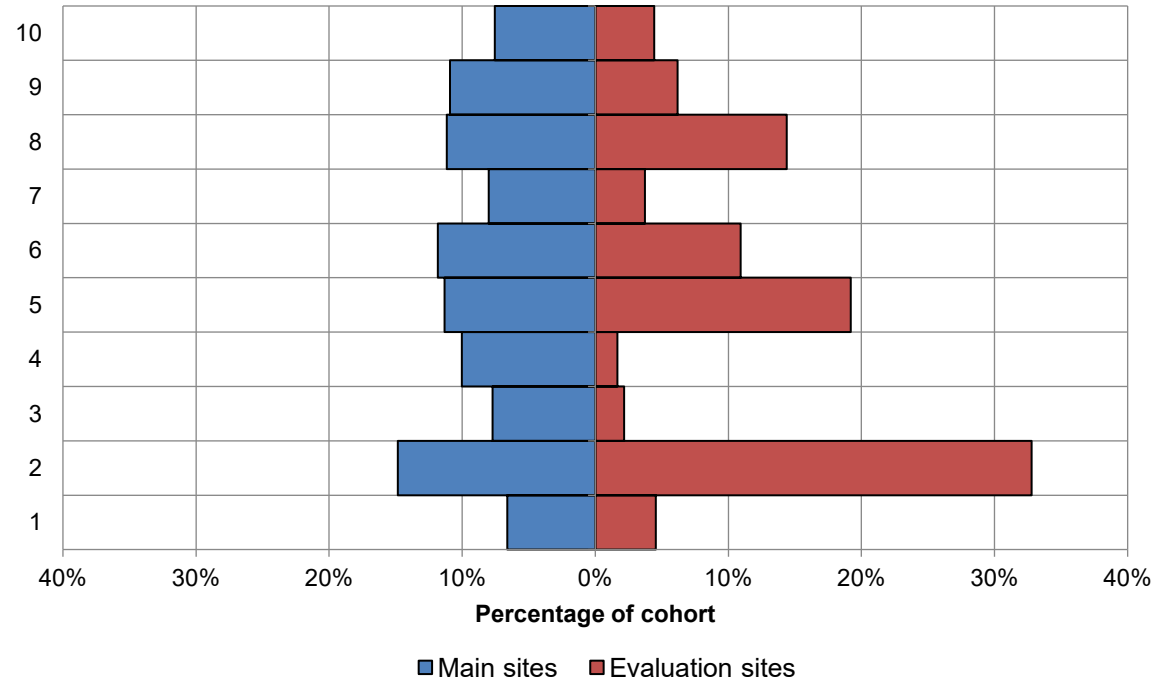


Figure 12 Comparison of participant socioeconomic status between the main and evaluation trial sites

Source: Participant data collected using GuildLink at the initial timepoint (n=8,239)

Reasons for referral to CPMC

Pharmacists were asked to record the reasons for inviting individuals to participate in the CPMC Trial. There were few differences in the proportions of participants being referred for various reasons between the two Groups and between main and evaluation sites.

The most common reason pharmacists invited individuals to participate in the CPMC Trial across all pharmacies was suboptimal chronic pain management (26.9%), followed by taking analgesics including non-prescription and complementary medicines (20.0%), difficulties in maintaining activities of daily living due to pain (10.8%), and taking opioids (<50 OME, 10.8%, Table 26).

Table 26 Number of participants by site and reason for referral in each Group

Reason for referral into CPMC	Group A		Group B		All participants*	
	Main	Evaluation	Main	Evaluation	Total responses	% total responses
Suboptimal chronic pain management	1,662	958	1,989	755	5,364	26.85
Taking analgesics	1,023	965	1,495	509	3,992	19.98
Having difficulties maintaining activities of daily living due to pain	649	486	803	223	2161	10.82
Taking opioids (<50 OME)	736	433	755	233	2,157	10.8

Reason for referral into CPMC	Group A		Group B		All participants*	
	Main	Evaluation	Main	Evaluation	Total responses	% total responses
Poor health literacy regarding pain management	248	393	285	113	1039	5.2
Taking CNS depressant medicines in addition to opioids	342	224	358	99	1,023	5.12
Experiencing difficulties managing their pain medicines	219	302	309	97	927	4.64
Taking higher dose opioids (≥50 OME)	329	122	291	69	811	4.06
Recent changes to their pain medication regimen	222	205	280	80	787	3.94
Experiencing adverse drug events to analgesics and adjuvant therapy	162	149	178	48	537	2.69
Exhibiting significant co-morbidities	134	93	176	57	460	2.30
Living alone or without access to social support	119	69	115	34	337	1.69
Accessing multiple prescribers	89	71	112	24	296	1.48
Other reason	20	23	39	8	90	0.45
TOTAL					**19,981**	**100.00**

Source: Participant data collected using GuildLink at the initial timepoint (n=8,239)

*The responses for this question were not mutually exclusive and respondents were asked to select all the options that applied

Pain sites

The number of pain sites reported by participants at their initial consultation was similar between Groups A and B (Figure 13), with the largest proportion of participants experiencing pain at 2-3 sites.

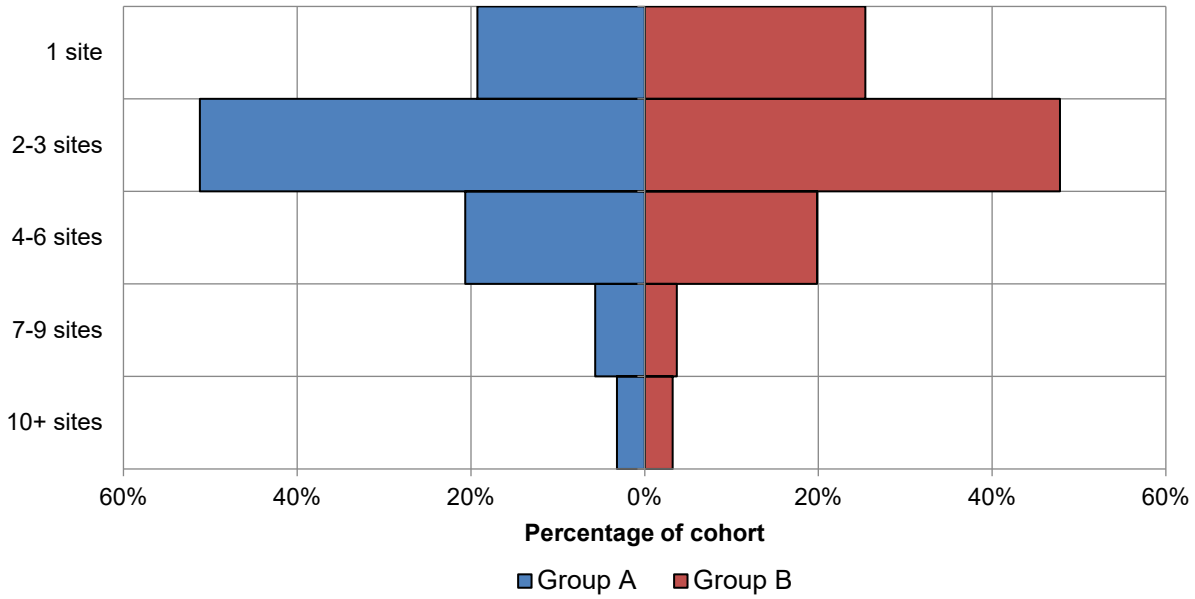


Figure 13 Comparison of the number of pain sites between two Groups

Source: Participant data collected using GuildLink at the initial timepoint (n=8,239)

There was a very small correlation between the level of pain severity experienced by participants and the number of pain sites in both Group A (r=0.164) and Group B (r=0.174) at the initial consultation.

The sites of pain reported by participants were similar between the main and evaluation sites as well as between the two Groups (Table 27). The site of pain most commonly reported by participants at their initial consultation across all pharmacies was the back (24.6%), followed by leg (11.1%), knee (10.4%) and arm/shoulder (10.3%). There were no observable patterns between the level of pain severity experienced by participants and the pain sites they reported at the start of the intervention.

Table 27 Number of participants by site and pain site in each Group

Pain site	Group A		Group B		All participants*	
	Main	Evaluation	Main	Evaluation	Total responses	% total responses
Back	1,588	964	1,799	610	4,961	24.58
Leg	690	452	821	267	2,230	11.05
Knee	609	488	729	266	2,092	10.37
Arm/Shoulder	623	485	709	260	2,077	10.29
Neck	637	403	719	213	1,972	9.77
Feet	359	320	458	173	1,310	6.49
Head	293	232	394	132	1,051	5.21
Hand	298	247	336	123	1,004	4.97
Whole body	419	155	303	72	949	4.70
Pelvic and/or genital	259	207	272	94	832	4.12
Other	200	129	236	64	629	3.12
Abdomen	126	85	155	52	418	2.07

Pain site	Group A		Group B		All participants*	
	Main	Evaluation	Main	Evaluation	Total responses	% total responses
Buttock	139	85	148	42	414	2.05
Chest	71	57	81	35	244	1.21
TOTAL					**20,183**	**100**

Source: Participant data collected using GuildLink at the initial timepoint (n=8,239)

*The responses for this question were not mutually exclusive and respondents were asked to select all the options that applied

Participants lost to follow-up

Table 28 provides an outline of participant flow through the Trial and proportion of participants who were lost to follow up by site in each Group. Almost half (47%) of the total initial sample were lost to follow up across all participating pharmacies.

Table 28 Number of trial participants who completed initial, midpoint and follow-up consultations

	Main sites				Evaluation sites			
	Initial	Midpoint	Follow-up	LTFU (% initial sample)	Initial	Midpoint	Follow-up	LTFU (% initial sample)
Group A	2,657	-	1,798	859 (32.3%)	1,659	-	1,055	604 (36.4%)
Group B	2,983	1,759	1,106	1,877 (62.9%)	940	576	415	525 (55.9%)
Total	**5,640**	**1,759**	**2,904**	**2,736 (48.5%)**	**2,599**	**576**	**1,470**	**1,129 (43.4%)**

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

Abbreviations: LTFU, Lost to follow up

The characteristics of participants who completed their follow-up consultation were comparable to those of participants that were lost to follow-up. In terms of the age distribution, higher proportions of participants that attended their follow-up consultation belonged in the older age categories defined as 65 years and above (Figure 14).

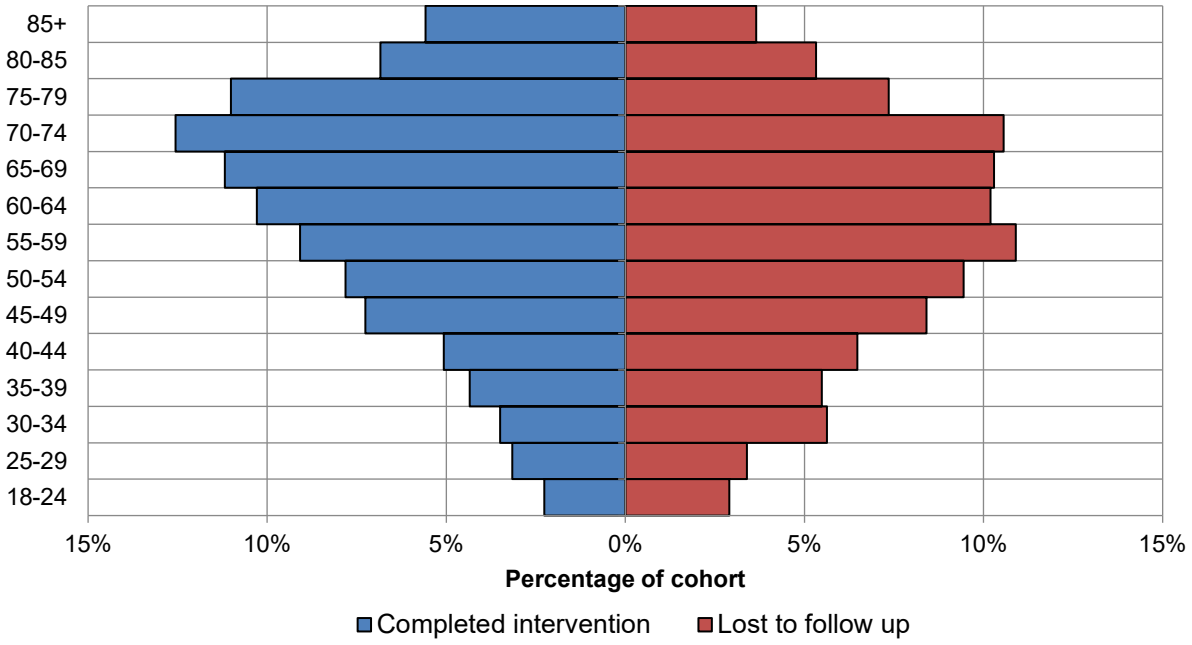


Figure 14 Comparison of age characteristics between those that completed and lost to follow up

Source: Participant data collected using GuildLink at the initial timepoint (n=8,120*)

*There were 119 participants for whom we currently have an incorrect the date of birth which is under investigation by the Guild and HealthConsult

The proportions of male and female participants were very similar between those that completed their follow-up consultation and those who were lost to follow-up (Table 29).

Table 29 Gender characteristics of participants that completed the intervention and those who were lost to follow-up

	Attended follow-up consultation (% total)	**Lost to follow-up (% total)**
Male	1,570 (35.9)	1,399 (36.2)
Female	2,664 (60.9)	2,304 (59.6)
Unknown	140 (3.2)	162 (4.2)
Total	**4,374 (100.0)**	**3,865 (100.0)**

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

The proportion of participants located in a major city was higher and the proportion located in a regional area was lower in those that completed their follow-up consultation compared to those who were lost to follow-up (Table 30). Participants' regionality was determined using the postcode of the pharmacy at which they participated in the CPMC Trial.

Table 30 Regionality of participants that completed the intervention and those who were lost to follow-up

	Attended follow-up consultation (% total)	**Lost to follow-up (% total)**
Major city	3,217 (73.5)	2,655 (68.7)
Regional	970 (22.2)	1,059 (27.4)

	Attended follow-up consultation (% total)	Lost to follow-up (% total)
Rural	187 (4.3)	151 (3.9)
Total	**4,374 (100.0)**	**3,865 (100.0)**

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

The frequency and severity of the pain experienced by participants prior to commencing the intervention were comparable between those that completed their follow-up consultation and those who were lost to follow-up (Table 31 and Table 32).

Table 31 Pain severity experienced at the initial consultation by participants that completed the intervention and those who were lost to follow-up

	Attended follow-up consultation (% total)	Lost to follow-up (% total)
Mild pain	962 (22.0)	854 (22.1)
Moderate pain	1,409 (32.2)	1,183 (30.6)
Severe pain	2,003 (45.8)	1,828 (47.3)
Total	**4,374 100.0)**	**3,865 (100.0)**

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

Table 32 Frequency of pain experienced at the initial consultation by participants that completed the intervention and those who were lost to follow-up

Frequency of pain	Attended follow-up consultation (% total)	Lost to follow-up (% total)
Rarely present pain that occurs every few days or weeks	201 (4.6)	197 (5.1)
Occasionally present with pain that occurs once to several times per day and lasts up to 1 hour	289 (6.6)	267 (6.9)
Often present with pain free periods that last less than 6 hours	547 (12.5)	433 (11.2)
Always present at varying levels of intensity	2,735 (62.5)	2,276 (58.9)
Always present at the same intensity (most frequently)	604 (13.8)	692 (17.9)
Total	**4,374 (100.0)**	**3,865 (100.0)**

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

B.5. Description of outcome measures

Table 33 summarises the outcome measures, data sources and measurement tools that were collected as part of the CPMC trial. A description each tool follows Table 33.

Table 33 Evaluation outcome measures and data sources

Parameter/Measure	Tool	Collected from Pharmacist/Pharmacy			Collected from participants€			Collected from referred service / provider
		Initial	6 weeks (Group B only)	~3 months	Initial	6 weeks (Group B only)	~3 months	
Characteristics of trial sites	Trial specific data elements on trial sites	✓ All sites	x	x	x	x	x	x
Characteristics of individuals invited to participate in the trial	Trial specific data elements on individuals invited to participate in the trial∞	✓ All sites	x	x	x	x	x	x
Additional characteristics of individuals who consent to participate in the trial	Trial specific data elements on individuals who consent to participate in the trial	✓ All sites	x	x	x	x	x	x
Pain severity	Mini-ePPOC incorporating 2 items of the BPI.	x	x	x	✓All sites	✓All Group B sites	✓All sites	x
Pain interference	Mini-ePPOC incorporating 2 items of the BPI	x	x	x	✓All sites	✓All Group B sites	✓All sites	x
Pain self-efficacy	Mini-ePPOC incorporating 2 items of the Pain Self-Efficacy Questionnaire (PSEQ=-2)	x	x	x	✓All sites	✓All Group B sites	✓All sites	x

Parameter/Measure	Tool	Collected from Pharmacist/Pharmacy			Collected from participants€			Collected from referred service / provider
		Initial	6 weeks (Group B only)	~3 months	Initial	6 weeks (Group B only)	~3 months	
Depression and anxiety	Mini-ePPOC incorporating items of the Patient Health Questionnaire-4 (PHQ-4)	x	x	x	✓All sites	✓All Group B sites	✓All sites	x
Medication Profile	Extracted from pharmacy software	x	x	x	✓All sites	✓All Group B sites	✓All sites	x
Quality of Life	Assessment of Quality of Life (AQoL-4D)	x	x	x	✓All evaluation sites	x	✓All evaluation sites	x
Self-management	Partners in Health Scale (PIH)	x	x	x	✓All evaluation sites	x	✓All evaluation sites	x
Health literacy	Six questions developed with advice from an expert panel	x	x	x	✓All evaluation sites	x	✓All evaluation sites	x
Intervention service outcomes data (e.g. average daily morphine equivalent dose, referral details, adherence to written action plan, any	Trial specific data elements	x	x	x	✓All sites	✓All Group B sites	✓All sites	x

Parameter/Measure	Tool	Collected from Pharmacist/Pharmacy			Collected from participants€			Collected from referred service / provider
		Initial	6 weeks (Group B only)	~3 months	Initial	6 weeks (Group B only)	~3 months	
changes in constipation symptoms (if being experienced by participant)								
Service satisfaction¥	Patient Survey Pharmacist Survey Referred Provider Survey	x	x	✓All evaluation sites	x	x	✓All evaluation sites	✓All evaluation sites
Health care resource use (emergency department visits and/or admissions due to pain, PBS utilisation)	Mini-ePPOC (all sites) plus linked MBS/PBS data for evaluation trial sites only (where participants provided consent)	x	x	x	✓All sites		✓All sites	x

€ Collected from participants by the pharmacist, and entered into Trial software ¥ These surveys were administered at the end of the trial independently by the HealthConsult evaluation team ∞ Data collected from individuals who were invited but did not participate in the Trial was not available for analysis.

Note: A copy of the tools used to collect key patient outcome data can be found in Appendix G.

Mini-ePPOC

The mini-electronic Persistent Pain Outcomes Collaboration (ePPOC) is a data collection tool based on ePPOC. Established in 2013, ePPOC is a program that aims to help improve services and outcomes for participants suffering with chronic pain through benchmarking of care and treatment. ePPOC is an initiative of the Faculty of Pain Medicine at the University of Wollongong, and has been further developed in recent years by the Faculty, the Australian Pain Society (APS) and the wider pain sector.

ePPOC involves the collection of a standard set of data items and assessment tools by specialist pain services throughout Australia and New Zealand to measure outcomes for their participants as a result of treatment. This information is used to guide treatment for individual participants, measure outcomes following treatment and develop a national benchmarking system for the pain sector. The benchmarking system is designed to provide comparative data to each pain service, identify best practice protocols and clinical variation, and drive quality improvement through setting aspirational targets for participant outcomes. The information collected by pain services also provides a valuable resource for research into the management of pain in Australia and New Zealand. Over 80 adult and paediatric pain management services currently participate in ePPOC.

The mini-ePPOC, also developed by the University of Wollongong, includes a subset of items from some of the tools utilised in ePPOC that is used by specialist pain management services. Mini-ePPOC was deemed to be more suitable and practical for use in the primary care setting where there are time limitations due to the workload of primary care clinicians. Most of the tools included in the mini-ePPOC have been validated in the primary care setting.

The mini-ePPOC included assessment tools that measure:

- **Pain interference and pain severity:** The **Brief Pain Inventory short form (BPI-sf)** is a 9-item self-administered questionnaire used to evaluate the severity of a participant's pain and the impact of this pain on the participant's daily functioning. The participant is asked to rate their worst, least, average, and current pain intensity, list current treatments and their perceived effectiveness, and rate the degree that pain interferes with general activity, mood, walking ability, normal work, relations with other persons, sleep, and enjoyment of life on a 10 point scale. The BPI generates two scales, Pain Severity and Pain Interference. The mini-ePPOC includes two of the nine items included in the BPI-sf.
- **Pain Self-Efficacy:** The **Pain Self-Efficacy Questionnaire (PSEQ)** is a 10-item measure of how confident a participant is that he or she can do a range of activities despite their pain. The mini-ePPOC includes the 2-item short form of the PSEQ (PSEQ-2) which consists of two of the 10 items of the full PSEQ and has been validated as a standalone instrument[20]. A total score is calculated as a sum of the two scores which are rated on a scale from 0 = 'Not at all' confident to 6 = 'Completely confident'. A score of less than or equal to 5 indicates the participant is in need of help to improve confidence to perform daily activities, and scores equal to or greater than 8 indicate that their self-efficacy is associated with meaningful functional outcomes.
- **Depression and anxiety:** The **'Patient Health Questionnaire-4' (PHQ-4)** is a brief screener for anxiety and depression that combines the Patient Health Questionnaire-2 (PHQ-2) and

Generalized Anxiety Disorder-2 (GAD-2)[21]. The PHQ-4 has four items, two each from the PHQ-2 and GAD-2, with response options provided on a 4-point Likert scale with 0 = not at all, 1 = several days, 2 = more than half the days, and 3 = nearly every day. The PHQ-2 is a measure of depression, which includes the first two items from the longer depression measure, the PHQ-9. The GAD-2 is a measure of anxiety, with this measure including the first two items from the GAD-7.

- **Nutrition:** Two questions on vegetable intake and consumption of sugar sweetened drinks were included. These questions are not included in ePPOC but it was considered to be important by members of the Australian Pain Society to include these questions. The hypothesis was that optimising diet with healthy food enables healthy gut bacteria to thrive which reduces inflammation and pain. Although vegetable intake and consumption of sugar sweetened drinks were not outcome measures for the Trial, they were important for some members of the EP and their analysis has been included.

Other outcome measure tools

In addition, the following outcome measures were collected from participants at trial sites:

- **Quality of Life (QoL):** The Assessment of QoL was determined using the **AQoL-4D questionnaire**. The AQoL-4D is a multi-attribute utility instrument comprised of 12 items across 4 dimensions (independent living, relationships, mental health, and physical senses i.e. seeing, hearing, and communication). The AQoL utility score is obtained by weighting the items then applying a multiplicative function to obtain an index which is transformed on a life-death utility scale. The utility score is presented on a scale where the upper boundary, 1.00, represents the best possible HRQoL, death equivalent HRQoL is represented by 0.00, and the lower boundary, -0.04, represents a HRQoL state worse than death. The weighted AQoL-4D domain utility scores for each dimension are scaled between a -0.04 (worst health state) and 1.00 (best health state). Only participants of evaluation trial sites completed this tool.
- **Self-management:** The **Partners in Health (PIH) Scale** is a validated questionnaire based on the principles of self-management. Participants complete the questionnaire by scoring their response to each of the 12 questions on a nine-point scale (0 being the lowest response, reflecting low self-management capacity, and 8 being the highest, reflecting good self-management capacity). Responses are combined into an overall measure of self-management. Only participants of evaluation trial sites completed this tool.
- **Health literacy**: A trial-specific **health literacy tool** was developed in consultation with the Expert Panel overseeing the Trial. The tool was developed for this Trial as no existing validated instrument was able to be found. Participants were asked to answer six questions by scoring their response to each question on a ten-point scale (1 being the lowest score and marked as 'very poor', and 10 being the highest score and marked as 'very good'). Responses are combined into an overall measure of health literacy. Only participants of evaluation trial sites completed this tool.
- **Satisfaction surveys**: Surveys were developed for participants, pharmacists and referred providers and administered at the end of the Trial independently by HealthConsult. The purpose

of the surveys was to understand their experiences of the Trial, any perceived impacts and suggestions for improving the CPMC service. All three surveys consisted of a mix of open-ended and closed questions.

A brief summary of analysis methods is presented below. More detailed information on analyses undertaken for various outcome measures is provided in the Section B.6.

The participant and pharmacy characteristics were analysed descriptively for each Group. Discrete variables were summarised by frequencies and percentages which were calculated according to the number of participants for whom data were available. Continuous variables were summarised by standard measures of central tendency and dispersion, with the mean and standard deviation calculated where appropriate.

Analyses on the participant outcome measures were undertaken on Groups A and B separately, with the intention of determining whether there were improvements in the outcomes over time. Changes in the two Groups were then compared for some outcome measures.

All primary outcome measures were treated as interval level variables. All available (unpaired) data was used in the analyses to maximise power. Outcome measures were analysed descriptively and using multi-level generalised mixed effects regression modelling, with time as the fixed effect and pharmacy and individual as the random effects. All significance testing was conducted was the 95% confidence level ($P < 0.05$) unless otherwise stated.

Subgroup analyses were conducted using paired initial and follow-up data. Independent variables treated as ordinal variables in the regression modelling and all models were adjusted for clustering by pharmacy. All significance testing was conducted was the 95% confidence level ($P < 0.05$) unless otherwise stated.

Multiple imputation to replace missing values has not been undertaken. Participants that completed their follow-up consultation were on average only slightly older than those who were lost to follow up and there were no differences in the other participant characteristics including gender and location. There was also no difference in the pain severity or pain interference (both general activities and sleep) experienced at the initial timepoint between participants that completed their follow-up consultation and those that were lost to follow up.

B.6. Results of the evaluation

Is it safe?

Safety was not measured as part of the study. However, given the slight reduction in emergency department presentations and hospitalisations (Table 55), it can be inferred that the intervention is non-inferior to the comparator (i.e. trial participant values at baseline).

Is it effective?

Does having three consultations over two consultations produce greater health outcomes for patients with chronic pain?

The Group B intervention (i.e. three consultations) showed greater improvements in most of the participant health outcomes from initial to follow-up compared to Group A (i.e. two consultations). Further subgroup analyses showed that participants' pain severity and interference to general activities both improved from initial to follow-up regardless of whether their pain was mild, moderate or severe at commencement of the intervention, but participants that had moderate or severe pain or experienced moderate or severe pain interference at the initial timepoint appeared to have benefited more from the intervention, demonstrating significantly larger improvements to their average pain severity and interference scores compared to those that had mild pain and interference at the start of the intervention.

IMPACT ON PAIN SEVERITY AND INTERFERENCE

Pain duration and frequency

All participants needed to have been experiencing pain for more than three months to be eligible to participate in the Trial. Around half of them (47% in Group A and 50% in Group B) had experienced pain for more than five years. The distribution of participants across the different pain duration categories was similar between Groups A and B (Figure 15), with the vast majority of participants having experienced it for over 12 months (85% in Group A and 82% in Group B).

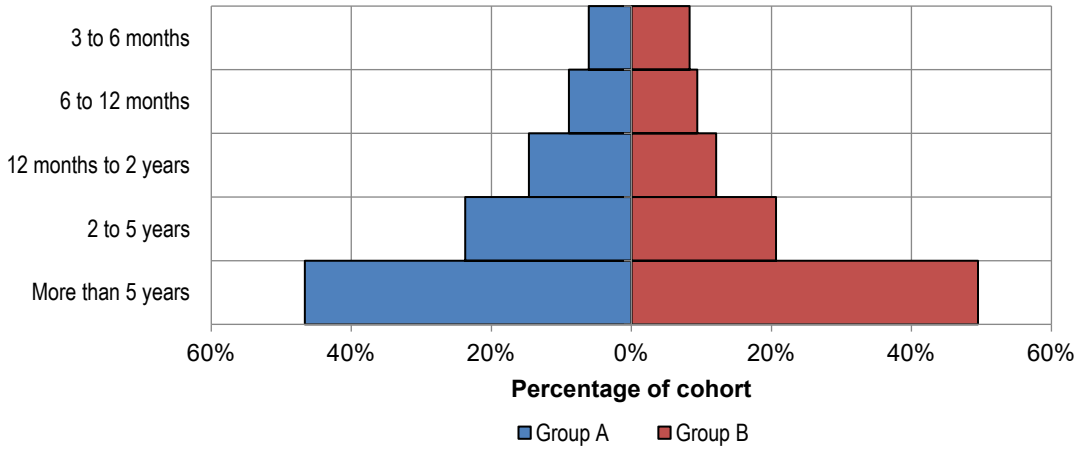


Figure 15 Comparison of pain duration between the main and evaluation trial sites
Source: Participant data collected using GuildLink at the initial timepoint (n=8,239)

Participants were also asked about how frequently they experienced pain. Around three quarters of the participants in both Groups A and B reported experiencing pain all the time, either at varying levels of intensity or the pain was always present at the same intensity (Figure 16). There was no significant difference in how frequently the participants experienced pain between the initial and follow-up timepoints in either group.

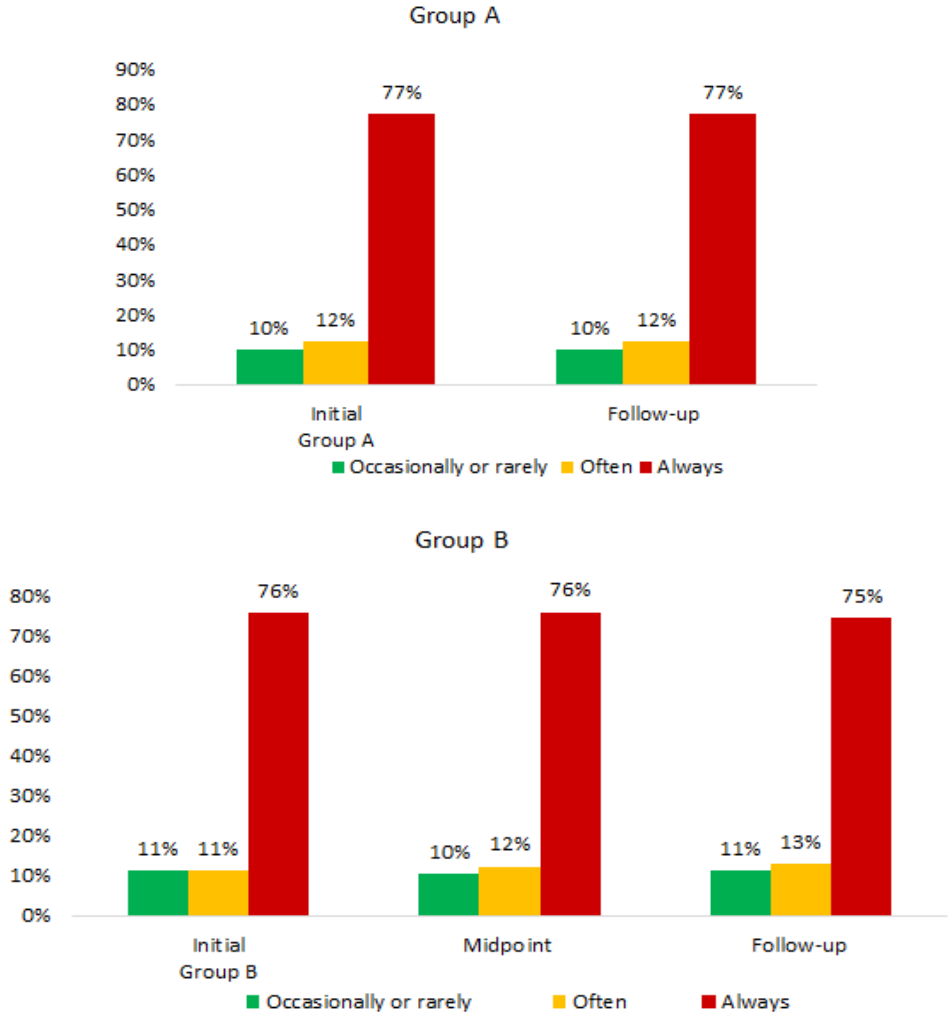


Figure 16 Comparison of pain frequency at different timepoints between Groups A and B

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

*All changes between the initial and follow-up timepoints were statistically significant ($p<0.05$)

Pain severity

All trial participants were asked to rate the severity of their pain in the past week using a scale from 0 to 10, with 0 being 'no pain' and 10 being 'pain as bad as you can imagine' at their initial, midpoint (Group B only) and follow-up consultations. There were improvements in the severity of pain experienced by participants from initial to follow-up in Groups A and B, and these changes were statistically significant in both groups (Table 34). On average, Group B participants demonstrated a greater improvement in their pain severity over time from initial to follow-up compared to Group A participants (decrease of 1.55 c.f. 0.89) (Figure 17).

Table 34 Average pain severity scores from initial to follow-up in Groups A and B

	Pain severity score at initial			Pain severity score at follow-up			Change in pain severity score from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value*
								Upper	Lower	
Group A	4,316	6.09 (2.08)	6	2,853	5.20 (2.24)	5	-0.89	-0.79	-0.99	0.00
Group B	3,923	6.15 (2.20)	6	1,521	4.60 (2.54)	5	-1.55	-1.41	-1.69	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

*Multilevel mixed-effects linear regression with time as the fixed effect and pharmacy and individual as the random effects

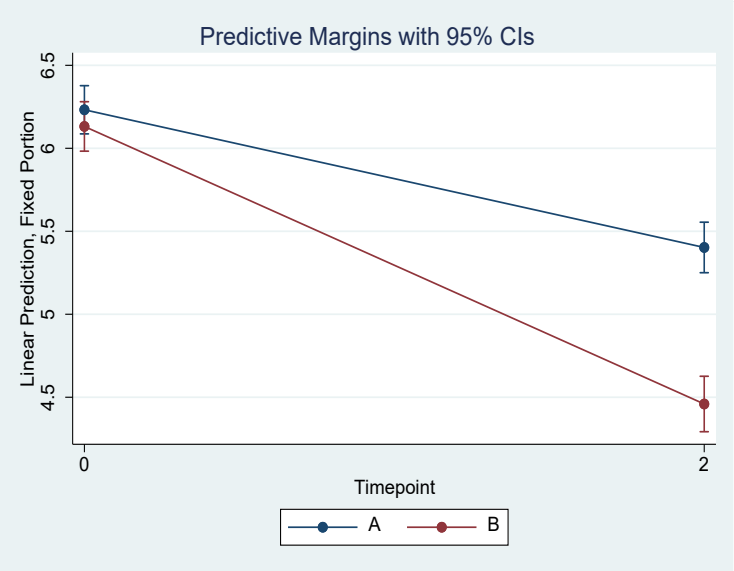


Figure 17 Comparison of changes to pain severity over time between Groups A and B.

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

There was no correlation between the participants' age, gender or regionality and their pain severity at any timepoint or changes in their pain severity from initial to follow-up.

There were also some positive changes to the proportions of participants that experienced mild, moderate and severe pain in both Groups A and B (Figure 18). The proportion of participants experiencing severe pain decreased while the proportion of individuals experiencing both mild pain and moderate pain increased. This suggests there was a general shift in participants experiencing severe pain to mild and moderate pain as a result of completing the CPMC intervention. Specifically:

- The proportion of participants that experienced severe pain decreased from 46% to 30% in Group A and from 47% to 24% in Group B, and these decreases were statistically significant in both Groups. Group B also had a lower proportion (32%) of participants experiencing severe pain at midpoint compared to the initial timepoint.
- Conversely, the proportion of participants that experienced mild pain significantly increased from 21% to 35% in Group A and from 23% to 48% in Group B.

There was also no difference in the pain severity experienced at the initial timepoint between participants that completed their follow-up consultation and those that were lost to follow up.

In addition, there was an increase in the proportion of participants who responded 'no pain' when questioned about their average pain level in the past week from initial to follow-up in both Group A (from 0.7% to 2.5%) and Group B (from 0.6% to 5.3%).

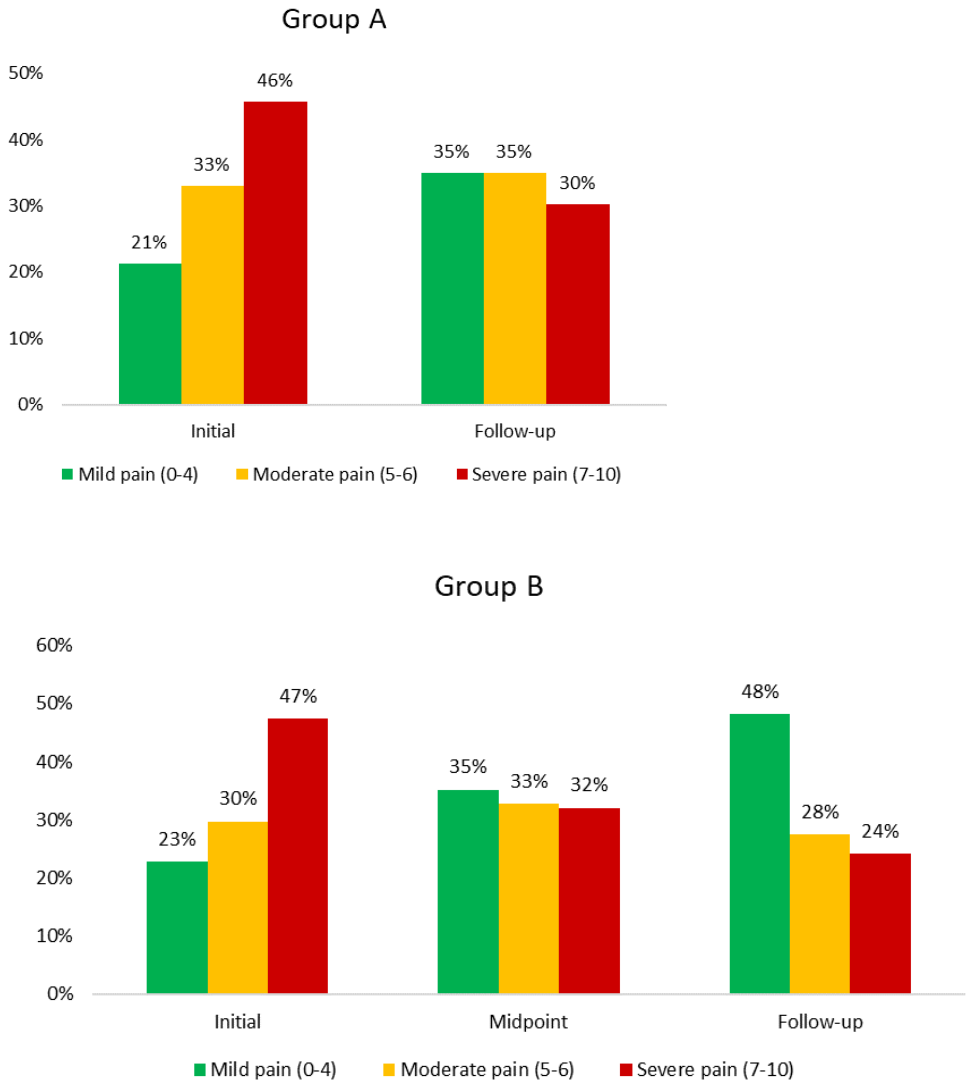


Figure 18 Comparison of pain severity at different timepoints between Groups A and B

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

*All changes between the initial and follow-up timepoints were statistically significant ($p<0.05$)

At the start of the intervention, 22% of participants (n=1,813) reported experiencing mild pain, 31% (n=2,591) reported experiencing moderate pain and 47% (n=3,835) reported experiencing severe pain. Subgroup analyses using data combined from both Groups A and B showed that, on average, participants' pain severity decreased from initial to follow-up regardless of whether their pain was mild (3.02 to 2.82), moderate (5.55 to 4.71) or severe (7.97 to 6.23) prior to commencing the intervention. However, participants that had moderate or severe pain at the initial timepoint benefited more from the intervention, demonstrating significantly larger improvements to their

average pain severity scores, with reductions of 15.3% and 21.5% respectively, compared to those that had mild pain, with a reduction of 8.3%, at the start of the intervention (Table 35).

Table 35 Changes to average pain severity scores for different categories of pain severity

	Pain severity score at initial			Pain severity score at follow-up			Change in pain severity score from initial to follow-up (using matched data)			
Level of pain severity at initial	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value ***
Mild pain	1,813	3.02 (1.03)	3	961	2.82 (1.77)	3	961	-0.25 (1.69)	-8.28	N/A#
Moderate pain	2,591	5.55 (0.50)	6	1,407	4.71 (1.81)	5	1,407	-0.85 (1.81)	-15.3	0.00
Severe pain	3,835	7.97 (1.00)	8	2,006	6.23 (2.13)	7	2,006	-1.71 (2.09)	-21.5	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

##Mild pain category was used the comparison group in this regression modelling

Pain interference

All trial participants were asked to rate the extent their pain had interfered with their general activities and sleep in the past week using a scale from 0 to 10, with 0 being 'does not interfere' and 10 being 'completely interferes' at their initial, midpoint (Group B only) and follow-up consultations.

There were improvements in the degree of interference the participants' pain had on both their general activities and sleep from initial to follow-up in Groups A and B, and these changes were statistically significant in both Groups (Table 36). On average, Group B participants demonstrated greater improvements in the degree of pain interference compared to Group A participants from initial to follow-up on both their general activities (decrease of 1.65 c.f. 0.91) and sleep (decrease of 1.69 c.f. 0.88) over time from initial to follow-up compared to Group A participants (Figure 19 and Figure 20).

Table 36 Average pain interference scores from initial to follow-up in Groups A and B

	Pain interference score at initial			Pain interference score at follow-up			Change in pain interference score from initial to follow-up			
	n	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**Mean**	**95% CI**		**P value**
								Upper	**Lower**	
Interference to general activities										
Group A	4,316	5.72 (2.62)	6	2,853	4.81 (2.58)	5	-.0.91	-0.78	-1.03	0.00

	Pain interference score at initial			Pain interference score at follow-up			Change in pain interference score from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value
								Upper	Lower	
Group B	3,923	5.80 (2.73)	6	1,521	4.15 (2.79)	4	-1.65	-1.49	-1.82	0.00
Interference to sleep										
Group A	4,316	5.27 (3.04)	6	2,853	4.38 (2.86)	5	-0.88	-0.74	-1.03	0.00
Group B	3,923	5.25 (3.15)	5	1,521	3.56 (2.91)	3	-1.69	-1.51	-1.88	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

** Multilevel mixed-effects linear regression with time as the fixed effect and pharmacy and individual as the random effects

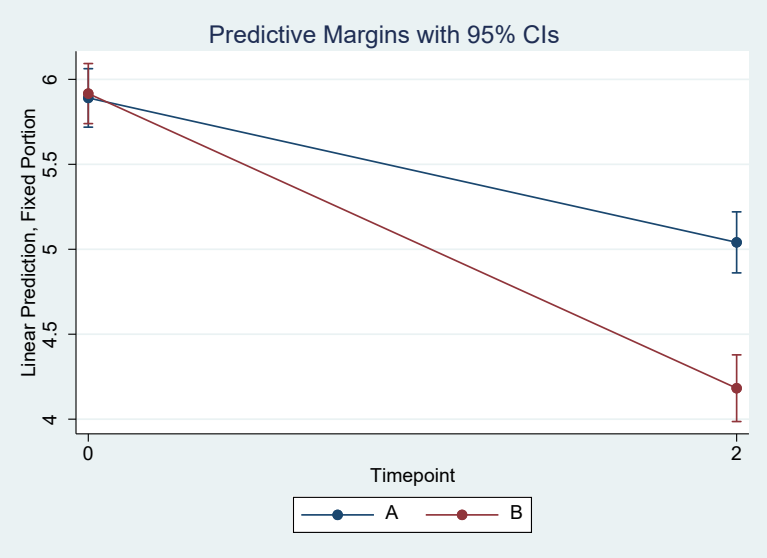


Figure 19 Comparison of changes to pain interference (general activities) over time between Groups A and B.

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

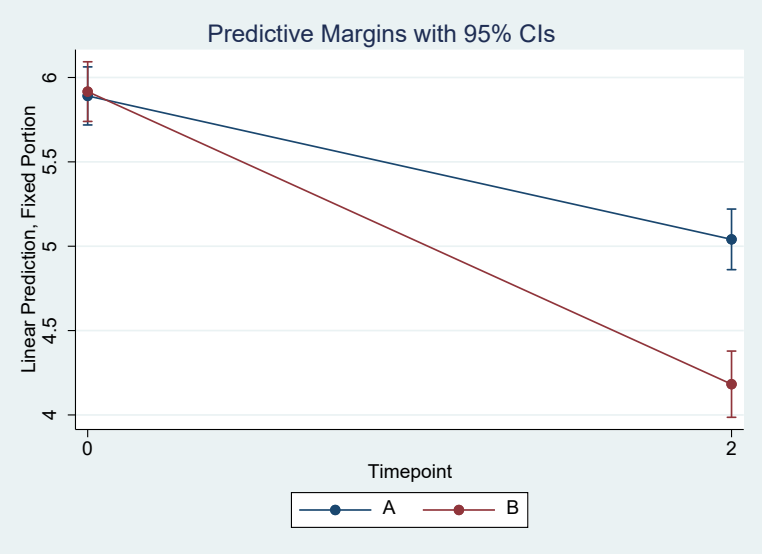


Figure 20 Comparison of changes to pain interference (sleep) over time between Groups A and B.

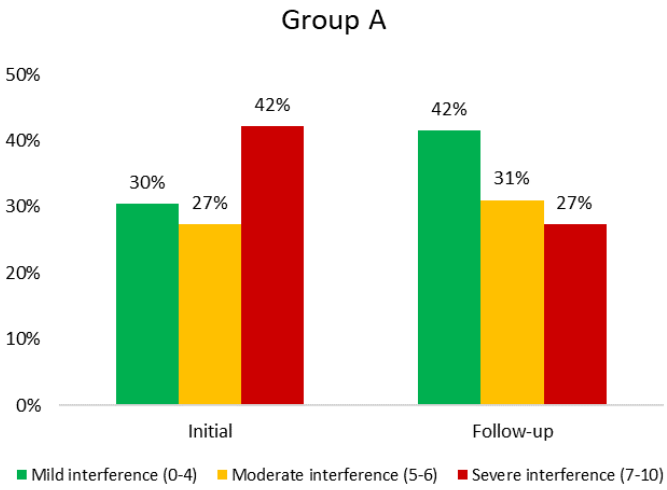
Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

There was no correlation between the participants' age, gender or regionality and the pain interference on both general activities and sleep at any timepoint or changes in their pain interference from initial to follow-up.

In terms of the pain interference on general activities, there were also some positive changes to the proportions of participants that experienced mild, moderate and severe interference as a result of their pain in both Groups A and B (Figure 21). The proportion of participants experiencing severe interference decreased while the proportion of individuals experiencing mild interference and moderate interference both increased. This suggests there was a general shift in participants experiencing severe interference to mild and moderate interference as a result of completing the CPMC intervention. Specifically:

- The proportion of participants that experienced only mild interference to their general activities as a result of their chronic pain increased from 30% to 42% in Group A and from 31% to 42% in Group B. These increases were statistically significant.
- The proportion of participants that experienced severe interference to their general activities as a result of their pain decreased from 42% to 27% in Group A and from 45% to 31% in Group B, and these decreases were statistically significant in both Groups. Group B also had an even lower proportion (23%) of participants experiencing severe interference to their general activities at midpoint compared to the initial timepoint and this was statistically significant.

  There was also no difference in the pain interference (both general activities and sleep) experienced at the initial timepoint between participants that completed their follow-up consultation and those that were lost to follow up.



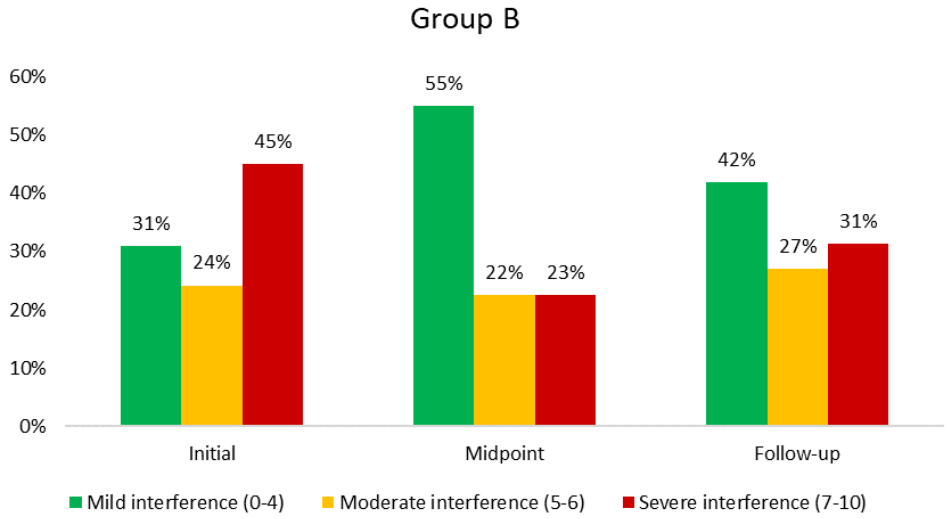


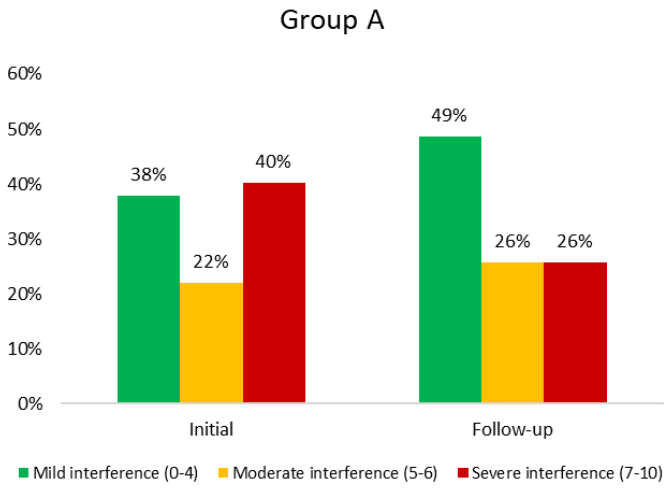
Figure 21 Comparison of pain interference (general activities) at different timepoints between Groups A and B

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

*All changes between the initial and follow-up timepoints were statistically significant ($p<0.05$)

Likewise, there were improvements in the self-reported pain interference to sleep from initial to follow-up in both Groups A and B (Figure 22):

- The proportion of participants that experienced only mild interference to their sleep as a result of their chronic pain increased from 38% to 49% in Group A and from 40% to 63% in Group B. These increases were statistically significant.
- The proportion of participants that experienced severe interference to their sleep as a result of their pain decreased from 40% to 26% in Group A and from 41% to 19% in Group B. These decreases were statistically significant in both Groups. Group B also had a lower proportion (27%) of participants experiencing severe interference to their general activities at midpoint compared to the initial timepoint.



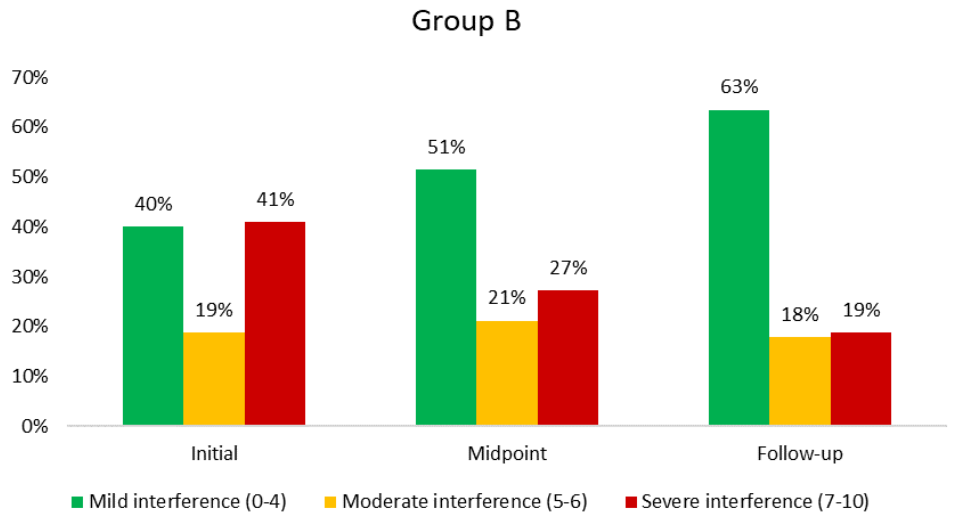


Figure 22 Comparison of pain interference (sleep) at different timepoints between Groups A and B

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

*All changes between the initial and follow-up timepoints were statistically significant using a two-sided test ($p<0.05$)

Overall, at the initial timepoint, 31% participants (n=2,528) reported experiencing mild interference to general activities, 26% (n=2,131) reported experiencing moderate interference and 43% (n=3,580) reported experiencing severe interference. Subgroup analyses using data combined from both Groups A and B showed that participants' pain interference to general activities improved from initial to follow-up regardless of whether their pain interference was mild, moderate or severe prior to commencing the intervention. However, participants that had experienced moderate or severe interference at the initial benefited more from the intervention, demonstrating significantly larger improvements to their average pain interference scores, with reductions of 15.7% and 24.6% respectively, compared to those that had mild interference, with a reduction of 6.5%, at the start of the intervention (Table 37).

Table 37 Changes to average pain interference (to general activities) scores for different categories of pain interference at the initial timepoint

	Pain interference score at initial			**Pain interference score at follow-up**			**Change in pain interference score from initial to follow-up (using matched data)**			
Level of pain interference at initial	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value ***
Mild interference	2,528	2.48 (1.34)	3	1,345	2.36 (1.89)	2	1,345	-0.16 (1.76)	-6.45	N/A#

	Pain interference score at initial			Pain interference score at follow-up			Change in pain interference score from initial to follow-up (using matched data)			
Level of pain interference at initial	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value ***
Moderate interference	2,131	5.47 (0.50)	5	1,155	4.61 (1.92)	5	1,155	-0.86 (1.91)	-15.72	0.00
Severe interference	3,580	8.25 (1.11)	8	1,874	6.16 (2.42)	6	1,874	-2.03 (2.36)	-24.61	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Mild interference category was used the comparison group in this regression modelling

Similarly, participants' pain interference to general activities also improved from initial to follow-up regardless of whether their pain was mild, moderate or severe prior to commencing the intervention. Participants that had moderate or severe pain at the initial timepoint were shown to have significantly larger improvements to their average pain interference scores, with reductions of 17.6% and 21.8% respectively, compared to those that had mild pain, with a reduction of 16.7%, at the start of the intervention (Table 38).

Table 38 Changes to pain interference (to general activities) levels for different categories of pain severity at the initial timepoint

	Pain interference score at initial			Pain interference score at follow-up			Change in pain interference score from initial to follow-up (using matched data)			
Level of pain severity at initial	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value ***
Mild pain	1,813	3.17 (2.10)	3	961	2.58 (2.07)	2	961	-0.53 (1.85)	-16.72	N/A#
Moderate pain	2,591	5.33 (2.06)	5	1,407	4.33 (2.29)	5	1,407	-0.94 (2.14)	-17.64	0.00
Severe pain	3,835	7.30 (2.16)	8	2,006	5.72 (2.57)	6	2,006	-1.59 (2.35)	-21.78	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Mild pain category was used the comparison group in this regression modelling

Further subgroup analyses showed that the average pain interference to general activities improved for participants whose pain severity improved from initial to follow-up and, conversely, became worse for participants whose pain became more severe (Table 39).

Table 39 Changes to pain interference (to general activities) levels depending on whether participants' pain severity improved from initial to follow-up

	Pain interference score at initial			Pain interference score at follow-up			Change in pain interference score from initial to follow-up (using matched data)			
Change in pain severity from initial to follow-up	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value ***
Pain severity improved	2,594	5.91 (2.60)	6	2,594	3.89 (2.51)	4	2,594	-2.02 (2.13)	-33.78	0.00
Pain severity unchanged	1,163	5.59 (2.63)	6	1,163	5.31 (2.61)	5	1,163	-0.28 (1.21)	-5.36	N/A#
Pain severity became worse	617	5.24 (2.68)	5	617	6.14 (2.46)	6	617	0.89 (2.10)	17.84	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Unchanged pain severity category was used the comparison group in this regression modelling

The positive changes to pain severity and interference experienced by the participants were also observed by the pharmacists at the trial sites. From the interviews conducted with pharmacies during the case study visits, some reported seeing an effect of the CPMC on the severity of pain experienced, with most reporting it had reduced their participants' pain severity or seemed to have alleviated their pain and only one pharmacist reporting they had a participant experience increased pain and did not continue with the trial.

IMPACT ON PSYCHOLOGICAL DISTRESS

All trial participants were asked to complete the PHQ-4 at their initial, midpoint and follow-up consultations which provided a very brief but accurate assessment of their depression and anxiety.

The average PHQ-4 scores at the initial timepoint were similar in Groups A and B and there were improvements in participants' experience of psychological distress as a result of the intervention in both Groups which were statistically significant (Table 40). There was moderate correlation

between the participants' pain severity and their level of psychological distress at the initial timepoint, that is, the level of psychological distress experienced by individuals increased as their pain severity increased. This correlation is statistically significant (p = 0.00) and shown in Figure 23.

Table 40 Average Patient Health Questionnaire-4 scores from initial to follow-up in Groups A and B

	Initial			Follow-up			Change from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value
								Upper	Lower	
Group A	4,316	3.35 (3.38)	2	2,853	2.62 (2.96)	2	-0.73	-0.58	-0.88	0.00
Group B	3,923	3.47 (3.60)	2	1,521	2.33 (3.20)	1	-1.13	-0.93	-1.34	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

** Multilevel mixed-effects linear regression with time as the fixed effect and pharmacy and individual as the random effects, adjusted for pain severity and pain interference

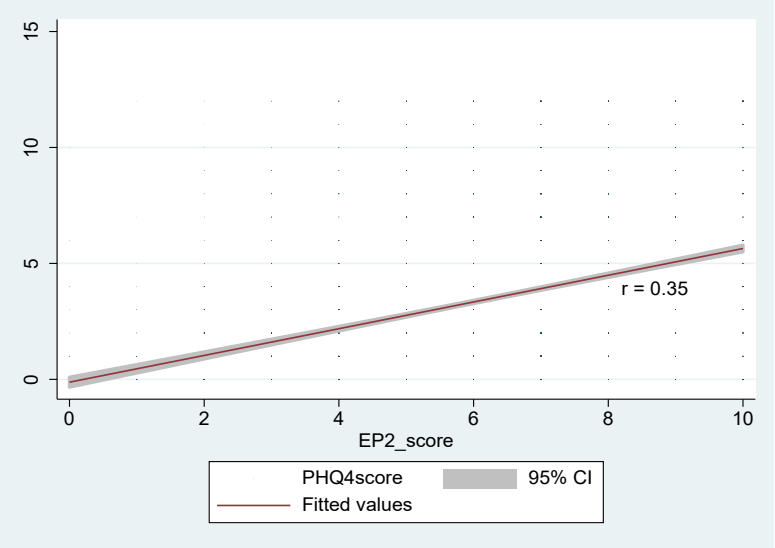


Figure 23 Relationship between pain severity and psychological distress in all trial participants at the initial timepoint

Source: Participant data collected using GuildLink at the initial (n=8,239) timepoint

There were also moderate correlations which were statistically significant between the degree of interference experienced by the participants to both general activities (Figure 24) and sleep (Figure 25) as a result of their pain and their psychological distress, that is, individuals that experienced more interference because of their pain also experienced more psychological distress.

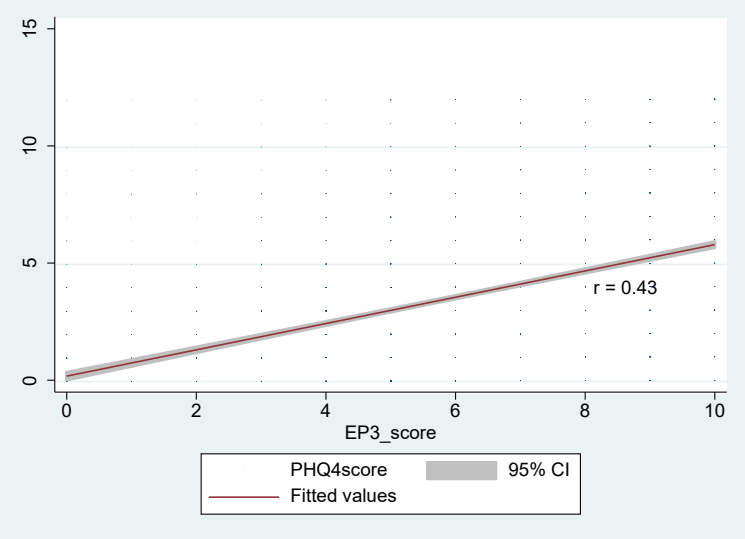


Figure 24 Relationship between pain interference (general activities) and psychological distress in all trial participants at the initial timepoint

Source: Participant data collected using GuildLink at the initial (n=8,239) timepoint

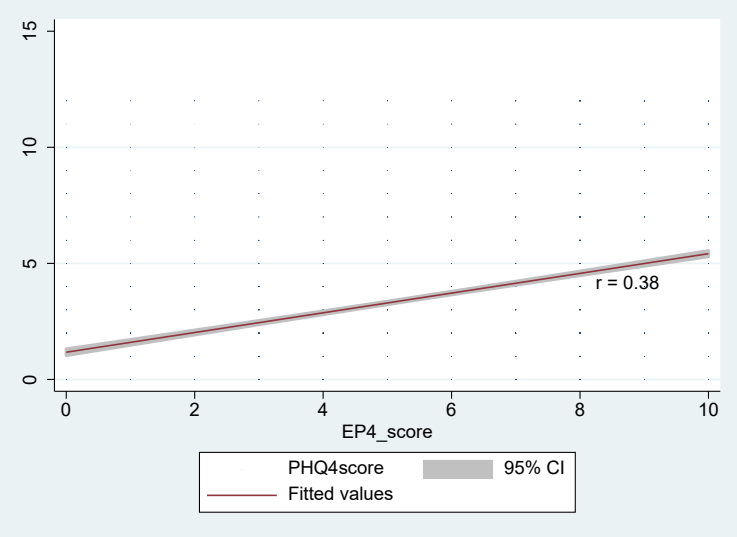


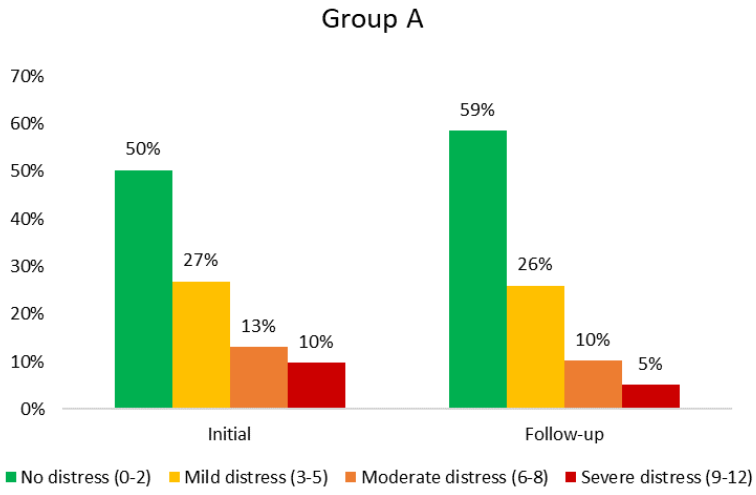
Figure 25 Relationship between pain interference (sleep) and psychological distress in all trial participants at the initial timepoint

Source: Participant data collected using GuildLink at the initial (n=8,239) timepoint

There was no correlation between the participants' regionality and their psychological distress at any timepoint or changes in their psychological distress from initial to follow-up.

Trial participants were also categorised into having 'no distress', 'mild distress', 'moderate distress' and 'severe distress' and the proportions of participants in each of the distress categories at the initial timepoint were similar in Groups A and B. Around 50% of participants experienced no distress, around 25% experienced mild distress, 13% experienced moderate distress and around 10% experienced severe distress at the start of the intervention. There were similar degrees of improvement in the proportions of participants experiencing these different levels of psychological distress from initial to follow-up in both Groups A and B, presented in Figure 26 and summarised below:

- The proportion of participants that experienced severe psychological distress decreased significantly from 10% to 5% in Group A and from 12% to 8% in Group B. Group B also had a lower proportion (7%) of participants experiencing severe psychological distress at midpoint compared to the initial timepoint.
- There were statistically significant decreases in the proportion of participants that experienced moderate psychological distress, from 13% to 10% in both Groups A and B. Group B also had a lower proportion (7%) of participants experiencing moderate psychological distress at midpoint compared to the initial timepoint.
- There were slight decreases in the proportion of participants experiencing mild distress, from 27% to 26% in Group A and 24% to 23% in Group B.
- There were resultant increases in the proportions of participants that experienced no psychological distress from 50% to 59% in Group A and from 51% to 59% in Group B. These increases were statistically significant.



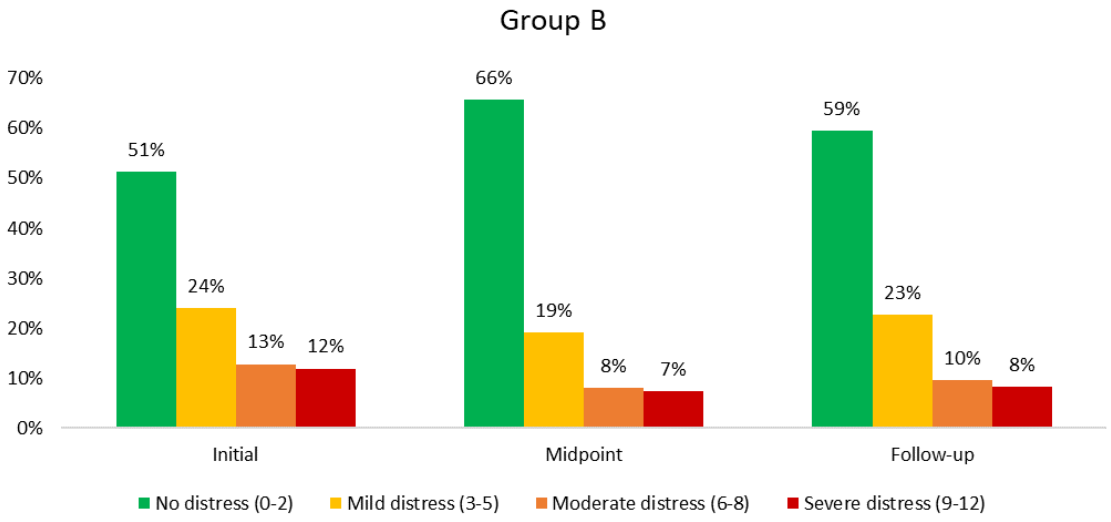


Figure 26 Comparison of psychological distress at different timepoints between Groups A and B

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

*All changes between the initial and follow-up timepoints were statistically significant using a two-sided test ($p<0.05$)

Some participants reported in the Patient Survey that they noticed their emotional state had improved as a result of the trial. Of the 181 participants who completed the relevant question in the survey, 110 (61%) reported they noticed their emotional state had become at least a little better. Almost a third of the participants (33%) felt their emotional state became slightly or moderately better and around a quarter of them (28%) reported their emotional state became better to the extent that their improved state made a real difference to them.

IMPACT ON PAIN SELF-EFFICACY AND MANAGEMENT

Pain self-efficacy

All trial participants were asked to complete the PSEQ-2 at their initial, midpoint and follow-up consultations.

The average PSEQ-2 scores at the initial timepoint were similar in Groups A and B, with 7.37 being the average score for Group A participants and 7.22 being the average score for Group B participants. There were improvements in participants' levels of self-efficacy from initial to follow-up in Groups A and B, and these changes were statistically significant in both Groups (Table 41). On average, Group B participants demonstrated a greater improvement in their self-efficacy in managing their pain over time from initial to follow-up compared to Group A participants (1.38 c.f. 0.77, Figure 27).

Table 41 Average pain self-efficacy (PSEQ-2) scores from initial to follow-up in Groups A and B

	PSEQ-2 score at initial			**PSEQ-2 score at follow-up**			**Change in PSEQ-2 score from initial to follow-up**			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value
								Upper	Lower	
Group A	4,316	7.37 (3.08)	8	2,853	8.14 (2.80)	8	0.77	0.91	0.63	0.00
Group B	3,923	7.22(3.31)	7	1,521	8.60 (3.19)	9	1.38	1.57	1.18	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

* Multilevel mixed-effects linear regression with time as the fixed effect and pharmacy and individual as the random effects

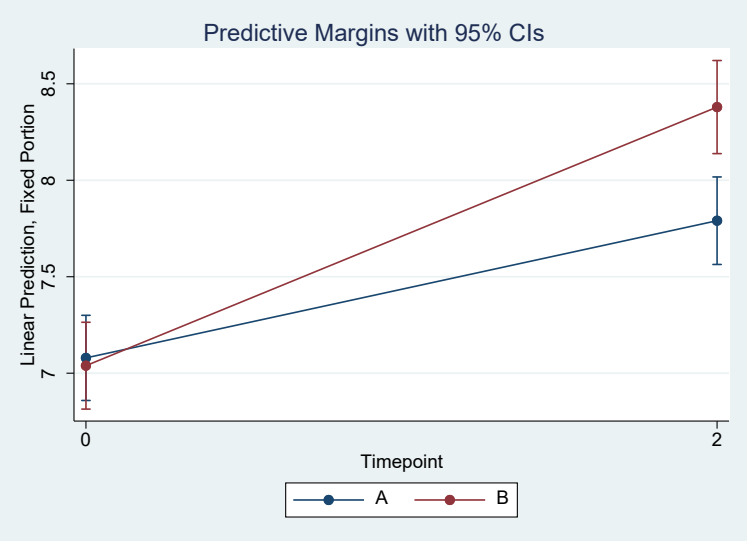
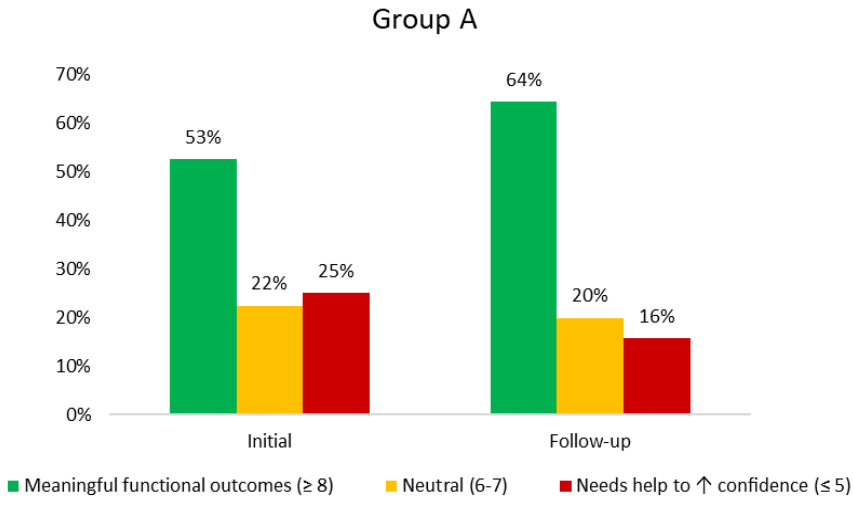


Figure 27 Comparison of changes to pain self-efficacy over time between Groups A and B.
Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

Around half of the participants having self-efficacy levels associated with meaningful functional outcomes and around a quarter had self-efficacy levels indicating they needed help to improve their confidence in performing daily activities despite their chronic pain at the initial timepoint. These proportions were similar across both Groups A and B.

There were improvements in the average level of self-efficacy from initial to follow-up in both Groups A and B, presented in Figure 28 and summarised below:

- The proportion of participants that had self-efficacy levels associated with meaningful functional outcomes increased significantly from 53% to 64% in Group A and from 50% to 62% in Group B. Group B had an even higher proportion (68%) of participants with these self-efficacy levels at midpoint and the change from the initial timepoint was statistically significant.
- There were also statistically significant decreases in the proportion of participants that had self-efficacy levels indicating they needed help to improve their confidence, from 25% to 16% in Group A and from 29% to 20% in Group B. Group B also had a lower proportion (16%) of participants with these levels of self-efficacy at midpoint compared to the initial timepoint.



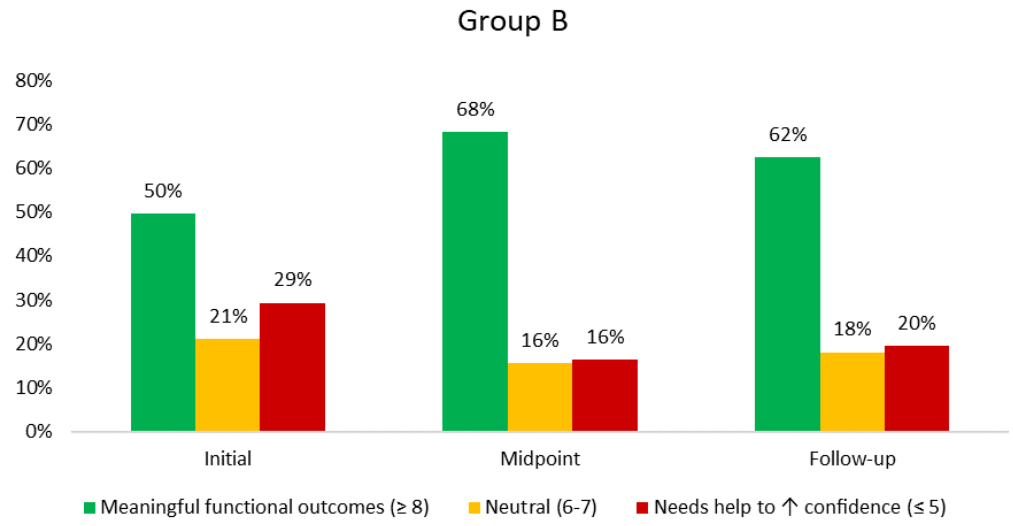


Figure 28 Comparison of pain self-efficacy at different timepoints between Groups A and B

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

*All changes between the initial and follow-up timepoints were statistically significant (p<0.05)

There was no correlation between the participants' regionality and their pain self-efficacy at any timepoint or changes in their pain self-efficacy from initial to follow-up.

Subgroup analyses using data combined from Groups A and B showed the average level of self-efficacy increased the most for participants whose pain severity improved and, conversely, became worse for participants whose pain severity became worse (Table 42). There were also slight improvements in the average level of self-efficacy for participants whose pain severity scores was unchanged from initial to follow-up, which suggests participants whose pain severity did not improve as a result of the intervention had more confidence in performing their daily activities despite their chronic pain.

Table 42 Average pain self-efficacy (PSEQ-2) scores depending on whether participants' pain severity changed from initial to follow-up

	PSEQ-2 score at initial			**PSEQ-2 score at follow-up**			**Change in PSEQ-2 score from initial to follow-up (using matched data)**			
Change in pain severity from initial to follow-up	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value***
Pain severity improved	2,594	7.30(3.22)	8	2,594	8.80 (2.78)	9	2,594	1.38 (2.23)	18.90	0.00

	PSEQ-2 score at initial			PSEQ-2 score at follow-up			Change in PSEQ-2 score from initial to follow-up (using matched data)			
Change in pain severity from initial to follow-up	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value***
Pain severity unchanged	1,163	7.21 (3.06)	8	1,163	7.67 (2.97)	8	1,163	0.45 (1.57)	6.24	N/A#
Pain severity became worse	617	7.45 (3.20)	8	617	7.39 (3.15)	8	617	-0.06 (2.43)	-0.81	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Unchanged pain severity category was used the comparison group in this regression modelling

This was also the case for pain interference to general activities, where the average level of self-efficacy increased most for participants whose pain interference improved but there was some improvement for those whose pain interference scores were unchanged from initial to follow-up (Table 43).

Table 43 Average pain self-efficacy (PSEQ-2) scores depending on whether participants' pain interference (to general activities) changed from initial to follow-up

	PSEQ-2 score at initial			PSEQ-2 score at follow-up			Change in PSEQ-2 score from initial to follow-up (using matched data)			
Change in pain interference from initial to follow-up	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value***
Interference improved	2,486	7.21 (3.08)	7	2,486	8.65 (2.83)	9	2,486	1.44 (2.27)	19.97	0.00
Interference unchanged	1,287	7.54 (3.17)	8	1,287	7.95 (3.06)	8	1,287	0.41 (1.51)	5.44	N/A#
Interference became worse	601	7.71 (3.01)	8	601	7.61 (2.98)	8	601	-0.10 (2.39)	-1.30	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Unchanged pain interference category was used the comparison group in this regression modelling

Pain self-management

Participants in both Groups A and B at the evaluation trial sites were asked to complete the PIH questionnaire which was a validated questionnaire used to assess their self-management of their chronic pain.

Despite the randomisation of pharmacies into the two Groups, the average total self-management score was slightly lower in Group A participants (71.08) than in Group B participants (72.82) and the difference was statistically significant even after adjusting for clustering by pharmacy (

Table 44).

Table 44 Average pain self-management (PIH) scores from initial to follow-up in Groups A and B

	PIH score at initial			PIH score at follow-up			Change in PIH score from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value *
								Upper	Lower	
Group A	1,452	71.08 (14.35)	72	725	76.69 (13.41)	78	5.61	6.86	4.36	0.00
Group B	565	72.82 (15.71)	76	239	73.98 (15.00)	76	1.16	3.51	1.18	0.00

Source: Evaluation data collected using Survey Monkey at the initial (n=1,452) and follow-up(n=565) timepoints

Note: The PIH scale was administered only at the evaluation sites during the initial and follow-up consultations

* Multilevel mixed-effects linear regression with time as the fixed effect and pharmacy and individual as the random effects

Group A participants improved their self-management from initial to follow-up, with the average total score increasing from 71.08 to 76.65 and the increase was statistically significant. Group B participants also had a higher total self-management score at follow-up compared to initial (73.98 c.f. 72.82), and this increase was statistically significant.

Similar to pain self-efficacy scores, subgroup analyses using data combined from Groups A and B showed the average level of self-management increased the most for participants whose pain severity improved. The average level of self-management also increased for participants whose pain severity scores were unchanged or worsened from initial to follow-up, which suggests that, on average, participants were better able to manage their chronic pain regardless of changes to their pain severity as a result of the intervention (Table 45).

Table 45 Average self-management (PIH) scores depending on whether participants' pain severity changed from initial to follow-up

	PIH score at initial			PIH score at follow-up			Change in PIH score from initial to follow-up (using matched data)			
Change in pain severity from initial to follow-up	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value***
Pain severity improved	758	71.56 (14.84)	73	563	76.94 (13.72)	79	385	6.94 (14.22)	9.7	0.02
Pain severity unchanged	314	70.83(14.50)	72	240	74.79 (14.85)	76	155	4.18 (15.55)	5.9	N/A#
Pain severity became worse	196	72.28 (14.53)	72.5	161	74.62 (12.59)	75	110	2.49 (13.81)	3.4	0.44

Source: Evaluation data collected using Survey Monkey at the initial (n=1,268) and follow-up (n=964) timepoints

Note: The PIH scale was administered only at the evaluation sites during the initial and follow-up consultations. Not all participants who responded to questions about their pain severity completed the PIH scale

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Unchanged pain severity category was used the comparison group in this regression modelling

This was also the case for pain interference to general activities, where the average level of self-efficacy increased for participants regardless of changes to their pain interference scores from initial to follow-up. However, the differences in the average self-management scores between groups of participants who experienced different changes to their pain interference were not statistically significant (Table 46).

Table 46 Average self-management (PIH) scores depending on whether participants' pain interference (to general activities) changed from initial to follow-up

	PIH score at initial			PIH score at follow-up			Change in PIH score from initial to follow-up (using matched data)			
Change in pain interference from initial to follow-up	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value***
Interference improved	704	71.43 (14.93)	73	540	77.62 (13.65)	80	367	6.98 (14.58)	9.8	0.07
Interference unchanged	366	71.01 (14.26)	72	276	74.01 (14.40)	74	179	3.88 (14.41)	5.5	N/A#
Interference became worse	198	72.59 (14.69)	75	148	73.91 (12.89)	74.5	104	3.25 (14.32)	4.5	0.82

Source: Evaluation data collected using Survey Monkey at the initial (n=1,268) and follow-up (n=964) timepoints

Note: The PIH scale was administered only at the evaluation sites during the initial and follow-up consultations. Not all participants who responded to questions about their pain interference completed the PIH scale

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Unchanged pain interference category was used the comparison group in this regression modelling

Further, of the 186 participants who completed the Patient Survey at the end of the intervention:

- 41 participants (22%) reported almost no change in the level of physical pain. Conversely, 30 participants (16%) reported that their level of physical pain got 'a little better' while the same number of participants reported a 'moderate change' and for 28 (15%) the CPMC service made a real difference in the level of physical pain
- the majority of participants (148 [80%]) responded with 'no' to the question if there has been any change in their work status since commencing the CPMC service
- overall participants noted a change in their level of social functioning with 25 (13%) reporting 'a little better', 24 (13%) 'somewhat better', 28 (15%) saying 'moderately better', and 24 (13%) reporting a 'definite improvement which made a real difference'
- 53 (29%) reported that there was almost no change in the level of physical functioning. However, 32 (17.2%) and 33 (17.7%) reported their level of physical functioning got 'moderately better' and 'better' with a real difference, respectively
- the majority reported that the CPMC service had an impact on managing their chronic pain with 76 (41%) saying the service had some impact and 43 (23%) reporting a large impact.

Nine of the 29 pharmacists participating in the case study interviews provided feedback on the impact of the intervention on participants' ability to self-manage pain. It was reported that self-management of pain improved for some participants but not others. The education and action plan

provided by pharmacists helped participants use medications appropriately, resulting in better pain control.

Pharmacists believed that they played a key role in helping participants manage their chronic pain. It was also reported that "*participants learn how to be their own doctor and learnt that there* [are] *limitations in relying on doctors"*. Pharmacists regarded this motivation as important for participants being able to self-manage their pain.

IMPACT ON QUALITY OF LIFE

Participants participating in the trial at evaluation sites were asked to complete the AQoL-4D questionnaire at their initial and follow-up consultations.

Table 47 presents the average AQoL utility score at the initial and follow-up timepoints in the two Groups. There was an improvement in the average AQoL utility score from initial to follow-up in Group A participants (from 0.58 to 0.63) that was almost clinically important (0.06 units)[22], and this change was statistically significant. Group B participants demonstrated a clinically important improvement in their average AQoL utility score over time from initial to follow-up (from 0.53 to 0.70), and this change was also statistically significant.

Table 47 Average AQoL utility scores from initial to follow-up in Groups A and B

	AQoL utility score at initial			AQoL utility score at follow-up			Change in AQoL utility score from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value*
								Upper	Lower	
Group A	1,443	0.58 (0.26)	0.61	725	0.63 (0.25)	0.68	0.05	0.07	0.03	0.00
Group B	562	0.53 (0.28)	0.54	234	0.70 (0.24)	0.75	0.17	0.21	0.13	0.00

Source: Evaluation data collected via Survey Monkey at the initial for Group A (n=1,443) and Group B (n=562), and at the follow-up for Group A (n=725) and Group B (n=234).

Note: AQoL questionnaire was administered only at the evaluation sites during the initial and follow-up consultations

* Multilevel mixed-effects linear regression with time as the fixed effect and pharmacy and individual as the random effects

Figure 29 presents a comparison of changes the average AQoL utility score over time between Groups A and B; the difference in scores between the two Groups at the initial timepoint was not statistically significant after adjusting for clustering by Pharmacy, with Group B doing better than Group A.

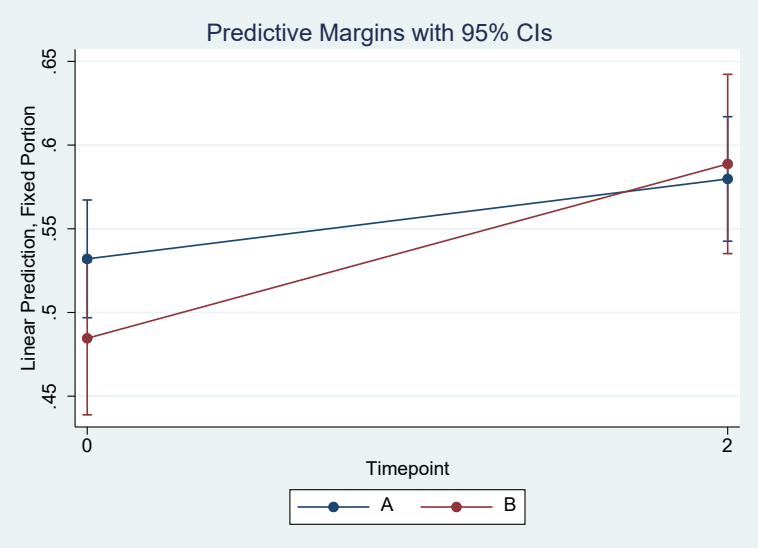


Figure 29 Comparison of changes the AQoL utility score over time between Groups A and B.

Source: Evaluation data collected via Survey Monkey at the initial for Group A (n=1,443) and Group B (n=562), and at the follow-up for Group A (n=725) and Group B (n=234).

Note: The AQoL questionnaire was administered only at the evaluation sites during the initial and follow-up consultations

* Multilevel mixed-effects linear regression with time as the fixed effect and pharmacy and individual as the random effects

There was no correlation between the participants' regionality and their AQoL utility scores at any timepoint or changes in their AQoL utility scores from initial to follow-up.

Subgroup analyses using data combined from Groups A and B showed the average AQoL utility scores increased the most for participants whose pain severity and pain interference to general activities improved and, conversely, became worse for participants whose pain severity and interference became worse (Table 48). There were also slight improvements in the average AQoL utility score, pain self-efficacy and self-management for participants whose pain severity and pain interference to general activities were unchanged from initial to follow-up. This suggests those that were more confident and able to manage their pain and perform their daily activities despite it experienced improved quality of life even though their chronic pain did not improve.

Table 48 Average AQoL utility scores depending on whether participants' pain severity and interference (to general activities) changed from initial to follow-up

	AQoL utility score at initial			**AQoL utility score at follow-up**			**Change in AQoL utility score from initial to follow-up (using matched data)†**			
	n	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value***
Changes in pain severity from initial to follow-up										
Pain severity improved	755	0.57 (0.26)	0.60	560	0.70 (0.24)	0.75	382	0.10 (0.22)	0.27	0.00

	AQoL utility score at initial			AQoL utility score at follow-up			Change in AQoL utility score from initial to follow-up (using matched data)ǂ			
	n	Mean (SD)	Median	n	Mean (SD)	Median	n	Mean (SD)	% change	P value*
Pain severity unchanged	313	0.52 (0.29)	0.56	239	0.58 (0.26)	0.62	155	0.03 (0.26)	0.10	N/A#
Pain severity became worse	194	0.59 (0.25)	0.64	160	0.57 (0.24)	0.56	109	-0.02 (0.24)	-0.07	0.22
Changes in pain interference (general activities) from initial to follow-up										
Interference improved	703	0.56 (0.26)	0.59	537	0.70 (0.23)	0.75	366	0.10 (0.22)	0.24	0.00
Interference unchanged	362	0.55 (0.28)	0.59	275	0.60 (0.27)	0.65	176	0.04 (0.25)	0.10	NA†
Interference became worse	197	0.59 (0.25)	0.64	147	0.54 (0.25)	0.55	104	-0.04 (0.26)	-0.10	0.05

Source: Evaluation data collected via Survey Monkey at the initial (n=1,443) and follow-up (n=565) timepoints, and participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

Note: AQoL questionnaire was administered only at the evaluation sites during the initial and follow-up consultations. Not all participants who responded to questions about their pain severity and interference completed the AQoL questionnaire.

ǂA merged data using patient IDs was used to identify participants in AQoL, ePPOC and PIH assessments. The matched IDs was analysed to estimate changes of AQoL score from initial to follow-up.

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Unchanged pain severity and interference categories were used the comparison groups in this regression modelling

Group A

In Group A, the average weighted AQoL-4D utility score at the initial timepoint was 0.58, and increased to 0.63 at follow-up. Based on population norms derived for the AQoL in the Australian population[23], scores of 0.58 and 0.63 were both indicative of being between 'poor health' and 'fair health'. This increase is not statistically significant, and is a little less than the value generally considered to be indicative of meaningful clinical change.

The average change in scores across each of the four AQoL dimensions for the trial participants are summarised below:

- The largest overall change was observed in the 'mental health' dimension, which increased on average by 0.04 from initial to follow up. This change was statistically significant.
- The 'independent living', 'relationships' and 'physical senses' dimensions all increased on average by 0.01 from initial to follow up. These changes were not statistically significant.

Group B

In Group B, the average weighted AQoL-4D utility score at the initial timepoint was 0.53, and increased to 0.70 at follow-up. Based on population norms derived for the AQoL in the Australian population[24], the initial score of 0.53 was indicative of being between 'poor health' and 'fair health' and the score of 0.69 at follow-up was indicative of 'fair health'. The value of the increase is generally considered to be indicative of meaningful clinical change, but this increase was not statistically significant.

The average change in scores across each of the four AQoL dimensions for the trial participants are summarised below:

- The largest overall change was observed in the 'mental health' dimension, which increased on average by 0.12 between initial and follow up. This change was statistically significant.
- There was a statistically significant increase in the 'relationships' dimension, which increased by an average of 0.08 from initial to follow up (mean 0.81 to 0.89 respectively). The clinical significance of this is questionable, as the initial score was relatively high at the initial timepoint.

The changes observed in the dimensions of 'independent living', which increased on average by 0.07, and 'physical senses', which increased on average by 0.01, were not statistically significant. In addition, pharmacists that participated in the case study interviews reported that the intervention improved the quality of life for some participants. According to these pharmacists, key changes as a result of participating in the trial reported by participants included:

- improvements in sleep
- weight loss
- improved mental health – "felt happier"
- reduced the number of medications
- was pain free or had better pain control
- improved ability to spend more time with their family
- increased mobility and capacity to exercise.

Conversely, some pharmacists during the case study visited reported being unsure if the intervention impacted participants' quality of life due to the short timeframe to observe effect (i.e. 6 weeks and 3 months). Although some pharmacists were not able to conclude that the CPMC intervention had made improvements to participant's quality of life, they emphasised that "*any opportunity that allows for participants to better manage their chronic pain could certainly impact on their quality of life*". Pharmacists also stated that involvement of a multidisciplinary team and participant motivation are key to improving quality of life.

Of the 186 respondents who completed the Patient Survey, around a fifth (21%) reported they felt there was almost no change in their general quality of life while 19% said it got 'a little better' (Figure 30). The same proportion of participants (19%) reported they felt they had a better quality of life since participating in the trial.

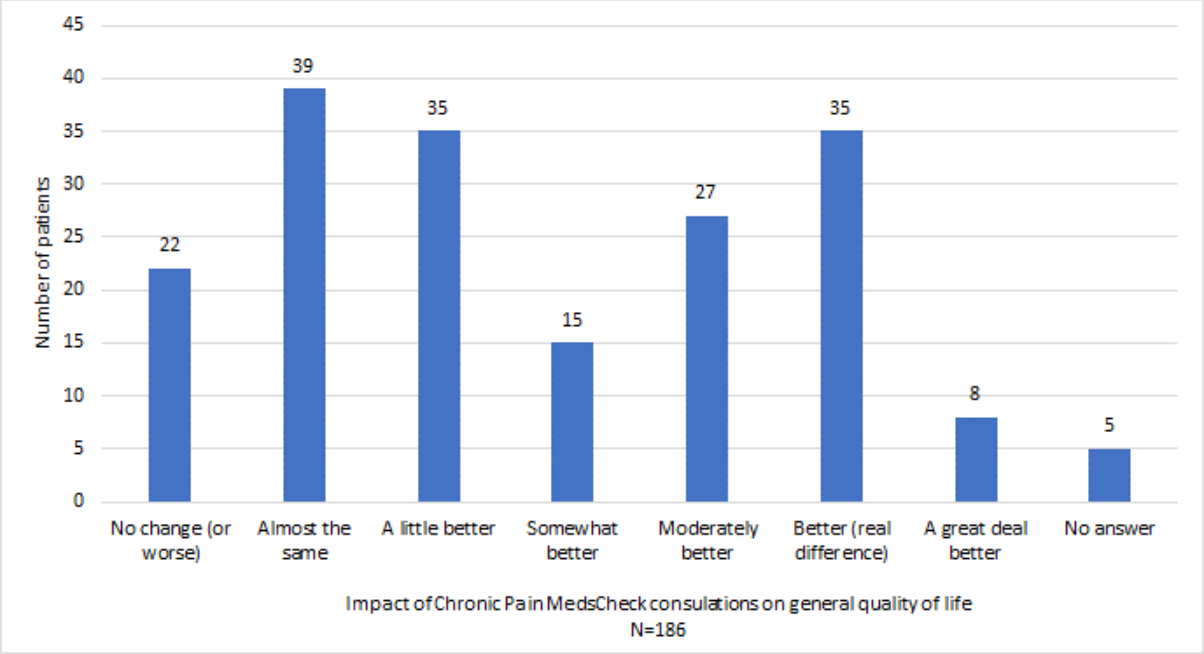


Figure 30 Impact on general quality of life
Source: HealthConsult Patient Satisfaction Survey, n=186

IMPACT ON UNDERSTANDING AND USE OF MEDICATIONS

Impact on use of medication

An assessment of the extent to which medication profiles changed as a result of the CPMC intervention focused on the average daily morphine equivalent dose for participants who were taking opioid medication for their chronic pain. This was because it has been shown that conducting well-focused medicine reviews (of which the CPMC is a type of) can allow pharmacists to help people use prescribed opioids and other analgesics effectively and safely[25].

Pharmacists asked all trial participants whether they were taking any opioid medication but not everyone responded to this question. Opioid usage was calculated by the pharmacists using an opioid conversion calculator built in the Trial software and recorded as morphine milligram equivalents (MME) at the initial and follow-up timepoints. Most of the participants who were taking opioid medication for their pain were on low doses (Figure 31). Doses that were higher than 600 MME and less than 1 MME were reviewed and corrected using the medication data available and the FPM ANZCA opioid equianalgesic calculator[26]. Doses of methadone (liquid only) were not included in the MME calculations.

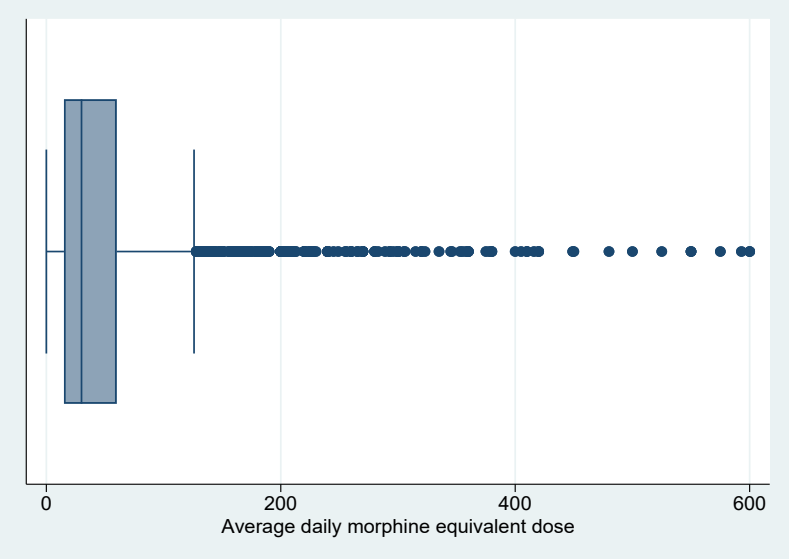


Figure 31 Spread of average daily morphine equivalent dose at the initial timepoint in Groups A and B.

Source: Participant data collected using GuildLink at the initial timepoint (n=3,970)

There was no change in the average daily morphine equivalent dose in Group A or Group B participants from initial to follow-up. Given the intervention was only over a three month period, advice from Expert Panel membership suggests this is not unexpected in the short timeframe.

Table 49 Average daily morphine equivalent dose from initial to follow-up in Groups A and B

	Daily morphine equivalent dose at initial			Daily morphine equivalent dose at follow-up			Change in daily morphine equivalent dose from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value*
								Upper	Lower	
Group A	2,161	50.84 (63.90)	30	1,359	49.87 (62.35)	30	-0.97	3.33	-5.26	0.07
Group B	1,809	47.74 (54.30)	30	700	47.82 (54.52)	30	0.07	4.82	-4.67	0.60

Source: Participant data collected using GuildLink at the initial (n=3,970) and follow-up (n=2,059) timepoints

* Multilevel mixed-effects linear regression with time as the fixed effect and pharmacy and individual as the random effects

The vast majority of participants' average daily morphine equivalent doses remained the same from their initial consultation to their follow-up consultation (Table 50).

Table 50 Average daily morphine equivalent dose from initial to follow-up in Groups A and B

	Change in daily morphine equivalent dose from initial to follow-up			
	Decreased (% total)	No change (% total)	Increased (% total)	Total
Group A	41 (3.06%)	1,276 (95.15%)	24 (1.79%)	1,341
Group B	25 (3.64%)	639 (93.01%)	23 (3.35%)	687

Source: Participant data collected using GuildLink at the initial (n=3,970) and follow-up (n=2,059) timepoints

Further, there was no correlation between the participants' regionality and their daily morphine equivalent doses at any timepoint or changes in their daily morphine equivalent doses from initial to

follow-up. Neither was there any statistically significant change in the opioid doses taken by participants with mild and moderate and severe pain at the start of the intervention between the initial and follow-up timepoints.

Subgroup analyses using data combined from Groups A and B showed the average opioid dose decreased for participants whose pain severity improved or remained unchanged and, conversely, increased for participants whose pain severity became worse (Table 51). However, only the increase in average opioid dose taken by participants whose pain severity became worse was significantly different to the average opioid dose for participants whose pain severity was unchanged from initial to follow-up.

Table 51 Average daily morphine equivalent dose depending on whether participants' pain severity changed from initial to follow-up

	Daily morphine equivalent dose at initial			Daily morphine equivalent dose at follow-up			Change in daily morphine equivalent dose from initial to follow-up			
Change in pain severity from initial to follow-up	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value***
Pain severity improved	1,169	45.08 (54.55)	30	1,135	45.48 (54.75)	30	1,118	-0.29 (7.43)	-0.64	0.22
Pain severity unchanged	608	52.40 (66.06)	30	605	50.30 (59.26)	30	595	-1.51 (23.41)	-2.89	N/A#
Pain severity became worse	326	58.40 (73.17)	31	319	60.15 (74.89)	32	315	1.03 (14.26)	1.76	0.05

Source: Participant data collected using GuildLink at the initial (n=3,970) and follow-up (n=2,059) timepoints

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Unchanged pain severity category was used the comparison group in this regression modelling

The impact on the use of medication was also examined qualitatively with the participating pharmacists. Around 20% pharmacists who participated in the case study interviews reported anecdotally that the participants' medication profile changed as a result of participating in the Trial. Medication changes included fewer number of analgesics used, reduced doses and changes in types of analgesics. These changes were brought about through referrals to GPs and pain specialists but were also initiated due to improvements in pain as a result of pain management strategies implemented by allied health services. The following vignette was from a pharmacist participating in the case study interviews:

"Referred to GPs physios, dieticians. Some people did follow up on those referrals- especially GP referrals. Exercise physiologist was another I encouraged people to consider. There was really good feedback from referrals"

Most of the pharmacists involved in the case study interviews reported anecdotally that the intervention resulted in optimising participants effective use of pharmacological or non-pharmacological services. Through this intervention, pharmacists were able to assess the efficacy of changes in treatment (during the follow up services), they identified non-compliance, abuse of medications and the use of sub-therapeutic medication dosages. The intervention also highlighted that some participants never used non-pharmacological services to manage their chronic pain.

In relation to pharmacological and non-pharmacological service use, the CPMC service provided pharmacists opportunities to:

- reiterate pain management strategies
- recommend and increase awareness of pharmacological and non-pharmacological treatments
- improve medication management and compliance
- educate on medication safety and provide reassurance

Although pharmacists recommend non-pharmacological treatment options in their daily practice, the intervention acted as a prompt to pharmacists.

Participants with mild to moderate pain were reported to be more receptive to pharmacists' recommendations and referrals to optimise pharmacological and non-pharmacological treatments. According to pharmacists, participants felt like they had better control over their medicine use and found the educational resources useful.

However, not all participants were motivated or interested in trying new treatment options. Pharmacists reported that to achieve better health outcomes, participants need to be motivated and "open to" trying new treatment options. To increase motivation, participants were informed of the possible positive lifestyle outcomes. However, higher costs involved with non-pharmacological treatments (e.g. physiotherapist or psychologist consultations, devices/aids for pain relief, etc.) and severity of their pain acted as barriers to the effective use of pharmacological and non-pharmacological services.

Impact on understanding of chronic pain and medications

The impact of the intervention on participants' understanding of their chronic pain and medication was assessed using a combination of data sources: health literacy questionnaire (evaluation sites only), patient satisfaction surveys (evaluation sites only) and case studies.

Participants at evaluation trial sites were asked a health literacy questionnaire which was comprised of six questions about their understanding of their chronic pain, medications they were taking to manage it and other pain management strategies. They were asked to rate their understanding using a scale of 1 (very poor) to 10 (very high) at their initial and follow-up consultations. Their response scores to the six questions were added to provide a health literacy total score out of 60.

There was a statistically significant improvement in the average health literacy total score in Group A participants from initial to follow-up. Group B participants had a higher health literacy total score at the initial timepoint but there was no significant change at follow-up (Table 52).

Table 52 Average health literacy total scores from initial to follow-up in Groups A and B

	Health literacy score at initial			Health literacy score at follow-up			Change in health literacy score from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value*
								Upper	Lower	
Group A	1,450	39.05 (11.3)	39	725	45.71 (9.52)	46	6.66	7.63	5.71	0.00
Group B	565	44.11 (12.27)	46	238	44.60 (12.01)	47	0.49	2.34	1.36	0.60

Source: Evaluation data collected via Survey Monkey at the initial for Group A (n=1,443) and Group B (n=562), and at the follow-up for Group A (n=725) and Group B (n=234).

Note: The health literacy questionnaire was administered only at the evaluation sites during the initial and follow-up consultations

* Multilevel mixed-effects linear regression with time as the fixed effect and pharmacy and individual as the random effects

There was strong correlation between the participants' health literacy total scores and their self-management scores at the initial timepoint, that is, their self-management of chronic pain increased as their level of health literacy increased. This correlation is statistically significant (p = 0.00) and shown in Figure 32.

Figure 32 Relationship between self-management scores and health literacy total scores in trial participants at the initial timepoint

Source: Evaluation data collected using Survey Monkey at the initial (n=1,268) timepoint

There was, however, a statistically significantly weak correlation between the participants' health literacy total scores (at the initial timepoint) and their socioeconomic status as determined by the SEIFA deciles (Figure 33). This may be because of the tool used to assess participants' health literacy, which was developed specifically for this Trial as no existing appropriate tool could be found was not validated prior to use due to the time constraints.

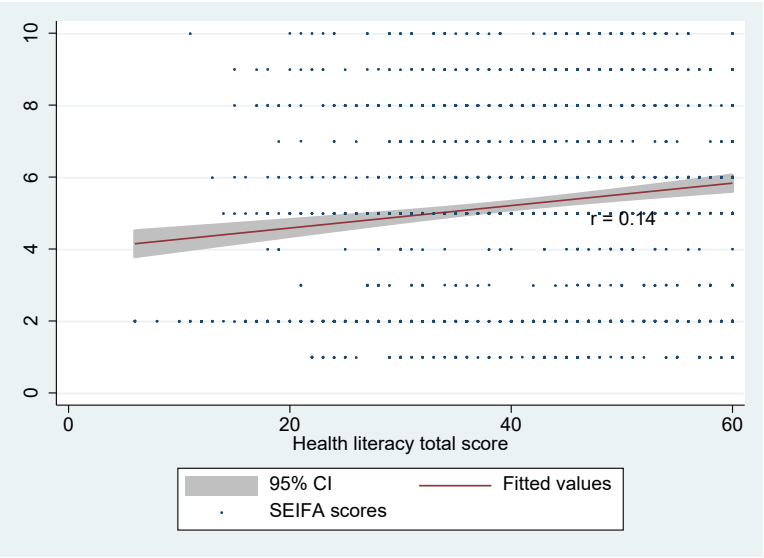


Figure 33 Relationship between health literacy total scores in trial participants and their SEIFA scores at the initial timepoint

Source: Evaluation data collected using Survey Monkey at the initial (n=1,268) timepoint

Similarly, there was a weak correlation between the participants' health literacy total scores (at the initial timepoint) and their regionality (r=0.16) which was statistically significant.

The participants' responses to each of the six health literacy questions were also examined. Overall, the average ratings by participants at the initial timepoint were relatively high across all measures and some improvements were demonstrated at follow-up, particularly in Group A. Between the initial and follow-up consultations:

- Group A participants' understanding of what was contributing to their chronic pain increased from an average rating of 6.95 to 7.92, and this was statistically significant. There was no significant difference in Group B participants' understanding.
- Group A participants' ratings of their understanding of their medications and when to take them to manage their chronic pain both increased, from 6.98 to 7.77 and 7.28 to 7.96 respectively, and these increases were statistically significant. There was no significant difference in Group B participants' understanding their medications but their understanding of when to take their medications decreased from 7.91 to 7.50.
- Group A participants' understanding of the interaction between their pain medication and other medications and the side effects of their chronic pain medication both increased, from 6.11 to 7.21 and 6.19 to 7.15, respectively, and these increases were statistically significant. Group B participants' understanding of both decreased slightly but neither of these decreases were statistically significant.
- Participants' awareness of other management strategies for their chronic pain increased in both Group A (5.96 to 7.51) and Group B (6.88 to 7.16) and both of these differences were statistically significant.

Similar to the self-management scores, subgroup analyses using data combined from Groups A and B showed the average health literacy total score increased the most for participants whose pain severity improved. The average health literacy total score also increased for participants whose pain severity

scores were unchanged or worsened from initial to follow-up (the difference between these two categories were not statistically significant). This suggests that, on average, participants had improved health literacy as a result of the intervention regardless of changes to their pain severity (Table 53).

Table 53 Average health literacy scores depending on whether participants' pain severity changed from initial to follow-up

	Health literacy score at initial			Health literacy score at follow-up			Change in health literacy score from initial to follow-up (using matched data)			
Change in pain severity from initial to follow-up	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value***
Pain severity improved	758	40.54 (11.94)	41	563	45.76 (10.29)	47	385	7.18 (11.31)	17.7	0.04
Pain severity unchanged	313	39.72 (11.16)	41	239	44.53 (10.61)	46	155	4.72 (11.16)	11.9	N/A#
Pain severity became worse	196	41.11 (11.82)	42	161	45.66 (9.15)	45	110	4.36 (10.35)	10.6	0.82

Source: Evaluation data collected using Survey Monkey at the initial (n=1,267) and follow-up(n=963) timepoints

Note: The health literacy questionnaire was administered only at the evaluation sites during the initial and follow-up consultations

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Unchanged pain severity category was used the comparison group in this regression modelling

The average health literacy total scores increased for participants regardless of changes to their pain interference to general activities from initial to follow-up. However, the differences in the average health literacy total scores between groups of participants who experienced different changes to their pain interference were not statistically significant (Table 54).

Table 54 Average health literacy scores depending on whether participants' pain interference (to general activities) changed from initial to follow-up

	Health literacy score at initial			Health literacy score at follow-up			Change in health literacy score from initial to follow-up (using matched data)			
Change in pain interference from initial to follow-up	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**Median**	**n**	**Mean (SD)**	**% change**	**P value***
Pain interference improved	704	40.28 (12.41)	42	539	46.37 (10.25)	48	367	7.14 (11.40)	17.7	0.71
Pain interference unchanged	365	38.73 (11.00)	39	276	38.73 (10.50)	44	179	5.11 (10.77)	13.2	N/A#
Pain interference became worse	198	41.22 (11.31)	43	148	45.53 (8.90)	45	104	4.27 (10.79)	10.4	0.19

Source: Evaluation data collected using Survey Monkey at the initial (n=1,267) and follow-up(n=963) timepoints

Note: The health literacy questionnaire was administered only at the evaluation sites during the initial and follow-up consultations

*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Unchanged pain interference category was used the comparison group in this regression modelling

In the Patient Survey, participants were asked to reflect on whether they felt their knowledge and understanding of their chronic pain medications had changed as a result of the Trial. A large majority (81.7%) of the 186 participants that responded to the survey felt their overall knowledge and understanding of their chronic pain medication had improved as a result of their participation in the CPMC service (Figure 34). A fifth (20%) of the participants said they noticed a definite improvement that has made a real and worthwhile difference and 10% felt their knowledge and understanding had become 'a great deal better'. Around 20% reported that overall knowledge and understanding of their chronic pain medication improved but the change has not made any real difference, and 17% reported a moderate improvement to their knowledge and understanding which had made a slight but noticeable change.

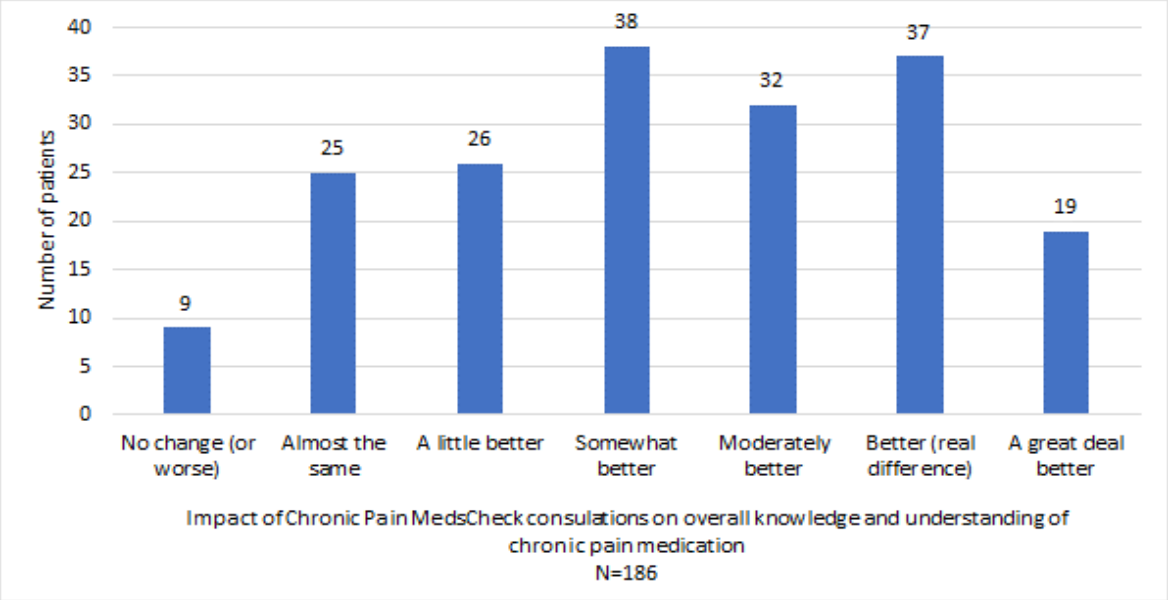


Figure 34 Impact on overall knowledge and understanding of chronic pain medication

Source: HealthConsult Patient Survey (n=186)

From the interviews conducted at a small number of trial sites, around a third of the pharmacists reported that the CPMC service improved participants' understanding of their medicines. For those who were "savvy with their medications", the CPMC service helped "reinforce their understanding, strengthening their interest in their health". The service also offered participants an opportunity to seek clarity by asking their pharmacist questions about their medication. Since participants had a better understanding of medications, they:

- were able to use pharmacological and non-pharmacological treatments appropriately,
- felt like they had more control over their medication
- had better pain control
- improved medication compliance, and
- reduced the use of benzodiazepines.

IMPACT ON HEALTH SERVICE USE

All trial participants were asked to report on the number of times they presented to a hospital ED and/or were admitted to hospital in the last month because of their pain.

Less than 10% of participants in both Groups reported at both the initial and follow-up timepoints that they had visited the hospital, either as a presentation to an ED or hospital admission, in the last month as a result of their pain. On average, participants in both Groups A and B reported less ED presentations due to their chronic pain at follow-up compared to the initial timepoint (0.15 c.f. 0.16 times in Group A and 0.14 c.f. 0.16 times in Group B) but these changes were not statistically significant (Table 55). Participants also reported less hospital admissions because of their pain, on average, at follow-up compared to the initial timepoint. This change was not statistically significant (Table 55).

Table 55 Average number of ED presentations and hospital admissions in Group A and Group B

	Initial measure			Follow-up measure			Change from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value*
								Upper	Lower	
ED presentations										
Group A	4,316	0.16 (0.65)	0	2,853	0.15 (0.62)	0	-0.01	0.01	-0.04	0.67
Group B	3,923	0.16 (0.69)	0	1,521	0.14 (0.65)	0	-0.02	0.01	-0.03	0.40
Hospital admissions										
Group A	4,316	0.10 (0.47)	0	2,853	0.09 (0.48)	0	-0.00	0.00	-0.02	0.26
Group B	3,923	0.10 (0.43)	0	1,521	0.09 (0.46)	0	-0.00	0.00	-0.02	0.50

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

* Multilevel mixed-effects linear regression with time as fixed effect and pharmacy and individual as random effects

IMPACT ON NUTRITION

All trial participants were asked to two questions about their nutrition at their initial, midpoint and follow-up consultations: vegetable intake and consumption of sugar sweetened drinks.

Vegetable intake

The average number of serves of vegetables consumed at the initial timepoint were similar in Groups A and B, with 2.51 being the average number of serves for Group A participants and 2.63 being the average number of serves for Group B participants. There were improvements in participants' vegetable intake from initial to follow-up in Groups A and B, and these changes were statistically significant in both Groups (Table 56). On average, Group B participants demonstrated a greater improvement in their vegetable intake over time from initial to follow-up compared to Group A participants (0.68 c.f. 0.23) (Figure 35).

Table 56 Average number of serves of vegetables from initial to follow-up in Groups A and B

	Number of serves of vegetables at initial			Number of serves of vegetables at follow-up			Change in vegetable serves from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value
								Upper	Lower	
Group A	4,316	2.51 (1.36)	2	2,853	2.74 (1.30)	3	0.23	0.17	0.29	0.00
Group B	3,923	2.63 (1.43)	2	1,521	3.31 (1.35)	3	0.68	0.59	0.76	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

* Multilevel mixed-effects linear regression with time as the fixed effect and pharmacy and individual as the random effects

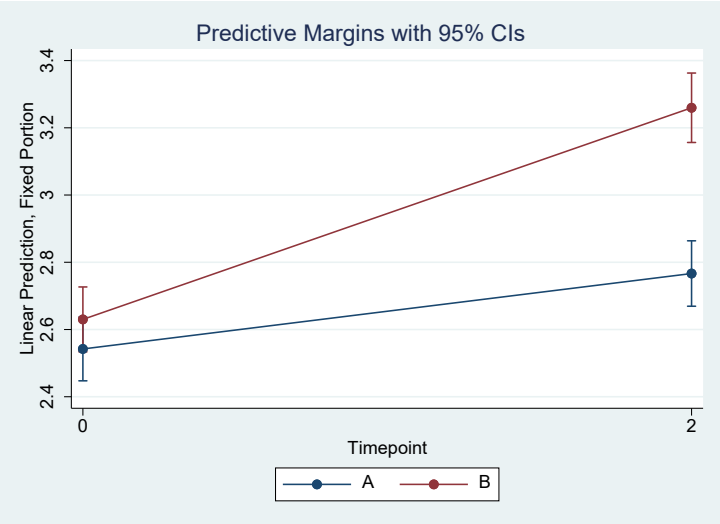
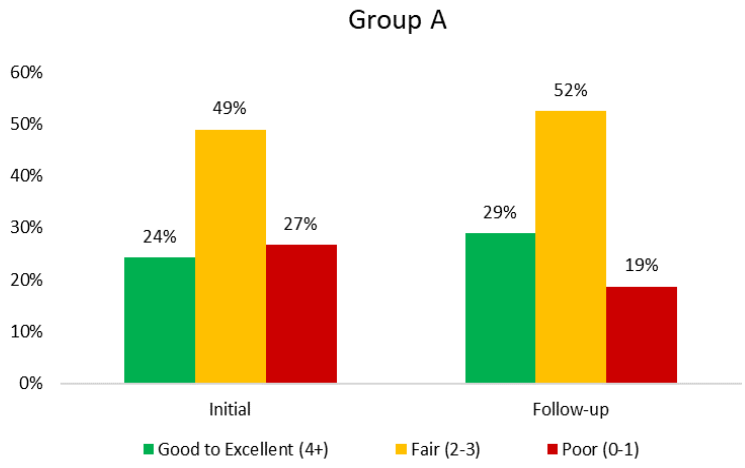


Figure 35 Comparison of changes to vegetable intake over time between Groups A and B.
Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

Around a quarter of the participants consumed a good to excellent amount of vegetables (4 or more serves) each day, around half ate a fair amount (2-3 serves) each day and the other quarter had a poor intake (0-1 serve) of vegetables at the initial timepoint. These proportions were similar across both Groups A and B.

There were improvements in the average number of serves of vegetables from initial to follow-up in both Groups A and B, presented in Figure 36 and summarised below:

- The proportion of participants that consumed a good to excellent amount of vegetables each day increased significantly from 24% to 29% in Group A and from 27% to 38% in Group B. Group B had an even higher proportion (44%) of participants with good to excellent intakes at midpoint and the change from the initial timepoint was statistically significant.
- There were also statistically significant decreases in the proportion of participants that had poor vegetable intakes, from 27% to 19% in Group A and from 25% to 13% in Group B. Group B also had an even lower proportion (9%) of participants with poor vegetable intakes at midpoint compared to the initial timepoint.



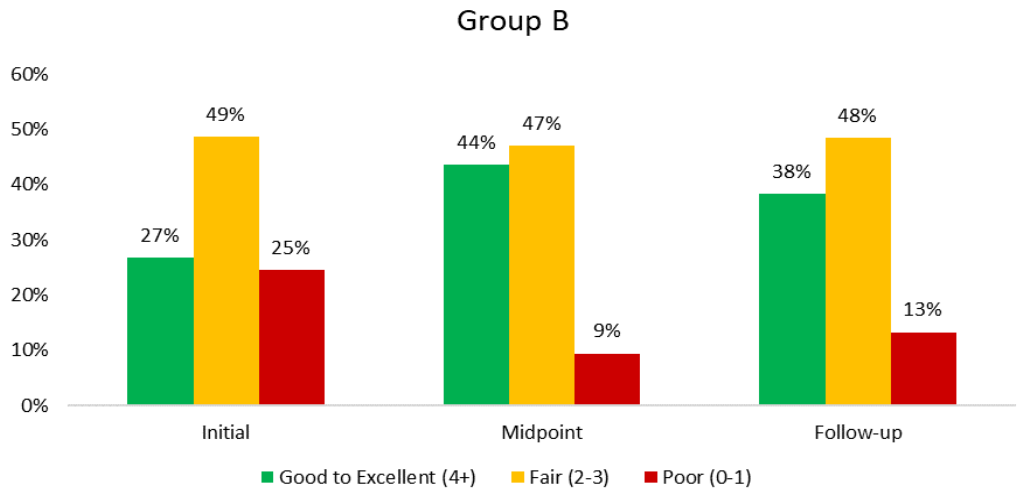


Figure 36 Comparison of vegetable intake at different timepoints between Groups A and B

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

*All changes between the initial and follow-up timepoints were statistically significant ($p<0.05$)

Sugar sweetened drink consumption

Around 80% of participants consumed a fair to excellent amount of sugar sweetened drinks (0-5 times per week), around 10% drank a poor amount (6-10 times per week) and a small percentage of participants had an extremely poor (11 or more times per week) intake of sugar sweetened drinks at the initial timepoint. These proportions were similar across both Groups A and B.

There were improvements in the average amount of sugar sweetened drinks consumed from initial to follow-up in both Groups A and B, presented in Figure 37 and summarised below:

- The proportion of participants that consumed a fair to excellent amount of sugar sweetened drinks increased significantly from 84% to 89% in Group A and from 82% to 89% in Group B. Group B had an even higher proportion (91%) of participants with good to excellent intakes at midpoint and the change from the initial timepoint was statistically significant.
- There were also statistically significant decreases in the proportion of participants that had poor and extremely poor consumptions of sugar sweetened drinks, with poor consumption reducing from 12% to 9% in Group A and from 11% to 8% in Group B, and extremely poor consumption reducing from 4% to 2% in Group A and from 6% to 3% in Group B. Group B also had even lower proportions of participants with poor and extremely poor intakes (7% and 2%, respectively) at midpoint compared to the initial timepoint.

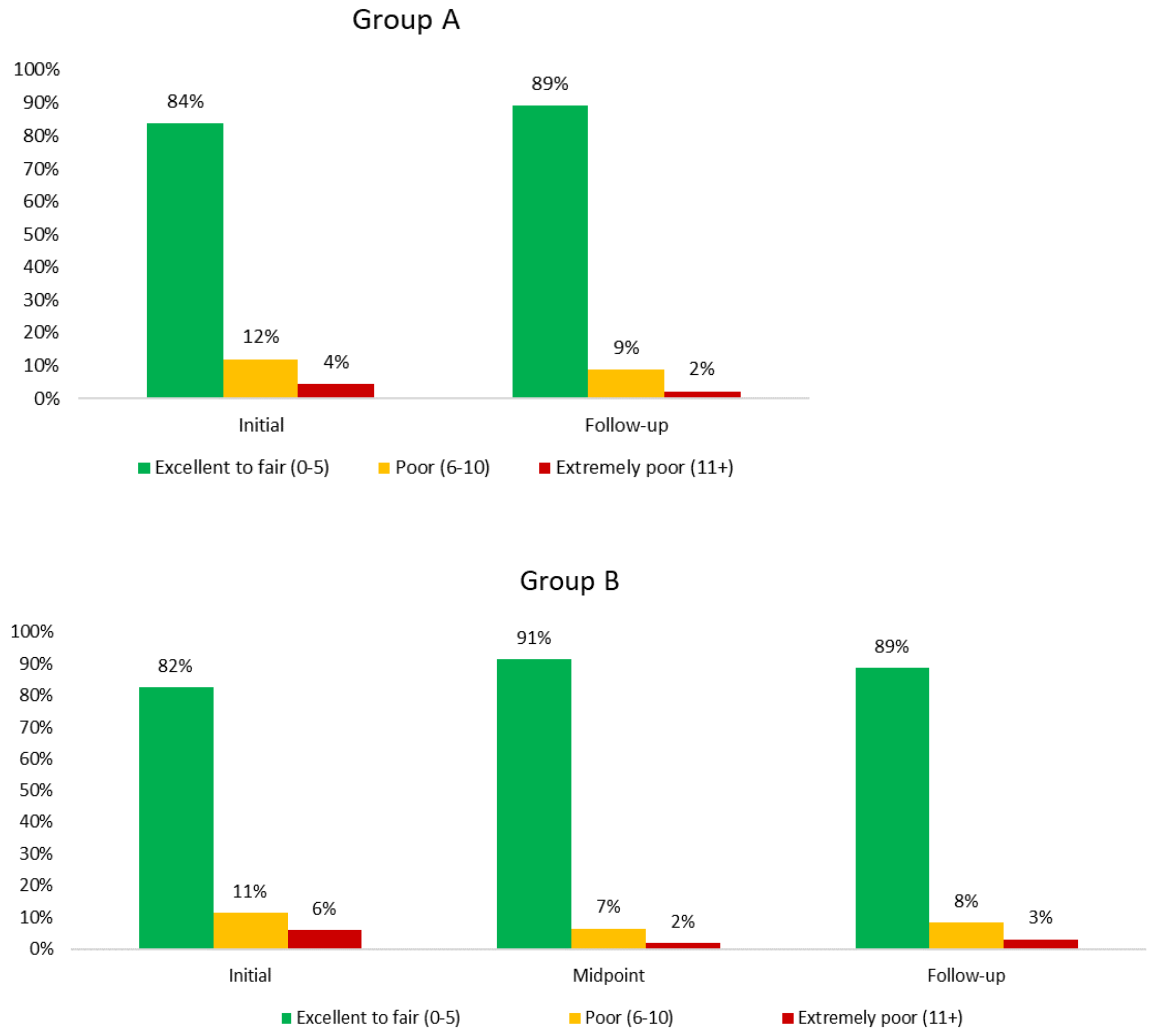


Figure 37 Comparison of sugar sweetened drink consumption at different timepoints between Groups A and B

Source: Participant data collected using GuildLink at the initial (n=8,239), midpoint (Group B, n=2,335) and follow-up (n=4,374) timepoints

*All changes between the initial and follow-up timepoints were statistically significant ($p<0.05$)

ACTION PLAN COMPLIANCE AND REFERRALS

Action plan compliance

At the follow-up timepoint, all pharmacists were asked to rate, on a scale of 1 (very unlikely) to 7 (highly likely), how compliant their participants had been at implementing the action plans provided as part of the Trial.

On average, Group B participants were reported to be more compliant with the action plans provided compared to Group A participants. The difference between the two Groups is statistically significant ($p=0.00$) (Table 57).

Table 57 Average action plan compliance scores at follow-up in Groups A and B

	Action plan compliance score at follow-up				
	n	Mean (SD)	Median	95% CI	
				Upper	Lower
Group A	1,420	4.43 (1.59)	5	4.52	4.35
Group B	493	5.02 (1.46)	5	5.15	4.89

Source: Action plan compliance as recorded by pharmacists at the follow-up (n=1,913) timepoint

A linear regression conducted using data from 1,913 participants showed that compliance with implementing the action plan could statistically significantly predict change in pain severity from the initial to follow-up timepoint, $F(1, 222) = 64.37$ ($p = 0.000$), after adjusting for clustering by pharmacy. This suggests that the more compliant a participant was with implementing the action plan, the more their pain severity improved from initial to follow-up. The regression equation was: predicted change in pain severity = -0.735 + 0.385 x (action plan compliance).

Similarly, another linear regression conducted using this data showed that compliance with implementing the action plan could statistically significantly predict change in pain interference to general activities from the initial to follow-up timepoint, $F(1, 222) = 58.56$ ($p = 0.000$), after adjusting for clustering by pharmacy. This suggests that the more compliant a participant was with implementing the action plan, the lesser the amount of pain interference experienced from initial to follow-up. The regression equation was: predicted change in pain interference = -0.700 + 0.392 x (action plan compliance).

Referrals to other services

Just over half of the trial participants (53.9%) were referred to another medical or health service as a result of their initial consultation. Although some participants were provided with referrals to multiple services, the main referral for these individuals as indicated by the pharmacists has been used for this analysis.

Pharmacists most commonly referred participants to GPs, making up 75% of referral across all trial sites. This was followed by dietitian referrals (8.7%), physiotherapist referrals (8.3%), and exercise physiologist referrals (2.7%). 'Other' referrals comprised of 4.5% of the referrals provided and included psychologist, sleep specialist and podiatrist (Figure 38).

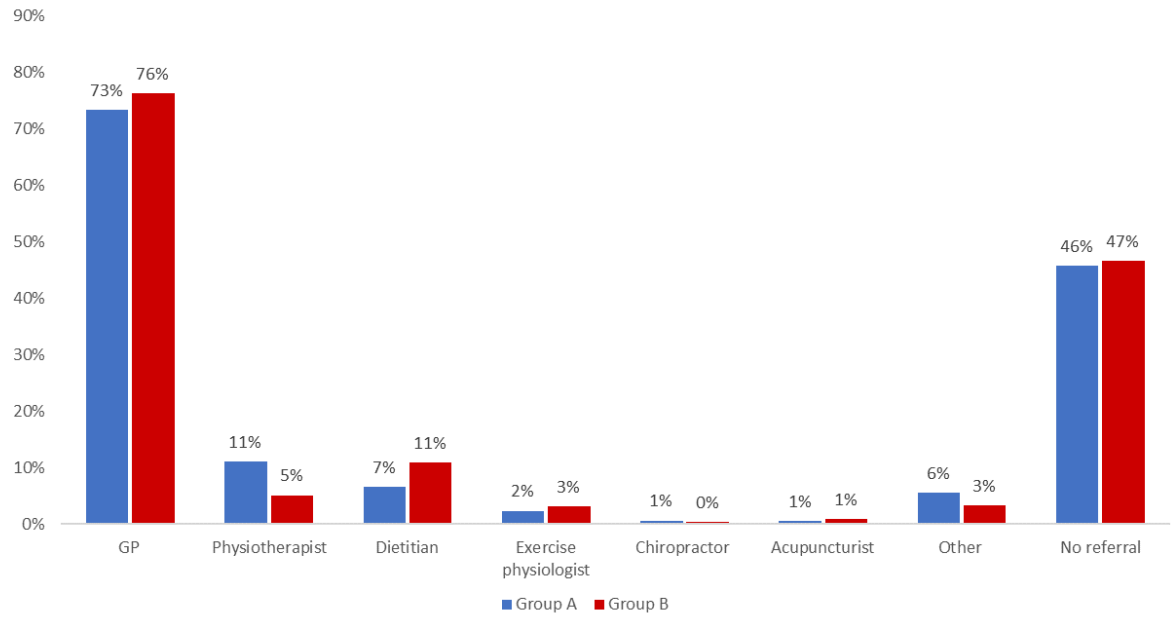


Figure 38 Comparison of the referrals to other services between Group A and Group B
Source: Referrals provided to participants as recorded by pharmacists at the initial timepoint (n=8,239)

During the case study visits, pharmacists reported that the referral process was an important way to inform GPs that their participant had attended the CPMC service and to encourage other health professionals to "reiterate" pain management strategies with the participant. They reported that referrals also resulted in improved health outcomes and changes in medication. Although pharmacists always referred to other health care services as part of their regular practice, they reported to develop a greater awareness of the health services available in the community through the CPMC service. It was also reported that participants and some GPs were receptive of the referral and provided positive feedback. This is reflected in the results of the Referred Provider survey where 33% (4 of 12 GPs who reported that they received a CPMC referral) of GPs described the referrals as 'somewhat' to 'extremely relevant'.

Pharmacists also provided the following feedback on barriers experienced with providing referrals:

- A few GPs did not provide feedback on the referral or action the recommendations and pharmacists experience difficulties with contacting them.
- Allied health services were not subsidised by Medicare when referred to by pharmacists. Due to the costs involved with these referrals, participants were unable to access them. Consequently, pharmacists were inclined to refer all participants to their GP, allowing for subsidised allied health services such as physiotherapy, dietician service, etc.
- Pharmacists noted that not all participants required a referral to another health care service, however they were unable to progress through the service until a referral was made in the Trial software. Because of this requirement, unnecessary referrals may have been made by the pharmacists in order to progress through the CPMC service.
- Pharmacists are unaware of the allied health services available in their community and feel wary about "stepping in their domain" when they provided pain management recommendations.

Pharmacists have also provided the following recommendations to overcome some of the barriers associated with the referral process:

- The initial consultation should be part of a multidisciplinary service, offering a holistic approach. For example, it should include consultation with an exercise physiologist (with access to a gym), a social worker, access to a transcutaneous electrical nerve stimulation (TENS) device and other non-pharmacological interventions
- Referral to other health care services should be optional
- Develop resources for participants to provide information on the type of services allied health professionals can offer.

PARTICIPANT EXPERIENCE OF THE SERVICE

Of the 186 participants who completed the Patient Survey, around three quarters (78%) stated that they would recommend the service to others (Figure 39).

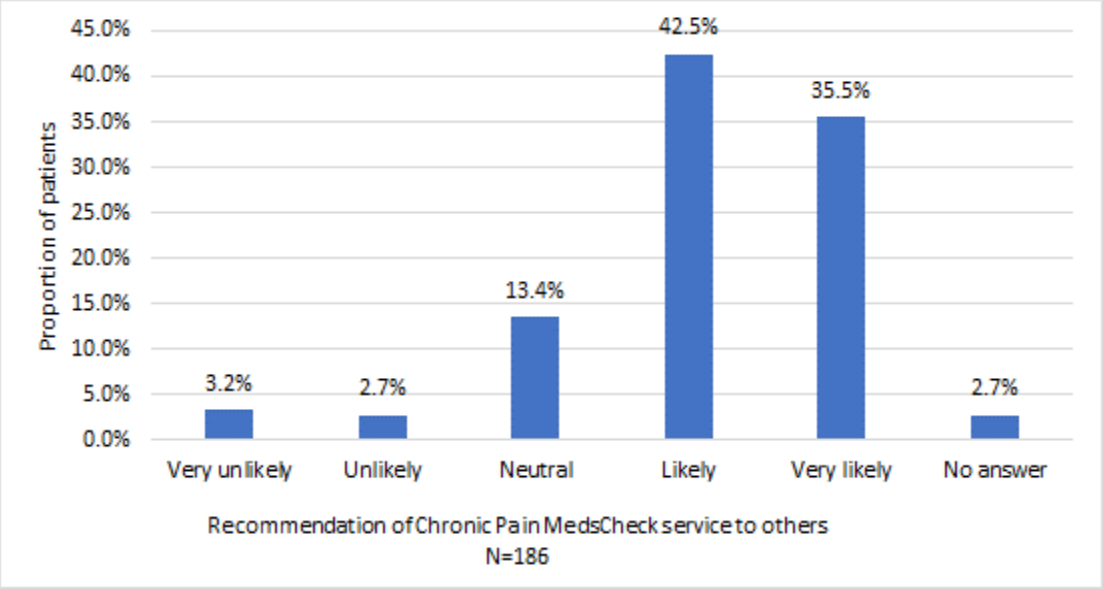


Figure 39 Proportion of participants that would recommend the service
Source: HealthConsult Patient Satisfaction Survey, n=186

The Patient Survey also asked participants to provide feedback on the favourable features of the CPMC service. The vast majority (95%) of the 161 participants who answered this question reported that they enjoyed all or various aspects of the service. The two aspects of the service enjoyed by the most participants were:

- Education and advice provided by the pharmacist (n=65, 40%)
- Opportunity to discuss their medications and symptoms with the pharmacist (n=55, 34%)

The other 5% of participants who responded to this question said they experienced little or no benefits from participating in the service.

Overall, participants described the service as “great”, “worthwhile” and “an excellent opportunity”. Other qualitative feedback from respondents includes that it:

- Improved their knowledge (reported by 84 respondents) in the following areas:

- types and causes of pain
- medication types, effects and quality
- pain management techniques such as pacing
- healthy diet and exercise (including types and frequency exercise)
- causes of poor sleep and techniques to improve sleep hygiene
- self-motivation techniques and positive thinking
- availability and access to allied health and other support services

- Improved use of medications (reported by 30 respondents) by encouraging the use of new treatments, reducing the amount of opioids and other analgesia and improved medication compliance.
- Led to more exercise, with some trying different forms of it such as walking, hydrotherapy, swimming and Pilates. Participants reported that exercise improved their health outcomes and assisted with pain management. They were able to perform more activities of daily living such as gardening due to their improved mobility and they had a better understanding of their physical limits.
- Improved their ability to manage their pain due to diversion, exercise, healthy eating, medication management and recognising their physical limits.

B.7. Extended Assessment of Harms

Not applicable due to the short duration of the CPMC trial. No follow-up data was provided.

B.8. Interpretation of the Clinical Evidence

On the basis of the evidence profile (summarised in section B.6), it is suggested that relative to the comparator, the intervention has non-inferior safety and superior effectiveness. Superior effectiveness can be seen in Table 58 whereby statistically significant improvements in outcomes are observed across all intervention Groups when compared to baseline (except for average morphine equivalence dose and health literacy). For safety, decreases in ED presentations (Grade 1 and 2) and hospitalisations which would be indicative of a Grade 3 and above adverse event (using Common Terminology Criteria for Adverse Events [CTCAE v5.0]),[27] were not statistically significant.

Table 58 Summary of the changes in the key outcomes from initial to follow-up in Groups A and B

	Initial measure			Follow-up measure			Change from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value
								Upper	Lower	
Pain severity										
Group A	4,316	6.09 (2.08)	6	2,853	5.20 (2.24)	5	-0.89	-0.79	-0.99	0.00
Group B	3,923	6.15 (2.20)	6	1,521	4.60 (2.54)	5	-1.55	-1.41	-1.69	0.00
Pain interference (general activities)										

	Initial measure			Follow-up measure			Change from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value
								Upper	Lower	
Group A	4,316	5.72 (2.62)	6	2,853	4.81 (2.58)	5	-0.91	-0.78	-1.03	0.00
Group B	3,923	5.80 (2.73)	6	1,521	4.15 (2.79)	4	-1.65	-1.49	-1.82	0.00
Pain interference (sleep)										
Group A	4,316	5.27 (3.04)	6	2,853	4.38 (2.86)	5	-0.88	-0.74	-1.03	0.00
Group B	3,923	5.25 (3.15)	5	1,521	3.56 (2.91)	3	-1.69	-1.51	-1.88	0.00
Psychological distress										
Group A	4,316	3.35 (3.38)	2	2,853	2.62 (2.96)	2	-0.73	-0.58	-0.88	0.00
Group B	3,923	3.47 (3.60)	2	1,521	2.33 (3.20)	1	-1.13	-0.93	-1.34	0.00
Pain self-efficacy										
Group A	4,316	7.37 (3.08)	8	2,853	8.14 (2.80)	8	0.77	0.91	0.63	0.00
Group B	3,923	7.22 (3.31)	7	1,521	8.60 (3.19)	9	1.38	1.57	1.18	0.00
Self-management total score										
Group A	1,452	71.08 (14.35)	72	725	76.69 (13.41)	78	5.61	6.86	4.36	0.00
Group B	565	72.82 (15.71)	76	239	73.98 (15.00)	76	1.16	3.51	1.18	0.00
AQoL utility score										
Group A	1,443	0.58 (0.26)	0.61	725	0.63 (0.25)	0.68	0.05	0.07	0.03	0.00
Group B	562	0.53 (0.28)	0.54	234	0.70 (0.24)	0.75	0.17	0.21	0.13	0.00
Average morphine equivalent dose										
Group A	2,161	50.84 (63.90)	30	1,359	49.87 (62.35)	30	-0.97	3.33	-5.26	0.07
Group B	1,809	47.74 (54.30)	30	700	47.82 (54.52)	30	0.08	4.82	-4.67	0.60
Healthy literacy total score										

	Initial measure			Follow-up measure			Change from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value
								Upper	Lower	
Group A	1,450	39.05 (11.3)	39	725	45.71 (9.52)	46	6.66	7.63	5.71	0.00
Group B	565	44.11 (12.27)	46	238	44.60 (12.01)	47	0.49	2.34	1.36	0.60
ED presentations										
Group A	4,316	0.16 (0.65)	0	2,853	0.15 (0.62)	0	-0.01	0.01	-0.04	0.67
Group B	3,923	0.16 (0.69)	0	1,521	0.14 (0.65)	0	-0.02	0.01	-0.03	0.40
Hospital admissions										
Group A	4,316	0.10 (0.47)	0	2,853	0.09 (0.48)	0	-0.00	0.00	-0.01	0.26
Group B	3,923	0.10 (0.43)	0	1,521	0.09 (0.46)	0	-0.00	0.00	-0.01	0.50
Vegetable intake										
Group A	4,316	2.51 1.36)	2	2,853	2.74 (1.30)	3	0.23	0.17	0.29	0.00
Group B	3,923	2.63 (1.43)	2	1,521	3.31 (1.35)	3	0.68	0.59	0.76	0.00

Source: Section B.6

Abbreviations: AQOL, The Assessment of quality of life instrument; CI, Confidence interval; ED, Emergency department; SD, Standard deviation

The Group B intervention with the additional midpoint consultation (i.e. three consultations) showed greater improvements in most of the participant health outcomes from initial to follow-up compared to Group A (i.e. two consultations). The value of the additional midpoint telephone consultation was highlighted by pharmacists who delivered the Group B intervention as it provided an opportunity for them to reinforce any key action points, answer questions and address any issues relatively soon after their initial consultation.

The usefulness of telephone follow-up of patients as part of pharmacy interventions is also evident in the literature. Gammaitoni and colleagues showed that the use of telephone-based prescription and medication counselling services for treating chronic pain increased patient satisfaction and remove some of the barriers to pharmaceutical care faced by patients with chronic pain, thereby optimising their treatment and improving their outcomes[28]. Also, although not specific to chronic pain, the use of telephone to interact and deliver intervention to patients has been demonstrated to be an effective method of delivery for clinical pharmacy interventions[29]. Consequently, the telephone consultation provided at midpoint may have been key to the achievement of the greater outcomes experienced by Group B participants.

SECTION C TRANSLATION ISSUES

The key evidence presented in Section B and relevant for use in the economic model is presented in Section D. Table 59 summarises the translation issues identified.

Table 59 Translation issues

Type	Issue	Comments
Applicability	Generalisability of the evidence • Comparability of trial population vs. general Australian population ○ Baseline characteristics • Determination of the cost of the pharmacy intervention by trial arm	In general, the population in the CPMC trial was comparable to the Australian population with chronic pain. HealthConsult conducted an activity-based costings study to determine costs of the interventions. However, to align with standard practice for MSAC assessment, the trial fees and not the representative cost of the interventions have been used in the economic model.
Extrapolation	• Time horizon of the model	The time horizon in the model was considered conservative as the condition does not lead to a reduction in survival. A pre vs post model was used with results after six months before and after trial initiation evaluated.
Transformation	• Derivation of reduction in PBS and MBS services and hospital costs data • Utilities applied in the economic evaluation • Application of participant reported outcomes using an unvalidated questionnaire in this population • Morphine equivalent units	Analysis on the reduction in PBS and MBS services undertaken from data provided from Services Australia. Self-reported emergency department presentation and hospitalisation data used. The utilities were calculated directly from the trial utilities The use of the mini-ePPOC tool and analysis of morphine units are discussed in Section C

Abbreviations: CPMC, Chronic pain MedsCheck; MBS, Medicare Benefits Schedule; mini-ePPOC, mini-electronic Persistent Pain Outcomes Collaboration; MSAC, Medical services advisory committee; PBS, Pharmaceutical Benefits Schedule

C.1. Applicability translation issues

WERE TRIAL PARTICIPANT COMPARABLE TO THE AUSTRALIAN POPULATION?

The main population in the CPMC intervention is discussed in detail in Section A. The trial population is similar to the Australian population suffering from chronic pain. This population was largely consistent with trial participant (≥18 years of age) enrolled in the CPMC trial, upon which the economic model was profiled (Table 60).

Table 60 Baseline characteristics of trial population vs. General Australian population with chronic pain

Criteria	CPMC - All trial participants (N=8,240*)	CPMC - Evaluation sites (N=2,600*)	General Australian population with chronic pain
Age, median (range)	Trial participants aged ≥ 18 years Median: 60 years (range: 18-102)	Trial participants aged ≥ 18 years Median: 59 years (range: 18-100)	Population aged ≥ 15 years Median: ~54 years (range: 1-90+)
Population	~60% female, ~36% male and ~4% undisclosed. All trial participants had a history of analgesic use	~60% female, ~36% male and ~4% undisclosed.	3.24 million Australians§; ~54% female and ~46% male
Clinical Criteria	• Chronic pain (≥3 months) – Defined as persistent pain for over three months • Non-oncological pain	• Chronic pain (≥3 months) – Defined as persistent pain for over three months • Non-oncological pain	• Chronic pain – Defined as pain "persists beyond normal healing time (3-6 months). Although chronic pain can be a symptom of other disease, it may occur without a clear reason and be a disease in its own right, characterised by changes in the central nervous system.

Abbreviation: CPMC, Chronic Pain MedsCheck; MBS, Medicare Benefits Schedule; SD, standard deviation

Source: CPMC trial; Sources used for MBS population: AIHW: Chronic Pain in Australia, May 2020; Miller et al. (2017). The prevalence of pain and analgesia use in the Australian population: Findings from the 2011 to 2012 Australian National Health Survey. Pharmacoepidemiology and Drug Safety, 26(11), 1403–1410.

***** Trial participant numbers are based on gender breakdown; more trial participants underwent the intervention but were not necessarily part of the evaluation group

§ Australians living with chronic pain in 2018

A comparison of demographics and disease characteristics of populations in the CPMC trial and any trial participant in Australia with chronic pain is presented in Table 60. Trial participants in the CPMC trial and evaluation group were relatively well representative of the General Australian population

with chronic pain. Approximately 60% (4,968/8,240 and 1,555/8,240 for the whole and evaluation group, respectively) of randomised trial participants in the trial were female. The median age of trial participants in the CPMC trial was 60 and 59 for the whole and evaluation group, correspondingly. The higher ratio of female to male trial participants in the CPMC trial is consistent with other Australian epidemiology sources (AIHW 202030 and Deloitte Access Economics 2019).[31] Overall, CPMC trial participants are similar to the general Australian population with chronic pain in terms of the ratio of females to males, and their clinical criteria/definition of their disease. However, trial participants in seem to be of slightly older age which might indicate that the general Australian with chronic pain may be less impacted in their physical functioning/activities than trial participants in the Trial.

DETERMINATION FOR THE COST OF THE PHARMACY INTERVENTION

A bottom-up activity-based costing methodology was designed to derive a representative cost (across the study sample) for the provision of a CPMC service. This was undertaken to determine the reasonableness of the trial fee. The representative cost was not used in the base economic model.

Primary data was collected from 20 randomly selected trial sites (10 Group A and 10 Group B pharmacies from both main and evaluation trial sites) from a pool of 1,276 pharmacies. Costing study pharmacies were located across NSW, VIC, SA, QLD, WA and the ACT. The full report is provided as an attachment named "HealthConsult CPMC Costing Report."

Process maps and activity definitions were developed detailing the provision of a CPMC intervention by Group which were refined using pilot site interviews. Supporting data collection tools documented the resource units used to perform the activities. Data about staff mix, activity time, local hourly rates, frequency-of-occurrence and consumable costs were obtained via face-to-face interviews. This data was then used to develop cost estimates for each study site.

The site-based data was then used to develop a representative cost model. Activity times and costs varied considerably amongst sites; the median was selected as the representative cost for both Group A and Group B sites, primarily, as this mitigated the effect of some significant high and low-cost outlier sites. Group A and Group B sites were analysed separately, in keeping with the fee schedule and the different protocols trialled at the pharmacies (services at Group A sites comprised an 'in-pharmacy' initial and a three-month follow-up consultation and services at Group B sites offered the same in-pharmacy consultations (at the same intervals) but added a further mid-point consultation at six weeks, via telephone).

Table 61 compares the Initial Consultation trial payment to the derived representative cost. The result shows that:

- **Group A** pharmacies cost $99.75 per consultation (median), which is $1.34, or 1.4% higher than the Trial payment of $98.41 and takes 99.5 minutes or 54.5 minutes (121%) longer than the 45 minutes indicated within the Trial payment description.

- **Group B** pharmacies cost $105.17 per consultation (median) which is $6.76 or 6.9% higher than the Trial payment of $98.41 and takes 109.3 minutes or 64.3 minutes (143%) longer than the 45 minutes indicated within the Trial payment description.

Table 61 Comparison on derived representative cost to trial payment - initial consultation

Fee Description	Trial Fee		Representative Cost		Variation	
	$	Mins	$	Mins	$	Mins
Group A: Trial Payment 1[α] – for the completion of the initial 45-minute face-to-face consultation between the pharmacist and the trial participant	$98.41	45 mins	$99.75	99.5 mins	+$1.34	+54.5 mins
Group B: Trial Payment 5 [α] – for the completion of the initial 45-minute face-to-face consultation between the pharmacist and the trial participant	$98.41	45 mins	$105.17	109.3 mins	+$7.30	+64.3 mins

Source: Chronic Pain MedsCheck Trial Pack – Group B Main Sites; October 2018 and HealthConsult activity-based costing study undertaken from August to September 2019. Please note that numbers in this table may not add due to rounding

α Refer to Appendix H for the schedule of trial payments

Only Group B pharmacies performed the midpoint consultation. Table 62 shows that the representative cost of $42.32 per consultation (median) is $9.51 or 29% higher than the Trial payment of $32.81 and takes 45 minutes or 30 minutes (200%) longer than the 15 minutes indicated in the payment description.

Table 62 Comparison of the derived representative cost to trial payment – six-week consultation

Fee Description	Trial Fee		Representative Cost		Variation	
	$	Mins	$	Mins	$	Mins
Group B: Trial Payment 6[α] – for the completion of midpoint telephone 15-minute face-to-face consultations between the pharmacist and the trial participant	$32.81	15 mins	$42.32	45 mins	+$9.51	+30 mins

Source: Chronic Pain MedsCheck Trial Pack – Group B Main Sites; October 2018 and HealthConsult activity-based costing study undertaken from August to September 2019

Please note that numbers in this table may not add due to rounding

α Refer to Appendix H for the schedule of trial payments

Table 63 compares the three-month consultation trial payment to the derived representative cost. The result shows that:

- **Group A** pharmacies cost $35.00 per consultation (median), which is $2.19 (or 6.7%) more than the payment of $32.81 and takes 38.5 minutes or 23.5 minutes (157%) longer than the 15 minutes indicated in the payment description.
- **Group B** pharmacies cost $38.50 per consultation (median) which is $5.69 (or 17.3%) higher than the payment of $32.81 and takes 41.3 minutes or 26.3 minutes (175%) longer than the 15 minutes indicated in the payment description.

Table 63 Comparison of derived representative cost to trial payment - three-month follow-up consultation

Fee Description	Trial Fee		Representative Cost		Variation	
	$	Mins	$	Mins	$	Mins
Trial Site A: Trial Payment 2[α] – for the completion of the 3-month follow-up in-pharmacy 15-minute face-to-face consultation between the pharmacist and the trial participant.	$32.81	15 mins	$35.00	38.5 mins	+$2.19	+23.5 mins
Trial Site B: Trial Payment 7[α] – for the completion of the 3-month follow-up in-pharmacy 15-minute face-to-face consultation between the pharmacist and the trial participant.	$32.81	15 mins	$38.50	41.3 mins	+$5.69	+26.3 mins

Source: Chronic Pain MedsCheck Trial Pack – Group B Main Sites; October 2018 and HealthConsult activity-based costing study undertaken from August to September 2019
Please note that numbers in this table may not add due to rounding

[α] Refer to Appendix H for the schedule of trial payments

As per the Trial payment schedule, the total fees received by pharmacies delivering the interventions in Group A and Group B was $131.22 and $164.03, respectively. A small difference was measured in trial and representative costs from the activity based costing study, Group A and Group B costed $134.75 (increase of $3.53 from trial fees) and $185.99 (increase of $21.96 from trial fees). Representative costs were not included in the base economic model as the trial fee align itself to the proposed MBS fee in any standard MSAC contracted assessment. The trial fee has been used in all Section D analyses.

C.2. Extrapolation translation issues

SURVIVAL

As stated in the PICO, the CPMC is an intervention seeking to reduce the impacts of chronic pain. The trial was not designed to impact or detect any deaths. However, a reduction in the use of opioids are associated with a reduction in negative side effects and deaths. No trial participants died

(there are no known deaths) during the trial period. Consequently, all trial participants were presumed alive in the economic analysis.

C.3. Transformation issues

Issues explored where changes in costs for PBS, MBS, hospitalisation and emergency department expenditure. Further issues identified included utilities and secondary outcome measures.

DERIVATION OF REDUCTION IN PBS AND MBS EXPENDITURE AND HOSPITALISATIONS

PBS usage

Trial participant PBS usage data was obtained from Services Australia. Data was linked to each individual trial participant in the CPMC trial. From the CPMC trial data, baseline analgesics usage was compared to the three month follow up values for Group A and B trial participants (Table 64 and Table 65, respectively). Data for system groups N02A N02B, N02C, M01A and M02A was originally analysed. These codes cover for opioids, anti-neuropathics, migraine medications and NSAIDs.

As presented in Section A.8, chronic pain has significant impacts on other patient outcomes which may be improved by reductions in pain and pain medication usage. There is a strong association between chronic pain and mental health conditions such as depression, anxiety or mental health problems in general. Pain is also associated with sleep disorders[32]. Consequently, additional codes analysed under system groups N03, N05 and N06 were included in the analysis. These codes cover for anticonvulsants, benzodiazepines and antidepressants, respectively. Long term use of antidepressants has been associated with falls, fractures, upper gastrointestinal bleeds and all-cause mortality,[33] while patients may feel sexual problems, weight gain and emotional effects.[34] Benzodiazepines impact on patient mortality is mixed with studies suggesting none to a minor risk increase of all cause mortality to substantial increases in mortality (both due to suicidal and non-suicidal deaths).[35,36] Consequently, anticonvulsants, benzodiazepines and antidepressants were also included in the PBS analysis, as the CPMC program may result in improvements in the quality use of medicines. This would result in more optimal treatment for trial participants.

Six months was used as an arbitrary cut off for the analysis (this was also conducted for the MBS analysis). The total amount of scripts in the preceding six months of trial initiation date was used as the baseline figure. Mean script usage from initiation to three months after the end of the trial period (i.e. six months total) was used to determine the change in scripts due to the CPMC intervention. Consequently, results bias in favour of the intervention (refer to Table 152 and Table 153 in Appendix I).

In both groups, there is a reduction in the mean number of scripts per trial participant from 13.26 to 10.70 in Group A (-2.56 scripts, 19.3% reduction) and 10.39 to 6.99 in Group B (-3.40 scripts, 32.7% reduction). Decreases in mean number of scripts were not statistically significant in Group A as demonstrated by the overlapping confidence intervals. Group B had a statistically significant reduction in the mean number of scripts dispensed per patient. Reductions were also seen with total benefits paid ($310.94 to $109.71 in Group A and $216.92 to $89.10 in Group B). Caution is required in the interpretation of these results given the large loss to follow-up and small sample size (Table 64

and Table 65). When analysing results by system groups (Appendix I, Table 150 and Table 151), every group (excluding NSAIDs) saw a decrease in scripts per patient in both Groups A and B. NSAID usage slightly increased by an average of 0.09 and 0.08 scripts per patient in Group A and B, respectively. This gain was not statistically significant. Group A had a significant decline in antidepressant usage (Table 150). Group B had a significant decline in all scripts (Table 151).

Overall, the decrease in mean total benefits paid is likely due to the volunteer effect as loss to follow up was over 60% in both groups for this analysis. This is evident as total benefits paid declined, which suggests that trial participants may have been healthier. Reaching a concessionary threshold (i.e. receiving medication for free or at a further subsidised price) would not have resulted in reductions to total benefits paid, as the cost of the medication would still have been covered by the government. Most scripts were claimed in Q2 and Q3 of 2019 (Appendix I: Figure 68-Figure 70). Given the average number of scripts claimed per trial participant in the six months prior and post CPMC initiation, trial participants were unlikely to have reached the concessionary threshold. Consequently, as a means of adjustment, the average cost per script at baseline as taken and applied to the average number of scripts at follow up (Table 66). As a limitation of this approach, the average cost per script does not change from baseline to follow up in both groups (average cost per script of $23.45 in Group A and $20.88 in Group B). Consequently, this adjustment biases against the intervention.

Trial participant benefits paid (Table 64 and Table 65) were used for the budget impact analysis in Section E. There is a notable difference between trial participant co-payment and total benefits paid between Groups A and B at baseline ($56.88 and $75.92 respectively, per participant). This would be suggestive of more trial participants in Group B appearing to have reached the concessional safety net or possibly use more OTCs than Group A trial participants. At six months post intervention initiation the cost to the PBS is greater in Group B vs Group A ($51.08 vs $45.90 per participant). However, when compared to baseline, costs to the PBS decreased in both Groups A and B ($56.88 and $75.92 respectively, per participant).

In Group A, out-of-pocket (OOP) expenditure at baseline and follow-up accounted for 81.7% and 92.5% (unadjusted) of total benefits paid, respectively. In Group B OOP expenditure at baseline and follow-up accounted for 65.0% and 81.8% of total trial participant benefits paid, respectively. Most of the PBS costs in Groups A and B is paid for the trial participants rather than the Federal Government.

Table 64 Medications usage in Group A

Baseline (n=497)	Mean	SD	95%CI Low	95%CI High
Total benefits paid 6 months prior to intervention	$310.94	$358.41	$276.07	$345.80
Trial participant benefit paid 6 months prior to intervention	$254.06	$350.48	$196.42	$311.71

Baseline (n=497)	Mean	SD	95%CI Low	95%CI High
Total scripts per trial participant 6 months prior to intervention	13.26	13.39	12.08	14.44
Follow up (n=171)				
Total benefits paid 6 months after trial initiation	$109.71	$145.36	$96.58	$122.84
Trial participant benefits paid 6 months after trial initiation	$101.53	$153.50	$77.13	$125.93
Total scripts per trial participant 6 months after trial initiation	10.70	11.55	8.97	12.43

Source: CPMC trial data
Abbreviations: CI, confidence interval; SD, standard deviation

Table 65 Medications usage in Group B

Baseline (n=275)	Mean	SD	95%CI Low	95%CI High
Total benefits paid 6 months prior to intervention	$216.92	$303.29	$177.55	$256.28
Trial participant benefit paid 6 months prior to intervention	$141.00	$208.14	$94.21	$187.80
Total scripts per trial participant 6 months prior to intervention	10.39	11.16	9.07	11.71
Follow up (n=90)				
Total benefits paid 6 months after trial initiation	$89.10	$113.95	$75.35	$102.84
Trial participant benefits paid 6 months after trial initiation	$72.86	$112.15	$49.01	$96.70
Total scripts per trial participant 6 months after trial initiation	6.99	7.74	5.39	8.59

Source: CPMC trial data
Abbreviations: CI, confidence interval; SD, standard deviation
Note: Bolded values signify statistically significant reduction ($p<0.05$)

Table 66 Analgesics usage updated for 6 months post trial initiation in Groups A and B

	Mean	SD	95%CI Low	95%CI High
Group A: Multiply average cost per script at baseline total services from follow up (10.70 scripts)				
Total benefits paid 6 months post trial initiation	$250.91	$289.21	$222.77	$279.04
Trial participant benefit paid 6 months post trial initiation	$205.01	$280.07	$173.98	$218.42
Group B: Multiply average cost per script at baseline total services from follow up (6.99 scripts)				
Total benefits paid 6 months post trial initiation	$145.94	$204.04	$119.45	$172.42
Trial participant benefit paid 6 months post trial initiation	$94.86	$130.37	$72.61	$103.45

Source: CPMC trial data
Abbreviations: CI, confidence interval; SD, standard deviation

Table 67 presents a summary of values used for the economic evaluation in Section D. The mean total benefits paid and mean total scripts per trial participant were used. Trial participant benefits paid (presented above) were used for the budget impact analysis in Section E.

Table 67 Summary of analgesics usage and costs used in the economic evaluation for Groups A and B

Group A	Mean	SD	95%CI Low	95%CI High
Total benefits paid 6 months prior to intervention	$310.94	$358.41	$276.07	$345.80
Total scripts per trial participant 6 months prior to intervention	13.26	13.39	12.08	14.44
Total benefits paid 6 months post trial initiation	$250.91	$289.21	$222.77	$279.04
Total scripts per trial participant 6 months post trial initiation	10.70	11.55	8.97	12.43
Group B				
Total benefits paid 6 months prior to intervention	$216.92	$216.92	$216.92	$216.92
Total scripts per trial participant 6 months prior to intervention	10.39	11.16	9.07	11.71

Group A	Mean	SD	95%CI Low	95%CI High
Total benefits paid 6 months post trial initiation	$145.94	$204.04	$119.45	$172.42
Total scripts per trial participant 6 months post trial initiation	6.99	7.74	5.39	8.59

Source: CPMC trial data
Abbreviations: CI, confidence interval; SD, standard deviation

MBS usage

For the analysis of reduction in MBS utilisation in both groups, codes relating to the following categories were analysed from the dataset provided by Services Australia (Table 154, Appendix J):

- GPs – General
- Specialists – General
- Case conferences (including telehealth)
- Allied Health – General
- Urgent or emergency consultations
- Specialists – Pain specific attendance/consultations
- Nurse practitioner consultations

In both groups, there is a reduction in the mean number of MBS services per trial participant from 10.49 to 7.85 in Group A (-2.64 services, 25.2% decrease) and 10.33 to 5.88 in Group B (-4.44 services, 43.1% decrease, Table 68 and Table 69, respectively). Decreases to mean number of services were statistically significant ($p<0.0001$ in both groups). As with the decrease in PBS utilisation, reductions in trial participant benefits paid were observed ($590.07 to $449.01 in Group A and $560.16 to $311.07 in Group B). As with PBS usage, by extending the initial and follow up period from three to six months, results for MBS service utilisation biased in favour of the intervention (refer to Table 155 and Table 156 in Appendix J).

A larger CPMC cohort were available for the MBS analysis. While the loss to follow up is high (>60%, as with the PBS analysis), overall numbers suggest that not all chronic pain trial participants require medications. Of note, when applying the method used to calculate values in Table 67, total provider benefit values reported were similar to those in Table 68 and Table 69 (costs of $441.57 and $318.85 in Groups A and B, respectively). It cannot be determined if the volunteer effect also impacts this subgroup when analysing the average cost per service. Trial participant benefits paid (in both tables) were used for the budget impact analysis in Section E. In Group A, OOP expenditure at baseline and follow-up accounted for 30.8% and 34.4% of total trial participant benefits paid, respectively. In Group B, OOP expenditure at baseline and follow-up accounted for 23.5% and 28.9% of total trial participant benefits paid, respectively.

Table 68 MBS utilisation in Group A

Baseline (n=539)	Mean	SD	95%CI Low	95%CI High
Total trial participant benefits paid 6 months prior to intervention	$590.07	$494.03	$548.36	$631.78
Total out of pocket expenditure paid 6 months prior to intervention	$181.93	$238.78	$151.34	$212.53
Total services utilised per trial participant 6 months prior to intervention	10.49	7.98	9.82	11.16
Follow up (n=141)				
Total trial participant benefits paid 6 months post trial initiation	$449.01	$401.57	$382.73	$515.29
Total out of pocket expenditure paid 6 months post trial initiation	$154.56	$193.59	$100.35	$208.76
Total services utilised per trial participant 6 months post trial initiation	7.85*	6.72	6.74	8.96

Source: CPMC trial data

Abbreviations: CI, confidence interval; SD, standard deviation

*A significant decline in MBS utilisation per trial participant was calculated using a 2 tailed t-test ($p<0.001$)

Table 69 MBS utilisation in Group B

Baseline (n=464)	Mean	SD	95%CI Low	95%CI High
Total trial participant benefits paid 6 months prior to intervention	$560.16	$436.60	$520.44	$599.89
Total out of pocket expenditure paid 6 months prior to intervention	$131.72	$117.66	$115.24	$148.19
Total services utilised per trial participant 6 months prior to intervention	10.33	7.89	9.61	11.04
Follow up (n=154)				
Total trial participant benefits paid 6 months post trial initiation	$311.07	$354.85	$255.03	$367.11

Baseline (n=464)	Mean	SD	95%CI Low	95%CI High
Total out of pocket expenditure paid 6 months post trial initiation	$89.92	$82.71	$69.66	$110.19
Total services utilised per trial participant 6 months post trial initiation	5.88*	6.58	4.84	6.92

Source: CPMC trial data

Abbreviations: CI, confidence interval; SD, standard deviation

*A significant decline in MBS utilisation per trial participant was calculated using a 2 tailed t-test ($p<0.001$)

As part of the CPMC intervention, patients may have been referred to their GP and allied health services if required. In Section F, 44% of healthcare providers that completed the Referred Provider Survey state that participants were referred to them as part of the CPMC. Most respondents were GPs (68%, Table 146), but uptake of allied health services has been examined to analyse uptake in non-pharmacological treatments for chronic pain. MBS item numbers that were utilised for this analysis have been italicised in Table 154 (Appendix J). An increase in Allied Health usage was observed in Group A (8.2% increase, 0.21 services), while service usage significantly declined in Group B (31.3% decrease, 0.76 services). Reasons for the disparity in results could be due to smaller participant numbers in Group B at follow up being unable to detect for increase service usage or due to have the additional contact with the pharmacists. Otherwise, as suggested from PBS script usage, Group B may have a greater number of concessional participants, which makes allied health interventions unaffordable. A similar trend was observed for the three month (trial period) analysis as well (refer to Table 157 and Table 158 in Appendix J).

Table 70 Allied Health utilisation in Group A

Baseline (n=182)	Mean	SD	95%CI Low	95%CI High
Total trial participant benefits paid 6 months prior to intervention	$142.07	$82.31	$130.11	$154.03
Total out of pocket expenditure paid 6 months prior to intervention	$45.04	$42.53	$32.33	$57.75
Total services utilised per trial participant 6 months prior to intervention	2.56	1.28	2.37	2.74
Follow up (n=60)				
Total trial participant benefits paid 6 months post trial initiation	$153.18	$86.63	$131.26	$175.10

Baseline (n=182)	Mean	SD	95%CI Low	95%CI High
Total out of pocket expenditure paid 6 months post trial initiation	$57.11	$61.54	$24.87	$89.35
Total services utilised per trial participant 6 months post trial initiation	2.77	1.49	2.39	3.14

Source: CPMC trial data
Abbreviations: CI, confidence interval; SD, standard deviation

Table 71 Allied Health utilisation in Group B

Baseline (n=142)	Mean	SD	95%CI Low	95%CI High
Total trial participant benefits paid 6 months prior to intervention	$129.53	$67.95	$118.35	$140.70
Total out of pocket expenditure paid 6 months prior to intervention	$43.49	$33.06	$31.66	$55.32
Total services utilised per trial participant 6 months prior to intervention	2.43	1.26	2.23	2.64
Follow up (n=27)				
Total trial participant benefits paid 6 months post trial initiation	$89.04	$55.28	$68.19	$109.89
Total out of pocket expenditure paid 6 months post trial initiation	$37.84	$35.11	$13.52	$62.17
Total services utilised per trial participant 6 months post trial initiation	1.67*	1.04	1.28	2.06

Source: CPMC trial data
Abbreviations: CI, confidence interval; SD, standard deviation
*A significant decline in MBS utilisation per trial participant was calculated using a 2 tailed t-test ($p<0.001$)

Hospitalisation admission costs

The types of presentations to hospital were not recorded for trial participants. However, trial participants were asked to self-report at initial and follow-up consultations, how many times in the last three months they visited an ED because of their pain and/or been admitted to hospital because of their pain.

To derive the cost of an acute hospitalisation, the cost of an average service in a public hospital in the 2017-18 financial year ($4,680)37 was inflated. The health price index (HPI, Series: A2331111C)

was used to inflate the figure from the end of Q2 2018 to Q2 (June) of 2020. Over this period, the HPI increased by 3.93%. This led to the derivation of cost per acute hospitalisation of $4,864.14 used in this report.

Trial participants in both Group A and Group B saw a reduction in hospitalisations from baseline to the 3-month follow up (10.2% to 9.0% and 10.2% to 9.4%, respectively). The cost per hospitalisation by Group was $498.13 and $438.16 (difference of $59.97) at baseline and follow up in Group A. In group B it was $494.85 and $457.31 (difference of $37.54) at baseline and follow-up, respectively (Table 72). Of note, hospitalisation numbers were obtained from trial participants self-reporting. Consequently, figures may be understated due to a perceived negative perception a trial participant may feel from their health care providers.

Table 72 Mean change from baseline and follow-up in hospitalisation admissions

Baseline	**Group A (n=4,316)**	**Group B (n=3,922)**
	0.102	**0.102**
3 months follow up	Group A (n=2,853)	Group B (n=1,521)
	0.090	0.094
Incremental difference	0.012	0.008

Source: CPMC trial data
Abbreviations: CPMC, Chronic Pain MedsCheck trial

ED presentation costs

The number of ED presentations was recorded for all trial participants. While it is not clear whether which ED presentations resulted in a hospital admission, the proportion of trial participants presenting to ED is greater than the hospital admissions in both Groups. The cost of an ED was $705.[38] Using the same inflation methods as used for acute hospitalisation fees, a cost of **$732.74** was calculated for Q2 (June) of 2020. Both Group A and Group B saw a reduction in ED presentations from baseline to the 3-month follow up (15.6% to 14.7% and 15.6% to 13.9%, respectively). The cost per ED presentation by Group was $114.43 and $109.15 (difference of $5.27) at baseline and follow up in A, respectively, and $114.34 and $101.65 (difference of $12.69) at baseline and follow-up in B, correspondingly (Table 73). Values used for ED presentations also relied on trial participant reported data.

Table 73 Mean change from baseline and follow-up in ED presentations

Baseline	**Group A (n=4,316)**	**Group B (n=3,922)**
	0.156	**0.156**
3 months follow up	Group A (n=2,853)	Group B (n=1,521)
	0.147	0.139
Incremental difference	0.009	0.017

Source: CPMC trial data
Abbreviations: CPMC, Chronic Pain MedsCheck trial

UTILITIES

Method

The AQoL-4D was used to determine trial participant utility scores. A total of 2,168 trial participants (Group A: n=1,443; Group B: n=725) completed the initial questionnaire. At the 3-month follow up, 38.9% (n=562) of Group A trial participants and 32.3% (n=234) of Group B trial participants completed the AQoL-4D questionnaire. The low response rate could be attributed to volunteer bias, whereby healthier trial participants answered questionnaires. This would bias in favour of the intervention (regardless of Group). Further, more Group A respondents were aged 65+ (i.e. they are likely retirees with more available time to complete the survey [72.7% vs 65.8% in Group B]. However, given the heterogeneity of pharmacies involved in the CPMC trial, the type of pharmacy (i.e. franchise vs small independents) and their impacts on service delivery may also be the cause of the smaller response rate. Further, there is some evidence to indicate that participant satisfaction scores improve following quality improvement interventions.[39] Consequently, by offering better services, trial participant well-being may improve.

When comparing the baseline AQoL-4D scores of the CPMC trial participants to Australian population norms, it is evident that trial participants scores were lower for both Group A (0.59) and Group B (0.53, Table 74). The difference in scores between the two Groups at baseline was not statistically significant after adjusting for clustering by Pharmacy (refer to Section B.8).

The AQoL-4D population norms from Hawthorne (2005)[40] and Hawthorne (2013)[41] were 0.83 (standard deviation: 0.2) and 0.81 (95%CI: 0.81-0.82), respectively. Consequently, trial participants in the CPMC trial had a lower reported QoL in comparison to the general Australian population. Given the prevalence of chronic pain in Australia, the population of AQoL-4D respondents although sizeable is smaller than published data for Australian norms. It is more prone to understate values (n=2,168 vs 2,934 [Hawthorne 2005] and 8,839 [Hawthorne 2013]).

Table 74 AQoL-4D utility weights at baseline from CPMC vs Australian population norms

	Age								
Study	**16-19**	**20-29**	**30-39**	**40-49**	**50-59**	**60-69**	**70-79**	**80+**	**Reported weight**
Hawthorne 2005 (SD)	0.87 (0.17)	0.87 (0.18)	0.85 (0.20)	0.85 (0.18)	0.80 (0.22)	0.79 (0.19)	0.75 (0.25)	0.66 (0.29)	0.83 (0.20)
Hawthorne 2013 (SD)	0.87 (0.17)	0.86 (0.19)	0.84 (0.21)	0.81 (0.23)	0.80 (0.24)	0.80 (0.22)	0.76 (0.23)	0.70 (0.26)	0.81 (0.22)
Group A at baseline (SD)	-	-	-	-	-	-	-	-	0.58 (0.26)
Group B at baseline (SD)	-	-	-	-	-	-	-	-	0.53 (0.28)

Source: CPMC trial data, Maxwell (2016)

Abbreviations: CPMC, Chronic pain meds check; SD, standard deviation

Mean change from baseline in the utility values of Group A and B trial participants

Table 75 presents the mean change from baseline in utility for Group A and Group B trial participants and at three-month follow-up that participated in the evaluation trial sites only (i.e. data not collected at main trial sites). Group B trial participants had a lower utility compared to Group A (0.53 vs 0.58, respectively) at baseline. As Group B trial participants had a lower utility score at baseline, they were likely to rate their disease as more severe. More severe trial participants tend to benefit greater from interventions as participants have large capacity for coping with an adapting to worse states.[42] Consequently, the intervention administered has resulted in a greater increase in trial participant outcomes.

Table 75 Mean change from baseline at follow-up in utility

	Group A		**Group B**	
	Baseline (n=1,443)	**3 months follow-up (n=725)**	**Baseline (n=562)**	**3 months follow-up (n=234)**
Mean (SD)	0.58 (0.26)	0.63 (0.25)	0.53 (0.28)	0.70 (0.24)
Mean change at follow-up (95% CI)	0.05 (0.03, 0.07)		0.17 (0.13, 0.21)	
Mean difference (Group A vs. Group B)	0.12 (0.100, 0.157; p-value < 0.0001)43			

Source: CPMC trial data

CI = confidence interval; SD = standard deviation; Bold =statistically significant at p-value<0.05

Table 75 shows that both treatment groups experienced statistically significant gains in their utility at follow-up. After three months, Group B trial participants had a greater increase in utility scores in comparison to Group A (0.70 vs 0.63, respectively). A statistically significant difference in trial participant utility scores between Groups A and B was observed at the three-months follow up (0.12 [95%CI: 0.100-0.157], p<0.0001). Whether this was attributed to the midpoint intervention, could not be determined as no AQoL-4D was obtained at this point.

Utility values applied in the economic model

The baseline average of the Group A and Group B trial population was used as TAU score (0.58 and 0.53, respectively). At three months, utility weights of 0.63 and 0.70 were used, correspondingly. The incremental difference from baseline to the three month follow up of 0.05 for Group A and 0.17 for Group B formed the denominator for the cost/QALY calculations presented in Section D (Table 76).

Table 76 Utility values applied in the model

	CPMC trial group that completed the AqoL-4D	
Baseline	Group A (n=4,316)	Group B (n=3,922)
	0.58	0.53
At 3 months	Group A (n=2,853)	Group B (n=1,521)

	CPMC trial group that completed the AqoL-4D	
	0.63	0.70
Incremental difference	0.05	0.17

Source: CPMC trial data

Disutilities associated with experiencing adverse events (e.g. pain flare up)

No disutilities related to trial participants experiencing adverse events were applied in the economic model as the utilities used in the economic model were sourced directly from trial participants in the trial (i.e. AQoL-4D) and hence, any disutility associated with adverse events would have been directly captured by the AQoL-4D questionnaire.

APPLICATION OF TRIAL PARTICIPANT REPORTED OUTCOMES USING MINI-EPPOC AND PIH

The pain assessment tool used for analyses is the mini-ePPOC. It includes a subset of items within a number of tools utilised in ePPOC by specialist pain management services. Mini-ePPOC is used to assist in determining a trial participant's chronic pain profile and which areas may need addressing to help the trial participant better manage own chronic pain. It is deemed to be more suitable and practical for use in the primary care setting where there are time limitations due to the workload of primary care clinicians.

The mini-ePPOC incorporates pain assessment tools that have been validated in the primary care setting and are deemed more useful in the context of community pharmacy service delivery. Tools used to measure trial participant related outcomes that are relevant to the cost analysis include (Table 77):

- Brief Pain Inventory (BPI) – Pain interference and pain severity
- Pain Self-efficacy Questionnaire (PSEQ) – Pain self-efficacy

In addition, the Partners in Health (PIH) Scale – Pain self-management, a validated tool, is also considered in this section. This tool is not part of the mini-ePPOC.

The mini-ePPOC plus the PIH, for both Groups A and Group B, consists of an initial questionnaire and a follow-up questionnaire (Section B.5).

Table 77 Pain assessment tools incorporated in the mini-ePPOC plus PIH and relevant to the cost analysis

Assessment tool	Domain	Item	Interpretation	Notes
BPI	Pain interference	Describe how pain has interfered with your general activities	0-4 = mild; 5-6 = moderate; 7-10 = severe	Used to assess and as an outcome following trial participation
	Pain severity	Describe your pain on average in the past week	0-4 = mild; 5-6 = moderate; 7-10 = severe	Used to assess and as an outcome

Assessment tool	Domain	Item	Interpretation	Notes
				measure following trial participation. NB: In chronic pain setting, pain severity alone does not guide which treatments are offered
PSEQ-2	Pain self-efficacy	Rate how confident you are that you can do the following things at present, despite the pain: • I can do some form of work (housework, paid and unpaid work) • I can live a normal lifestyle	0-2 = not at all confident; 3-4 = reasonably confident; 5-6 = completely confident	Used to assess and as an outcome following trial participation. ≥ 8 = self-efficacy associated with meaningful functional outcomes
PIH	Self-management	Questions cover areas such as: • Knowledge of the condition; treatment • Ability to take medication; deal with health professionals; etc.	Eight-point scale: 0 = low self-management capacity; 8 = good self-management capacity	Used to assess and as an outcome following trial participation.

Abbreviations: BPI: Brief pain inventory; PIH, The Partners in health scale; PSEQ-2, Pain self-efficacy questionnaire

Brief Pain Inventory (BPI)

The BPI is used to evaluate the severity of a trial participant's pain and the impact of this pain on the trial participant's daily functioning. The BPI generates two scales, pain severity and pain interference. Pain Severity describes how severe the pain is. Pain Interference describes how much the pain interferes with everyday life. Each scale has a range of 0-10, where 10 represents the worst possible scenario. Severity/interference bands for these items are: 0-4 = mild pain; 5-6 = moderate pain; and 7-10 = severe pain.

For the purposes of the economic analysis for the outcomes below, the change in number of trial participants with moderate-severe scores as determined by the BPI were analysed. The rationale behind this approach is as follows:

- By using proportions of moderate-severe patients, values at baseline can be compared to those at follow-up (rather than just an increment). Without a baseline value, an ICER could not be calculated.
- Proportions allow for a gauge to determine the number of patients achieving the most optimal outcome which is more conservative than an arbitrary 30% increase on an instrument. It is likely a greater representation of patients with severe pain will achieve this (as more severe trial participants tend to benefit greater from interventions) but this would not be reflective of the greater CPMC cohort.
- The moderate-severe group had greater opioid use in comparison to the mild group. As the instrument has three categories, moderate-severe trial participants can only move to the mild group, which would indicate better trial participant outcomes. The moderate-severe trial participants accounted for 80-85% of opioid users in the trial. Reductions in opioids and analgesic usage was also one of the goals of the CPMC trial.

Consequently, utilising the proportion of moderate-severe patients at baseline and follow-up values would result in a more robust and certain economic evaluation.

In Group A there was a reduction in the number of moderate-severe trial participants of 13.6% and 11.1% from baseline to the 3-month follow up for trial participant interference and severity, respectively. In Group B the change was 25.5% and 10.9%, respectively. These changes suggest that the CPMC service reduces trial participant reported pain interference and severity (Table 78 and Table 79, correspondingly).

Results from trial data is reflected in the participants' perceptions of the impact of the CPMC service. Around two-thirds of the 186 participants (n=119, 64%) who completed the Patient Survey reported that the CPMC Trial had an impact on their level of physical pain. A total of 30 (16.2% of total) respondents reported their level of physical pain became 'moderately better' and for 28 (15.1% of total) the CPMC service made a "real difference" in the level of physical pain. This suggests that the CPMC intervention was perceived by most participants to have reduced the interference and severity of their chronic pain.

Table 78 Pain interference scores (change in number of moderate-severe) using the BPI in the whole CPMC trial population by group status

Baseline	**Group A (n=4,316)**	**Group B (n=3,923)**
	0.787	**0.772**
At 3 months	Group A (n=2,853)	Group B (n=1,521)
	0.651	0.517
Incremental difference	0.136	0.255

Source: CPMC trial data

CPMC = Chronic Pain MedsCheck trial

Bolded values are significant using a two-sided test, p <0.05
Note: Results presented in this table are different to Table 3 as they report proportion of moderate-severe patients.

Table 79 Pain severity scores (change in number of moderate-severe) using the BPI in the whole CPMC trial population by group status

Baseline	**Group A (n=4,316)**	**Group B (n=3,923)**
	0.695	**0.691**
At 3 months	Group A (n=2,853)	Group B (n=1,521)
	0.584	0.582
Incremental difference	0.111	0.109

Source: CPMC trial data

CPMC = Chronic pain MedsCheck trial

Bolded values are significant using a two-sided test, p <0.05

Note: Results presented in this table are different to Table 3 as they report proportion of moderate-severe patients.

Pain Self-Efficacy Questionnaire (PSEQ-2)

The PSEQ questionnaire is used to assess the confidence people with ongoing pain have in performing activities while in pain. To measure change the PSEQ needs to be measured at two time points. Increases in score represent an improvement in self-efficacy.

The mini-ePPOC includes the 2-item short form of the PSEQ (PSEQ-2) which consists of two of the 10 items of the full PSEQ and has been validated as a standalone instrument.[44] A total score is calculated as a sum of the two scores which are rated on a scale from 0 = 'Not at all' confident to 6 = 'Completely confident'. A score of less than or equal to 5 indicates the participant is in need of help to improve confidence to perform daily activities, and scores equal to or greater than 8 indicate that their self-efficacy is associated with meaningful functional outcomes.

In general, higher PSEQ scores are strongly associated with clinically significant functional levels and provide a useful gauge for evaluating outcomes in chronic pain trial participants. For trial participants to be considered to have 'meaningful functional outcomes' they needed to have a score equal or greater than 8. Consequently, the proportion of these trial participants was analysed.

In Group A and B, the number of trial participants achieving self-efficacy levels associated with meaningful functional outcomes increased from baseline to the 3-month follow up by 11.8% and 12.8%, respectively (Figure 28). This suggests that the CPMC intervention increased self-confidence in performing activities while experiencing pain in just over 10% of participants. Table 80 provides a

summary of the changes in participants' levels of self-efficacy from initial to follow-up in Groups A and B.

Table 80 Pain self-efficacy scores (change in number of moderate-severe) using the PSEQ-2 in the whole CPMC trial population by group status

Baseline	**Group A (n=4,316)**	**Group B (n=3,923)**
	0.526	**0.496**
At 3 months	Group A (n=2,853)	Group B (n=1,521)
	0.645	0.624
Incremental difference	0.118*	0.128

Source: CPMC trial data

CPMC = Chronic Pain MedsCheck trial

Note: * Rounding error. Results presented in this table are different to Table 3 as they report proportion of moderate-severe patients.

Bolded values are significant using a two-sided test, p <0.05

These results corroborate with responses from 186 participants who completed the Patient Survey, of which 32 (17.2%) reported their level of physical functioning became 'moderately better' and 33 (17.7%) said it became 'better and had made a real difference'.

Partners in Health (PIH) Scale

The PIH Scale is a validated questionnaire based on the principles of self-management. The trial participant completes the questionnaire by scoring their response to each of the 12 questions on an eight-point scale (zero being the lowest response, reflecting low self-management capacity, and eight being the highest, reflecting good self-management capacity). The results of this scale presented are only those from the evaluation site trial participants (Table 81).

A clinically significant difference requires a 10% change between baseline and follow-up. This was obtained from a paper that evaluated the Flinders Program in improving self-management in common chronic and examined properties of the PIH.[45] However, a report[46] that describes a study which further evaluated construct validity of the PIH scale showed that higher PIH scores are associated with higher probability of better health. Trial participants are therefore considered less likely to gain significant changes in their self-management capabilities.

While the questionnaire provides categorical answers, for the purpose of this analysis they were treated as continuous variables (range of 0-96) to provide the results in Table 81. Groups A and B saw small but significant increases to PIH scores of 5.61 and 1.16, respectively.

Table 81 Pain self-management scores using the PIH in the CPMC evaluation site population

Baseline	**Group A (n=4,316)**	**Group B (n=3,923)**
	71.08	**72.82**
At 3 months	Group A (n=2,853)	Group B (n=1,521)
	76.69	73.98
Incremental difference	5.61	1.16

Source: CPMC trial data

CPMC = Chronic pain MedsCheck trial

Bolded values are significant using a two-sided test, p <0.05

These results corroborate with responses from 186 participants who completed the Patient Survey, of which n=119 (64%) reported that the CPMC intervention had an impact on managing their chronic pain. Around two-fifths (n=76 [41%]) said the service had some impact and almost a quarter (n=43 [23%]) reported a large impact.

MORPHINE EQUIVALENCE

The cost analysis looked at cost per mg change in average daily morphine equivalent dose for trial participants taking opioid medication. Average daily morphine equivalent dose calculated by pharmacists at initial, midpoint (Group B only) and follow-up for each trial participant taking opioid medication was used as the data source. For comparative purposes, Oxycodone (Endone®) 5 mg is equivalent to 7.5 mg of oral morphine.[47]

There are many different opioids and formulations (e.g. tablets, patches).[48] Prescription opioids include, for example, buprenorphine, oxycodone, fentanyl, and tapentadol[49] and a different amount of each opioid is needed to have the same analgesic effect.[50] However, while opioids are commonly used to relieve acute or cancer pain, the use of opioids in chronic pain is controversial; and may not be effective in reducing chronic pain in the long term. Further, opioids often cause adverse effects such as constipation or opioid dependence.[51]

An Australian cohort study published in 2014, the Pain and Opioids IN Treatment (POINT) study, was a 2-year prospective cohort study of around 1,500 people across Australia who had been prescribed opioids for chronic non-cancer pain. The study examined the extent to which opioid therapy for chronic pain may be associated with pain reduction, improved QoL, and favourable mental and physical health outcomes. About 15% of the cohort were taking more than 200 mg oral morphine equivalent (OME) per day and approximately 40% were consuming 90 mg OME or more per day. Trial participants taking higher doses (>90 mg OME/day) had the highest rates of problems associated with opioid medication (e.g. dependence) and reported less pain relief than trial participants taking lower doses.[52]

While no clinically meaningful reduction in opioid intake could be identified from the literature, a reduction in opioid consumption (particularly > 90mg OME/day) was assumed to be beneficial for chronic pain trial participants.

From the CPMC trial, there was a difference of 0.967 and -0.08 mg of morphine from baseline to the 3-month follow up in Group A and B trial participants, respectively (Table 82). In Group A there were 2,161 trial participants on opioids at baseline with 1,359 at follow up (63% of initial trial participants). Group B was worse with 1,809 trial participants on opioids at baseline, decreasing to 700 at follow up (39% of initial trial participants). These decreases were due to lost to follow up (refer to Section D.5 - Limitations). There was a very small increase in opioid usage in Group B patients. However, trial participant opioid intake in Groups A and B did not change much as values were very similar at baseline and follow up.

Table 82 Change in morphine doses (mg) in the CPMC evaluation site population

Baseline (mg)	**Group A (n=2,161)**	**Group B (n=1,814)**
	50.84	**47.74**
At 3 months (mg)	Group A (n=1,359)	Group B (n=702)
	49.87	47.82
Incremental difference (mg)	0.967	-0.08*

Source: CPMC trial data

CPMC = Chronic Pain MedsCheck

*Negative value used to signify the increase in morphine equivalence units

C.4. Any other translation issues

No other translation issues were identified.

C.5. Relationship of each Pre-Modelling Study to the Economic Evaluation

An electronic copy of the calculations is provided in the Excel file for the Section D economic evaluation. A summary of the pre-modelling studies conducted in this section and the uses of the results in Section D is presented in Table 83.

Table 83 Summary of results of pre-modelling studies and their uses in the economic evaluation

Section	**Pre-modelling study**	**Results used in Section D**	**Cross-reference**
Applicability			
Baseline characteristics	Trial participants in CPMC trial were similar to relevant Australian population. Trial characteristics - Median age = 59-60 years - 60% female - Chronic pain greater than 3 months (median of 5 years)	All CPMC data as provided was used. This allowed for an ITT analysis to be conducted.	Section C.1
Cost of intervention	From HealthConsult activity based costing study in 2019 the cost for Group A was: $131.22 and $164.03 for Group B.	Group A: $131.22 Group B: $164.03	Section C.1

Section	Pre-modelling study	Results used in Section D	Cross-reference
Extrapolation			
Survival	No reported deaths in the trial or in the extended arms tables.	No deaths	Section C.2 and D.4
Transformation			
Utilities	CPMC collected AQoL-4D data from trial participants at baseline and follow-up.	Trial based utilities were applied; from baseline (0 months) to 3 months.	Section C.3, and Section D.4
Costs	Costs were based on MBS, PBS, hospital and emergency department costing data	Total cost of Group A: • Initial: $1,513.57 • Follow-up: $1,378.46 PBS costs: • Initial: $310.94 • Follow-up: $250.91 MBS costs: • Initial: $590.07 • Follow-up: $449.01 Hospitalisation fees: • Initial: $498.13 • Follow-up: $438.16 Emergency department fees: • Initial: $114.43 • Follow-up: $109.15 Total cost of Group B: • Initial: $1,386.27	Section C.3, and Section D.4

Section	Pre-modelling study	Results used in Section D	Cross-reference
		• Follow-up: $1,180.00 PBS costs: • Initial: $216.92 • Follow-up: $145.94 MBS costs: • Initial: $560.16 • Follow-up: $311.07 Hospitalisation fees: • Initial: $494.85 • Follow-up: $457.31 Emergency department fees: • Initial: $114.34 • Follow-up: $101.65	
Additional PRO data	Used for secondary analysis to determine the impact of the intervention on other trial participant reported outcomes	Changes per unit utilised in the economic model	Section C.3, and Section D.4

SECTION D ECONOMIC EVALUATION

D.1. Overview

The clinical evaluation suggested that, relative to TAU, the pharmacist-led CPMC intervention has superior effectiveness and non-inferior safety based on the evidence profile given in Section B.8. Section D therefore presents a cost-utility analysis (CUA) for primary outcomes (QALYs) and a cost effectiveness analysis (CEA) for secondary outcomes (cost per unit change, Table 84).[53]

Table 84 Classification of the comparative effectiveness and safety of the pharmacist lead pain medication check compared with to TAU and guide to the suitable type of economic evaluation

Comparative safety		**Comparative effectiveness**		
-	**Inferior**	**Uncertaina**	**Non-inferiorb**	**Superior**
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertaina	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Non-inferiorb	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

CEA=cost-effectiveness analysis; CMA=cost-minimisation analysis; CUA=cost-utility analysis

? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis

a 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations

b An adequate assessment of 'non-inferiority' is the preferred basis for demonstrating equivalence

This section presents a modelled economic evaluation based on baseline versus follow-up results from the CPMC trial (i.e. pre vs post). Costs and outcomes at baseline were assumed to be TAU. Results of the 3-month follow up were used to determine whether the intervention was effective in providing benefits to trial participants.

D.2. Populations and settings

The population in the economic evaluation is the population from CPMC trial.

D.3. Structure and rationale of the economic evaluation

A summary of the key characteristics of the economic evaluation is given in Table 85.

Table 85 Summary of the economic evaluation

Perspective	**Healthcare system**
Comparator	Treatment-As-Usual (TAU)
Type of economic evaluation	Cost utility analysis (CUA) and cost effectiveness analysis (CEA)
Sources of evidence	CPMC trial
Time horizon	Six months
Outcomes	**Primary outcome:** Cost per QALY **Secondary Outcomes:** Cost per unit reduction in pain interference measured using the BPI as part of the mini-ePPOC Cost per unit reduction in pain severity measured using the BPI as part of the mini-ePPOC Cost per unit reduction in pain self-efficacy measured using the PSEQ-2 as part of the mini-ePPOC Cost per unit increase in self-management measured using the PIH Cost per unit reduction in morphine equivalent units Cost per PBS script reduction Cost per MBS service reduction
Methods used to generate results	Trial based. A quasi-experiment of pre vs post intervention
Discount rate	Not applicable as the model duration is less than one year
Software packages used	Microsoft Excel 2016

Abbreviations: BPI: Brief pain inventory; CPMC, Chronic Pain MedsCheck trial; MBS, Medicare benefits schedule; mini-ePPOC, The miniature electronic persistent pain outcomes collaboration questionnaire; QALY, Quality adjusted life years; PBS, Pharmaceutical benefits scheme; PIH, The Partners in health scale; PSEQ-2, Pain self-efficacy questionnaire; TAU, treatment as usual

The analysis of the primary outcome is presented first, followed by the secondary outcomes. Given the lack of control group from the analysis, the economic evaluation was not extrapolated beyond the 3-month follow up as this would result in greater uncertainty in results.

LITERATURE REVIEW

A literature search was conducted on 6 May 2020 to identify any cost-effectiveness studies which evaluated pharmacist led pain interventions. Searches were conducted in Medline, Embase and the Cochrane library, using the search strategy described in Table 86.

Table 86 Search terms used in each platform

Platform	Element of clinical question	Search terms
Medline	Intervention	'pharmacy'(all fields) OR "pharmacist" (all fields) AND pain (all fields)
	Study type	'cost effectiveness analysis' (exp) OR 'cost-utility analysis (exp)
Cochrane library	Intervention	'pharmacy'(all fields) OR "pharmacist" (all fields) AND pain (all fields)
	Study type	'cost effectiveness analysis' (exp) OR 'cost-utility analysis (exp)
Embase	Intervention	'pharmacy'(all fields) OR "pharmacist" (all fields) AND pain (all fields)
	Study type	'cost effectiveness analysis' (exp) OR 'cost-utility analysis (exp)

The search identified two notable publications (Neilson 2015, Bruhn 2013).[54,55]

Neilson (2015) was a pilot RCT conducted in the primary setting with a small sample size (n=125) with outcomes measured using the SF-6D questionnaire. Results were available at baseline, three months and six months. It was a three-armed study analysing the effectiveness of either pharmacist medication review with face-to-face pharmacist prescribing (n=39), or pharmacist medication review with feedback to the GP (n=44); or standard of care (placebo, n=42). Costs and effects were measured at six months. However, this study did not produce a cost/QALY. Instead it estimated the differences in mean costs and mean effectiveness (in terms of QALYs, Table 87) of pharmacist medication review with or without prescribing as compared with usual GP care for the treatment of chronic pain in primary care. Using these results, the study conducted an expected value of sample information analysis (EVSI) to determine the cost-effectiveness of conducting a larger RCT.

Similar to the findings of the CPMC trial, QALY gains in Neilson (2015) were higher than those reported at baseline in both pharmacist intervention groups. However, these gains were smaller than those of CPMC evaluation trial participants. No transformational equations were found which could convert AQoL-4D scores to the SF-6D or SF-12 and vice-versa. It could not be determined if the CPMC evaluation trial and Nielson (2015) cohorts were similar, and therefore Nielson (2015) utility scores were not used in any analysis. However, an increase in QoL was observed in both the CPMC and Nielson (2015) trials at baseline and at three months corroborates with Patient Survey responses presented in Section F.

Table 87 SF-6D health utility scores and QALYs over 6 months follow-up in Neilson 2015 (n=125)

	Prescribing (n=39)	Review (n=44)	TAU (n=42)
SF-6D at baseline, mean (SD)	0.6349 (0.1336)	0.6173 (0.1431)	0.6077 (0.1140)
SF-6D at 3 months, mean (SD)	0.6428 (0.1396)	0.6411 (0.1469)	0.6226 (0.1405)
SF-6D at 6 months, mean (SD)	0.6500 (0.1462)	0.6291 (0.1471)	0.6105 (0.1336)
Unadjusted total QALYs, mean (SD)	0.3213 (0.0659)	0.3161 (0.0684)	0.3079 (0.0606)
Adjusted difference in total QALYs versus TAU, mean (95% CI)*	0.0069 (−0.0091 to 0.0229)	0.0097 (−0.0054 to 0.0248)	

The number of patients with data on all these baseline variables: prescribing (n=35); review (n=39), TAU (n=34).
*Estimates from regression analyses with adjustment for differences in baseline costs, baseline SF-6D health utility score and other patient characteristics (age, sex, marital status, work status, education, income, baseline CPG—intensity).
QALYs, quality-adjusted life years; SF-6D, short form six-dimension; TAU, treatment as usual.

Source: Neilson 2015 Table 3

Bruhn (2013) presented SF-12 results for each arm at baseline and at six months (Table 88). As there was no three-month data, this publication was not further analysed.

Table 88 SF-12 Physical and Mental component scores of the SF-12 questionnaire at baseline and at 6 months follow up in Bruhn 2013 (n=125)

	N*	Prescribing Mean (SD)	N*	Review Mean (SD)	N*	TAU Mean (SD)	p Value (between groups†)
Baseline SF-12 PCS	41	33.5 (10.8)	43	32.59 (11.38)	45	29.60 (9.71)	
6-month follow-up SF12 PCS		35.3 (10.8)		34.62 (11.26)		32.59 (9.14)	
Difference SF-12 PCS		1.8 (7.5)		2.02 (7.56)		2.99 (8.11)	
p (within groups‡)		0.12		0.09		0.02	0.75
Effect size (r)		0.24		0.26		0.35	
		Median (IQR)		Median (IQR)		Median (IQR)	
Baseline SF-12 MCS	42	52.4 (42.0;58.8)	43	47.9 (38.5;59.9)	45	51.5 (41.3;60.7)	
6-month follow-up SF-12 MCS		49.6 (42.8;58.1)		47.9 (38.9;56.2)		44.7 (37.6;55.8)	
Difference SF-12 MCS		−0.4 (−3.7;6.0)		−1.2 (−6.6;4.2)		−3.0 (−10.0;1.3)	
p (within groups‡)		0.64		0.37		0.002	0.04
Effect size (r)		0.07		0.14		0.46	

Within-arm and between-arm p values are also reported.
*Number of participants in each group who completed the appropriate part of the SF-12 at both baseline and follow-up.
†From analysis of variance on mean difference or Kruskall-Wallis test on median difference as appropriate.
‡From paired t test or Wilcoxon signed rank test as appropriate.

Source: Bruhn 2013 Table 3

STRUCTURE OF THE ECONOMIC EVALUATION

The economic evaluation was analysed in Microsoft Excel 2016. Analysis was conducted utilising pre versus post intervention (baseline versus follow up). This is consistent with the approach based on Neilson (2015). In the CPMC trial after randomised, baseline scores for the AQoL-4D and secondary outcome measures were collected by group. These were reassessed at 3-months follow up. At 3 months, all costs incurred and offset during the trial by group were calculated. All changes in trial participant outcomes were also collected.

The economic evaluation consists of three sets of analyses. The results of the Group A analysis will determine whether two intervention points are cost effective (i.e. baseline and three months). Group B will determine whether three intervention points are cost effective. The analysis of Group A compared to Group B will determine whether the two or three intervention points are more cost-effective.

The structure of the economic evaluation is shown in Figure 40.

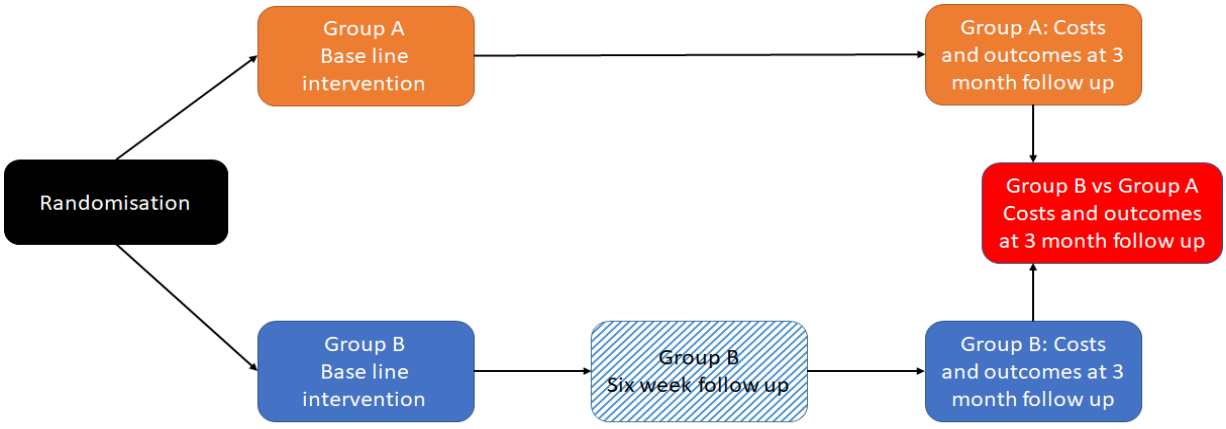


Figure 40 Decision analytic structure of the economic evaluation

Assumptions incorporated into the model structure:

All analyses assume that baseline results obtained prior to the first intervention would be indicative of TAU

D.4. Inputs to the economic evaluation

The inputs to the economic evaluation are costs and outcomes.

COSTS

The costs used in the economic evaluation are: PBS and MBS costs, hospitalisation cost, ED presentation cost and intervention cost. Usage at baseline was assumed to be TAU, while usage at three months was expected to have changed due to the pharmacist-led intervention. The cost per trial participant included in the trial, based on the activity based costing study, is presented in this section.

PBS costs

Table 89 presents a summary of PBS values used for the economic evaluation. The mean total benefits paid and mean total scripts per trial participant were used. The mean benefits paid per trial participant decreased from $310.94 to $250.91 in Group A and $216.92 to $145.94 in Group B. For Groups A and B these decreases result in a 19.3% and 32.7% reduction in the average cost per participant.

Table 89 Summary of analgesics usage and costs used in the economic evaluation for Groups A and B

Group A	Mean	SD	95%CI Low	95%CI High
Total benefits paid 6 months prior to intervention	$310.94	$358.41	$276.07	$345.80
Total scripts per trial participant 6 months prior to intervention	13.26	13.39	12.08	15.27
Total benefits paid 6 months post trial initiation	$250.91	$289.21	$222.77	$279.04
Total scripts per trial participant 6 months post trial initiation	10.70	11.55	8.97	12.43
Group B				
Total benefits paid 6 months prior to intervention	$216.92	$216.92	$216.92	$216.92
Total scripts per trial participant 6 months prior to intervention	10.39	11.16	9.07	12.69
Total benefits paid 6 months post trial initiation	$145.94	$204.04	$119.45	$172.42
Total scripts per trial participant 6 months post trial initiation	6.99	7.74	5.39	8.59

Source: CPMC trial data

Abbreviations: CI, confidence interval; SD, standard deviation

MBS costs

Table 90 presents a summary of MBS values used for the economic evaluation. The mean total benefits paid and mean total scripts per trial participant were used. The mean benefits paid per trial participant decreased from $590.07 to $449.01 in Group A and $560.16 to $311.07 in Group B. For Groups A and B these decreases result in a 24% and 47% reduction in the average cost per service, respectively.

Table 90 Summary of MBS utilisation and costs used in the economic evaluation for Groups A and B

Group A	Mean	SD	95%CI Low	95%CI High
Total benefits paid 6 months prior to intervention	$590.07	$494.03	$548.36	$631.78
Total services per trial participant 6 months prior to intervention	10.49	7.98	9.82	11.16
Total benefits paid 6 months post trial initiation	$449.01	$401.57	$382.73	$515.29
Total services per trial participant 6 months post trial initiation	7.85	6.72	6.74	8.96
Group B				
Total benefits paid 6 months prior to intervention	$560.16	$436.60	$520.44	$599.89
Total services per trial participant 6 months prior to intervention	10.33	7.89	9.61	11.04
Total benefits paid 6 months post trial initiation	$311.07	$354.85	$255.03	$367.11
Total services per trial participant 6 months post trial initiation	5.88	6.58	4.84	6.92

Source: CPMC trial data
Abbreviations: CI, confidence interval; SD, standard deviation

Hospitalisation cost

The cost per hospitalisation was $4,864.14 (see Section C.3). To determine the cost per hospitalisation in each group, the proportion of trial participants that were hospitalised was multiplied by the cost per hospitalisation. Group A cost per hospitalisation at baseline was $498.13

and at 3 months $438.16 (difference of $59.97). Group B at baseline $494.85 and at follow up was $457.31 (difference of $37.54, Table 91).

Table 91 Mean change from baseline and follow-up in hospitalisation costs

	CPMC trial group that were admitted to hospital	
	Group A	**Group B**
Baseline	$498.13	$494.85
3 months follow up	$438.16	$457.31
Incremental difference	$59.97	$37.54

Source: Table 72

Abbreviations: CPMC, Chronic Pain MedsCheck

Emergency department (ED) presentation cost

As presented in Section C.3, the cost of $732.74 per ED presentation was calculated. Groups A and B saw a reduction in ED presentations from baseline to the 3-month follow up (15.6% to 14.7% and 15.6% to 13.9%, respectively). The cost per ED presentation by Group A was $114.43 and $109.15 (difference of $5.27) at baseline and follow up and Group B $114.34 and $101.65 (difference of $12.69) at baseline and follow-up (Table 92).

Table 92 Mean change from baseline and follow-up in emergency department presentation costs

	CPMC trial group that were admitted to an emergency department	
	Group A	**Group B**
Baseline	$114.43	$114.34
3 months follow up	$109.15	$101.65
Incremental difference	$5.27	$12.69

Source: Table 73

Abbreviations: CPMC, Chronic Pain MedsCheck

Intervention cost

The intervention cost in Group A and Group B was $131.22 and $164.03, respectively. This was a flat fee applied to each arm.

To calculate the total cost of Neilson (2015) as of September 2020 in AUD, the value of 1 AUD to GBP was calculated as of 1 January 2010 (1 AUD bought 0.55 GBP, www.xe.com). Costs in Neilson (2015) were reported in 2009/2011 values, consequently 1 January 2010 was chosen as a midpoint. The total cost was inflated using the health price index (HPI) up to Q2 (June) of 2020.

From Neilson (2015) at both baseline and follow-up, medications accounted for the largest percentage of the total cost in all study arms (prescribing 37%, review 31%, TAU 55%). The pharmacist intervention accounted for 18% of costs in both the prescribing and review arms (Table 93). The highest cost category in the CPMC trial was MBS costs, followed by hospitalisation costs and PBS costs. This is different to the Neilson (2015) trial where medications (PBS costs in the CPMC trial) accounted for the highest cost.

Total costs were lower in the CPMC trial than those reported in Neilson (2015). In contrast with Neilson (2015), costs decreased from baseline to follow up (costs in Group A and B decreased from: $1,513.57 and $1,386.27 to $1,378.46 and $1,180 respectively). The cost of the intervention arm was lower than TAU arm (Table 94).

The Group A intervention resulted in a saving of $135.11 while Group B had a saving of $206.27 per participant. The incremental difference at baseline between Group A and B is $127.30. Even with greater intervention fees, if Group B were to have the same baseline cost as Group A, the cost saving generated for Group B participants is able to overcome the differences at baseline. This would result in a saving of approximately $79.

Table 93 Proportion of unadjusted total mean costs per trial participant at baseline and at 6 months follow-up, by each main cost component and study arm in Neilson (2015).

	Prescribing		**Review**		**TAU**	
Cost composition	**Baseline**	**6 months**	**Baseline**	**6 months**	**Baseline**	**6 months**
Medications	38%	37%	41%	31%	45%	55%
Hospital out trial participant	20%	16%	21%	16%	24%	19%

	Prescribing		Review		TAU	
Cost composition	**Baseline**	**6 months**	**Baseline**	**6 months**	**Baseline**	**6 months**
Hospital in trial participant	24%	12%	11%	15%	13%	11%
Primary care	18%	17%	27%	20%	19%	16%
Pharmacist intervention	NA	18%	NA	18%	NA	NA
Total cost	£364.8	£452.2	£436.6	£569.7	£624.7	£668.2
Total cost in AUD, Q2 2020	$984.25	$1,220.06	$1,177.97	$1,537.08	$1,685.47	$1,802.84

Source; Neilson 2015

Abbreviations; AUD, Australian dollars; NA, not applicable; Q2, Second quarter

Table 94 Cost composition for each participant in Groups A and B at baseline and at 6 months follow-up, by each main cost component

	Group A		Group B	
Cost composition	**Baseline**	**6 months**	**Baseline**	**6 months**
PBS costs	21%	18%	16%	12%
MBS costs	39%	33%	40%	26%
Hospitalisation costs	33%	32%	36%	39%
ED presentation costs	8%	8%	8%	9%
Pharmacy intervention	NA	10%	NA	14%
Total	$1,513.57*	$1,378.46*	$1,386.27	$1,180.00

Source; CPMC trial data

Abbreviations; MBS, Medicare benefits schedule; PBS, Pharmaceutical benefits scheme

Note: Six months data available for PBS and MBS costs, rest are three months

* Percentages add up to 101% due to rounding error.

OUTCOMES

The primary outcome considered in the economic evaluation is QALYs as measured using the AQoL-4D. Secondary outcomes that were analysed included:

- self-management measured using the PIH
- morphine equivalent units
- pain interference measured using the BPI as part of the mini-ePPOC
- pain severity measured using the BPI as part of the mini-ePPOC
- pain self-efficacy measured using the PSEQ-2 as part of the mini-ePPOC
- Mean PBS scripts per trial participant
- Mean MBS services per trial participant

Primary outcomes Utilities – Evaluation sites only

Table 95 presents the utility values applied in the economic model.

Table 95 Utility values applied in the model

	CPMC trial group that completed the AqoL-4D	
Baseline	**Group A (n=4,316)**	**Group B (n=3,922)**
	0.58	0.53
At 3 months	**Group A (n=2,853)**	**Group B (n=1,521)**
	0.63	0.70
Incremental difference	**0.05**	**0.17**

Source: Table 76

SECONDARY OUTCOMES

Units used for secondary outcomes analyses are presented in Table 96 to Table 102.

Table 96 Self-management measured using the PIH values applied in the model

Baseline	**Group A (n=4,316)**	**Group B (n=3,923)**
	71.08	**72.82**
At 3 months	Group A (n=2,853)	Group B (n=1,521)
	76.69	73.98
Incremental difference	5.61	1.16

Source: Table 81

Table 97 Morphine equivalent unit values applied in the model

Baseline (mg)	**Group A (n=2,161)**	**Group B (n=1,814)**
	50.84	47.74
At 3 months (mg)	Group A (n=1,359)	Group B (n=702)
	49.87	47.82
Incremental difference (mg)	0.967	-0.08*

Source: Table 82

*Negative increment in Group B, as morphine usage went up (undesirable outcome)

Table 98 Pain interference scores using the BPI in the whole CPMC trial population by group status

Baseline	**Group A (n=4,316)**	**Group B (n=3,923)**
	0.787	**0.772**
At 3 months	Group A (n=2,853)	Group B (n=1,521)
	0.651	0.517
Incremental difference	0.136	0.255

Source: Table 78

Note: The change in proportion of moderate to severe patients from baseline to follow-up is presented

Table 99 Pain severity scores using the BPI in the whole CPMC trial population by group status

Baseline	**Group A (n=4,316)**	**Group B (n=3,923)**
	0.695	**0.691**
At 3 months	Group A (n=2,853)	Group B (n=1,521)
	0.584	0.582

Baseline	Group A (n=4,316)	Group B (n=3,923)
	0.695	**0.691**
Incremental difference	0.111	0.109

Source: Table 79

Note: The change in proportion of moderate to severe patients from baseline to follow-up is measured/presented

Table 100 Pain self-efficacy scores using the PSEQ-2 in the whole CPMC trial population by group status

Baseline	Group A (n=4,316)	Group B (n=3,923)
	0.526	**0.496**
At 3 months	Group A (n=2,853)	Group B (n=1,521)
	0.645	0.624
Incremental difference	0.118*	0.128

Source: Table 80

Note: The change in proportion of moderate to severe patients from baseline to follow-up is measured/presented

* rounding error

Table 101 Mean PBS script usage in the whole CPMC trial population by group status

Baseline	Group A (n=497)	Group B (n=275)
	13.26	**10.39**
3 months follow up	Group A (n=171)	Group B (n=90)
	10.70	6.99
Incremental difference	2.56	3.40

Source: Adapted from Table 66

Table 102 Mean MBS service usage in the whole CPMC trial population by group status

Baseline	Group A (n=539)	Group B (n=464)
	10.49	**10.33**
3 months follow up	Group A (n=141)	Group B (n=154)
	7.85	5.88
Incremental difference	2.64	4.44

Source: Adapted from Table 68 and Table 69

D.5. Results of the Economic Evaluation

The incremental cost per outcome is presented in this section. The primary outcome of QALYs is presented first, followed by secondary trial outcomes.

INCREMENTAL COST PER QALY

The incremental costs per QALY for the pharmacist-led intervention in Group A and Group B are shown in Table 103 and Table 104. In both groups, the CPMC intervention resulted in lower costs and higher QALYs than TAU. Therefore, the CPMC intervention is dominant in both groups.

Table 103 Group A: Incremental cost per QALY for the pharmacist-led pain intervention compared to TAU

	Group A CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11

	Group A CPMC intervention	TAU	Increment
QALYs	0.63	0.58	0.05
Cost per QALY	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; QALY, quality adjusted life year; TAU, treatment as usual

Table 104 Group B: Incremental cost per QALY for the pharmacist-led pain intervention compared to TAU

	Group B CPMC intervention	TAU	Increment
Costs	$1,180.00	$1,386.27	-$206.27
QALYs	0.70	0.53	0.17
Cost per QALY	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; QALY, quality adjusted life year; TAU, treatment as usual

INCREMENTAL COSTS AND EFFECTIVENESS IN SECONDARY OUTCOMES

The incremental costs per unit change for secondary outcomes in the CPMC intervention and TAU are shown from Table 105 to Table 118. As there is a paucity of data in the use of the nominated outcomes in this section for economic evaluations, there is a limitation to determine whether a good or bad value for money is being achieved. However, from results of the primary analysis (cost/QALY), it can be inferred that the value for money is excellent as the intervention dominates TAU. Units evaluated in this section are not comparable with one another.

Change in self-management measured using the PIH

The incremental cost per unit change in self-management measured using the PIH was lower than TAU in both groups (Table 105 and Table 106). The additional midpoint follow-up in Group B saw a lower change in units in comparison to Group A. As the reduction in units was less than 10% for both arms, changes were not clinically meaningful although the intervention is dominant to TAU.

Table 105 Group A: Incremental cost per unit change for self-management in the CPMC intervention compared to TAU

	Group A CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11
Units	76.69	71.08	5.61
Cost per unit change	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; TAU, treatment as usual

Table 106 Group B: Incremental cost per unit change for self-management in the CPMC intervention compared to TAU

	Group B CPMC intervention	TAU	Increment
Costs	$1,180.00	$1,386.27	-$206.27
Units	73.98	72.82	1.16
Cost per unit change	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; TAU, treatment as usual

Change in morphine equivalent

The incremental cost per unit change in morphine equivalent was lower in both Group A (Table 107) and Group B (Table 108). As a negative increment is the desired outcome, the CPMC intervention was dominant over TAU for Group A patients. In Group B, a saving of $2,578.43 per morphine unit lost was calculated. As there is no defined threshold for cost per morphine unit lost or gained, it is difficult to determine if this suffices the willingness to accept threshold (this is a two-fold or greater increase of the willingness to pay value [e.g. $50,000/QALY]).[56] However, when accounting for the results of the primary analysis (cost/QALY), it is likely that the cost saving per morphine unit lost is acceptable.

Table 107 Group A: Incremental cost per unit change of morphine equivalent in the CPMC intervention compared to TAU

	Group A CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11
Units	49.87	50.84	0.97
Cost per unit change	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; TAU, treatment as usual

Table 108 Group B: Incremental cost per unit change of morphine equivalent in the CPMC intervention compared to TAU

	Group B CPMC intervention	TAU	Increment
Costs	$1,180.00	$1,386.27	-$206.27
Units	47.82	47.74	-0.08
Cost per unit change	$2,578.43		

Abbreviations: CPMC, chronic pain MedsCheck; TAU, treatment as usual

Change in pain interference measured using the BPI as part of the mini-ePPOC

A 14-26% reduction for all intervention trial participants when comparing follow up scores to baseline was observed (Table 109 and Table 110). These results suggest a clinically significant change in pain interference. With lower costs for the intervention in both Groups A and B was dominant towards TAU.

Table 109 Group A: Incremental cost per reduction change in severity for pain interference in the CPMC intervention compared to TAU

	Group A CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11
Proportion moderate-severe	0.65	0.79	0.14
Cost per reduction in moderate-severe trial participants	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; TAU, treatment as usual

Table 110 Group B: Incremental cost per reduction change in severity for pain interference in the CPMC intervention compared to TAU

	Group B CPMC intervention	TAU	Increment
Costs	$1,180.00	$1,386.27	-$206.27
Proportion moderate-severe	0.52	0.77	0.26
Cost per reduction in moderate-severe trial participants	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; TAU, treatment as usual

Change in pain severity measured using the BPI as part of the mini-ePPOC

An 11% reduction for Group A and B trial participants when comparing follow up scores to baseline was observed (Table 111 and Table 112). As with morphine units, decreases in outcomes was desirable. Consequently, the CPMC program is dominant over TAU.

Table 111 Group A: Incremental cost per reduction change in severity of trial participants for pain severity in the CPMC intervention compared to TAU

	Group A CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11
Proportion moderate-severe	0.58	0.70	0.11*
Cost per reduction in moderate-severe trial participants	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; TAU, treatment as usual

* Rounding error

Table 112 Group B: Incremental cost per reduction change in severity of trial participants for pain severity in the CPMC intervention compared to TAU

	Group B CPMC intervention	TAU	Increment
Costs	$1,180.00	$1,386.27	-$206.27
Proportion moderate-severe	0.58	0.69	0.11
Cost per reduction in moderate-severe trial participants	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; TAU, treatment as usual

Change in pain self-efficacy measured using the PSEQ-2 as part of the mini-ePPOC

For trial participants achieving meaningful functional outcomes as assessed using pain self-efficacy measured using the mini-ePPOC for Groups A and Group B; a 12-15% increase for intervention trial participants when comparing follow up scores to baseline was observed (Table 113 and Table 114). Consequently, a modest proportion of trial participants experienced increased benefits from the intervention when assessed using the PSEQ-2 as part of the mini-ePPOC. As the costs for the intervention was lower than TAU, the intervention is dominant.

Table 113 Group A: Incremental cost per unit change for pain self-efficacy in CPMC intervention compared to TAU

	Group A CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11
Change	0.65	0.53	0.12
Cost per unit change	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; TAU, treatment as usual

Table 114 Group B: Incremental cost per unit change for pain self-efficacy in CPMC intervention compared to TAU

	Group B CPMC intervention	TAU	Increment
Costs	$1,180.00	$1,386.27	-$206.27
Change	0.62	0.50	0.13
Cost per change	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; TAU, treatment as usual

Changes in PBS script usage

Changes in PBS script usage per trial participant is presented in Table 115 and Table 116 for Group A and B respectively. In both groups, there is a reduction in the mean number of scripts per trial participant from 9.78 to 8.10 in Group A (17% reduction) and 7.84 to 5.69 in Group B (27% reduction). As the costs for the intervention was lower than TAU, the intervention is dominant.

Table 115 Group A: Incremental cost per usage change in PBS script usage in the pharmacist-led pain intervention compared to TAU

	Group A CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11
PBS item usage	10.70	13.26	2.56
Cost per usage change	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; PBS, Pharmaceutical benefits scheme; TAU, treatment as usual

Table 116 Group B: Incremental cost per usage change in PBS script usage in the pharmacist-led pain intervention compared to TAU

	Group B CPMC intervention	TAU	Increment
Costs	$1,180.00	$1,386.27	-$206.27
PBS item usage	6.99	10.39	3.40
Cost per usage change	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; PBS, Pharmaceutical benefits scheme; TAU, treatment as usual

Changes in MBS service usage

Changes in MBS service volume per trial participant is presented in Table 117 and Table 118 for Group A and B respectively. The mean number of MBS services per trial participant decreases from 10.49 to 7.85 in Group A (25% reduction) and 10.33 to 5.88 in Group B (43% reduction). As the costs for the intervention was lower than TAU, the intervention is dominant.

Table 117 Group A: Incremental cost per change in MBS service usage in the pharmacist-led pain intervention compared to TAU

	Group A CPMC intervention	TAU	Increment
Costs	$1,378.46	$1,513.57	-$135.11
MBS item usage	7.85	10.49	2.64
Cost per change in item usage	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; MBS, Medicare benefits schedule; TAU, treatment as usual

Table 118 Group B: Incremental cost per change in MBS service usage in the pharmacist-led pain intervention compared to TAU

	Group B CPMC intervention	TAU	Increment
Costs	$1,180.00	$1,386.27	-$206.27
MBS item usage	5.88	10.33	4.44
Cost per change in item usage	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; MBS, Medicare benefits schedule; TAU, treatment as usual

GROUP B VS A ANALYSIS

The costs and outcome gains from Groups A and B are compared in this subsection. All outcomes presented for Groups A and B have been analysed. As the midpoint intervention of Group B is believed to increase the efficacy of the CPMC intervention, it has been treated as the intervention for this set of analyses (Table 119-Table 126).

When comparing Groups B and A, Group B is dominant to Group A for cost/QALY. In addition, Group B:

- has lower costs and greater outcomes (in most analyses) compared to Group A
- has slightly lower morphine equivalence, self-management and pain severity scores after the intervention. This resulted in cost saving ICERs per unit lost (~$45 and ~$189 and $99,000 per outcome, respectively). As there are no published willingness to pay thresholds for these outcomes, it is difficult to determine if these cost savings are acceptable. If the cost/QALY serves as an indicator, it is likely these loses are acceptable.

Group B was dominant over Group A in other outcomes.

Table 119 Group B vs A: Incremental cost per QALY for the CPMC intervention

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental QALYs	0.17	0.05	0.12
Cost per QALY	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; QALY, quality adjusted life year

Table 120 Group B vs A: Incremental cost per unit change for self-management in the CPMC intervention

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46

	Group B	Group A	Increment
Incremental units	1.16	5.61	-4.45
Cost per unit change	$44.57		

Abbreviations: CPMC, chronic pain MedsCheck

Table 121 Group B vs A: Incremental cost per unit change for morphine equivalent in the CPMC intervention

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental units	-0.08	0.97	-1.05
Cost per unit change	$189.42		

Abbreviations: CPMC, chronic pain MedsCheck

Table 122 Group B vs A: Incremental cost per reduction change in severity for pain interference in the CPMC intervention

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental proportion of moderate-severe participants	0.26	0.14	0.12
Cost per reduction in moderate-severe trial participants	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck

Table 123 Group B vs A: Incremental cost per reduction change in severity for pain severity in the CPMC intervention

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental proportion of moderate-severe participants	0.109*	0.111*	-0.002*
Cost per reduction in moderate-severe trial participants	$99,231.13		

Abbreviations: CPMC, chronic pain MedsCheck

Note: * 3 decimal places to demonstrate incremental difference

Table 124 Group B vs A: Incremental cost per unit change for pain self-efficacy in CPMC intervention

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental units	0.13	0.12	0.01
Cost per unit change	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck

Table 125 Group B vs A: Incremental cost per item usage change in PBS item usage severity in CPMC intervention

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental units	3.40	2.56	0.84
Cost per item usage change	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; PBS, Pharmaceutical benefits scheme

Table 126 Group B vs A: Incremental cost per item usage change in MBS item usage in CPMC intervention

	Group B	Group A	Increment
Costs	$1,180.00	$1,378.46	-$198.46
Incremental units	4.44	2.64	1.80
Cost per item usage change	DOMINANT		

Abbreviations: CPMC, chronic pain MedsCheck; MBS, Medicare benefits schedule

For brevity, all analyses (i.e. Group A and B vs TAU and Group B vs A) have been summarised in Table 127.

Table 127 Summary of all analyses conducted in Section D.5

Outcome	Group A vs TAU	Group B vs TAU	Group B vs A
QALYs	DOMINANT	DOMINANT	DOMINANT
Pain self-management units	DOMINANT	DOMINANT	Lower cost, lower outcomes – SW quadrant
Morphine equivalence units	DOMINANT	Lower cost, lower outcomes – SW quadrant	Lower cost, lower outcomes – SW quadrant
Pain severity scores	DOMINANT	DOMINANT	Lower cost, lower outcomes – SW quadrant
Pain interference units	DOMINANT	DOMINANT	DOMINANT
Pain self-efficacy scores	DOMINANT	DOMINANT	DOMINANT
PBS scripts	DOMINANT	DOMINANT	DOMINANT
MBS services	DOMINANT	DOMINANT	DOMINANT

Abbreviations: MBS, Medicare benefits schedule; QALY, Quality adjusted life years; PBS, Pharmaceutical benefits scheme; SW, South west; TAU, Treatment as usual

LIMITATIONS

The CPMC trial results in greater quality of life. The main limitation is that there is a paucity of data in this specific area of research to enable extrapolation from these results for the long term follow up (i.e. post three months) of the CPMC interventions. Additionally, there was no placebo group followed for three months. If the analysis were extrapolated, costs may have continued to decrease (as demonstrated by average PBS script and MBS service usage per patient), and additional yet diminishing gains in QALYs would be expected (refer to incremental QALY gains from 3 to 6 months in Table 87). If extrapolated, this would have likely resulted in increased cost-effectiveness over time and bias in favour of the CPMC intervention. It is unclear how secondary outcomes would change over time or what they're impacts on patients would be.

Additional limitations of the CPMC trial include:

- The measurement of outcomes such as prescription changes and health service utilisation at the three to six month mark may provide an indication of the CPMC program's effects. Given how this is a relatively short time frame for outcome measurement, positive results may lead to the CPMC program being misconceived as a 'quick fix.' The type of pain experienced by trial participants is not reported. This may influence which medications and services they would use. For example, a participant with nerve pain may take an anti-convulsant instead of an opioid based drug.
- Even though pharmacies were randomly allocated to either Group A or Group B, Group A had almost twice the number of trial participants of Group B resulting in allocation bias. This resulted in an approximate ratio of 2:1 trial participants for Groups A and B, respectively. The smaller number of trial participants in Group B results in lower certainty of results as they are more prone to overstating benefits.
- Reliance on self-reported data, which is prone to underestimation due to trial participant's perceptions of their healthcare providers. Outcomes assessed in both arms were the same, thus, minimising bias for one arm over another.
- Duration of chronic pain prior and analgesic usage prior to intervention - greater time on opioids can increase tolerance and therefore dose. However, morphine equivalent dosing between groups was similar, thus, minimising the impact of this limitation.
- Analysis of some unvalidated outcomes and inferred impact on trial participants is not known. The same outcomes were assessed across both arms, thereby, minimising the impact of this limitation.
- Low completion rates for outcomes of trial participants in both Groups A and B (refer to Table 21 for total number of participants in Groups A and B). This can result in overstating benefits and would impact both arms.
- Large amount of selection bias as loss to follow up was over 60% in evaluation sites Group A and B (61% and 68%, respectively). This impacted both arms similarly.
- The impact of allocating the randomly allocated Group A and Group B main sites to evaluation sites as a result of insufficient trial participant recruitment at the original evaluation sites is also unknown. The impact of this is uncertain as baseline assessments were likely missing for several trial participants, hence the low completion rates. To measure the impact, several statistical tests were conducted to determine the effect of sample size.
- As participants could join at any time point within a year, they may have reached concessional safety net thresholds. This would result in lower PBS expenditures for these participants in both arms. From Figure 68 (Appendix I), this was not the case for most participants.
- Results used at baseline and at 3 months follow-up are unmatched. Ideally, it would have been best to match patients at baseline to those at follow-up for a more robust analysis of the intervention. However, from biostatistician advice, the use of unmatched data was unlikely to impact on results. Several analysis testing this assumption supported the expert biostatistical advice. These tests include *Cohen's D* test and *Hedges' G* test to measure the effect between two means of those participants who complete or incomplete the trial.

- Unable to track longer term outcomes due to limitations in participant data that was collected (refer to Appendix I, Figure 68-Figure 70).

Despite these limitations, the CPMC intervention is the largest pharmacy-based pain intervention with n=8,240 trial participants. Of this, n=2,600 were part of the evaluation sites that were used to determine the cost per QALY. Consequently, this results in greater certainty in comparison to Nelson (2015) and Bruhn (2013) with n=125 trial participants spread across three groups. The CPMC is also conducted in an entirely Australian cohort, which allows for greater applicability of results.

D.6. Sensitivity analyses

Results for the primary and secondary sensitivity analyses have been presented in this section. For upper and lower bounds, 95% confidence of intervals (CIs) were used. When unavailable, an arbitrary 20% was used for upper and lower bounds. This was only applied to trial costs. The primary outcome of the economic evaluation (cost/QALY) is generally perceived to be the most credible outcome analysed. Consequently, a table of drivers (Table 128), and tornado plots have been produced to display the results for the cost/QALY. AS some of the secondary outcomes include unvalidated measures, tornado plots have not been produced representing this data.

PRIMARY OUTCOME SENSITIVITY ANALYSES

The sensitivity analysis was conducted to characterise the impact of variation in parameters on the results of the economic evaluation. Univariate sensitivity analyses and the impact of these changes on the cost-effectiveness ratios for both Group A and B are presented in Table 128. The impact of these changes is considered separately. As Group B had lower costs and greater QALYs, it is dominant to Group A.

Table 128 Key drivers of the economic model

Description	ICER
Group A	
Base case	DOMINANT
Intervention hospitalisation costs increased from $438.16 to $514.40 (Upper bound of 95% CI)	DOMINANT
Intervention hospitalisation costs decreased from $438.16 to $361.93 (Lower bound of 95% CI)	DOMINANT
Intervention emergency department presentation costs from $109.15 to $125.92 (Upper bound of 95% CI)	DOMINANT
Intervention emergency department presentation costs from $109.15 to $92.39 (Lower bound of 95% CI)	DOMINANT
Intervention trial costs increased from $131.22 to $157.46 (20% relative increase)	DOMINANT
Intervention trial costs decreased from $131.22 to $104.98 (20% relative decrease)	DOMINANT
Intervention PBS costs increased from $250.91 to $279.04 (Upper bound of 95% CI)	DOMINANT
Intervention PBS costs decreased from $250.91 to $222.77 (Lower bound of 95% CI)	DOMINANT
Intervention MBS costs increased from $449.01 to $515.29 (Upper bound of 95% CI)	DOMINANT

Description	ICER
Intervention MBS costs decreased from $449.01 to $382.73 (Lower bound of 95% CI)	DOMINANT
Intervention QALYs increased from 0.63 to 0.65 (Upper bound of 95% CI)	DOMINANT
Intervention QALYs decreased from 0.65 to 0.61 (Lower bound of 95% CI)	DOMINANT
TAU hospitalisation costs increased from $498.13 to $565.98 (Upper bound of 95% CI)	DOMINANT
TAU hospitalisation costs decreased from $498.13 to $430.29 (Lower bound of 95% CI)	DOMINANT
TAU emergency department presentation costs from $114.43 to $128.55 (Upper bound of 95% CI)	DOMINANT
TAU emergency department presentation costs from $114.43 to $100.30 (Lower bound of 95% CI)	DOMINANT
TAU PBS costs increased from $310.94 to $345.80 (Upper bound of 95% CI)	DOMINANT
TAU PBS costs decreased from $310.94 to $276.07 (Lower bound of 95% CI)	DOMINANT
TAU MBS costs increased from $590.07 to $631.78 (Upper bound of 95% CI)	DOMINANT
TAU MBS costs decreased from $590.07 to $548.36 (Lower bound of 95% CI)	DOMINANT
TAU QALYs increased from 0.59 to 0.60 (Upper bound of 95% CI)	DOMINANT
TAU QALYs decreased from 0.59 to 0.57 (Lower bound of 95% CI)	DOMINANT
Group B	
Base case	DOMINANT
Intervention hospitalisation costs increased from $457.31 to $568.78 (Upper bound of 95% CI)	DOMINANT
Intervention hospitalisation costs decreased from $457.31 to $345.84 (Lower bound of 95% CI)	DOMINANT
Intervention emergency department presentation costs from $101.65 to $125.67 (Upper bound of 95% CI)	DOMINANT
Intervention emergency department presentation costs from $101.65 to $77.63 (Lower bound of 95% CI)	DOMINANT
Intervention trial costs increased from $164.03 to $196.84 (20% relative increase)	DOMINANT
Intervention trial costs decreased from $164.03 to $131.22 (20% relative decrease)	DOMINANT
Intervention PBS costs increased from $145.94 to $172.42 (Upper bound of 95% CI)	DOMINANT
Intervention PBS costs decreased from $145.94 to $119.45 (Lower bound of 95% CI)	DOMINANT
Intervention MBS costs increased from $311.07 to $367.11 (Upper bound of 95% CI)	DOMINANT
Intervention MBS costs decreased from $311.07 to $252.03 (Lower bound of 95% CI)	DOMINANT
Intervention trial QALYs increased from 0.70 to 0.73 (Upper bound of 95% CI)	DOMINANT
Intervention trial QALYs decreased from 0.70 to 0.67 (Lower bound of 95% CI)	DOMINANT
TAU hospitalisation costs increased from $495.91 to $568.47 (Upper bound of 95% CI)	DOMINANT

Description	ICER
TAU hospitalisation costs decreased from $495.91 to $423.35 (Lower bound of 95% CI)	DOMINANT
TAU emergency department presentation costs from $101.87 to $125.94 (Upper bound of 95% CI)	DOMINANT
TAU emergency department presentation costs from $101.87 to $77.79 (Lower bound of 95% CI)	DOMINANT
TAU PBS costs increased from $216.92 to $256.28 (Upper bound of 95% CI)	DOMINANT
TAU PBS costs decreased from $216.92 to $177.55 (Lower bound of 95% CI)	DOMINANT
TAU MBS costs increased from $560.16 to $599.89 (Upper bound of 95% CI)	DOMINANT
TAU MBS costs decreased from $560.16 to $520.44 (Lower bound of 95% CI)	DOMINANT
TAU QALYs increased from 0.53 to 0.55 (Upper bound of 95% CI)	DOMINANT
TAU QALYs decreased from 0.53 to 0.51 (Lower bound of 95% CI)	DOMINANT
Group B vs A	
Base case	DOMINANT
Group B hospitalisation costs increased from $457.31 to $568.78 (Upper bound of 95% CI)	DOMINANT
Group B hospitalisation costs decreased from $457.31 to $345.84 (Lower bound of 95% CI)	DOMINANT
Group B emergency department presentation costs from $101.65 to $125.67 (Upper bound of 95% CI)	DOMINANT
Group B emergency department presentation costs from $101.65 to $77.63 (Lower bound of 95% CI)	DOMINANT
Group B trial costs increased from $164.03 to $196.84 (20% relative increase)	DOMINANT
Group B trial costs decreased from $164.03 to $131.22 (20% relative decrease)	DOMINANT
Group B PBS costs increased from $145.94 to $172.42 (Upper bound of 95% CI)	DOMINANT
Group B PBS costs decreased from $145.94 to $119.45 (Lower bound of 95% CI)	DOMINANT
Group B MBS costs increased from $311.07 to $367.11 (Upper bound of 95% CI)	DOMINANT
Group B MBS costs decreased from $311.07 to $255.03 (Lower bound of 95% CI)	DOMINANT
Group B trial incremental QALYs increased from 0.17 to 0.20 (Arbitrary 20% increase)	DOMINANT
Group B trial QALYs decreased from 0.17 to 0.14 (Arbitrary 20% decrease)	DOMINANT
Group A hospitalisation costs increased from $438.16 to $514.40 (Upper bound of 95% CI)	DOMINANT
Group A hospitalisation costs decreased from $438.16 to $361.93 (Lower bound of 95% CI)	DOMINANT
Group A emergency department presentation costs from $109.15 to $125.92 (Upper bound of 95% CI)	DOMINANT
Group A emergency department presentation costs from $109.15 to $92.39 (Lower bound of 95% CI)	DOMINANT

Description	ICER
Group A trial costs increased from $131.22 to $157.46 (20% relative increase)	DOMINANT
Group A trial costs decreased from $131.22 to $104.98 (20% relative decrease)	DOMINANT
Group A PBS costs increased from $250.91 to $279.04 (Upper bound of 95% CI)	DOMINANT
Group A PBS costs decreased from $250.91 to $222.77 (Lower bound of 95% CI)	DOMINANT
Group A MBS costs increased from $449.01 to $515.29 (Upper bound of 95% CI)	DOMINANT
Group A MBS costs decreased from $449.01 to $382.73 (Lower bound of 95% CI)	DOMINANT
Group A trial QALYs increased from 0.05 to 0.06 (Arbitrary 20% increase)	DOMINANT
Group A trial QALYs decreased from 0.05 to 0.04 (Arbitrary 20% decrease)	DOMINANT

Tornado diagrams for the sensitivity analyses performed above are presented in Figure 41 for the Group A analysis, Figure 42 for the Group B analysis and Figure 43 for the Group B vs A analysis. The use of tornado diagrams for univariate sensitivity analyses are supported in the MSAC guidelines. [57] Hospitalisation costs and MBS service usage were the main drivers in the Group A and B analyses. For Group B vs A, the same variables in addition to QALYs were key drivers. The upper and lower bounds reflect the higher and lower 95% confidence interval values.

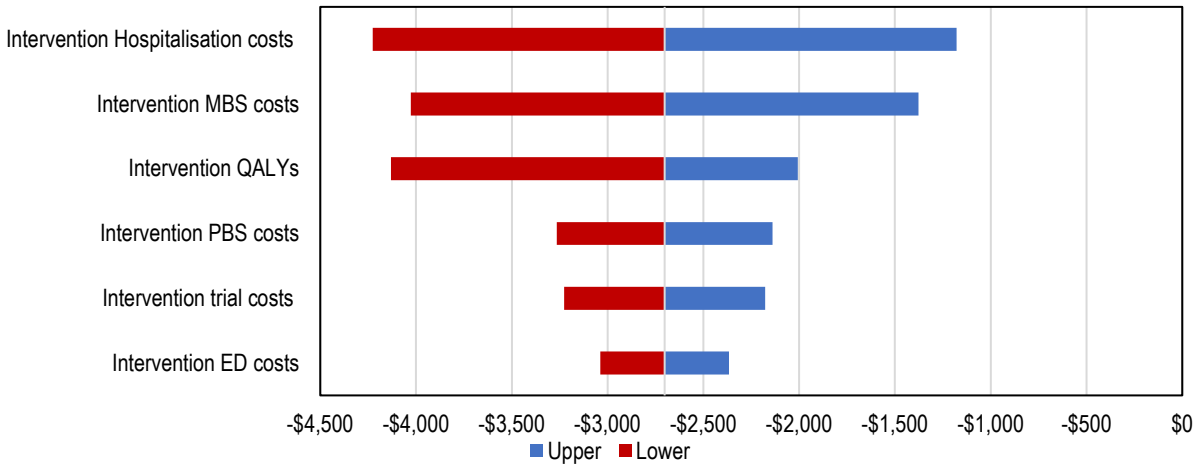


Figure 41Group A: Tornado diagram – cost/QALY

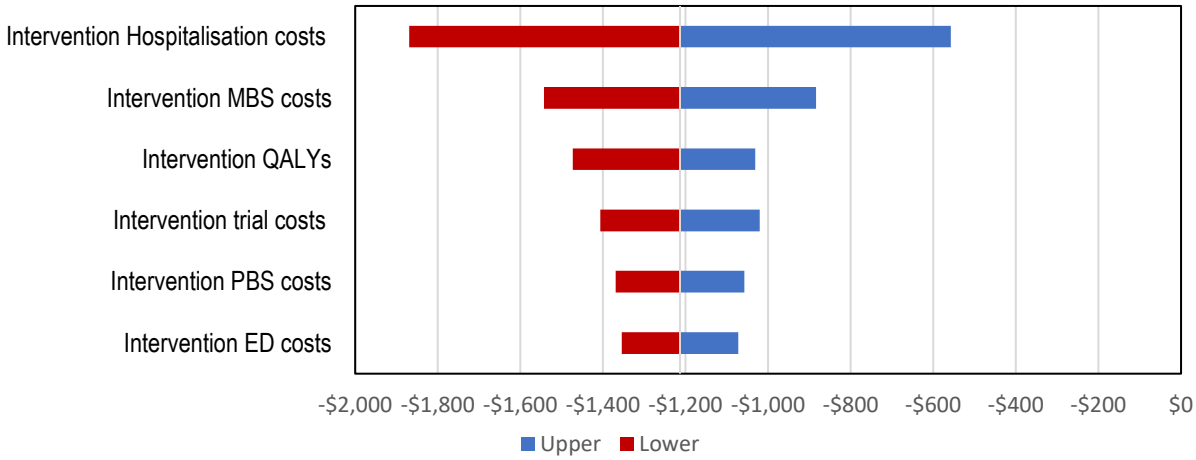


Figure 42 Group B: Tornado diagram – cost/QALY

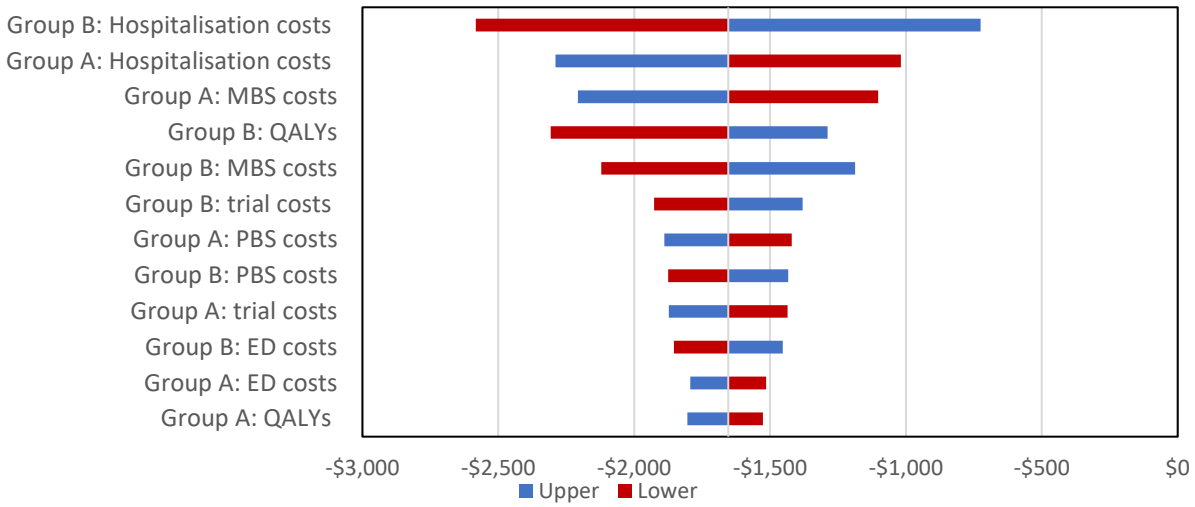


Figure 43 Group B vs A: Tornado diagram – cost/QALY

SECONDARY OUTCOME SENSITIVITY ANALYSES

Tornado diagrams for the change per unit in the PIH health scale sensitivity analyses are presented in Figure 44 for the Group A analysis and Figure 45 for the Group B analysis. The base case ICER for Group A and B are dominant to TAU. Hospitalisation and MBS costs were the main driver in Group A, while self-management scores and hospitalisation costs were the main driver in Group B. The base case cost-saving per unit lost ICER for Group B vs Group A was $44.57 (Figure 46). Hospitalisations and trial costs were the main drivers for this analysis. Upper and lower bounds were +/- 20% of the base case cost/outcome score analysed.

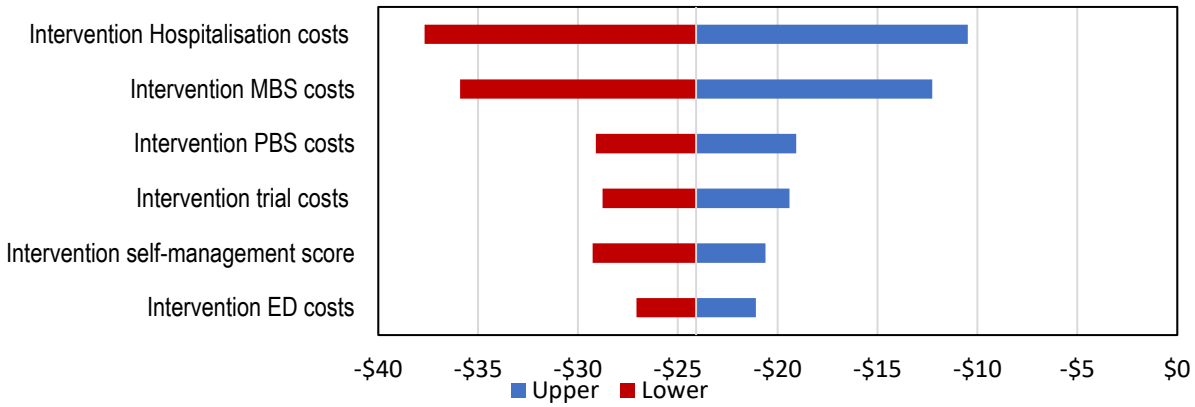


Figure 44 Group A: Tornado diagram – cost/PIH unit

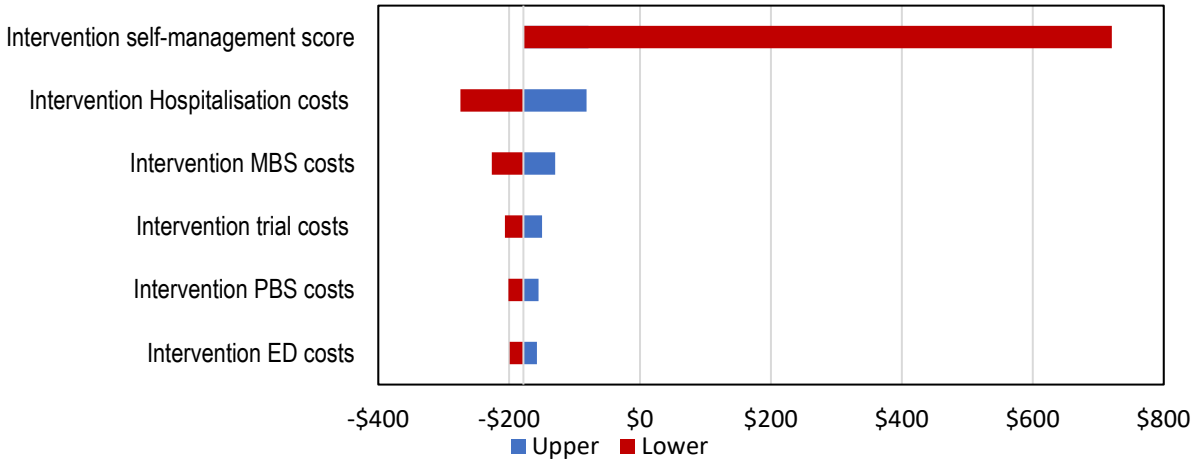


Figure 45 Group B: Tornado diagram – cost/PIH unit

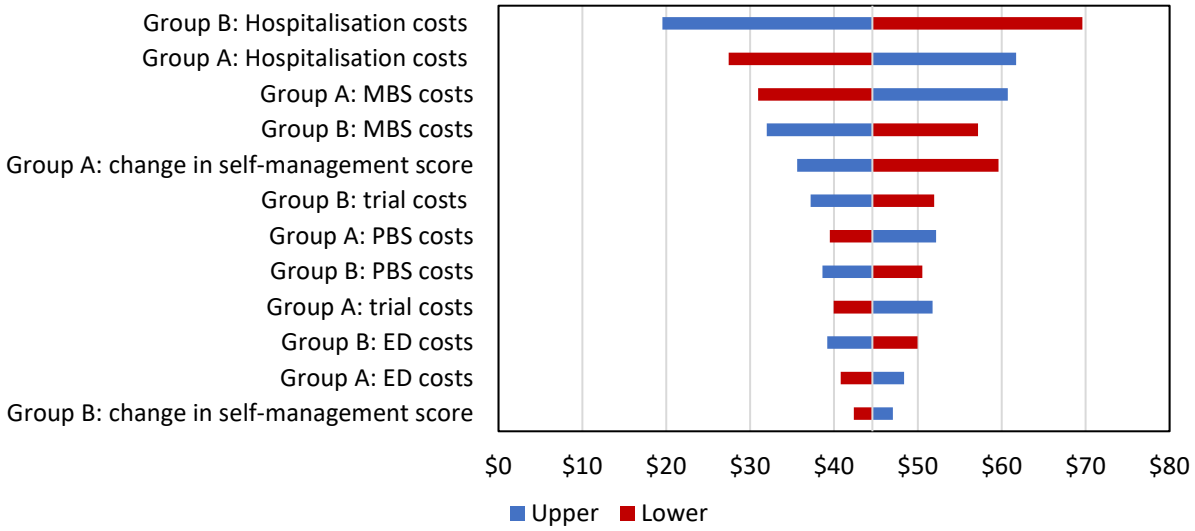


Figure 46 Group B vs A: Tornado diagram – cost/PIH unit

Change in morphine equivalence

Tornado diagrams for the change per unit in morphine equivalent units sensitivity analyses are presented in Figure 47 and Figure 48 for the Group A and B analysis, respectively. The base case ICER for Group A is dominant to TAU. For Group B, the intervention results in worse outcomes but at a lower cost. This results in a cost saving ICER of $2,573.43 per unit of morphine. Hospitalisation and MBS costs were the main drivers in both Group A and B. Group B had a cost saving ICER of $189.42 compared to Group A (Figure 49). Hospitalisations and MBS costs were the main drivers for this analysis. The upper and lower bounds reflect the higher and lower 95% confidence interval values.

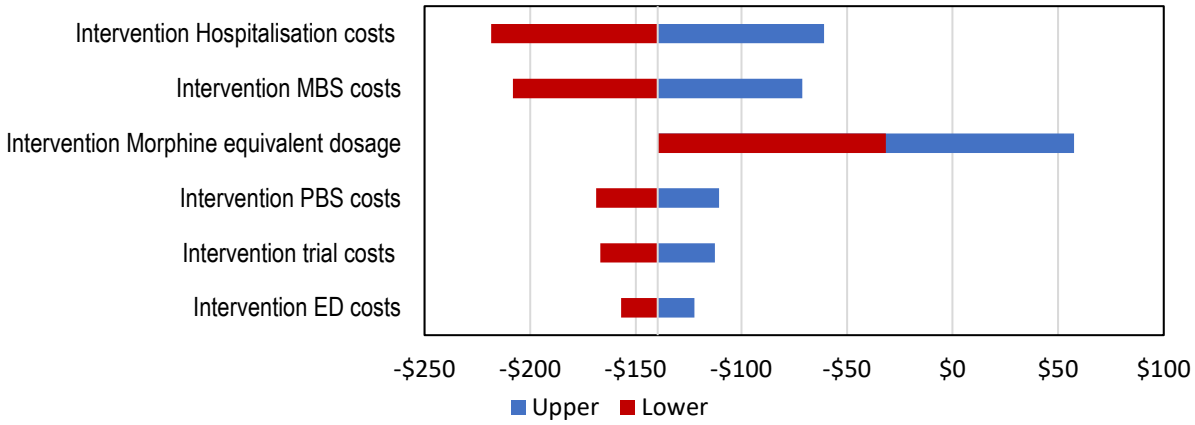


Figure 47 Group A: Tornado diagram – Change in morphine equivalence units

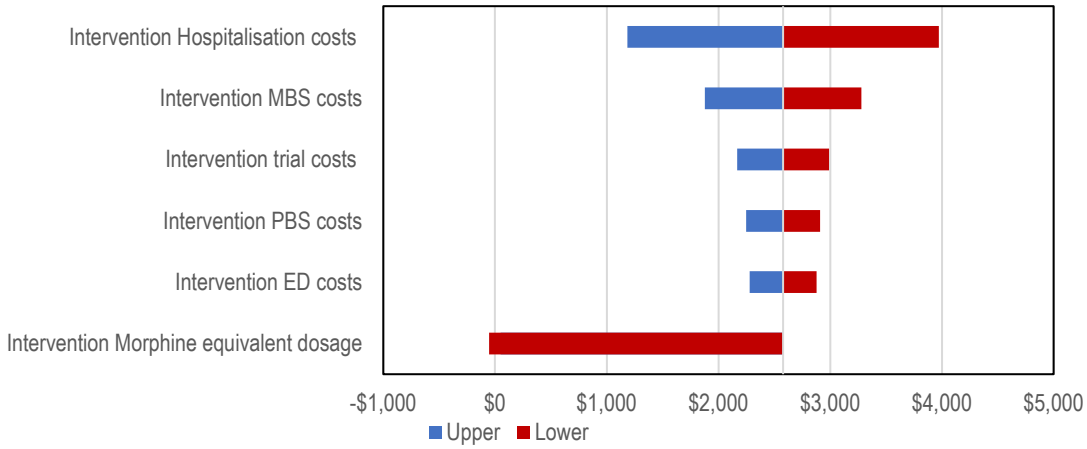


Figure 48 Group B: Tornado diagram – Change in morphine equivalence units

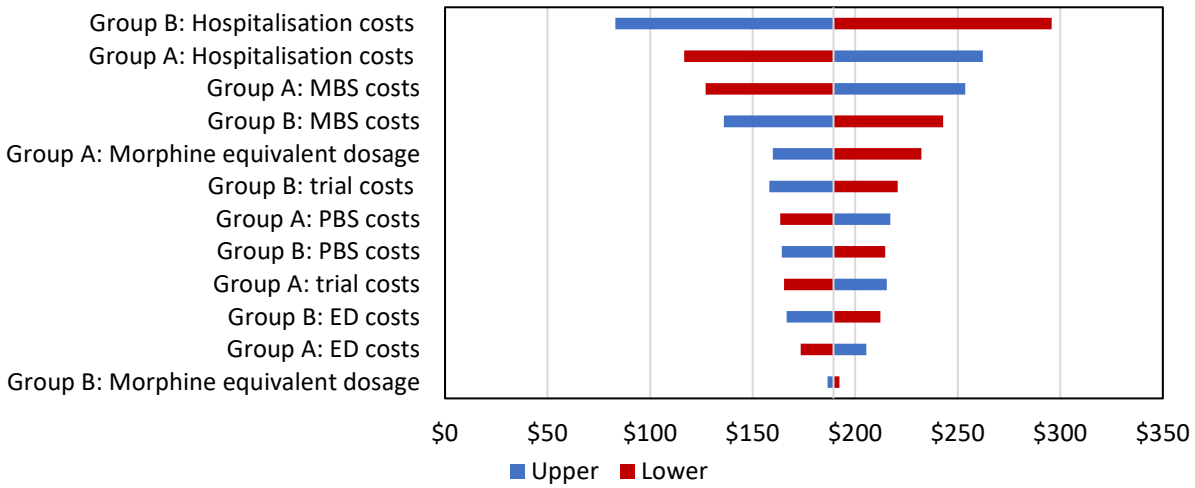


Figure 49 Group B vs A: Tornado diagram – Change in morphine equivalence units

Pain interference analyses

Tornado diagrams for the reduction in pain-severity group sensitivity analyses are presented in Figure 50 and Figure 51 for Group A and B, respectively. The base case ICER for Group A and B was dominant over TAU. The proportion of severe trial participants and hospitalisation costs were the

main drivers in Group A. For Group B hospitalisation, trial and ED presentation costs were the major ICER influencers. For the base case, Group B is dominant to Group A (Figure 52). Hospitalisations and severe trial participant proportions were the main drivers for this analysis. Upper and lower bounds were +/- 20% of the base case cost/outcome score analysed.

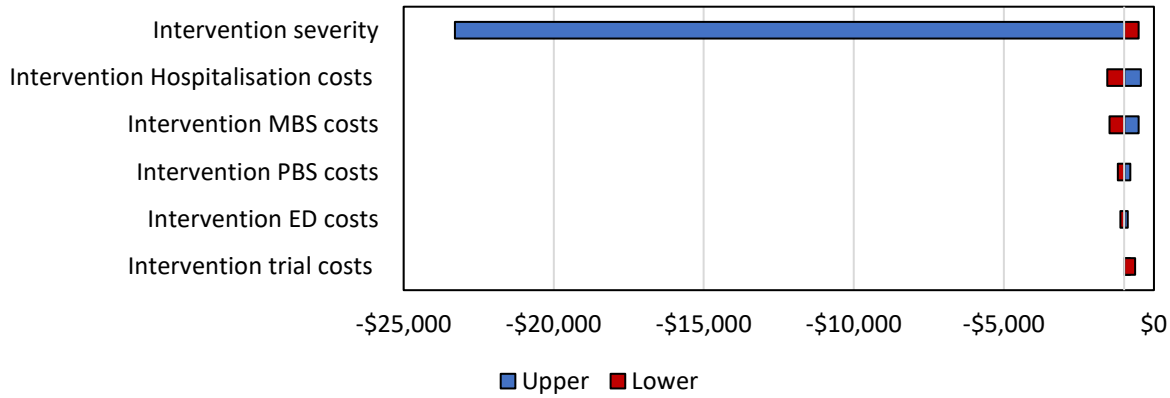


Figure 50 Group A: Tornado diagram – Pain interference

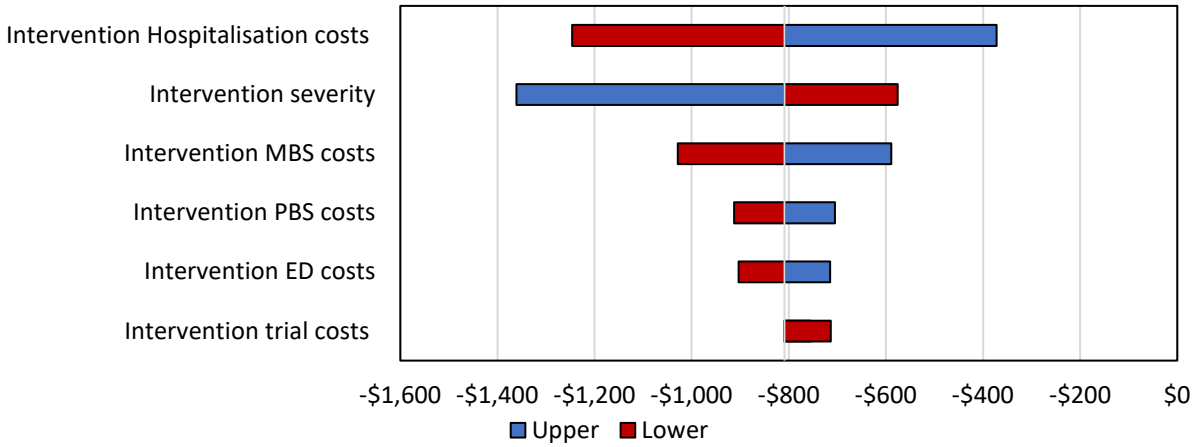


Figure 51 Group B: Tornado diagram – Pain interference

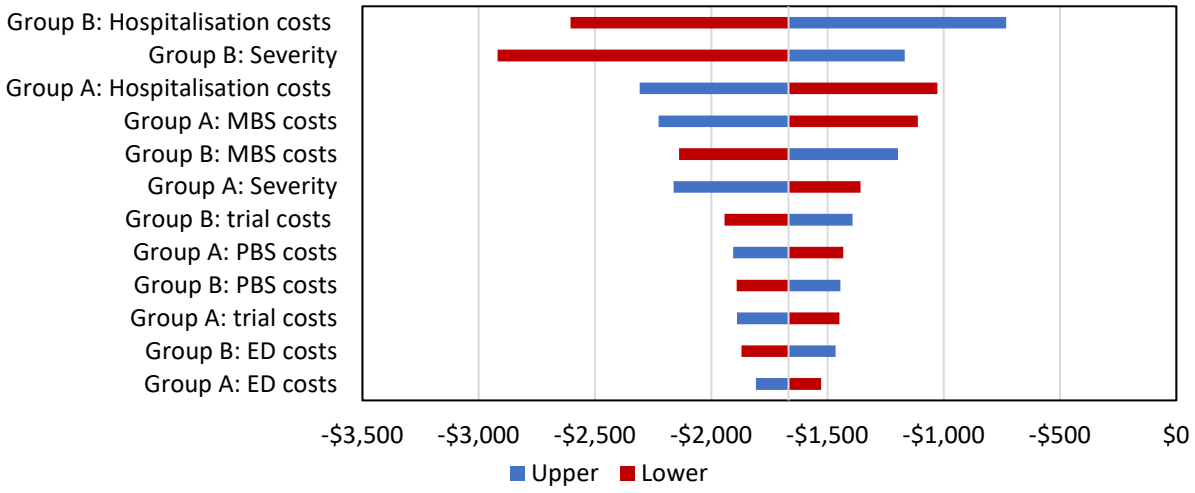


Figure 52 Group B vs A: Tornado diagram – Pain interference

Pain severity analyses

Tornado diagrams for the reduction in pain-interference severity group sensitivity analyses are presented in Figure 53 and Figure 54 for Group A and B, respectively. The base case ICER for Group A and B are dominant to TAU. The proportion of severe trial participants and hospitalisation costs were the main drivers in all analyses. For Group B, the intervention results in worse outcomes but at a lower cost. This results in a cost saving ICER of $99,231.13 per unit of morphine (Figure 55). The proportion of severe trial participants was the main driver for this analysis. Upper and lower bounds were +/- 20% of the base case cost/outcome score analysed.

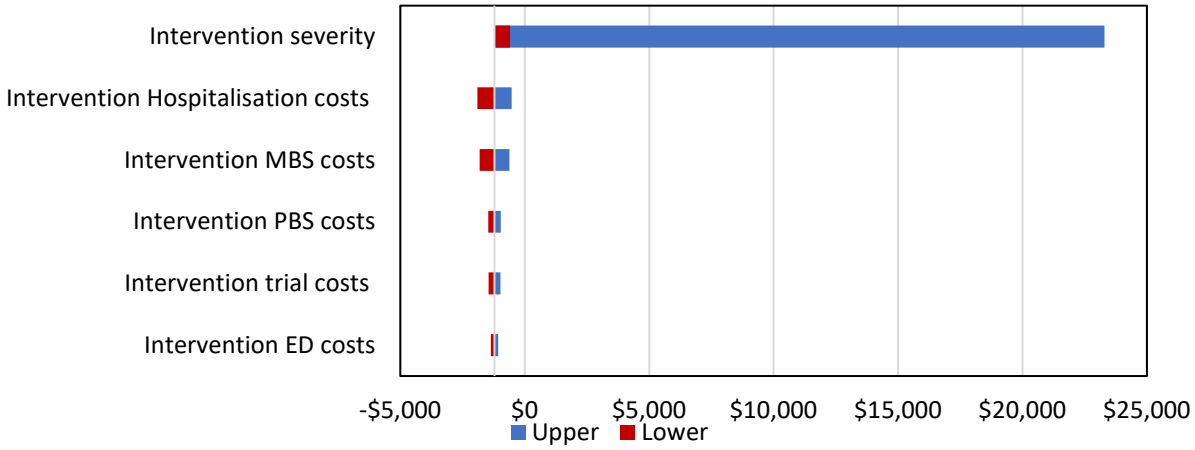


Figure 53 Group A: Tornado diagram – Pain severity

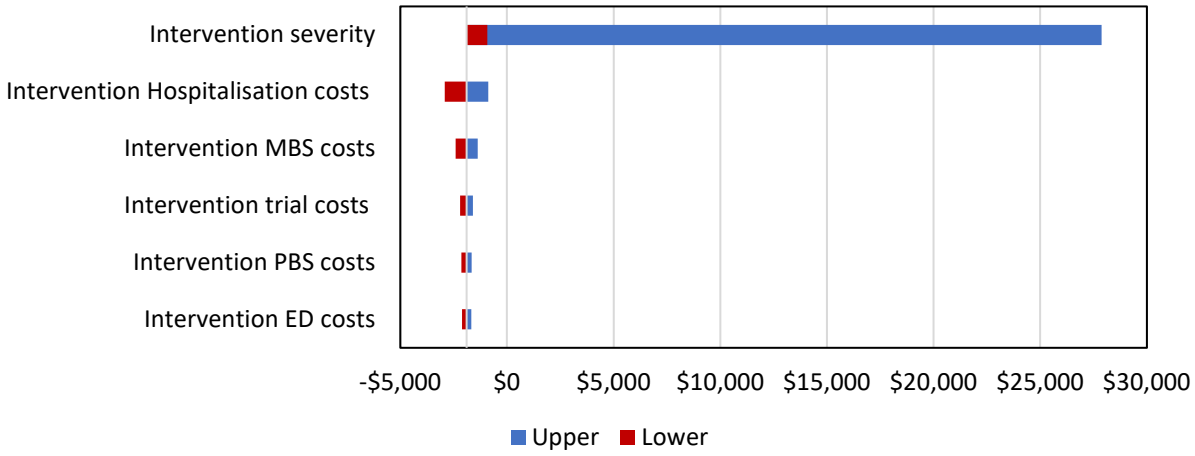


Figure 54 Group B: Tornado diagram – Pain severity

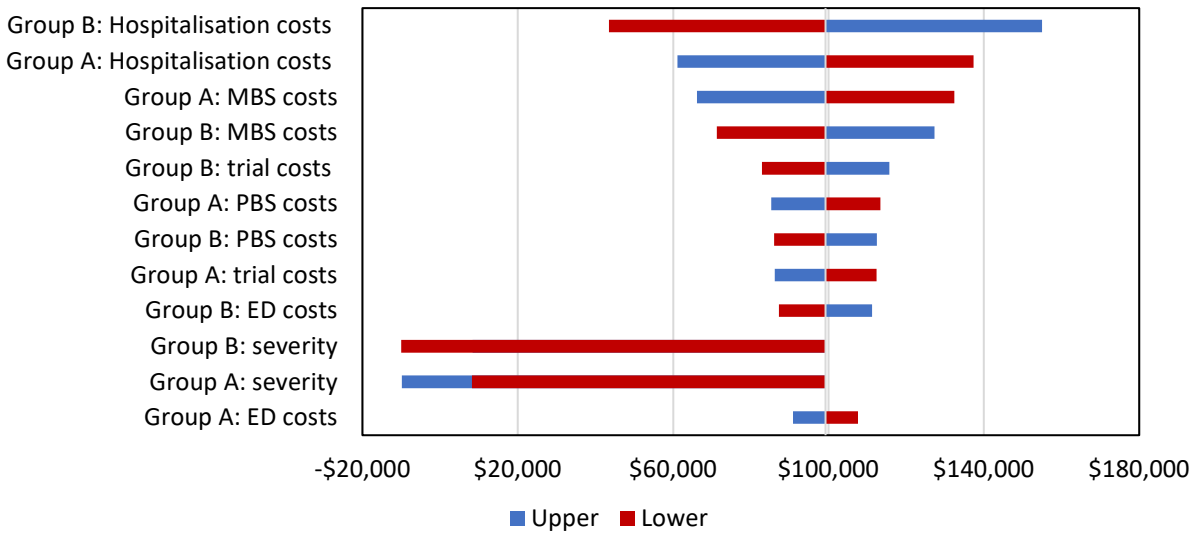


Figure 55 Group B vs A: Tornado diagram – Pain severity

Pain self-efficacy analyses

Tornado diagrams for the reduction in pain self-efficacy sensitivity analyses are presented in Figure 56 and Figure 57 for Group A and B, respectively. The base case ICER for Group A and B is dominant to TAU. The proportion of severe trial participants and hospitalisations were main drivers for all analyses. For the base case ICER, Group B is dominant over A (Figure 58). Upper and lower bounds were +/- 20% of the base case cost/outcome score analysed.

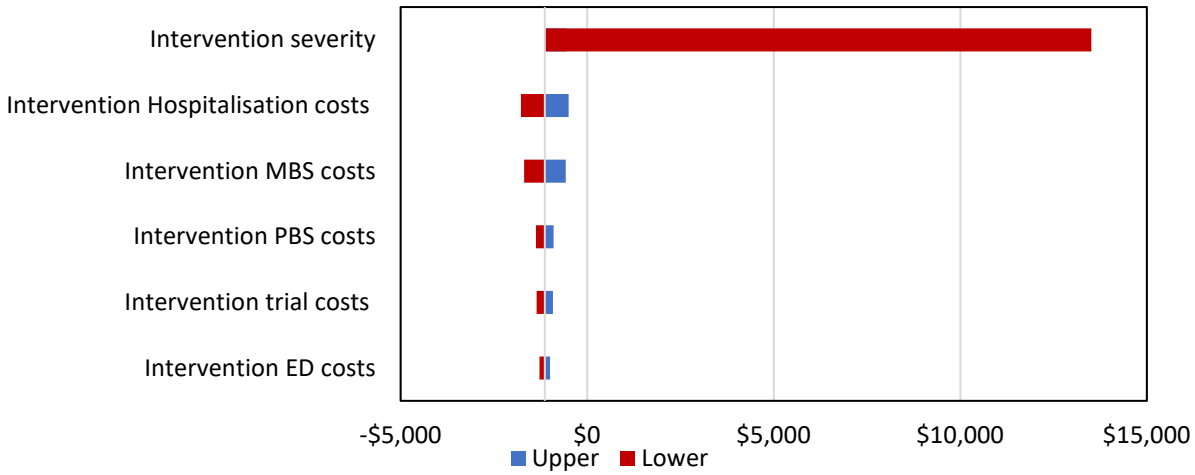


Figure 56 Group A: Tornado diagram – Pain self-efficacy

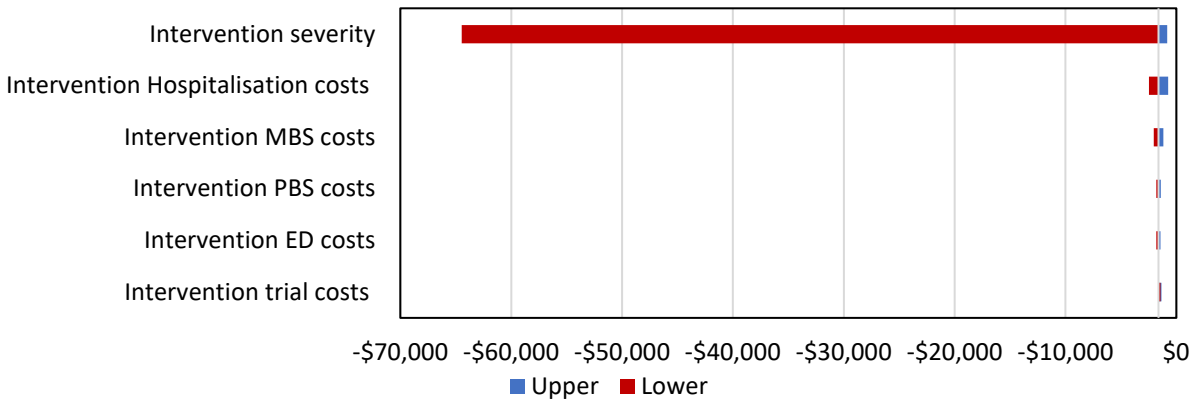


Figure 57 Group B: Tornado diagram – Pain self-efficacy

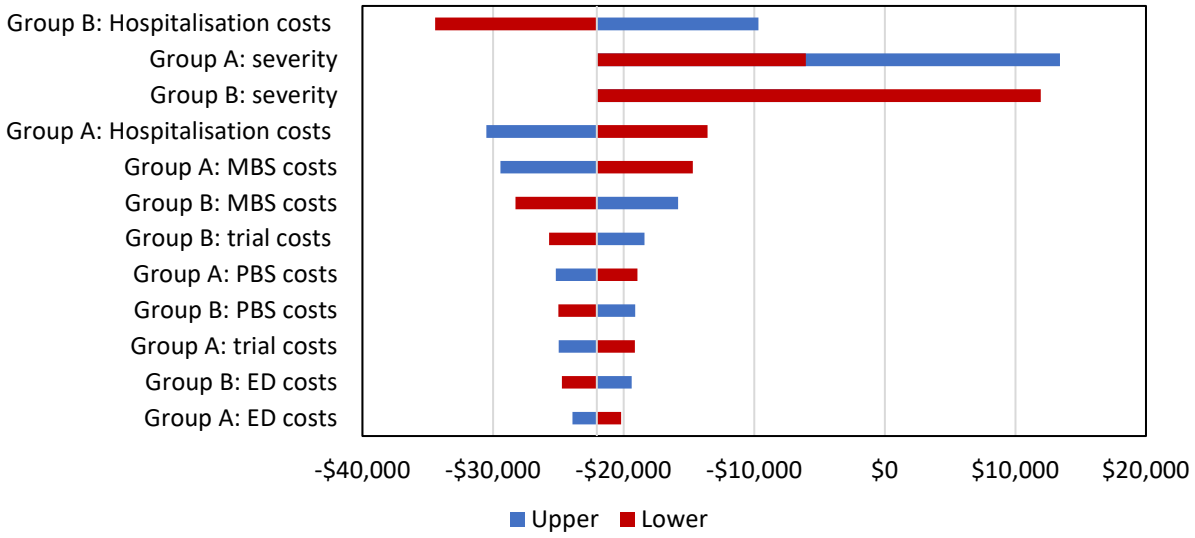


Figure 58 Group B vs A: Tornado diagram – Pain self-efficacy

PBS scripts (item usage)

Tornado diagrams for the reduction in PBS item usage sensitivity analyses are presented in Figure 59 and Figure 60 for Group A and B, respectively. The base case ICER for Group A and B is dominant to TAU. The number of PBS scripts per trial participant and hospitalisation costs were main drivers for all analyses. For the base case ICER, Group B is dominant to Group A (Figure 61). The upper and lower bounds reflect the higher and lower 95% confidence interval values.

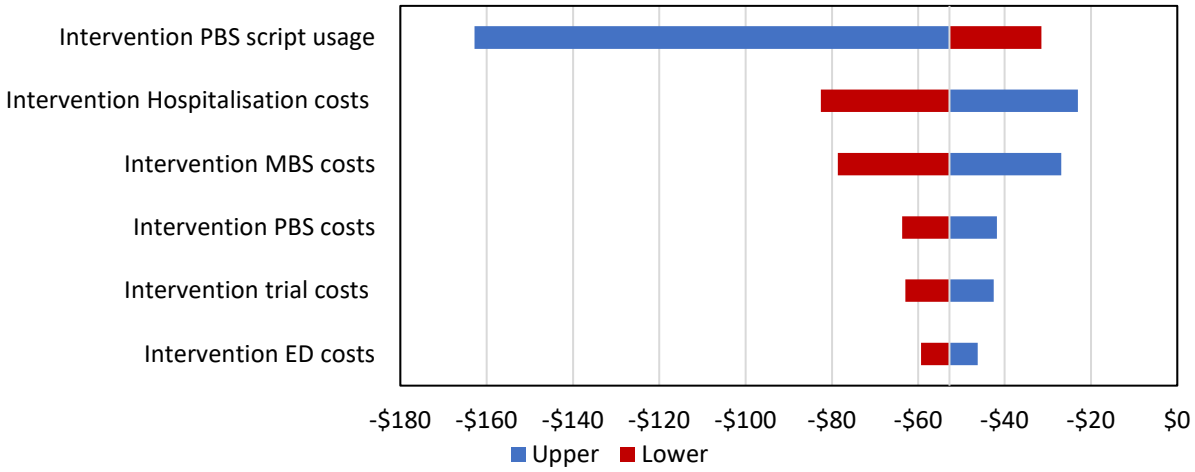


Figure 59 Group A: Tornado diagram – PBS item usage

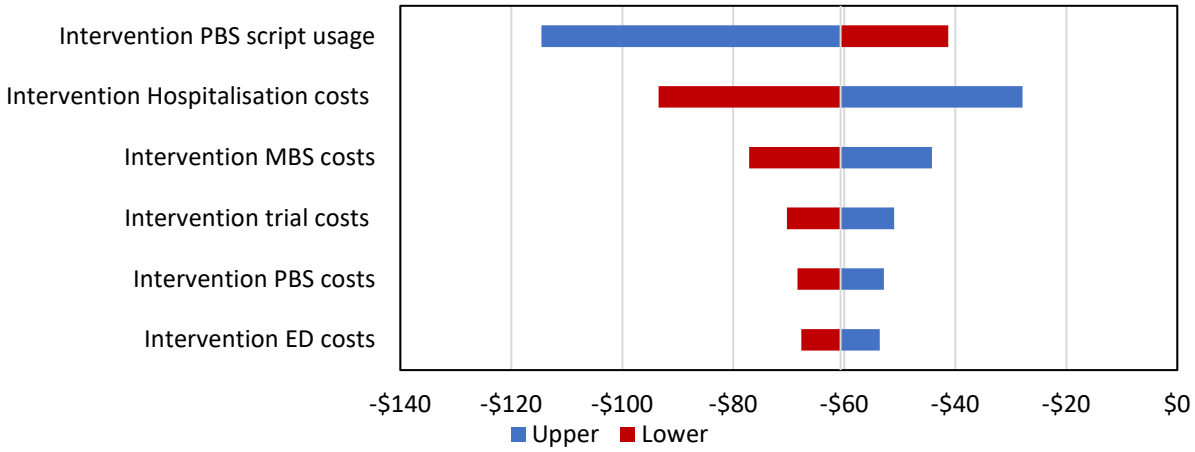


Figure 60 Group B: Tornado diagram – PBS item usage

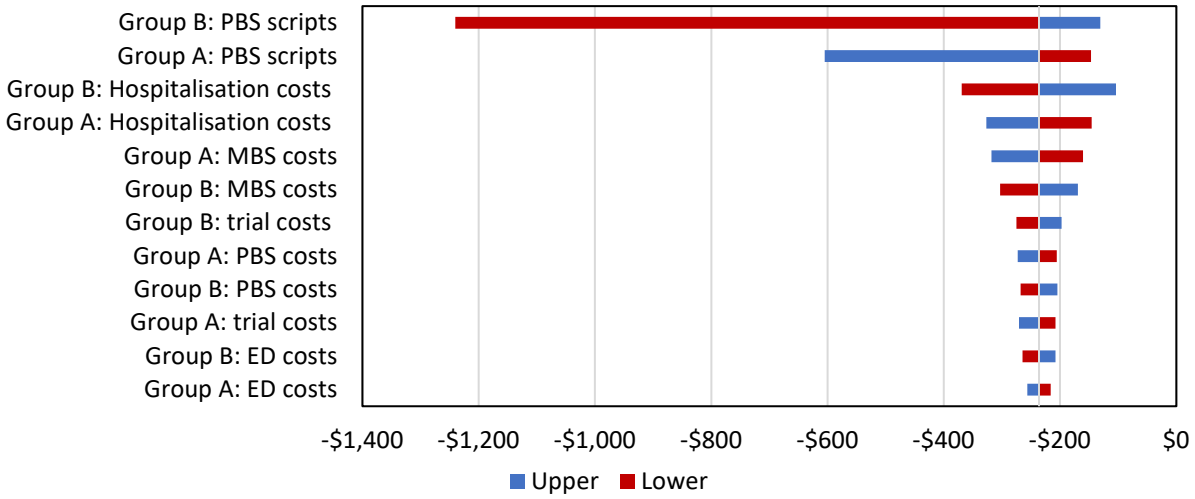


Figure 61 Group B vs A: Tornado diagram – PBS item usage

MBS service usage

Tornado diagrams for the reduction in pain self-efficacy sensitivity analyses are presented in Figure 62 and Figure 63 for Group A and B, respectively. The base case ICER for Group A and B are dominant to TAU. The number of MBS services per trial participant and hospitalisation costs were main drivers for all analyses. For the base case ICER, Group B is dominant to Group A (Figure 64). The upper and lower bounds reflect the higher and lower 95% confidence interval values.

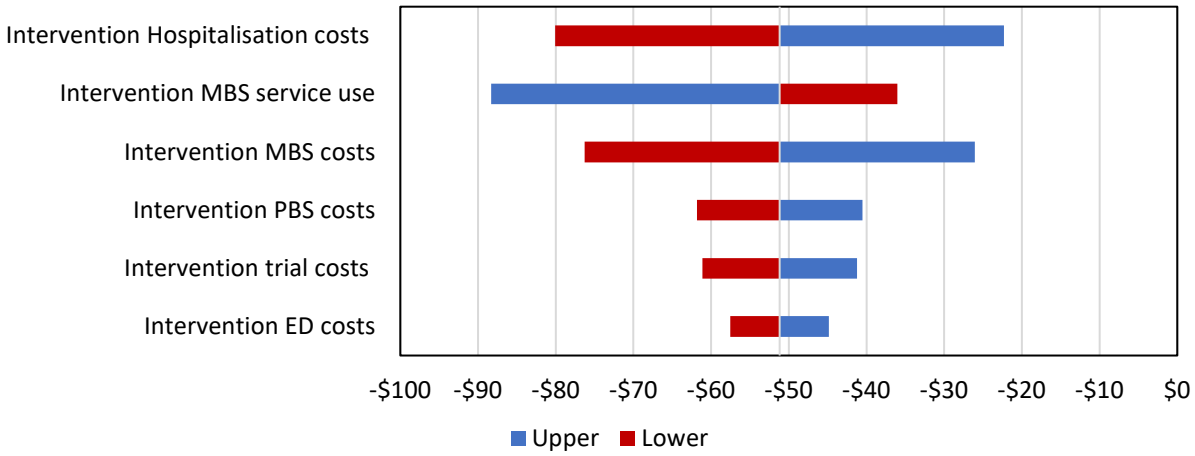


Figure 62 Group A: Tornado diagram – MBS service usage

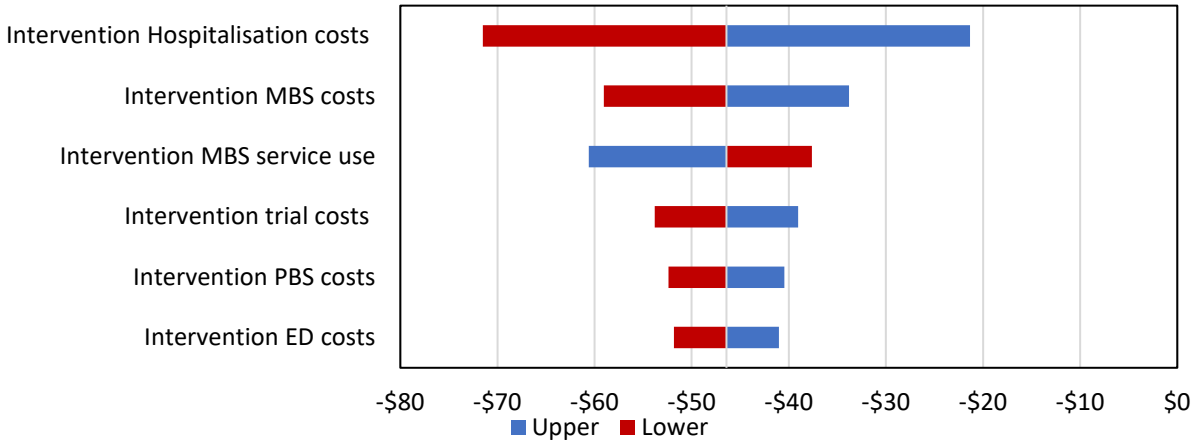


Figure 63 Group B: Tornado diagram – MBS service usage

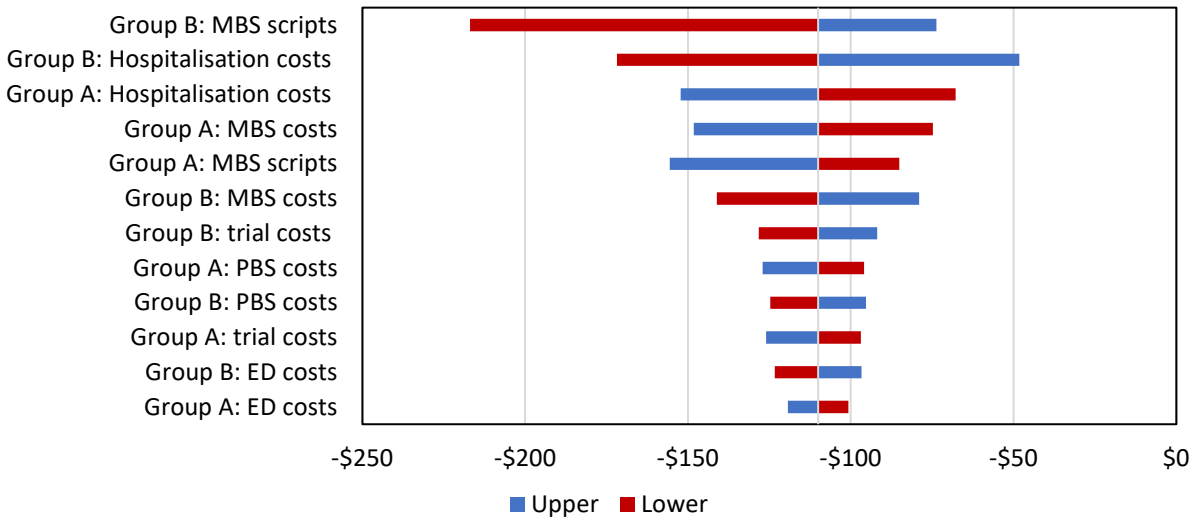


Figure 64 Group B vs A: Tornado diagram – MBS service usage

SECTION E FINANCIAL IMPLICATIONS

E.1. Justification of the Selection of Sources of Data

An epidemiological approach was used to estimate the financial implications of the introduction of the CPMC service.

ELIGIBLE POPULATION

The following steps were taken to calculate the eligible population.

1. Population projections over the next five years (up to 2025) were derived from Series B projection (1.6% growth rate) of the ABS Australian Population Projections[58]. Population projections are based on assumptions of future levels of fertility, life expectancy and migration, which are guided by recent population trends and Series B reflects current trends.
2. The proportion of the population under the age of 15 (18.7%) was also derived from Series B projection of the ABS Australian Population Projections. As the ABS population projections assume the proportion of people >15 years of age to be 18.8% in 2021 and 2022; 18.7% in 2023 and 2024; and 18.6% in 2025, the proportion was averaged ([2*18.8+2*18.7+18.6]/5).
3. The proportion of the population aged 15-17 (3.6% of the total population) was derived from latest published figures[59]. Although published for 2016 statistics, it was assumed in this analysis that this proportion remained the same.
4. The prevalence rate of chronic pain (15.4%) was obtained from Miller (2017)[60] and applied to ABS population data to estimate the total prevalence of chronic pain in Australia. Miller used cross-sectional, nationally representative data collected by the ABS 2011 to 2012 National Health Survey with the objective to estimate the prevalence of chronic pain in the Australian population.
5. The proportion of people with oncological chronic pain (7.1%) was obtained from the AIHW report[61] and applied to the estimated Australian population aged ≥18 years with chronic pain. The report aims to provide insight into the experience of Australians managing chronic pain by using the latest national data on the proportion of people with chronic pain, as well as its impact, treatment and management.
6. It is assumed in the previous step, that this population is catered to by all pharmacies in Australia (n~5,700).[62] From the CPMC pharmacy participants, 34% (n=549/1,630) of all pharmacies recruited at least one trial participant. When applied to the total number of pharmacies in Australia, this results in approximately 1,920 pharmacies administering the CPMC program. The reduction in pharmacies is expected to reduce coverage, thereby decreasing the estimated amount of eligible participants.
7. The step above assumes that each pharmacy will administer the program to 509 trial participants in 2021, increasing to 542 by 2025 per year (this is italicised in Table 129, as this calculation serves as an intermediate step). Participating pharmacies that were able to recruit at least one participant, had on average recruited 15 trial participants (n=8239/549) over the

course of one year (Figure 4). This equates to a ~97% reduction to eligible trial participants from Step 6.

Although not presented as part of calculations for row L, a coefficient was applied to account for yearly population growth. The value for J in the projected year (e.g., 2022) was divided by the value of J at baseline (i.e., 2021).

E.2. Use and Costs of CPMC service

Table 129 presents the estimated eligible population with chronic pain in Australia.

Table 129 Estimated population with chronic pain

	Source/Calculation	2021	2022	2023	2024	2025
A	ABS population projections, Series B	25,873,480	26,301,274	26,727,025	27,147,199	27,562,195
B	Proportion of population <15 yoa (%)	18.7	18.7	18.7	18.7	18.7
C=A*(1-B)	Australian population ≥15 yoa	21,035,139	21,382,936	21,729,071	22,070,673	22,408,065
D	Proportion of population aged 15-17 yrs (%)	3.6	3.6	3.6	3.6	3.6
E=C*(1-D)	Australian population ≥18 yoa	20,277,874	20,613,150	20,946,825	21,276,129	21,601,374
F	Prevalence rate (%)	15.4	15.4	15.4	15.4	15.4
G=E*F	Australian population ≥18 yoa with chronic pain	3,122,793	3,174,425	3,225,811	3,276,524	3,326,612
H	Proportion with chronic cancer pain (%)	7.1	7.1	7.1	7.1	7.1
I=G*(1-H)	Eligible Population	2,901,074	2,949,041	2,996,778	3,043,891	3,090,422
J = I * 33.7%	Eligible population accounting for pharmacies	977,662	993,827	1,009,914	1,025,791	1,041,472

	Source/Calculation	2021	2022	2023	2024	2025
	administering the program					
K = (J/1920)	Average number of eligible participants per pharmacy	509	518	526	534	542
L = (15†/K)*J ‡	Eligible population using mean trial participant per pharmacy	28,814	29,290	29,765	30,232	30,695

Abbreviations: ABS, Australian Bureau of Statistics; yoa, years of age; yrs, years
Note: Italicised text in table serves as an intermediate step
† (8239/549) was used in this calculation
‡The value for J in the projected year (e.g. 2022) was divided by the value of J at baseline (i.e. 2021).
Row K is italicised as it serves as an intermediate step

It was estimated that the number of trial participants ≥18 years of age with non-cancer pain would be 28,814 in 2021, increasing to 30,695 in 2025. If all eligible trial participants were to partake in the intervention, the Group A costs would increase from $3.78 million in 2021 to $4.03 million by 2025. The Group B costs would increase from $4.73 million in 2021 to $5.03 million by 2025 (Table 130). Over the five years, total costs for Groups A and B equate to $19.53 million and $24.41 million, respectively, when the intervention is applied to all eligible trial participants. Costs in Table 130 were calculated by applying trial fees of $131.22 for Group A and $164.03 for Group B to the eligible population in row L of Table 129.

Table 130 Estimated cost of intervention by group when utilising all eligible trial participants

	2021	2022	2023	2024	2025
Group A: Total cost	$3,780,972	$3,843,487	$3,905,703	$3,967,104	$4,027,749
Group B: Total cost	$4,726,359	$4,804,505	$4,882,277	$4,959,031	$5,034,839

E.3. Changes in Use and Cost of Other Medical Services

All calculations assume all eligible trial participants undergo and complete the two or three consultation pharmacist intervention per annum (the failure and uptake rates, as well as limits to the number of interventions that can be provided are not known). This assumption biases in favour of the intervention as greater uptake results in better savings, given the results of the CPMC trial.

E.4. Financial Implications for the MBS

As MBS data was obtained from Services Australia, there was no need to adjust MBS fees paid (i.e. 100%, 85% or 75% of the MBS item fee paid). Nonetheless, as MBS items selected were services primarily administered out of hospital by non-specialists, the cost to the MBS would be closer to 100% of the item code fee.

The financial implications to the MBS resulting from the proposed listing of the CPMC intervention are summarised in Table 131 and Table 132 for Group A and B, respectively. As the CPMC trial resulted in a reduction in mean MBS services per trial participant (refer to Section C.3 and Table 154 in Appendix J for the list of item numbers analysed), this results in cost savings to the MBS. The number of services was calculated by multiplying the eligible population in row L of Table 129 by the incremental differences in services for Group A (-2.64 services per participant) and Group B (-4.44 services per participant). Utilising Group A results, an estimated saving of $10.7 million is expected in 2021, increasing to $11.4 million by 2025 for the MBS. For Group B, estimated savings of $31.9 million in 2021, increasing to $34 million by 2025 for the MBS were calculated. When comparing Group B to Group A, Group B resulted in greater estimated savings to the MBS of $21.2 million in 2021, increasing to $22.5 million by 2025.

Table 131 Total costs to the MBS associated with utilising Group A results from the CPMC trial

	2021	2022	2023	2024	2025
Number of services	-76,071	-77,329	-78,581	-79,816	-81,036
Total cost of MBS services	-$12,812,999	-$13,024,850	-$13,235,689	-$13,443,766	-$13,649,280
Total MBS benefits paid	-$10,730,475	-$10,907,894	-$11,084,465	-$11,258,723	-$11,430,834
Total out-of-pocket cost	-$2,082,523	-$2,116,956	-$2,151,224	-$2,185,043	-$2,218,446

Source: CPMC trial data, Services Australia
Abbreviations: MBS, Medicare benefits schedule

Table 132 Total costs to the MBS associated with utilising Group B results from the CPMC trial

	2021	2022	2023	2024	2025
Number of services	-128,043	-130,160	-132,267	-134,346	-136,400
Total cost of MBS services	-$37,245,925	-$37,861,752	-$38,474,638	-$39,079,495	-$39,676,899
Total MBS benefits paid	-$31,894,760	-$32,422,110	-$32,946,942	-$33,464,899	-$33,976,473
Total out-of-pocket cost	-$5,351,165	-$5,439,642	-$5,527,696	-$5,614,596	-$5,700,426

Source: CPMC trial data, Services Australia
Abbreviations: MBS, Medicare benefits schedule

E.5. Financial Implications for Government Health Budgets

The financial implications to the PBS resulting from the proposed listing of the CPMC intervention are summarised in Table 133 and Table 134 for Group A and B, respectively. As the CPMC trial resulted in a reduction in mean PBS scripts (for system groups N02A N02B, N02C, N03, N05, N06, M01A and M02A) per trial participant (refer to Section C.3), this results in cost savings to the PBS. The number of

scripts was calculated by multiplying the eligible population in row L of Table 129 by the incremental differences in scripts for Group A (-2.56 scripts per participant) and Group B (-3.40 scripts per participant). Utilising Group A results, an estimated saving of $810,027 is expected in 2021, increasing to $862,896 by 2025 for the PBS. For Group B, estimated savings of $2.43 million in 2021, increasing to $2.59 million by 2025 for the PBS were calculated. When comparing Group B to Group A, Group B resulted in greater estimated savings to the PBS of $1.62 million in 2021, increasing to $1.73 million by 2025.

Table 133 Total costs to the PBS associated with utilising Group A results from the CPMC trial

	2021	2022	2023	2024	2025
Number of scripts	-73,764	-74,983	-76,197	-77,395	-78,578
Total provider benefits paid	-$4,428,089	-$4,501,304	-$4,574,169	-$4,646,079	-$4,717,103
Total cost to PBS	-$810,027	-$823,420	-$836,749	-$849,903	-$862,896
Total out-of-pocket cost	-$3,618,063	-$3,677,884	-$3,737,420	-$3,796,175	-$3,854,207

Source: CPMC trial data, Services Australia
Abbreviations: PBS, Pharmaceutical benefits scheme

Table 134 Total costs to the PBS associated with utilising Group B results from the CPMC trial

	2021	2022	2023	2024	2025
Number of scripts	-97,968	-99,587	-101,199	-102,790	-104,362
Total provider benefits paid	-$6,954,169	-$7,069,150	-$7,183,582	-$7,296,515	-$7,408,055
Total cost to PBS	-$2,433,895	-$2,474,137	-$2,514,187	-$2,553,713	-$2,592,751
Total out-of-pocket cost	-$4,520,274	-$4,595,013	-$4,669,394	-$4,742,802	-$4,815,304

Source: CPMC trial data, Services Australia
Abbreviations: PBS, Pharmaceutical benefits scheme

THE BROADER IMPACT ON THE MBS

Not all MBS items provided by Services Australia was used in this evaluation. Several items were administered in a hospital setting. However, the dates for when trial participants presented to an emergency department or were hospitalised and their duration was not known. Consequently, the costs for emergency department presentations and hospitalisations were costed separately to avoid potential double counting.

OTHER GOVERNMENT IMPACTS

No other government impacts were identified.

STATE AND TERRITORY GOVERNMENT HEALTH BUDGETS

From CPMC trial data, the number of hospitalisations and ED visits at baseline and at follow up was available. For trial participants in Group A, hospitalisations and ED presentations decreased from

10% and 15.6% to 9.0% and 14.7%, respectively. For Group B, reductions from 10.2% and 15.6% to 9.4% and 13.9%, respectively. For all trial site trial participants, hospitalisations and ED visits were reduced from 10.2% and 15.6% to 9.4% and 14.5%, respectively. From these results, Group A trial participants saw the greatest reduction in hospitalisations (1.2%) and Group B experienced the greatest decrease in ED presentations (1.7%). These changes are reflected in the estimated change of hospitalisations and ED presentations presented in Table 135 and Table 136 for Groups A and B, respectively.

Table 135 Estimated change in ED presentations and hospitalisations using Group A results

	2021	2022	2023	2024	2025
Eligible population	28,814	29,290	29,765	30,232	30,695
Emergency Department presentations at baseline	4,495	4,569	4,643	4,716	4,788
Hospitalisations at baseline	2,939	2,988	3,036	3,084	3,131
Number of Emergency Department presentations	-259	-264	-268	-272	-276
Number of Hospitalisations	-346	-351	-357	-363	-368

Table 136 Estimated change in ED presentations and hospitalisations using Group B results

	2021	2022	2023	2024	2025
Eligible population	28,814	29,290	29,765	30,232	30,695
ED presentations at baseline	4,495	4,569	4,643	4,716	4,788
Hospitalisations at baseline	2,939	2,988	3,036	3,084	3,131
Number of ED presentations	-490	-498	-506	-514	-522
Number of Hospitalisations	-231	-234	-238	-242	-246

As the intervention is associated with fewer ED presentations and hospitalisations, changes to these outcomes are cost saving. The financial implications to state and territory health budgets resulting from the pharmacist led intervention are summarised in Table 137 and Table 138 for Group A and B, respectively. As hospitalisations were more expensive than an ED visits ($4,864.14 vs $732.74, respectively), Group A trial participants offered the greatest savings to state and territory governments.

Table 137 Total costs to State and Territory health budgets associated with the pharmacist led intervention in Group A

	2021	2022	2023	2024	2025
Hospitalisations					
Number of services	-346	-351	-357	-363	-368
Sub-total cost	-$1,681,864	-$1,709,672	-$1,737,348	-$1,764,660	-$1,791,636
ED presentations					
Number of services	-259	-264	-268	-272	-276
Sub-total cost	-$190,018	-$193,160	-$196,287	-$199,373	-$202,420
Total services	-605	-615	-625	-635	-645
Total cost	-$1,871,883	-$1,902,832	-$1,933,634	-$1,964,033	-$1,994,057

Table 138 Total costs to State and Territory health budgets associated with the pharmacist led intervention in Group B

	2021	2022	2023	2024	2025
Hospitalisations					
Number of services	-231	-234	-238	-242	-246
Sub-total cost	-$1,121,243	-$1,139,782	-$1,158,232	-$1,176,440	-$1,194,424
ED presentations					
Number of services	-490	-498	-506	-514	-522
Sub-total cost	-$358,923	-$364,858	-$370,764	-$376,593	-$382,350
Total services	-720	-732	-744	-756	-767
Total cost	-$1,480,166	-$1,504,639	-$1,528,996	-$1,553,033	-$1,576,774

SUMMARY

The total costs to all government budgets (commonwealth, state and territories) have been presented in Table 139 for Group A and Table 140 For Group B. When applying the results of Groups A and B to the estimated eligible population, cost savings of $9.63-$31.08 million are estimated in the first year of implementation of the CPMC program. Savings are projected to increase to $10.26-$33.11 million by 2025.

Table 139 Total costs to all Government health budgets associated with the CPMC intervention in Group A

	2021	2022	2023	2024	2025
Cost of intervention	$3,780,972	$3,843,487	$3,905,703	$3,967,104	$4,027,749
MBS costs to Government	-$10,730,475	-$10,907,894	-$11,084,465	-$11,258,723	-$11,430,834
PBS costs to Government	-$810,027	-$823,420	-$836,749	-$849,903	-$862,896
Total cost to Commonwealth Government	-$7,759,530	-$7,887,827	-$8,015,511	-$8,141,522	-$8,265,981
Cost to States and Territories	-$1,871,883	-$1,902,832	-$1,933,634	-$1,964,033	-$1,994,057
Total cost of CPMC program	-$9,631,413	-$9,790,659	-$9,949,145	-$10,105,555	-$10,260,038

Source: Table 130, Table 131, Table 133 and Table 137

Abbreviations: CPMC, Chronic Pain MedsCheck; MBS, Medicare benefits schedule; PBS, Pharmaceutical benefits scheme

Table 140 Total costs to all Government health budgets associated with the pharmacist led intervention in Group B

	2021	2022	2023	2024	2025
Cost of intervention	$4,726,359	$4,804,505	$4,882,277	$4,959,031	$5,034,839
MBS costs to Government	-$31,894,760	-$32,422,110	-$32,946,942	-$33,464,899	-$33,976,473
PBS costs to Government	-$2,433,895	-$2,474,137	-$2,514,187	-$2,553,713	-$2,592,751
Total cost to Commonwealth Government	-$29,602,296	-$30,091,743	-$30,578,852	-$31,059,580	-$31,534,384
Cost to States and Territories	-$1,480,166	-$1,504,639	-$1,528,996	-$1,553,033	-$1,576,774
Total cost of CPMC program	-$31,082,463	-$31,596,382	-$32,107,848	-$32,612,613	-$33,111,159

Source: Table 130, Table 132, and Table 134 and Table 138

Abbreviations: CPMC, Chronic Pain MedsCheck; MBS, Medicare benefits schedule; PBS, Pharmaceutical benefits scheme

E.6. Identification, Estimation and Reduction of Uncertainty

A series of sensitivity analyses were undertaken to characterise uncertainty in the financial estimates of the CPMC intervention. Descriptions of the variation in parameters as well as the results of the sensitivity analyses performed are provided in Table 141 and Table 142 for Groups A and B, respectively. An arbitrary 20% increase and decrease were conducted for these analyses. The wide thresholds reflect the uncertainty of trial results. Of note, one analysis halved the uptake of trial participants partaking in the program. This was conducted to reflect high rates of loss to follow-up seen in Groups A and B. Group B had a lower cost (range of $52.9-$132.6 million, Table 143) than Group A in all analyses. This is primarily due to the greater number of MBS services averted in Group B.

Table 141 Sensitivity analyses for Group A

Sensitivity analysis	Net costs (over 5 years)
Base case	-$49,736,811
Increase in eligible trial participants by 20%	-$63,589,176
Decrease in eligible trial participants by 20%	-$35,884,446
Decrease in trial participant uptake from 100% to 80%	-$35,884,446
Decrease in trial participant uptake from 100% to 50%	-$15,105,899
Increase in reduction of trial participants hospitalised by 20%	-$51,473,847

Sensitivity analysis	Net costs (over 5 years)
Decrease in reduction of trial participants hospitalised by 20%	-$47,999,775
Increase in reduction of trial participants presenting to emergency departments by 20%	-$49,933,063
Decrease in reduction of trial participants presenting to emergency departments by 20%	-$49,540,559
Increase in reduction of PBS scripts by 20%	-$50,573,410
Decrease in reduction of PBS scripts by 20%	-$48,900,212
Increase in reduction of MBS services by 20%	-$60,819,289
Decrease in reduction of MBS services by 20%	-$38,654,333

Abbreviations: MBS, Medicare benefits schedule; PBS, Pharmaceutical benefits scheme

Table 142 Sensitivity analyses for Group B

Sensitivity analysis	Net costs (over 5 years)
Base case	-$160,510,465
Increase in eligible trial participants by 20%	-$197,493,960
Decrease in eligible trial participants by 20%	-$123,526,970
Decrease in trial participant uptake from 100% to 80%	-$123,526,970
Decrease in trial participant uptake from 100% to 50%	-$68,051,727
Increase in reduction of trial participants hospitalised by 20%	-$161,668,489
Decrease in reduction of trial participants hospitalised by 20%	-$159,352,441
Increase in reduction of trial participants presenting to emergency departments by 20%	-$160,881,162
Decrease in reduction of trial participants presenting to emergency departments by 20%	-$160,139,767
Increase in reduction of PBS scripts by 20%	-$163,024,202
Decrease in reduction of PBS scripts by 20%	-$157,996,728
Increase in reduction of MBS services by 20%	-$193,451,501
Decrease in reduction of MBS services by 20%	-$127,569,428

Abbreviations: MBS, Medicare benefits schedule; PBS, Pharmaceutical benefits scheme

Table 143 Sensitivity analyses for Group B vs A

Sensitivity analysis	Group A costs (over 5 years)	Group B costs (over 5 years)	Difference (B – A)
Base case	-$49,736,811	-$160,510,465	-$110,773,654
Increase in eligible trial participants by 20%	-$63,589,176	-$197,493,960	-$133,904,784
Decrease in eligible trial participants by 20%	-$35,884,446	-$123,526,970	-$87,642,524
Decrease in trial participant uptake from 100% to 80%	-$35,884,446	-$123,526,970	-$87,642,524

Sensitivity analysis	Group A costs (over 5 years)	Group B costs (over 5 years)	Difference (B – A)
Decrease in trial participant uptake from 100% to 50%	-$15,105,899	-$68,051,727	-$52,945,828
Increase in reduction of trial participants hospitalised by 20%	-$51,473,847	-$161,668,489	-$110,194,642
Decrease in reduction of trial participants hospitalised by 20%	-$47,999,775	-$159,352,441	-$111,352,666
Increase in reduction of trial participants presenting to emergency departments by 20%	-$49,933,063	-$160,881,162	-$110,948,099
Decrease in reduction of trial participants presenting to emergency departments by 20%	-$49,540,559	-$160,139,767	-$110,599,208
Increase in reduction of PBS scripts by 20%	-$50,573,410	-$163,024,202	-$112,450,792
Decrease in reduction of PBS scripts by 20%	-$48,900,212	-$157,996,728	-$109,096,516
Increase in reduction of MBS services by 20%	-$60,819,289	-$193,451,501	-$132,632,212
Decrease in reduction of MBS services by 20%	-$38,654,333	-$127,569,428	-$88,915,095

Abbreviations: MBS, Medicare benefits schedule; PBS, Pharmaceutical benefits scheme

SECTION F OTHER RELEVANT CONSIDERATIONS

This section presents the qualitative findings from case studies visits to 24 pharmacies that were participating in the Trial, findings from a survey of health professionals who were referred participants recruited into the Trial, and a survey of pharmacists involved in delivering the interventions. Their characteristics are described below.

Characteristics of qualitative data sources

Only 45% pharmacists (44 of 98 pharmacists) involved in the Trial completed the Pharmacist Satisfaction Survey (Table 144). Most were located in metropolitan areas (30 of 44, 68%) in NSW and Qld (26 of 44, 59%). There were no participants from the NT and the ACT.

Table 144 Location and remoteness of pharmacists who responded to the Pharmacist Satisfaction Survey

State	Major City	Inner Regional	Outer Regional	Total
NSW	8	4	0	12
QLD	8	3	3	14
SA	5	0	0	5
TAS	0	2	2	4
VIC	5	0	0	5
WA	4	0	0	4
Total	30	9	5	44

Source: HealthConsult Pharmacist Satisfaction Survey

Case studies were conducted on 24 pharmacies enrolled in the Trial (Table 145). Pharmacies that participated in the case studies were randomly selected by the HealthConsult team. They were located in NSW, QLD, SA, TAS, VIC and WA, with the majority located in metropolitan areas (80%) and the remaining 20% located in regional Australia. No case studies were conducted in the NT or the ACT. One to two pharmacists participated in each case study site, with a total of 29 pharmacists contributing qualitative data to the case studies.

Table 145 Distribution of case study pharmacies by state/territory and remoteness

State	Group A		Group B		Total number of pharmacies	Number of pharmacists
	Major City	Regional	Major City	Regional		
NSW	3		3	1	7	7
QLD	2		0	1	3	6
SA	1		2	0	3	5
TAS	0	1	0	1	2	2
VIC	2		1	0	3	3
WA	3		2	1	6	6
Total	11	1	8	4	24	29

Only 62 of 191 (32%) healthcare providers completed the Referred Provider Survey (Table 146) and of these, only 27 (44%) reported receiving referrals of trial participants enrolled in the Trial. This

lower-than-expected proportion is most likely due to recall bias and sometimes referrals were printed for the trial participants to give to the service providers. Most participants of the Referred Provider Survey were GPs (42 of 62, 68%) and the majority were located in NSW, Qld, SA and WA (36 of 62, 58%). As expected, given the Trial did not run in NT, there were no surveys from NT.

Table 146 Location and types of referred providers who completed the Referred Provider Survey

Referred Provider	ACT	NSW	QLD	SA	TAS	VIC	WA	Total
General Practitioner	1	8	8	11	1	4	9	42
Physiotherapist	1	2	3	0	0	0	1	7
Nutritionist/Dietician	0	1	0	1	0	0	0	2
Psychologist	0	0	0	1	0	0	0	1
Other*	3	3	0	1	0	1	2	10
Total	5	14	11	14	1	5	12	62

*Other providers included: specialist sport and exercise physician, exercise scientist, gynaecologist, pain management specialist, osteopath, rheumatologist and pharmacists

Source: HealthConsult Referred Provider Survey

Change in pharmacist role as a result of CPMC

The change in pharmacist role as a result of the CPMC was examined by exploring the proportion of pharmacists who reported that the intervention had resulted in an expansion of their role within the primary health care team and the proportion of other health professionals who reported that the intervention resulted in an expansion of the community pharmacist's role within the primary health care team.

Most (n=38) pharmacists who completed the Pharmacist Survey (n=44) reported that the Trial did lead to an expansion of their role as a community pharmacist of some kind. Over 50% of respondents noted it had a slight or moderate impact on their role, with 34% stating it had a high or very high impact (25% and 27% respectively). Of the referred providers who provided a response regarding whether they perceived pharmacists' roles to have changed as a result of the Trial (n=17), eight (47%) stated that they did not perceive a change, eight (47%) stated that they saw some change and one (6%) reported seeing a significant change.

Of the 29 pharmacists interviewed for the pharmacy case studies, only three reported that the Trial had expanded their role within the primary health care team. Some pharmacists believed that they already played a significant role in the community, with the Trial having no perceivable impact. Some pharmacists noted that while some GPs appreciated pharmacists' recommendations as a result of the Trial, others were not so receptive and found it *"intrusive"*. Others reported much more positive communications as a result of the Trial, including with local GPs, physiotherapists and exercise physiologists through referrals and during awareness raising activities for the Trial.

Many pharmacists who participated in the case studies reported that the intervention changed their scope of practice in some way. The intervention and its associated renumeration provided pharmacists the opportunity to delve deeper into the various aspects (quality of life, pain severity, diet, exercise) of chronic pain. The intervention was reported to encourage in-depth patient

assessments resulting in holistic treatment and care. Pharmacists felt that this helped them provide better advice to their patients.

Pharmacist experience of providing the service

The pharmacist's experience of providing CPMC services was examined by exploring the impact of completing training, assessing the consistency of service delivery and by determining pharmacists' perception of the ease and usefulness of the Trial resources.

IMPACT OF COMPLETING THE TRAINING

To be able to provide the CPMC service at their pharmacy, pharmacists at main sites were required to complete three online training modules and those at evaluation sites completed an additional module. Information on the Trial protocol was also provided by HealthConsult. Three-quarters of the pharmacists (n=33) who responded to the Pharmacist Survey (n=44) reported that the training (CPMC training modules) was adequate. This was also reflected by the pharmacists participating in the case study interviews who noted that they felt confident and prepared to provide the service and it improved their knowledge on chronic pain management. While most pharmacists reported to be satisfied with the training modules, some stated that it was time consuming and that they lacked motivation to complete it. There was also a lengthy delay between pharmacists completing the training and commencing the service, which affected retention of information.

Some pharmacists attended an additional 'Tackling chronic pain: A practical approach to the Chronic Pain MedsCheck Trial' workshop hosted by the PSA that was held in August and September 2019. A total of nine pharmacies that participated in the Trial attended this workshop and altogether these nine pharmacies had only 27 participants commence the Trial (out of a total of 8,239 participants). The impact of this workshop on the Trial could not be established due to the low proportion of pharmacists that attended the training and recruited participants into the Trial.

SATISFACTION WITH PROVIDING THE SERVICE

Over 50% of pharmacists (n=24) who completed the Pharmacist Survey (n=44) reported that the Trial had a moderate to very high impact on improving their job satisfaction. These results were also reflected by the case study interviews where most pharmacists reported greater career satisfaction as a result of the Trial. Positive participant outcomes and feedback, opportunities to help participants and build trust and rapport and an enhanced sense of purpose and knowledge of pain management were the main contributors to improved career satisfaction.

Pharmacists expressed their dissatisfaction with some aspects of service provision such as its time-consuming nature, the repetitiveness (e.g. questions about being able to perform housework is the mini-ePPOC and AQOL-4D), ambiguity (e.g. response options in the mini-ePPOC questionnaire is not clearly defined: 'several days', 'more than half the days') and irrelevance of some patient assessment questions (e.g. body weight; BMI is preferred) and some features of the Trial software (poor integration with dispensing software, lack of free text fields for pharmacist notes).

EASE OF PERFORMING THE TRIAL AS PER THE PROTOCOL

The Pharmacist Survey asked participants (n=43, 1 participant did not respond to this question) to rate the ease performing these activities on a scale of 1 (extremely difficult) to 7 (easy). Just over half of the pharmacists rated 'following the service protocol' (n=22) and 'using the mini-ePPOC tool' (n=23) between '5' to '7' on the scale, suggesting that these activities were easy to perform. However, for 'developing an action plan', two-thirds of the pharmacists (n=27) rated it between '3' to '5', suggesting that this task somewhat difficult to perform. Pharmacists participating in the case study interviews suggested that completing all five areas of the action plan is time consuming and unnecessary and that only two areas of focus should be completed in the action plan.

The Pharmacist Satisfaction Survey also explored the consistency of pharmacists conducting follow up services (6-week and 3-month follow up services). Two thirds of the pharmacists (n=29) reported that follow up services were conducted for almost all individuals participating in the Trial. The most frequently-reported reason for not conducting follow up services was individuals declining to participate in the Trial after the initial consultation.

USEFULNESS OF THE KEY COMPONENTS OF THE CPMC SERVICE

Pharmacists who participated in the case studies noted that the CPMC service worked well as a whole intervention in encouraging a multidisciplinary approach to chronic pain management and providing easier and faster access to health advice on chronic pain management, particularly for those patients who would otherwise be waiting for extended periods to visit a GP or a specialist. The key components of the CPMC service that pharmacists provided feedback on, during the case studies and in their survey responses, included the action plan, participant education resources, follow-up consultation and participant assessment.

Six of the 29 pharmacists who participated in the case studies reported that the **action plan** was useful as it provided a proactive and collaborative approach to chronic pain management. The action plan was reported to be "personal", "motivating" and it highlighted key issues that the patient should address. They also noted that the action plan was a very useful tool to use during follow up consultations.

A total of 14 pharmacists interviewed as part of the case studies noted that the **follow up consultations** were useful for assessing changes in pain severity and management. These pharmacists also noted that follow ups were useful for assessing compliance to recommendations (e.g. referrals, pharmacological and non-pharmacological treatments) and provided them with an opportunity to reinforce key information and answer any questions the participants had.

Group B pharmacists preferred the 6-week phone consultation to the 3-month follow up because a phone call consultation was easier to conduct than a face-to-face consultation and following up sooner with the participants meant key action points could be reinforced and any issues addressed earlier.

Besides providing them with an understanding of the participant's health and pain experience, ten pharmacists that participated in the case studies suggested that the **patient assessment** was a useful

prompt for pharmacists and participants to consider the key factors (e.g. pain severity, mental health, sleep) that impacted on their condition and quality of life. Pharmacists also noted that it was important that a pharmacist asked the participant these questions rather than the patient completing a survey on their own since pharmacists were able to explain the questions if needed.

Pharmacists were asked to rate the usefulness of the **education resources** on a scale of 1 (not useful at all) to 7 (very useful) in the Pharmacist Satisfaction Survey (Figure 65). Most pharmacists (26 of 43, 60%) rated these resources between '5' to '7' on the scale, suggesting that the education resources were useful.

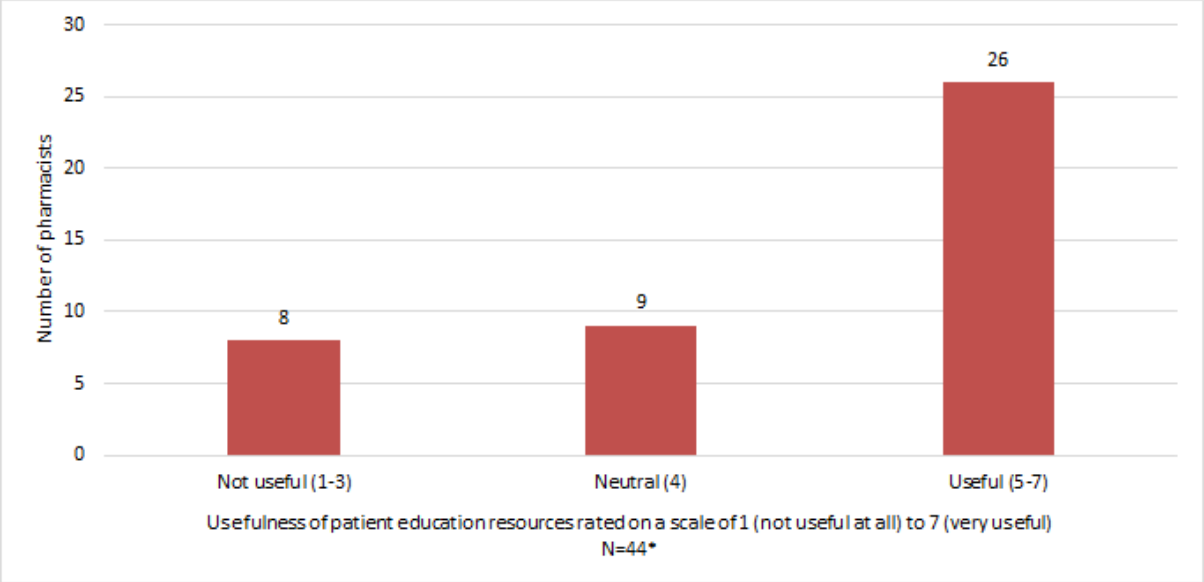


Figure 65 The usefulness of participant education resources as rated by pharmacists
Source: HealthConsult Pharmacist Survey
*one participant did not answer and is not included in the graph

These results were also reflected by the case study interviews where pharmacists described these resources as *"extensive"*, *"useful"* and *"good"*. Some pharmacists reported that the participant education resources were lengthy, *"overwhelming"* and did not target all levels of health literacy. As such, there were doubts about participants using this resource. To address these issues, some pharmacists highlighted key pieces of information during the service.

Perceived enablers to delivering the service

The Pharmacist Survey sought feedback on whether the CPMC service benefited participants with varying levels (mild, moderate, severe) of pain and depression and anxiety (Figure 66).

A total of 44 pharmacists completed the Pharmacist Survey. Their responses indicated they believed slightly higher proportions of participants with **mild to moderate** pain and with **mild** depression, anxiety, or stress at the start of the intervention (green bars) would experience large benefits from the CPMC service compared to participants with **severe** pain and **mild to severe** depression, anxiety or stress. This differed to the results of the Trial which showed that participants with moderate or severe pain or experienced moderate or severe pain interference at the initial timepoint benefited more from the intervention. The vast majority of pharmacists who responded to the survey,

however, believed that all participant groups, regardless of their level of pain and depression, anxiety or stress, would benefit from the CPMC service, which aligns to the findings from this Trial.

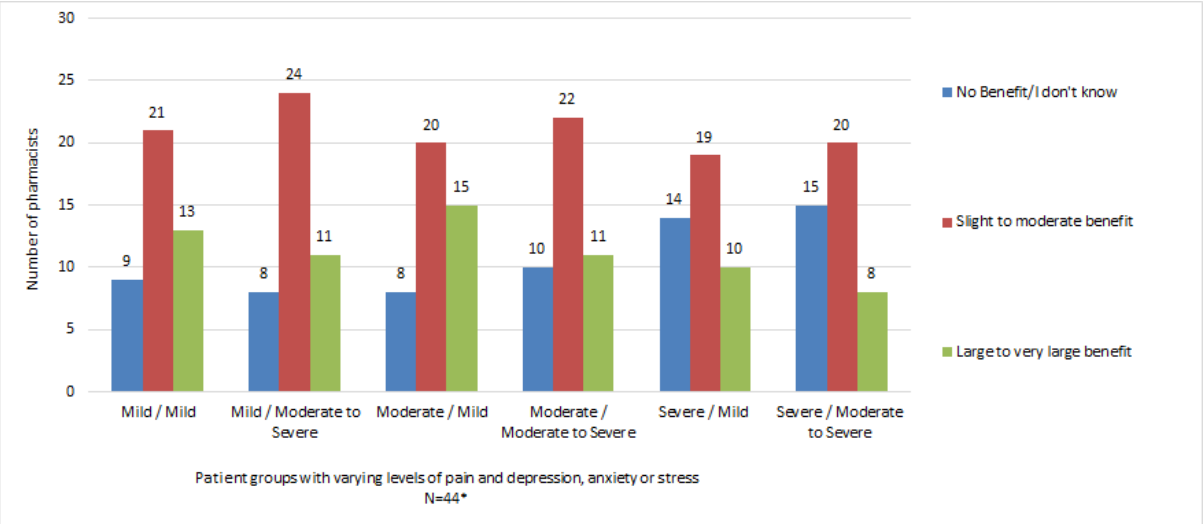


Figure 66 Benefit for different participant groups

Source: HealthConsult Pharmacist Survey, n=44

*one missing answer in each category; not included in the graph

Definitions:

Mild/Mild: mild pain and mild anxiety, depression or stress

Mild/moderate to severe: mild pain and moderate to severe anxiety, depression or stress

Moderate/mild: moderate pain and mild anxiety, depression or stress

Moderate/moderate to severe: moderate pain and moderate to severe anxiety, depression or stress

Severe/mild: severe pain and mild anxiety, depression or stress

Severe/moderate to severe: severe pain and moderate to severe anxiety, depression or stress

Out of 44 pharmacists who completed the Satisfaction Survey, 13 (29.5%) were 'very likely' to participate if the CPMC Service was to continue in the future, while another 11 (25.0%) responded that they would be 'likely' to participate (Figure 67).

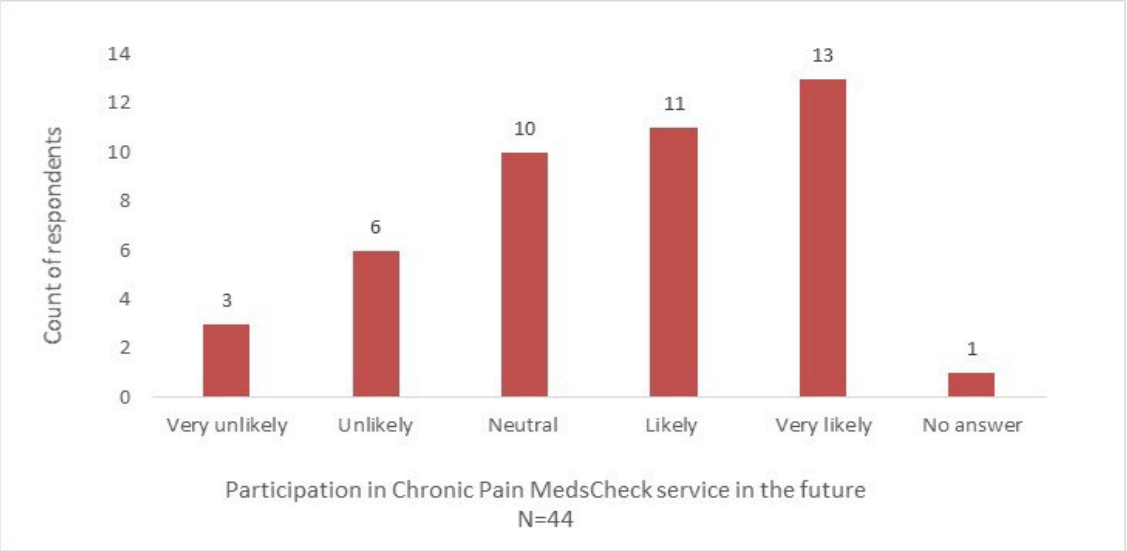


Figure 67 Likeliness of participation if the CPMC service was to continue in the future

Source: HealthConsult Pharmacist Survey, n=44

A total of 28 respondents to the Pharmacist Survey provided feedback on the types of participants they felt that would benefit the most from the service. Nine of the 28 participants (32%) stated that participants with mild to moderate pain are more likely to benefit from the service since their pain can be controlled with over-the-counter medication and non-pharmacological options. Pharmacists reported that participants with pain due to arthritis, back pain, headache and other musculoskeletal pain, would also benefit from this service. They also noted that participants are more likely to adhere to the recommendations of the service if they are motivated to do so.

Only three of the 28 respondents (11%) reported that participants with severe pain would benefit from the service, while two participants reported that participants with all levels of chronic pain would benefit from the service.

Opportunities for improvement

A total of 27 respondents to the Pharmacist Survey provided feedback on how the service design could be improved. Seven of the 27 participants (26%) reported that the service was time consuming and thus requested that the number of participant assessments and data entry requirements be reduced. Pharmacists also noted that:

- questions were repetitive, non-specific and did not include physical examinations
- greater flexibility with answering the questions was preferred (for example, being able to skip irrelevant questions, free-text fields to add more detail when needed)
- participant assessments relating to diet (number of serves of vegetables/day and number of sugar-sweetened drinks/week) did not provide enough insight to recommend changes
- participant assessment questions were challenging for older participants to understand when read by a pharmacist, and thus printed versions of the survey would enable participants to complete the assessments.

Pharmacists also provided open-ended responses in the Pharmacist Survey. Five of the 27 participants provided the following suggestions for improvement:

- to include comment boxes for free text notes on participant's diagnosis, medical history, previous treatments
- to be able to preview the action plan to check for errors or omissions before printing
- simplify the layout of the software
- receive further training to effectively provide the service (including on managing the emotional aspect of chronic pain, suitable exercise and activity for participants with a high falls risk and information on treatment options
- the Brainman video should be modified to make it more suitable for participants with low health literacy
- increase the reimbursement for follow up services, allowing pharmacists to be supported in providing this service. Part of the reimbursement should be directed to the pharmacist offering the service

- the initial follow up should be conducted after one month and further follow up services be offered every six months
- the action plan should focus on one or two aspects
- service design should be changed to a 30 to 45-minute consultation.

A total of 111 of respondents to the Patient Survey provided feedback the features of the service that they did not like and would recommend changing. Although most participants (77 of 111, 69%) reported that no further changes were required, others noted that:

- the consultations were time consuming, with too many assessment questions
- they were unable to access this service at a local pharmacy
- there were insufficient numbers of follow-up services
- they were unaware of the purpose of this service
- there was a lack of participant education resources in other languages
- the questionnaire response options did not accurately represent participants' symptoms/condition
- participant assessment questions were repetitive.

APPENDIX A CLINICAL EXPERTS AND ASSESSMENT GROUP

Expert Panel

Member	Expertise or affiliation
Nick Logan (Chair)	Pharmacist Advice
Danica Davies (Secretariat)	Pharmacy Guild of Australia
Helen O'Byrne	Pharmacy Guild of Australia
Debbie Rigby	Pharmaceutical Society of Australia
Fiona Hodson	Australian Pain Society
Joyce McSwan	GCPHN Persistent Pain Clinical Director
Benjamin Graham	Chronic Pain Australia
Dr Lisa Fodero	HealthConsult Pty Ltd
Dr Hilarie Tardiff	University of Wollongong
Prof Lloyd Sansom	Department of Health
Natasha Ploenges	Department of Health
Michelle Bradley	Department of Health
Sinem Tulpar	Pharmacy Guild of Australia

Clinical Expert

Name	Expertise
Not applicable	

Assessment group

Name	Position
Dr Lisa Fodero	Partner, HealthConsult
Dr Amy Monk	Associate Director, HealthConsult
Adam Sawers	Associate Director, HealthConsult
Vincy Li	Manager, HealthConsult
Cathy Hoadley	Manager, HealthConsult
Hayden Collins	Senior Consultant, HealthConsult
Meghna Manoharan	Consultant, HealthConsult
Rob Zabara	Consultant, HealthConsult
Katrin Schulz	Consultant, HealthConsult

Noted conflicts of interest

There were no conflicts of interest.

APPENDIX B SEARCH STRATEGIES

Not applicable

Bibliographic databases

Not applicable

Additional sources of literature (including websites)

Not applicable

APPENDIX C STUDIES INCLUDED IN THE SYSTEMATIC REVIEW

Not applicable

APPENDIX D EVIDENCE PROFILE TABLES

Not applicable

APPENDIX E EXCLUDED STUDIES

Not applicable

APPENDIX F EVALUATION FRAMEWORK

The evaluation framework sets out evaluation questions and the corresponding evaluation/performance indicators. The data sources that will be used to answer each of the evaluation questions are listed along with a short description of the analysis method. The evaluation framework aims to ensure that all key aspects of the Trial are effectively and consistently considered against the specified questions and intended outcomes.

Key changes to the Evaluation Framework from development to implementation include:

- Data on trial participants who were offered the Chronic Pain MedsCheck intervention but did not participate in the trial was not available for analysis
- It was clarified that the analyses of participants' medication would focus on their opioid dose as the data on other medications was downloaded from the dispensing software and it was not possible to verify the participant was taking those medications at the time of the trial
- There was interest in understanding the pharmacists' experience of the service delivery which was explored during the case study visits and using the Pharmacist Satisfaction Survey.

Evaluation Questions	**Key Performance Indicators (KPI)**	**Data source(s)/Data collection strategy**	**Analysis method(s)**
Does the Chronic Pain MedsCheck intervention improve trial participants understanding of their pain medication (including medication safety and efficacy) and their ability to use self-management strategies in relation to managing their chronic pain? Is there any difference between Group A and Group B trial participants?	Proportion of trial participants that participate in the Chronic Pain MedsCheck service compared to those that were offered access Improvements in self-management of pain (analysis of PIH tool output Improvements in health literacy associated with managing their chronic pain and their pain medication	Data collected by community pharmacists on the number of trial participants offered the Chronic Pain MedsCheck intervention Referral data collected by the community pharmacist at initial, midpoint (group B only) and follow-up intervention Trial participant survey data (e.g., includes health literacy	The following analysis will be done on Group A and B: Descriptive analysis of the proportion of trial participants that participated in the intervention compared to those who were invited Descriptive analysis of the proportion of trial participants that were referred to other services by type of service

Evaluation Questions	Key Performance Indicators (KPI)	Data source(s)/Data collection strategy	Analysis method(s)
	Proportion of trial participants that are referred to other services (e.g., GP, allied health, etc) and attend the referred service Proportion of trial participants that report improved education and support levels associated with their chronic pain as a result of the intervention	questions, PIH etc) collected at initial and follow-up intervention	compared to trial participants that attended other service by type (e.g. GP, physiotherapy etc) of referred service. Descriptive analysis of the characteristics (e.g. age, gender, geography, types of medication currently taking etc) of trial participants that participated in the intervention Statistical analysis of differences in improvements in health literacy and self-management of pain from initial to midpoint (Group B only) to follow up intervention (and analysis of any correlation between health literacy and self-management). Descriptive analysis of proportion of trial participants that reported improved education levels associated with their chronic pain as a result of the intervention

Evaluation Questions	Key Performance Indicators (KPI)	Data source(s)/Data collection strategy	Analysis method(s)
			Comparative statistical analysis of the difference in the KPIs in Group A compared to Group B
Does the Chronic Pain MedsCheck intervention result in an improved use of pharmacological services, and increase access and awareness to non-pharmacological services, that help trial participants manage their chronic pain? Is there any difference between Group A and Group B trial participants?	Proportion of trial participants whose medication profile changes as a result of the intervention Reduction in average daily morphine equivalent dose for trial participants taking opioid medication Proportion of pharmacists that report that the intervention has resulted in optimising trial participants effective use of pharmacological or non-pharmacological services Proportion of trial participants that report that any change in pharmacological or non-pharmacological use to manage their chronic pain has resulted in a positive improvement (e.g. to managing their pain, reduced	Medication profiles of trial participants at initial intervention, midpoint intervention (Group B only) and follow-up intervention Average daily morphine equivalent dose calculated by pharmacists at initial, midpoint (Group B only) and follow-up for each trial participant taking opioid medication Pharmacist survey (administered at end of trial) Service outcomes data (includes questions about constipation) mini-ePPOC (includes question about sleep) Patient Survey (includes questions about changes in	The following analysis will be done on Group A and B: Analysis of change in medication profile by type of medication change (e.g., change in opioid dose, decrease in CNS depressants etc) Statistical analysis of change in average daily morphine equivalent dose for trial participants taking opioid medication from initial to follow up intervention Descriptive analysis of the characteristics of pharmacists (e.g., location, type of pharmacy) that report that the intervention has resulted in optimising trial participants' effective use of pharmacological or non-pharmacological services.

Evaluation Questions	Key Performance Indicators (KPI)	Data source(s)/Data collection strategy	Analysis method(s)
	financial burden, improved sleep, less constipation etc)	constipation, sleep and financial impact as a result of Trial)Semi-structured interviews conducted at case study visits	Thematic analysis of how pharmacists report that the intervention has resulted in optimising trial participants effective use of pharmacological or non-pharmacological services Analysis of change in medication profiles of trial participants that report that a change in pharmacological or non-pharmacological use has resulted in a positive improvement in managing their chronic pain Comparative statistical analysis of the difference in the KPIs in Group A compared to Group B
Is the Chronic Pain MedsCheck intervention cost-effective? Is there any difference between Group A and Group B trial participants?	Cost per trial participant involved in the trial Cost per unit change in pain severity Cost per unit change in pain interference Cost per unit change in pain self-efficacy	Activity based costing data obtained by activity/component Trial participant outcome validated tools administered at initial, midpoint (Group B only) and follow-up intervention	Health economics analysis (refer to Chapter 9)

Evaluation Questions	Key Performance Indicators (KPI)	Data source(s)/Data collection strategy	Analysis method(s)
	Cost per unit change in capacity to self-manage pain		
Does the Chronic Pain MedsCheck intervention improve the health outcomes of trial participants who are taking medication to manage ongoing chronic pain? Is there any difference between Group A and Group B trial participants?	Improvements in quality of life Improvements in health literacy Improvements in self-management of pain Decrease in pain severity Decrease in pain interference Improvement in pain self-efficacy Proportion of trial participants that report that the intervention has resulted in an improvement in their health outcomes	Trial participant outcome validated tools (refer to section 8.3) administered at initial, midpoint (Group B only) and follow-up intervention	Statistical analysis of changes in trial participant outcome measures (refer to Chapter 10) from initial to midpoint (Group B only) to follow-up intervention will be undertaken on Group A and Group B separately Statistical analysis of changes in trial participant outcome measures will then be undertaken in Group A compared to Group B (refer to Chapter 10)
Does the Chronic Pain MedsCheck intervention expand the role of community pharmacists within the primary health care team? Is there any difference between Group A and Group B trial participants?	Proportion of pharmacists that report that the intervention has resulted in an expansion of their role within the primary health care team Proportion of other health professionals that report the intervention has resulted in an expansion of the community	Pharmacist service satisfaction survey administered at end of trial Referred providers service satisfaction survey administered at end of the trial Semi-structured interviews conducted at case study visits	The following analysis will be done on Group A and B: Descriptive analysis (e.g., by location, type of pharmacy, years of experience) of the proportion of pharmacists that report that the intervention has resulted in an expansion of their role within the primary health care team

Evaluation Questions	Key Performance Indicators (KPI)	Data source(s)/Data collection strategy	Analysis method(s)
	pharmacists role within the primary health care team		Thematic analysis of examples of how the pharmacists report how the intervention has resulted in an expansion of their role within the primary health care team Descriptive analysis of types of services (and/or disciplines) that report that the intervention has resulted in an expansion of the community pharmacists role within the primary health care team Comparative statistical analysis of the difference in the KPIs in Group A compared to Group B

APPENDIX G TRIAL QUESTIONNAIRES

This Appendix presents the data collection tools used to collect the key outcome data from participants during their initial and follow-up consultations

Participant characteristics

1) **Medicare Number**
2) **Postcode where patient live (provide a four digit postcode)**
3) **Age group of patients (please tick only one box)**

- ☐ 18 to 30 years of age
- ☐ 31 to 40 years
- ☐ 41 to 50 years
- ☐ 51 to 60 years
- ☐ 61 to 70 years
- ☐ 71 to 80 years
- ☐ 81 years or older

4) **Patient gender (please tick only one box)**

- ☐ Female
- ☐ Male
- ☐ Other
- ☐ Prefer not to disclose

5) **Language patient mainly speaks at home? (please tick only one)**

- ☐ English ☐ Italian ☐ Greek ☐ Mandarin ☐ Vietnamese
- ☐ Cantonese ☐ Arabic ☐ Turkish ☐ Hindi ☐ Punjabi
- ☐ Another language (please specify)

6) **Patients' Aboriginal nor a Torres Strait Islander background? (please tick only one box)**

- ☐ Neither an Aboriginal nor a Torres Strait Islander
- ☐ An Aboriginal but not a Torres Strait Islander
- ☐ A Torres Strait Islander but not an Aboriginal
- ☐ Both an Aboriginal and a Torres Strait Islander

7) Reason pharmacist invited patient to participate in the Chronic Pain MedsCheck trial

- ☐ Patients with sub-optimal chronic pain management
- ☐ Patients taking analgesics including non-prescription and complementary medicines
- ☐ Patients taking opioids (<50 OME)
- ☐ Patients taking higher dose opioids (≥50 OME)
- ☐ Patients taking CNS depressant medicines in addition to opioids
- ☐ Patients experiencing adverse drug events to analgesics and adjuvant therapy
- ☐ Patients with recent changes to their pain medication regimen (e.g. escalating doses, number of pain medicines)
- ☐ Patients with poor health literacy regarding pain management
- ☐ Patients accessing multiple prescribers
- ☐ Patients experiencing difficulties managing their pain medicines
- ☐ Patients having difficulties maintaining activities of daily living due to pain
- ☐ Patients exhibiting significant co-morbidities including mental health problems, cognitive impairment, substance abuse, pregnancy, polypharmacy, significant renal or hepatic impairment that may be associated with pain
- ☐ Patients experiencing chronic pain who are living alone or without access to social support
- ☐ Other *(please specify)*_____

8) Does the patient have any "red flag" issues? (select as many as appropriate)

- ☐ Organic pathology
- ☐ Substance abuse
- ☐ Drug interactions
- ☐ Adverse effects
- ☐ None

9) Does the patient have any "yellow flag" issues? (select as many as appropriate)

- ☐ Low health literacy
- ☐ Sleep disturbance
- ☐ Unable to work due to chronic pain
- ☐ Social isolation
- ☐ Suspected over medicating

☐ None

10) Site of pain as reported by patient (more than one can be selected)

☐ Head

☐ Neck

☐ Chest

☐ Back

☐ Leg

☐ Arm/shoulder

☐ Abdomen

☐ Hand

☐ Feet

☐ Pelvic and/or genital

☐ Buttock

☐ Knee

☐ Whole body

☐ Other (please specify)

11) Frequency of pain

☐ Always present (always the same intensity)

☐ Always present (level of pain varies)

☐ Often present (pain free period lasts less than six hours)

☐ Occasionally present (pain occurs once to several times per day, lasting up to an hour)

☐ Rarely present (pain occurs every few days or weeks)

12) Number of pain sites

☐ 1

☐ 2-3

☐ 4-6

☐ 7-9

☐ 10+

13) Are there any existing co-morbidities

☐ Depression/anxiety

- ☐ Osteoarthritis, degenerative arthritis
- ☐ High blood pressure
- ☐ Diabetes
- ☐ Heart disease
- ☐ Ulcer or stomach disease
- ☐ Rheumatoid arthritis
- ☐ Lung disease
- ☐ Stroke or neurological condition
- ☐ Cancer
- ☐ Anaemia or other blood disease
- ☐ Kidney disease
- ☐ Other kidney disease

14) Current work status?

- ☐ Full-time job
- ☐ Part-time job
- ☐ Retired
- ☐ Temporary or permanent disability
- ☐ Unemployed
- ☐ Other *(please specify)*

Today's date __ /__ /____

[Chronic Pain MedsCheck] – Initial questionnaire

Family name			
Given name			
Date of birth		**Gender**	☐ Male ☐ Female

1. How long has your pain been present?

☐ 3 to 6 months ☐ 12 months to 2 years ☐ More than 5 years
☐ 6 to 12 months ☐ 2 to 5 years

2. What number best describes your pain **on average** in the past week?

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

3. What number best describes how, during the past week, pain has interfered with your **general activities?**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

4. What number best describes how, during the past week, pain has interfered with your **sleep?**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

5. Over the **last 2 weeks**, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge	0	1	2	3
Not being able to stop or control worrying	0	1	2	3
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3

6. How many serves of vegetables do you usually eat each day?(e.g. ½ cup cooked vegetables, 1 cup salad vegetable, ½ medium potato)

☐ None ☐ One ☐ Two ☐ Three ☐ Four ☐ Five or more

7. How many times per week do you have sugar-sweetened drinks? (e.g. soft drink, iced tea, energy drinks)

☐ None ☐ 1 to 5 ☐ 6 to 10 ☐ 10 or more

8. Please rate how confident you are that you can do the following things at present, **despite the pain**

I can do some form of work, despite the pain ("work" includes housework, paid and unpaid work)	0	1	2	3	4	5	6
I can live a normal lifestyle, despite the pain	0	1	2	3	4	5	6
	Not at all confident						Completely confident

9. How many times in the last three months have you ….

…. visited a hospital emergency department because of your pain?	..... times
…. been admitted to hospital as an inpatient because of your pain?	..... times

10. Please list all of the medications you are taking (include all prescriptions and over-the-counter medicines)

Medicine name (as on the label)	Medicine strength (as on the label)	How many do you take per day?	How many days per week do you take this medication?

Today's date __ /__ /____

[Chronic Pain MedsCheck] – Follow Up Questionnaire

Family name

Given name

What number best describes your pain **on average** in the past week?

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

What number best describes how, during the past week, pain has interfered with your **general activities?**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

What number best describes how, during the past week, pain has interfered with your **sleep?**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Over the **last 2 weeks**, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge	0	1	2	3
Not being able to stop or control worrying	0	1	2	3
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3

How many serves of vegetables do you have per day?(e.g. ½ cup cooked vegetables, 1 cup salad vegetable, ½ medium potato)

☐ None ☐ One ☐ Two ☐ Three ☐ Four ☐ Five or more

How many times per week do you have sugar-sweetened drinks? (e.g. soft drink, iced tea, energy drinks)

☐ None ☐ 1 to 5 ☐ 6 to 10 ☐ 10 or more

Please rate how confident you are that you can do the following things at present, **despite the pain**

I can do some form of work, despite the pain ("work" includes housework, paid and unpaid work)	0	1	2	3	4	5	6
I can live a normal lifestyle, despite the pain	0	1	2	3	4	5	6
	Not at all confident						Completely confident

How many times in the last three months have you ….

…. visited a hospital emergency department because of your pain?	..... times
…. been admitted to hospital as an inpatient because of your pain?	..... times

Please list all of the medications you are taking (include all prescriptions and over-the-counter medicines)

Medicine name (as on the label)	Medicine strength (as on the label)	How many do you take per day?	How many days per week do you take this medication?

AQoL questionnaire

AQoL-4D Data Collection Copy

Tick the box that best describes your situation as it has been over the past week

aqol1. Do you need any help looking after yourself? ***(For example: dressing, bathing, eating)***

- ☐ I need no help at all.
- ☐ Occasionally I need some help with personal care tasks.
- ☐ I need help with the more difficult personal care tasks.
- ☐ I need daily help with most or all personal care tasks.

aqol2. When doing household tasks: ***(For example: cooking, cleaning the house, washing)***

- ☐ I need no help at all.
- ☐ Occasionally I need some help with household tasks.
- ☐ I need help with the more difficult household tasks.
- ☐ I need daily help with most or all household tasks.

aqol3. Thinking about how easily you can get around your home and community:

- ☐ I get around my home and community by myself without any difficulty.
- ☐ I find it difficult to get around my home and community by myself.
- ☐ I cannot get around the community by myself, but I can get around my home with some difficulty.
- ☐ I cannot get around either the community or my home by myself.

aqol4. Because of your health, your relationships (for example: with your friends, partner or parents) generally:

- ☐ Are very close and warm.
- ☐ Are sometimes close and warm.
- ☐ Are seldom close and warm.
- ☐ I have no close and warm relationships.

aqol5. Thinking about your relationship with other people:

- ☐ I have plenty of friends, and am never lonely.
- ☐ Although I have friends, I am occasionally lonely.
- ☐ I have some friends, but am often lonely for company.
- ☐ I am socially isolated and feel lonely.

aqol6. Thinking about your health and your relationship with your family:

- ☐ My role in the family is unaffected by my health.
- ☐ There are some parts of my family role I cannot carry out.
- ☐ There are many parts of my family role I cannot carry out.
- ☐ I cannot carry out any part of my family role.

Tick the box that best describes your situation as it has been over the past week

aqol7. Thinking about your vision, including when using your glasses or contact lenses if needed:

- ☐ I see normally
- ☐ I have some difficulty focusing on things, or I do not see them sharply.
  For example: small print, a newspaper or seeing objects in the distance.
- ☐ I have a lot of difficulty seeing things.
  My vision is blurred. For example: I can see just enough to get by with.
- ☐ I only see general shapes, or am blind.
  For example: I need a guide to move around.

aqol8. Thinking about your hearing, including using your hearing aid if needed:

- ☐ I hear normally
- ☐ I have some difficulty hearing or I do not hear clearly.
  For example: I ask people to speak up, or turn up the TV or radio volume.
- ☐ I have difficulty hearing things clearly.
  For example: Often I do not understand what is said. I usually do not take part in conversations because I cannot hear what is said.
- ☐ I hear very little indeed.
  For example: I cannot fully understand loud voices speaking directly to me.

aqol9. When you communicate with others: (For example: by talking, listening, writing or signing.)

- ☐ I have no trouble speaking to them or understanding what they are saying
- ☐ I have some difficulty being understood by people who do not know me. I have no trouble understanding what others are saying to me.
- ☐ I am only understood by people who know me well. I have great trouble understanding what others are saying to me.
- ☐ I cannot adequately communicate with others.

aqol10. Thinking about how you sleep:

- ☐ I am able to sleep without difficulty most of the time.
- ☐ My sleep is interrupted some of the time, but I am usually able to go back to sleep without difficulty.
- ☐ My sleep is interrupted most nights, but I am usually able to go back to sleep without difficulty.
- ☐ I sleep in short bursts only. I am awake most of the night.

aqol11. Thinking about how you generally feel:

- ☐ I do not feel anxious, worried or depressed.
- ☐ I am slightly anxious, worried or depressed.
- ☐ I feel moderately anxious, worried or depressed.
- ☐ I am extremely anxious, worried or depressed.

aqol12. How much pain or discomfort do you experience:

- ☐ None at all.
- ☐ I have moderate pain.
- ☐ I suffer from severe pain.
- ☐ I suffer unbearable pain.

Self-management tool

PARTNERS IN HEALTH SCALE

Patient Name:..... ID: n n n n n n

Assessment Date:...../...../..... Review Date:...../...../.....

Patient to complete this section * Please circle the number that most closely fits your answer*

1. My knowledge of my condition is:

0 1 2 3 4 5 6 7 8

Very Good Satisfactory Very Poor

2 My knowledge of the treatment of my condition is:

0 1 2 3 4 5 6 7 8

Very Good Satisfactory Very Poor

3 My ability to share in decisions made about the management of my condition is:

0 1 2 3 4 5 6 7 8

Very Good Satisfactory Very Poor

4 My ability to arrange appointments as recommended by my Doctor or Health Service Provider is:

0 1 2 3 4 5 6 7 8

Very Good Satisfactory Very Poor

5 My attendance at appointments is:

0 1 2 3 4 5 6 7 8

Very Good Satisfactory Very Poor

6 My ability to take my medication as directed by my doctor is:

0 1 2 3 4 5 6 7 8

Very Good Satisfactory Very Poor

7 My understanding of why I need to observe, measure and record symptoms is:

0 1 2 3 4 5 6 7 8

Very Good Satisfactory Very Poor

8 My ability to observe, measure and record my symptoms is:

0 1 2 3 4 5 6 7 8

Very Good Satisfactory Very Poor

9 My understanding of what to do when my symptoms get worse is:

0 1 2 3 4 5 6 7 8

Very Good Satisfactory Very Poor

10 My ability to take the right action when my symptoms get worse is:

0 1 2 3 4 5 6 7 8

Very Good Satisfactory Very Poor

11 My progress towards adopting habits that improve my health is:

0 1 2 3 4 5 6 7 8

Very Good Satisfactory Very Poor

Health literacy questionnaire

The following questions will be used to assess any change in a patient's health literacy in regard to pain management strategies including their pain medication

1. On a scale of 1 (very poor) to 10 (very good), how well do you understand what is causing your chronic pain? Please circle the patients answer

1	2	3	4	5	6	7	8	9	10

2. On a scale of 1 (very poor) to 10 (very good), how well do you understand the types of medicines you are taking to manage your chronic pain?

1	2	3	4	5	6	7	8	9	10

3. On a scale of 1 (very poor) to 10 (very good), how well do you understand when to take your medicines to help you manage your chronic pain?

1	2	3	4	5	6	7	8	9	10

4. On a scale of 1 (very poor) to 10 (very good), how well do you understand the interaction your pain medication may have on other medications you are taking?

1	2	3	4	5	6	7	8	9	10

5. On a scale of 1 (very poor) to 10 (very good), how well do you understand the side effects of the medication you are taking to help you manage your chronic pain?

1	2	3	4	5	6	7	8	9	10

6. On a scale of 1 (very unaware) to 10 (very aware), how aware are you of other strategies (besides taking medication) that can help you manage your chronic pain?

1	2	3	4	5	6	7	8	9	10

APPENDIX H TRIAL PAYMENT SCHEDULE

This costing report's focus was to measure the actual cost to pharmacies of providing a CPMC service in line with Trial Site A and B protocols and to compare the Trial Payments with the actual (representative cost) of providing the service. The Trial Payments are as follows:

Trial Payments for Trial Site A[1]

$98.41 Trial Payment 1 – for the completion of the initial 45-minute face-to-face consultation between the pharmacist and the patient

$32.81 Trial Payment 2 – for the completion of the 3-month follow-up in-pharmacy 15-minute face-to-face consultation between the pharmacist and the patient.

Trial Payments for Trial Site B[1]

$98.41 Trial Payment 5 – for the completion of the initial 45-minute face-to-face consultation between the pharmacist and the patient

$32.81 Trial Payment 6 – for the completion of midpoint telephone 15-minute face-to-face consultations between the pharmacist and the patient

$32.81 Trial Payment 7 – for the completion of the 3-month follow-up in-pharmacy 15-minute face-to-face consultation between the pharmacist and the patient.

Initial consultation - Trial Payments 1 and 5

Table 147 compares the initial consultation's Trial Payments and expected consultation duration and representative costs and minutes (Site A and B are shown separately). The results show that the variance between the representative cost and Trial Payment is much narrower than the variance in expected duration and the representative time taken to perform the consultation.

Costs

- **Trial Site A** – the representative cost of $99.75 is $1.34 or 1.4% higher than the Trial Payment of $98.41
- **Trial Site B** – the representative cost of $105.17 is $6.76 or 6.9% higher than the Trial Payment of $98.41.
- **All Sites (A and B combined)** – the representative cost of $104.63 is $6.22 or 6.3% higher than the Trial Payment of $98.41

Time

- **Trial Site A** – the representative time taken was 99.5 minutes which is 54.5 minutes or 121% higher than the expected duration of 45 minutes

[1] Chronic Pain MedsCheck Trial Pack – Group B Main Sites; October 2018

- **Trial Site B** – the representative time taken was 105.17 minutes which is 64.3 minutes or 143% higher than the expected duration of 45 minutes
- **All Sites (A and B combined)** – the representative time taken was 109 minutes which is 64 minutes or 142% higher than the expected duration of 45 minutes.

Table 147: Initial consultation - representative costs and time vs Trial Payment and expected duration

Fee Description	Trial Fee		Representative Cost		Variation	
	$	Mins	$	Mins	$	Mins
Trial Site A: Trial Payment 1 – for the completion of the initial 45-minute face-to-face consultation between the pharmacist and the patient	$98.41	45 mins	$99.75	99.5 mins	+$1.34	+54.5 mins
Trial Sie B: Trial Payment 5 – for the completion of the initial 45-minute face-to-face consultation between the pharmacist and the patient	$98.41	45 mins	$105.17	109.3 mins	+$6.76	+64.3 mins
Blended Trial Payment 1 and 5 (Trial Site A and B payments combined)	$98.41	45 mins	$104.63	109 mins	+$6.22	+64 mins

Source: Chronic Pain MedsCheck Trial Pack – Group B Main Sites; October 2018 and HealthConsult activity-based costing study undertaken from August to September 2019

Please note that numbers in this table may not add due to rounding

The results indicate that while the Trial Payments mostly covered the pharmacy costs, the service duration was significantly underestimated. Both Trial Site groups reported that the time spent was more than double the 45-minute expectation. Anecdotal evidence collected during the fieldwork, supported these numbers and pharmacies routinely indicated that the initial face-to-face in-pharmacy patient consultation took more than an hour (excluding the preceding recruitment activities).

Trial Site B pharmacies also showed a marginally higher cost for the initial consultation by $5.42 (5.4%) than Trial Site A pharmacies, reflecting the longer service delivery time.

Midpoint consultation - Trial Payment 6

The midpoint consultation is only performed by Trial Site B pharmacies (per the Trial protocol). The results in Table 148 show:

- **Cost** – the representative cost of $42.32 is $9.51 or 29% higher than the Trial Payment of $32.81
- **Time** – the representative time taken was 45 minutes which was 30 minutes, or 200% higher than the expected duration of 15 minutes.

Table 148: Midpoint consultation representative costs and time vs Trial Payment and expected duration

Fee Description	Trial Fee		Representative Cost		Variation	
	$	Mins	$	Mins	$	Mins
Trial Site B: Trial Payment 6 – for the completion of midpoint telephone 15-minute face-to-face consultations between the pharmacist and the patient	$32.81	15 mins	$42.32	45 mins	+$9.51	+30 mins

Source: Chronic Pain MedsCheck Trial Pack – Group B Main Sites; October 2018 and HealthConsult activity-based costing study undertaken from August to September 2019

Please note that numbers in this table may not add due to rounding

The representative pharmacy costs were higher than the Trial Payment, and the representative time taken was higher than the expected duration. Again, the time variance was greater relative to the cost variance.

Three-month follow-up consultation - Trial Payments 2 and 7

Table 149 compares the three-month follow-up consultation's Trial Payments and expected consultation duration and representative costs and minutes (Site A and B are shown separately). The results show that the variance between the representative cost and Trial Payment is much narrower than the variance in expected duration and the representative time taken to perform the consultation:

Costs

- **Trial Site A** – the representative cost of $35.00 is $2.19 or 6.7% higher than the Trial Payment of $32.81.
- **Trial Site B** – the representative cost of $38.50 is $5.69 or 17.3% higher than the Trial Payment of $32.81
- **All Sites (A and B combined)** – the cost of $37.06 is $4.25 or 12.9% higher than the Trial Payment of $32.81

Time

- **Trial Site A** – the representative time taken was 38.5 minutes which is 23.5 minutes or 157% higher than the expected duration of 15 minutes
- **Trial Site B** – the representative time taken was 41.3 minutes which is 26.3 minutes or 175% higher than the expected duration of 15 minutes
- **All Sites (A and B combined)** – representative time taken was 40 mins which is 25 minutes or 167% higher than the expected duration of 15 minutes

Table 149: Three-month follow-up consultation representative costs and time vs Trial Payment and expected duration

Fee Description	Trial Fee		Representative Cost		Variation	
	$	Mins	$	Mins	$	Mins
Trial Site A: Trial Payment 2 – for the completion of the 3-month follow-up in-pharmacy 15-minute face-to-face consultation between the pharmacist and the patient.	$32.81	15 mins	$35.00	38.5 mins	+$2.19	+23.5 mins
Trial Site B: Trial Payment 7 – for the completion of the 3-month follow-up in-pharmacy 15-minute face-to-face consultation between the pharmacist and the patient.	$32.81	15 mins	$38.50	41.3 mins	+$5.69	+26.3 mins
Blended Trial Payment 2 and 7 (Trial Site A and B payments combined)	$32.81	15 mins	$37.06	40 mins	+$4.25	+25 mins

Source: Chronic Pain MedsCheck Trial Pack – Group B Main Sites; October 2018 and HealthConsult activity-based costing study undertaken from August to September 2019 Please note that numbers in this table may not add due to rounding

For both Trial groups, the time variance was well over double the expected duration (157% and 175% for Sites A and B respectively). Site B pharmacies reported marginally higher cost at $3.50 (or 10%) more than Site A pharmacies and took 2.8 minutes (7.3%) longer to deliver.

APPENDIX I PBS SCRIPT ANALYSIS

Table 150 and Table 151 present PBS item usage by different dug class for Group A and B, respectively.

Table 150 Summary of medicine usage by class in Group A

	Mean	SD	95%CI Low	95%CI High
All medications				
Baseline (n=497)				
Total benefits paid 6 months prior to intervention	$310.94	$358.41	$276.07	$345.80
Trial participant benefit paid 6 months prior to intervention	$254.06	$350.48	$196.42	$311.71
Total scripts per trial participant 6 months prior to intervention	13.26	13.39	12.08	15.27
Follow up (n=171)				
Total benefits paid 6 months after trial initiation	$109.71	$145.36	$96.58	$122.84
Trial participant benefits paid 6 months after trial initiation	$101.53	$153.50	$77.13	$125.93
Total scripts per trial participant 6 months after trial initiation	10.70	11.55	8.97	12.43
Opioids				
Baseline (n=377)				
Total benefits paid 6 months prior to intervention	$290.03	$323.22	$254.73	$325.33
Trial participant benefit paid 6 months prior to intervention	$238.14	$316.92	$182.36	$293.92
Total scripts per trial participant 6 months prior to intervention	10.03	9.66	9.06	11.63
Follow up (n=141)				
Total benefits paid 6 months after trial initiation	$90.54	$131.78	$76.61	$104.46
Trial participant benefits paid 6 months after trial initiation	$84.31	$137.27	$60.05	$108.57

	Mean	SD	95%CI Low	95%CI High
Total scripts per trial participant 6 months after trial initiation	7.72	8.09	6.39	9.06
Anti-depressants				
Baseline (n=291)				
Total benefits paid 6 months prior to intervention	$63.56	$56.29	$56.32	$70.80
Trial participant benefit paid 6 months prior to intervention	$48.99	$44.87	$38.83	$59.14
Total scripts per trial participant 6 months prior to intervention	5.33	3.15	4.97	5.96
Follow up (n=95)				
Total benefits paid 6 months after trial initiation	$44.61	$43.27	$39.45	$49.77
Trial participant benefits paid 6 months after trial initiation	$34.08	$33.51	$26.91	$41.24
Total scripts per trial participant 6 months after trial initiation	4.05	2.51	3.55	4.56
Anti-neuropathics				
Baseline (n=227)				
Total benefits paid 6 months prior to intervention	$157.40	$145.45	$137.63	$177.17
Trial participant benefit paid 6 months prior to intervention	$118.12	$108.11	$92.61	$143.63
Total scripts per trial participant 6 months prior to intervention	5.21	3.90	4.70	6.10
Follow up (n=73)				
Total benefits paid 6 months after trial initiation	$56.74	$76.07	$45.95	$67.53
Trial participant benefits paid 6 months after trial initiation	$63.53	$82.70	$43.27	$83.79

	Mean	SD	95%CI Low	95%CI High
Total scripts per trial participant 6 months after trial initiation	4.44	3.62	3.61	5.27
NSAIDs				
Baseline (n=189)				
Total benefits paid 6 months prior to intervention	$30.40	$22.00	$26.71	$34.10
Trial participant benefit paid 6 months prior to intervention	$27.08	$26.26	$18.12	$36.03
Total scripts per trial participant 6 months prior to intervention	2.70	1.80	2.45	3.22
Follow up (n=47)				
Total benefits paid 6 months after trial initiation	$24.22	$21.33	$21.05	$27.39
Trial participant benefits paid 6 months after trial initiation	$33.98	$37.27	$22.13	$45.83
Total scripts per trial participant 6 months after trial initiation	2.79	2.21	2.16	3.42
Benzodiazepines				
Baseline (n=133)				
Total benefits paid 6 months prior to intervention	$58.35	$88.12	$41.73	$74.97
Trial participant benefit paid 6 months prior to intervention	$38.19	$67.41	$18.71	$57.67
Total scripts per trial participant 6 months prior to intervention	4.92	6.87	3.76	6.76
Follow up (n=54)				
Total benefits paid 6 months after trial initiation	$31.43	$39.44	$24.19	$38.67
Trial participant benefits paid 6 months after trial initiation	$19.53	$15.24	$14.81	$24.26

	Mean	SD	95%CI Low	95%CI High
Total scripts per trial participant 6 months after trial initiation	3.81	5.66	2.31	5.32
Migraine medications				
Baseline (n=20)				
Total benefits paid 6 months prior to intervention	$136.80	$224.64	$19.13	$254.47
Trial participant benefit paid 6 months prior to intervention	$115.54	$128.89	$26.22	$204.85
Total scripts per trial participant 6 months prior to intervention	6.25	8.21	2.65	11.34
Follow up (n=10)				
Total benefits paid 6 months after trial initiation	$50.05	$62.87	$21.78	$78.32
Trial participant benefits paid 6 months after trial initiation	$25.92	$21.44	$10.04	$41.80
Total scripts per trial participant 6 months after trial initiation	4.90	5.09	1.75	8.05
Anticonvulsants				
Baseline (n=19)				
Total benefits paid 6 months prior to intervention	$125.62	$108.37	$70.78	$180.46
Trial participant benefit paid 6 months prior to intervention	$27.91	$14.80	$17.65	$38.17
Total scripts per trial participant 6 months prior to intervention	4.74	2.00	3.84	6.04
Follow up (n=9)				
Total benefits paid 6 months after trial initiation	$40.47	$29.86	$26.28	$54.67
Trial participant benefits paid 6 months after trial initiation	$18.19	$14.15	$7.71	$28.68

	Mean	SD	95%CI Low	95%CI High
Total scripts per trial participant 6 months after trial initiation	2.00	1.66	0.92	3.08

Source: CPMC trial data
Abbreviations: CI, confidence interval; NSAIDs, non-steroidal anti-inflammatory drugs; SD, standard deviation
Note:
Values in bold signify a statistically significant reduction in scripts per patient for the nominated class of medication.
Several individual patients have been analysed under multiple medication classes.

Table 151 Summary of medicine usage by class in Group B

	Mean	SD	95%CI Low	95%CI High
All medications				
Baseline (n=275)				
Total benefits paid 6 months prior to intervention	$216.92	$303.29	$177.55	$256.28
Trial participant benefit paid 6 months prior to intervention	$141.00	$208.14	$94.21	$187.80
Total scripts per trial participant 6 months prior to intervention	10.39	11.16	9.07	12.69
Follow up (n=90)				
Total benefits paid 6 months after trial initiation	$89.10	$113.95	$75.35	$102.84
Trial participant benefits paid 6 months after trial initiation	$72.86	$112.15	$49.01	$96.70
Total scripts per trial participant 6 months after trial initiation	6.99	7.74	5.39	8.59
Opioids				
Baseline (n=209)				
Total benefits paid 6 months prior to intervention	$202.19	$286.57	$160.78	$243.59
Trial participant benefit paid 6 months prior to intervention	$139.85	$189.81	$92.22	$187.49
Total scripts per trial participant 6 months prior to intervention	7.70	8.24	6.58	9.63

	Mean	SD	95%CI Low	95%CI High
Follow up (n=70)				
Total benefits paid 6 months after trial initiation	$77.44	$109.99	$62.00	$92.88
Trial participant benefits paid 6 months after trial initiation	$65.96	$101.05	$41.58	$90.34
Total scripts per trial participant 6 months after trial initiation	5.46	5.38	4.20	6.72
Anti-depressants				
Baseline (n=145)				
Total benefits paid 6 months prior to intervention	$54.74	$44.49	$46.72	$62.77
Trial participant benefit paid 6 months prior to intervention	$40.56	$43.65	$25.88	$55.23
Total scripts per trial participant 6 months prior to intervention	4.43	2.78	3.98	5.23
Follow up (n=47)				
Total benefits paid 6 months after trial initiation	$32.19	$23.51	$28.24	$36.15
Trial participant benefits paid 6 months after trial initiation	$28.14	$28.82	$19.52	$36.75
Total scripts per trial participant 6 months after trial initiation	3.26	2.88	2.43	4.08
Anti-neuropathics				
Baseline (n=119)				
Total benefits paid 6 months prior to intervention	$159.81	$272.58	$108.87	$210.75
Trial participant benefit paid 6 months prior to intervention	$116.31	$159.35	$61.94	$170.67
Total scripts per trial participant 6 months prior to intervention	4.55	5.23	3.62	6.26

	Mean	SD	95%CI Low	95%CI High
Follow up (n=36)				
Total benefits paid 6 months after trial initiation	$36.09	$44.87	$27.42	$44.75
Trial participant benefits paid 6 months after trial initiation	$47.54	$72.00	$21.78	$73.30
Total scripts per trial participant 6 months after trial initiation	4.00	3.91	2.72	5.28
NSAIDs				
Baseline (n=92)				
Total benefits paid 6 months prior to intervention	$33.57	$33.77	$25.48	$41.66
Trial participant benefit paid 6 months prior to intervention	$31.61	$32.43	$15.72	$47.50
Total scripts per trial participant 6 months prior to intervention	2.87	2.65	2.33	4.06
Follow up (n=19)				
Total benefits paid 6 months after trial initiation	$23.99	$23.36	$18.96	$29.02
Trial participant benefits paid 6 months after trial initiation	$22.78	$23.47	$11.94	$33.62
Total scripts per trial participant 6 months after trial initiation	2.95	2.59	1.78	4.11
Benzodiazepines				
Baseline (n=69)				
Total benefits paid 6 months prior to intervention	$54.33	$85.87	$31.42	$77.23
Trial participant benefit paid 6 months prior to intervention	$18.36	$24.66	$4.41	$32.32
Total scripts per trial participant 6 months prior to intervention	4.59	6.42	3.08	7.95

	Mean	SD	95%CI Low	95%CI High
Follow up (n=14)				
Total benefits paid 6 months after trial initiation	$30.44	$42.28	$20.00	$40.88
Trial participant benefits paid 6 months after trial initiation	$14.38	$14.85	$6.30	$22.45
Total scripts per trial participant 6 months after trial initiation	2.36	2.73	0.92	3.79
Migraine medications				
Baseline (n=8)				
Total benefits paid 6 months prior to intervention	$171.17	$197.93	-$2.31	$344.66
Trial participant benefit paid 6 months prior to intervention	$130.17	NA†	NA†	NA†
Total scripts per trial participant 6 months prior to intervention	9.63	15.60	-1.19	31.25
Follow up (n=2)				
Total benefits paid 6 months after trial initiation	$74.93	$111.07	-$7.35	$157.21
Trial participant benefits paid 6 months after trial initiation	$58.82	$36.32	$8.47	$109.16
Total scripts per trial participant 6 months after trial initiation	7.50	7.78	-3.28	18.28
Anticonvulsants				
Baseline (n=6)				
Total benefits paid 6 months prior to intervention	$122.52	$113.42	$23.10	$221.93
Trial participant benefit paid 6 months prior to intervention	$80.05	NA*	NA*	NA*
Total scripts per trial participant 6 months prior to intervention	4.00	3.90	0.88	11.64

	Mean	SD	95%CI Low	95%CI High
Follow up (n=1)				
Total benefits paid 6 months after trial initiation	$26.80	$25.83	$4.16	$49.43
Trial participant benefits paid 6 months after trial initiation	$32.50	NA†	NA†	NA†
Total scripts per trial participant 6 months after trial initiation	5.00	NA†	NA†	NA†

Source: CPMC trial data

Abbreviations: CI, confidence interval; NSAIDs, non-steroidal anti-inflammatory drugs; SD, standard deviation

Note:

Values in bold signify a statistically significant reduction in scripts per patient for the nominated class of medication.

Several individual patients have been analysed under multiple medication classes.

* Only one participant paid out-of-pocket for their scripts at baseline

† Only one participant was available for analysis at follow up

Figure 68 presents total PBS scripts claims six months prior and post intervention initiation. Figure 69 and Figure 70 presents the same findings for Groups A and B, respectively. Months of usage in both Groups were similar. Most scripts were claimed between Q2 and Q3 of 2019. It is unlikely that participants would have reached concessional safety nets (minimum 60 scripts) as seen with average script usage in Table 150 and Table 151. Interestingly, there was a small expected peak in December 2018 as patients collect their scripts to avoid price rises in the new year. Participant collection data drops off after August 2019 in both groups due to ethics being approved for six months post initial intervention. Further, high dropout rates and participants not consenting to their PBS data being analysed were contributory factors for this steep decline. No claims were made in 2020. However, as stated in Section B.4, data provided from the Guild was dated up to December 2019. Consequently, longer term and follow-up data (as well as lack of 2020 data) of the participants that joined the program later may not have been captured. The allocated group of these participants could not be determined. Although, this group accounted for a very small portion of total participants (n=10 [1.3% and 3.8% of participants at baseline and follow-up, respectively]) and are unlikely to impact on results. Therefore, these participants were not included in the analyses.

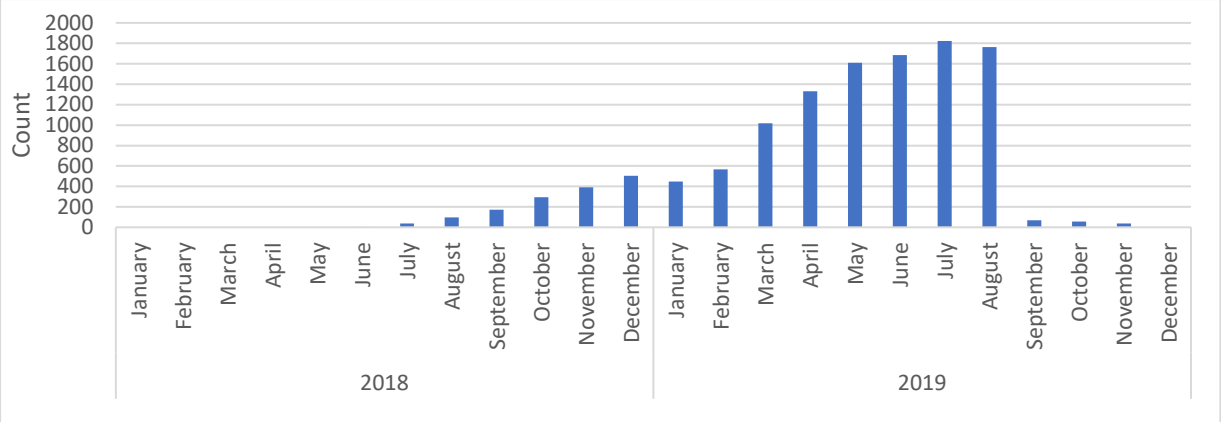


Figure 68 Total script usage in the CPMC trial by month

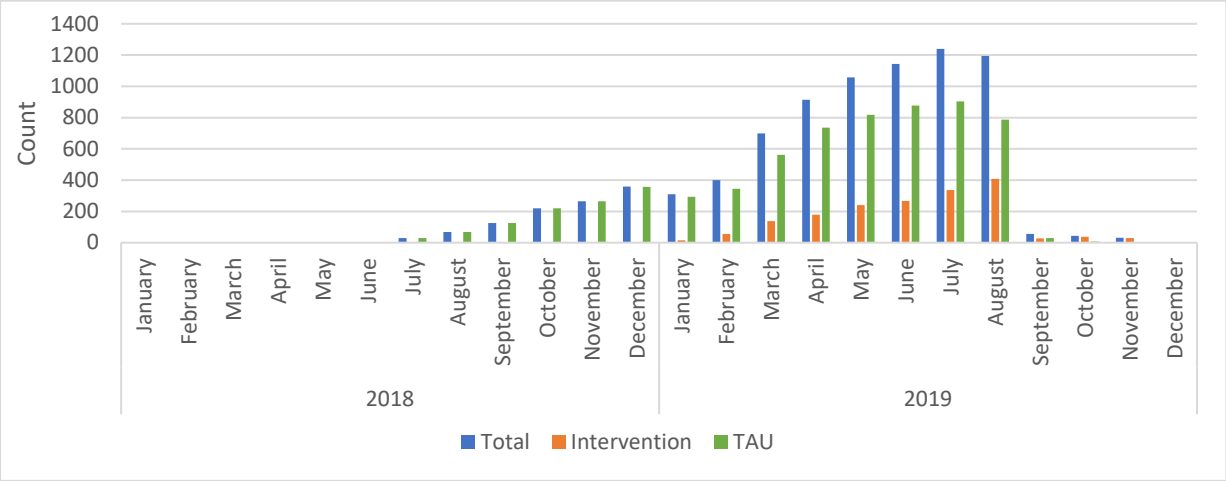


Figure 69 Total script usage in Group A by month

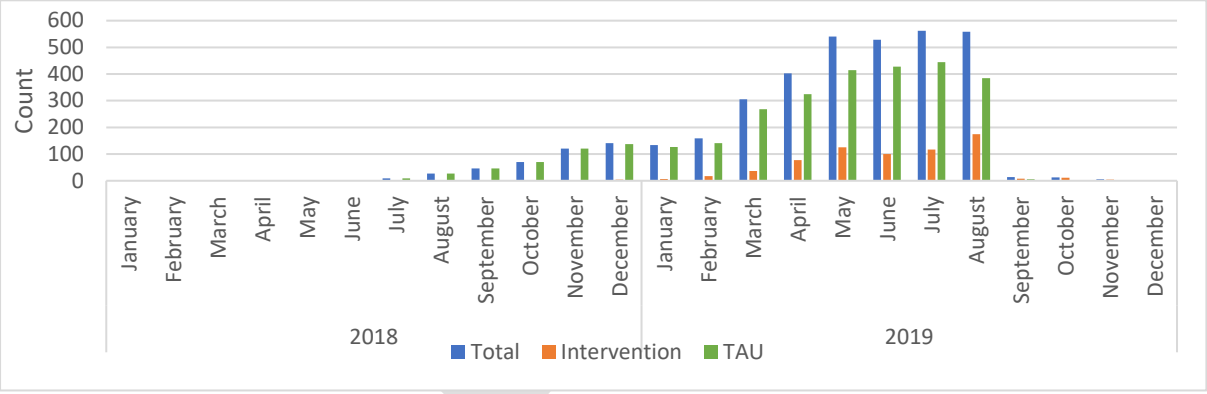


Figure 70 Total script usage in Group B by month

Table 152 and Table 153 presents total PBS scripts claims three months prior and post intervention initiation. Script usage was lower than the six month analysis (Table 150 and Table 151 for Group A and B, respectively). During the trial period, Group A average script usage increased (9.9%, not-significant) while Group B script usage decreased (13.3%, not significant). Of note, for the six months analysis used in the model, both Groups experienced a decrease in average scripts per patient.

Table 152 Three-month medication usage in Group A

Baseline (n=432)	Mean	SD	95%CI Low	95%CI High
Total benefits paid 6 months prior to intervention	$151.42	$178.80	$132.74	$170.10
Trial participant benefit paid 6 months prior to intervention	$170.93	$228.86	$133.29	$208.57
Total scripts per trial participant 6 months prior to intervention	6.66	7.01	6.00	7.72
Follow up (n=171)				
Total benefits paid 6 months after trial initiation	$60.47	$94.49	$50.97	$69.97
Trial participant benefits paid 6 months after trial initiation	$71.39	$94.55	$56.36	$86.42
Total scripts per trial participant 6 months after trial initiation	7.32	7.71	6.17	8.48

Source: CPMC trial data
Abbreviations: CI, confidence interval; SD, standard deviation

Table 153 Three-month medication usage in Group B

Baseline (n=232)	Mean	SD	95%CI Low	95%CI High
Total benefits paid 6 months prior to intervention	$115.03	$157.85	$92.59	$137.48
Trial participant benefit paid 6 months prior to intervention	$89.68	$110.10	$64.76	$114.60
Total scripts per trial participant 6 months prior to intervention	5.41	5.54	4.69	6.56
Follow up (n=89)				
Total benefits paid 6 months after trial initiation	$45.26	$57.46	$37.58	$52.95
Trial participant benefits paid 6 months after trial initiation	$49.76	$65.84	$35.68	$63.84

Baseline (n=232)	Mean	SD	95%CI Low	95%CI High
Total scripts per trial participant 6 months after trial initiation	4.69	4.23	3.81	5.56

Source: CPMC trial data

Abbreviations: CI, confidence interval; SD, standard deviation

APPENDIX J MBS CODES ANALYSIS

The list of MBS codes analysed for the CPMC trial are presented below in Table 154. Italicised MBS codes were included in the Allied health analysis.

Table 154 List of MBS item numbers analysed

MBS code	Item Description	Type of consult
3	CONSULTATION AT CONSULTING ROOMS Professional Att	GPs - General
4	Level A Professional attendance by a general pract	GPs - General
23	CONSULTATION AT CONSULTING ROOMS - LEVEL 'B'.	GPs - General
24	Level B Professional attendance by a general pract	GPs - General
36	CONSULTATION AT CONSULTING ROOMS - LEVEL 'C'.	GPs - General
37	Level C Professional attendance by a general pract	GPs - General
44	CONSULTATION AT CONSULTING ROOMS - LEVEL 'D'	GPs - General
47	Level D Professional attendance by a general pract	GPs - General
52	BRIEF CONSULTATION of not more than 5 minutes dura	Specialists - General
53	STANDARD CONSULTATION of more than 5 minutes dura	Specialists - General
54	LONG CONSULTATION of more than 25 minutes duratio	Specialists - General

MBS code	Item Description	Type of consult
57	PROLONGED CONSULTATION of more than 45 minutes du	Specialists - General
58	BRIEF CONSULTATION of not more than 5 minutes dur	Specialists - General
59	STANDARD CONSULTATION of more than 5 minutes dura	Specialists - General
60	LONG CONSULTATION of more than 25 minutes duratio	Specialists - General
65	PROLONGED CONSULTATION of more than 45 minutes dur	Specialists - General
104	Initial Specialist Attendance	Specialists - General
105	Subsequent Specialist Attendance.	Specialists - General
107	Initial Specialist Referred Consultation - Home Vi	Specialists - General
108	Subsequent Specialist Referred Consultation - Home	Specialists - General
110	Initial Attendance, Consultant Physician	Specialists - General
111	Subsequent Specialist Attendance - Same day operat	Specialists - General
112	Professional Attendance by video conference on a p	Case conferences (including telehealth)
116	Subsequent Consultant Physician attendance.	Specialists - General
117	Subsequent C/Physician Attendance - Same day opera	Specialists - General
119	Each MINOR attendance SUBSEQUENT to the first atte	Specialists - General

MBS code	Item Description	Type of consult
122	INITIAL consultant physician attendance at a place	Specialists - General
128	SUBSEQUENT consultant physician attendance at a pl	Specialists - General
132	Professional attendance by a consultant physician	Specialists - General
133	Professional attendance by a consultant physician	Specialists - General
141	Consultant Physician or Specialist in Geriatric Me	Specialists - General
143	Consultant Physician or Specialist in Geriatric Me	Specialists - General
145	Consultant Physician or Specialist in Geriatric Me	Specialists - General
147	Consultant Physician or Specialist in Geriatric Me	Specialists - General
173	LEVEL 'A' ACUPUNCTURE - Attendance at which ACUPU	Allied Health - General
185	Professional at consulting rooms of more than 5 mi	Specialists - General
189	Professional attendance at consulting rooms of mor	Specialists - General
193	CONSULTATION AT A PLACE OTHER THAN A HOSPITAL Con	GPs - General
197	CONSULTATION AT A PLACE OTHER THAN A HOSPITAL by	GPs - General
199	CONSULTATION AT A PLACE OTHER THAN A HOSPITAL Cons	GPs - General
225	Professional attendance by a medical practitioner	Allied Health - General

MBS code	Item Description	Type of consult
226	Professional attendance by a medical practitioner	Allied Health - General
227	Professional attendance by a medical practitioner	Allied Health - General
229	Preparation of a GP management plan.	GPs - General
230	Coordinate the development of team care arrangemen	Allied Health - General
233	Review or coordinate a review of a GP management p	GPs - General
235	Organise and coordinate a case conference.	Case conferences (including telehealth)
237	Organise and coordinate a case conference.	Case conferences (including telehealth)
245	Domiciliary Medication Management Review	GPs - General
385	Professional attendance by a Consultant Occupation	Allied Health - General
386	Professional attendance by a Consultant Occupation	Allied Health - General
411	PUBLIC HEALTH PHYSICIAN ATTENDANCES - AT CONSULTIN	GPs - General
503	Medical Practitioner (Emergency Physician) Consult	Urgent or emergency consultations
507	Medical Practitioner (Emergency Physician) Consult	Urgent or emergency consultations
511	Medical Practitioner (Emergency Physician) Consult	Urgent or emergency consultations
515	Medical Practitioner (Emergency Physician) Consult	Urgent or emergency consultations

MBS code	Item Description	Type of consult
585	URGENT ATTENDANCE AFTER HOURS Professional attenda	Urgent or emergency consultations
588	URGENT AFTER-HOURS Professional attendance by a me	Urgent or emergency consultations
591	URGENT AFTER-HOURS Professional attendance by a me	Urgent or emergency consultations
594	URGENT AFTER-HOURS Professional attendance by a me	Urgent or emergency consultations
599	URGENT ATTENDANCE UNSOCIABLE AFTER HOURS Professio	Urgent or emergency consultations
600	URGENT ATTENDANCE UNSOCIABLE AFTER HOURS Professi	Urgent or emergency consultations
699	Professional attendance by a general practitioner	GPs - General
701	Professional attendance by a general practitioner	GPs - General
703	Professional attendance by a general practitioner	GPs - General
705	Professional attendance by a general practitioner	GPs - General
707	Professional attendance by a general practitioner	GPs - General
715	Professional attendance by a general practitioner	GPs - General
721	ATTENDANCE BY A MEDICAL PRACTITIONER for the PREP	GPs - General

MBS code	Item Description	Type of consult
723	ATTENDANCE BY A MEDICAL PRACTITIONER to COORDINATE	GPs - General
729	Contribution by a medical practitioner to a Multid	GPs - General
732	Review a GP Management Plan or Coordinate a Review	GPs - General
735	Organise and coordinate a GP Case Conference at le	GPs - General
739	Organise and coordinate a GP Case Conference at le	GPs - General
741	Professional attendance at consulting rooms of mor	GPs - General
743	Organise and coordinate a GP Case Conference at le	GPs - General
747	Participate in a GP Case Conference at least 15 mi	GPs - General
750	Participate in a GP Case Conference at least 20 mi	GPs - General
763	Attendance at other than at consulting rooms, a ho	GPs - General
820	Case Conference - Consultant Physician	Case conferences (including telehealth)
823	Case Conference - Consultant Physician	Case conferences (including telehealth)
825	Case conference - consultant physician	Case conferences (including telehealth)
826	Case Conference - Consultant Physician	Case conferences (including telehealth)
830	Case Conference - Consultant Physician	Case conferences (including telehealth)

MBS code	Item Description	Type of consult
834	Case Conference - Consultant Physician	Case conferences (including telehealth)
880	Case Conference - Consultant Physician in Geriatri	Case conferences (including telehealth)
900	Domiciliary Medication Management Review	GPs - General
903	Residential Medication Management Review	GPs - General
2126	Level B - Telehealth Attendance at Consulting Room	Case conferences (including telehealth)
2143	Level C - Telehealth Attendance at Consulting Room	Case conferences (including telehealth)
2195	Level D - Telehealth Attendance at Consulting Room	Case conferences (including telehealth)
2801	Medical Practitioner (Pain Medicine Specialist) At	Specialists – Pain specific attendance/consultations
2806	Medical Practitioner (Pain Medicine Specialist) At	Specialists – Pain specific attendance/consultations
2946	Case Conferences - Pain Medicine Specialist, of at	Case conferences (including telehealth)
2958	Case Conferences - Pain Medicine Specialist, of at	Case conferences (including telehealth)
5000	CONSULTATION AT CONSULTING ROOMS - LEVEL 'A' (AFT	GPs - General
5020	CONSULTATION AT CONSULTING ROOMS - LEVEL 'B' (AFTE	GPs - General
5040	CONSULTATION AT CONSULTING ROOMS - LEVEL 'C' (AFTE	GPs - General

MBS code	Item Description	Type of consult
5060	CONSULTATION AT CONSULTING ROOMS - LEVEL 'D' (AFTE	GPs - General
5203	STANDARD CONSULTATION OF MORE THAN 5 MINS DURATION	Allied Health - General
5207	LONG CONSULTATION OF MORE THAN 25 MINS DURATION BU	Allied Health - General
5208	PROLONGED CONSULTATION OF MORE THAN 45 MINS.	Allied Health - General
10953	Exercise Physiology Health Service provided to a p	Allied Health - General
10954	Dietetics Health Service provided to a person by a	Allied Health - General
10958	Occupational Therapy Health Service	Allied Health - General
10960	Physiotherapy Health Service	Allied Health - General
10962	Podiatry Health Service	Allied Health - General
10964	Chiropractic Health Service	Allied Health - General
10966	Osteopathy Health Service	Allied Health - General
10983	Attendance by a practice nurse, an Aboriginal heal	Nurse practitioner consultations
10987	Follow up service provided by a Practice Nurse or	Nurse practitioner consultations
10997	Services provided by a Practice Nurse Or an ATSIHP	Nurse practitioner consultations
81300	Aboriginal and Torres Strait Islander Health Servi	Allied Health - General
81315	Exercise physiology health service	Allied Health - General
81320	Dietetics health service	Allied Health - General

MBS code	Item Description	Type of consult
81335	Physiotherapy health service	Allied Health - General
81340	Podiatry health service	Allied Health - General
81350	Osteopathy health service	Allied Health - General
82200	Nurse Practitioner LEVEL 'A'	Nurse practitioner consultations
82205	Nurse Practitioner LEVEL 'B'	Nurse practitioner consultations
82210	Nurse Practitioner LEVEL 'C'	Nurse practitioner consultations
82215	Nurse Practitioner LEVEL 'D'	Nurse practitioner consultations

Figure 74 presents total MBS service claims (listed in Table 154) six months prior and post intervention initiation. Figure 75 and Figure 76 presents the same findings for Groups A and B, respectively. Months of usage in both Groups were similar. Most scripts were claimed between Q2 and Q3 of 2019.As seen from Figure 68-Figure 70, a steep decline in service utilisation is observed in September 2019 onwards. No claims were made in 2020. Possible reasons for the decline have been discussed in Appendix I above (PBS script analysis). The group allocation for n=13 participants could not be determined (1.2% and 3.0% of participants at baseline and follow-up, respectively) and are unlikely to impact on results. These participants were not analysed.

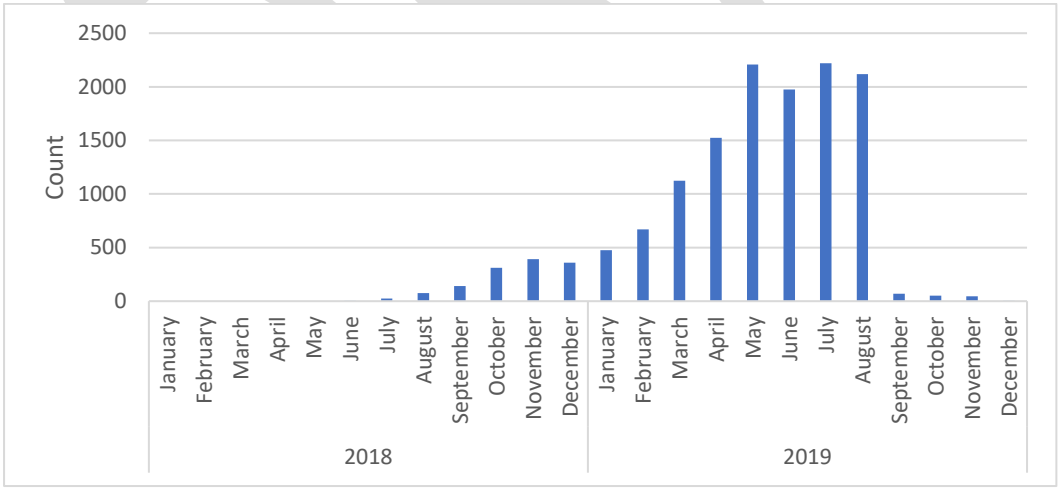


Figure 71 Total MBS service usage in the CPMC trial by month

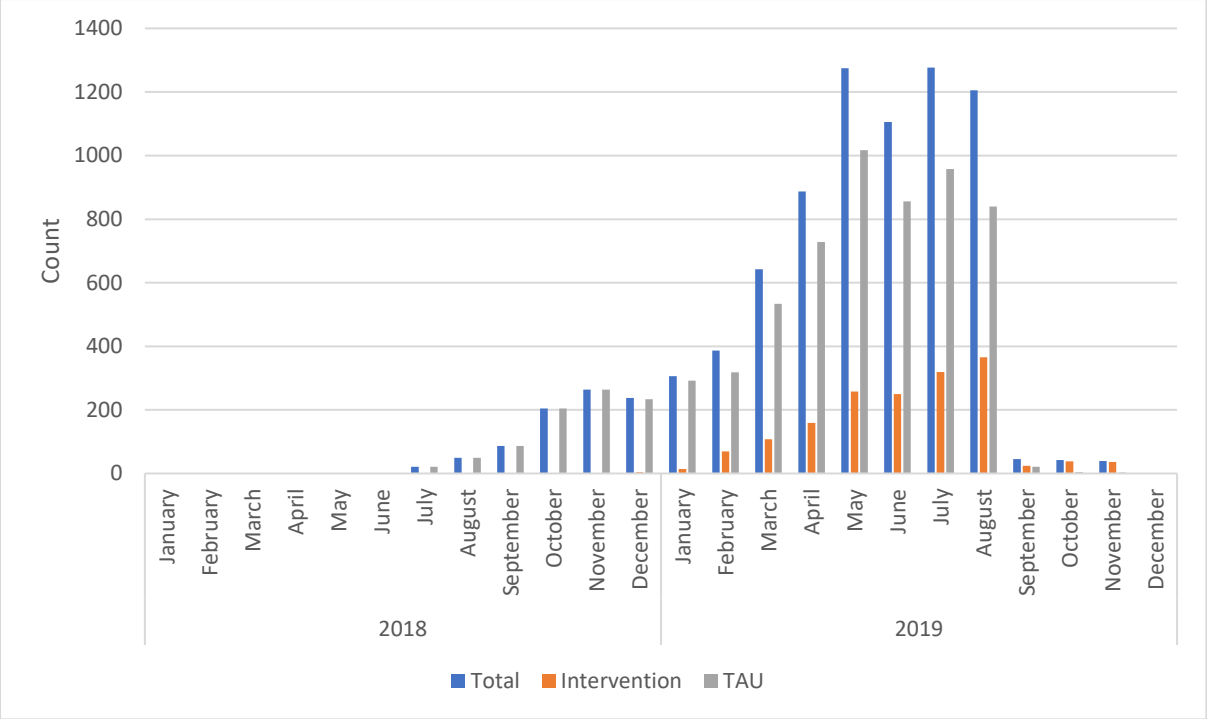


Figure 72 Total MBS service usage in Group A by month

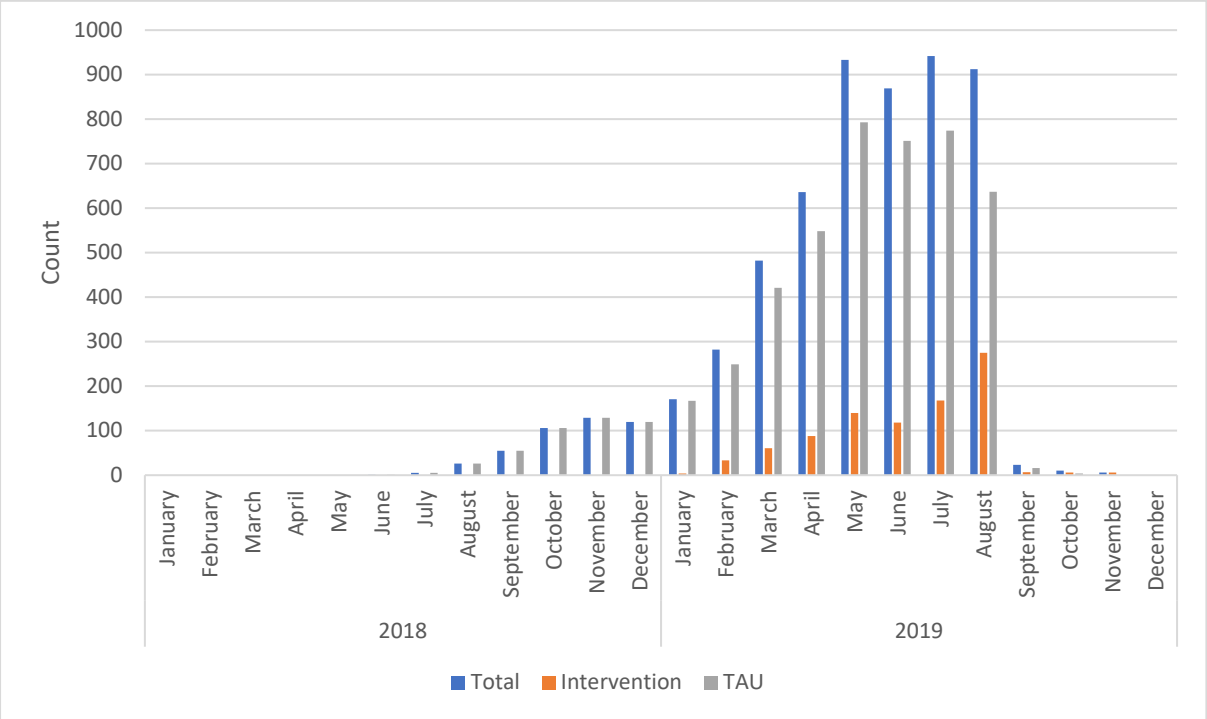


Figure 73 Total MBS service usage in Group B by month

Figure 74 presents Allied Health MBS service claims (numbers analysed are italicised in Table 154) six months prior and post intervention initiation. Figure 75 and Figure 76 presents the same findings for Groups A and B, respectively. Months of usage in both Groups were similar. Most scripts were claimed between Q2 and Q3 of 2019.As seen from Figure 74-Figure 76, a steep decline in service utilisation is observed in September 2019 onwards. No claims were made in 2020.

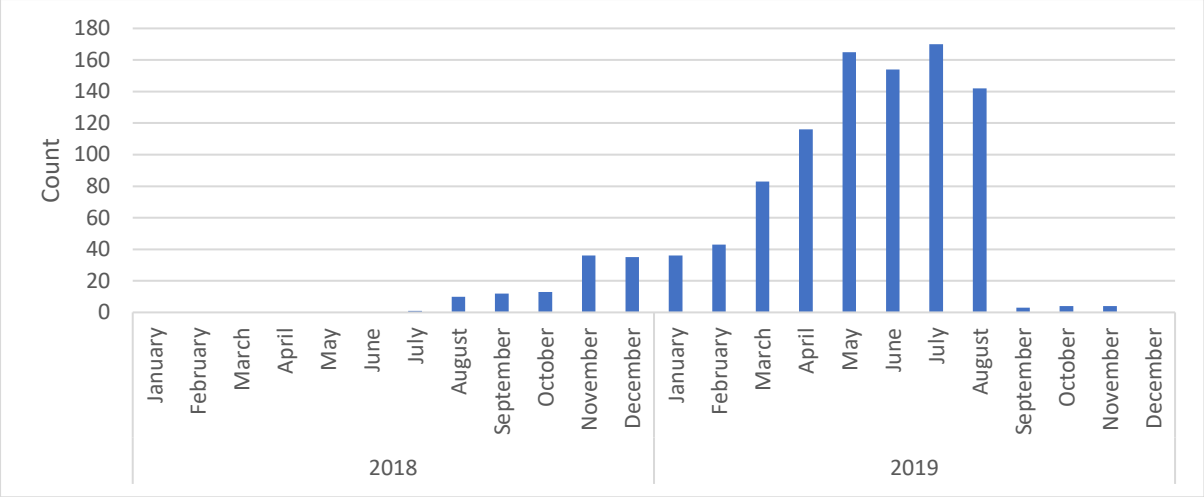


Figure 74 Total Allied Health service usage in the CPMC trial by month

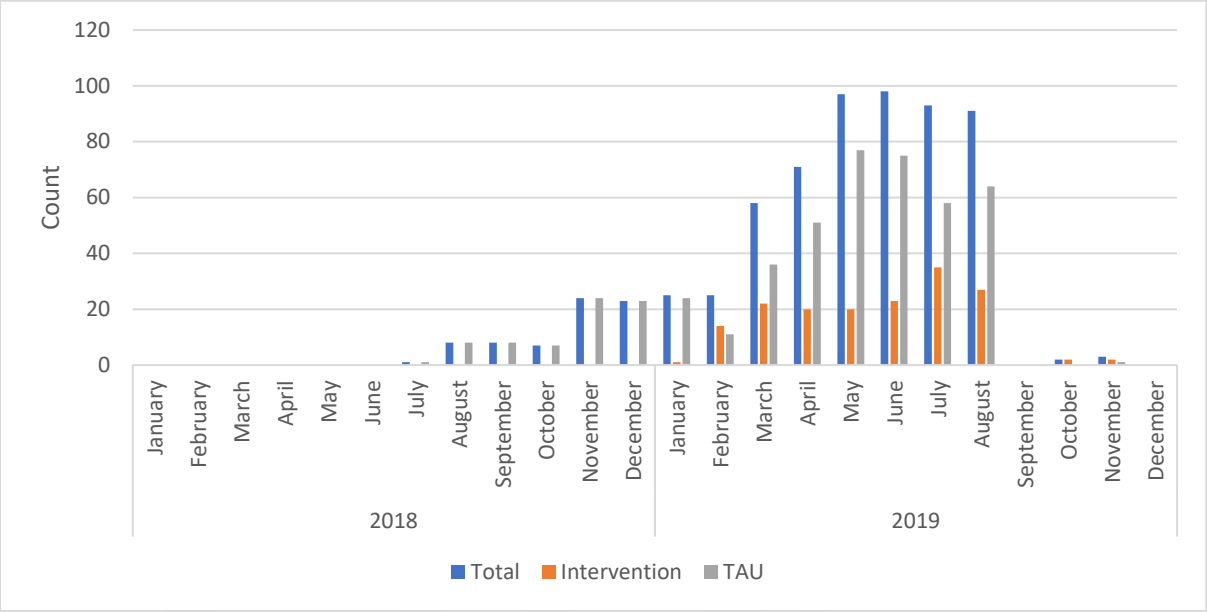


Figure 75 Total Allied Health usage in Group A by month

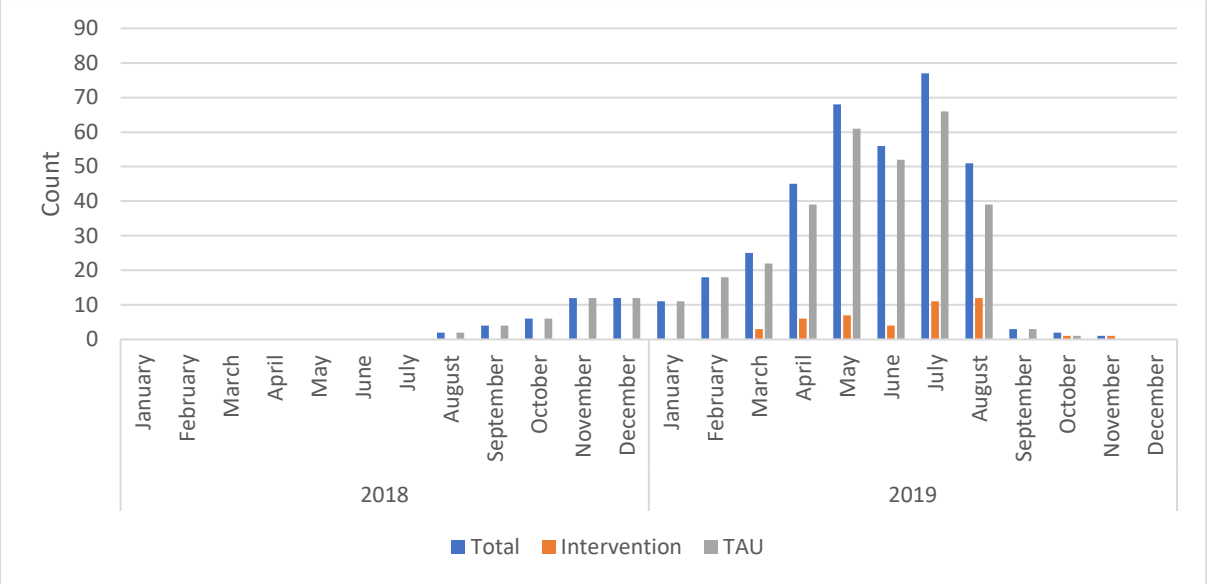


Figure 76 Total Allied Health usage in Group B by month

Table 155 and Table 156 presents total MBS service claims (listed in Table 154) three months prior and post intervention initiation for Groups A and B, respectively. During the trial period, Group A average MBS service usage increased (10.2%, not-significant) while Group B MBS service usage decreased (21.6%, not significant). Of note, for the six months analysis used in the model, both Groups experienced a decrease in average scripts per patient (Table 154).

Table 155 MBS utilisation in Group A

Baseline (n=439)	**Mean**	**SD**	**95%CI Low**	**95%CI High**
Total trial participant benefits paid 3 months prior to intervention	$304.24	$264.77	$279.47	$329.00
Total out of pocket expenditure paid 3 months prior to intervention	$114.47	$139.19	$91.24	$137.69
Total services utilised per trial participant 3 months prior to intervention	5.38	4.16	4.99	5.77
Follow up (n=183)				
Total trial participant benefits paid 3 months post trial initiation	$334.30	$287.63	$292.62	$375.97
Total out of pocket expenditure paid 3 months post trial initiation	$145.07	$183.64	$98.99	$191.16

Baseline (n=439)	Mean	SD	95%CI Low	95%CI High
Total services utilised per trial participant 3 months post trial initiation	5.93	4.85	5.22	6.63

Source: CPMC trial data
Abbreviations: CI, confidence interval; SD, standard deviation

Table 156 MBS utilisation in Group B

Baseline (n=393)	Mean	SD	95%CI Low	95%CI High
Total trial participant benefits paid 3 months prior to intervention	$285.90	$261.86	$260.02	$311.79
Total out of pocket expenditure paid 3 months prior to intervention	$85.04	$79.13	$70.64	$99.44
Total services utilised per trial participant 3 months prior to intervention	5.33	4.64	4.87	5.79
Follow up (n=152)				
Total trial participant benefits paid 3 months post trial initiation	$222.18	$210.06	$188.79	$255.58
Total out of pocket expenditure paid 3 months post trial initiation	$88.30	$75.34	$68.39	$108.21
Total services utilised per trial participant 3 months post trial initiation	4.18	3.77	3.58	4.78

Source: CPMC trial data
Abbreviations: CI, confidence interval; SD, standard deviation

Table 157 and Table 158 presents Allied Health MBS service claims (numbers analysed are italicised in Table 154) three months prior and post intervention initiation for Groups A and B, respectively. During the trial period, Group A average Allied Health usage increased (10.2%, not-significant) while Group B script usage decreased (33.8%, $p < 0.05$, significant). Of note, for the six months analysis used in the model, both Groups experienced a decrease in average scripts per patient (Table 154).

Table 157 Allied Health utilisation in Group A

Baseline (n=115)	Mean	SD	95%CI Low	95%CI High
Total trial participant benefits paid 3 months prior to intervention	$89.73	$57.57	$79.21	$100.25
Total out of pocket expenditure paid 3 months prior to intervention	$30.68	$48.80	$9.81	$51.55
Total services utilised per trial participant 3 months prior to intervention	1.60	0.92	1.43	1.77
Follow up (n=50)				
Total trial participant benefits paid 3 months post trial initiation	$120.80	$78.90	$98.93	$142.67
Total out of pocket expenditure paid 3 months post trial initiation	$34.08	$27.59	$18.47	$49.68
Total services utilised per trial participant 3 months post trial initiation	2.14*	1.23	1.80	2.48

Source: CPMC trial data
Abbreviations: CI, confidence interval; SD, standard deviation
Note: *A significant increase in MBS utilisation per trial participant was calculated using a 2 tailed t-test (p<0.001)

Table 158 Allied Health utilisation in Group B

Baseline (n=86)	Mean	SD	95%CI Low	95%CI High
Total trial participant benefits paid 3 months prior to intervention	$94.61	$58.94	$82.16	$107.07
Total out of pocket expenditure paid 3 months prior to intervention	$32.22	$26.96	$20.10	$44.34
Total services utilised per trial participant 3 months prior to intervention	1.77	1.10	1.54	2.00
Follow up (n=22)				
Total trial participant benefits paid 3 months post trial initiation	$67.89	$33.58	$53.86	$81.92

Baseline (n=86)	Mean	SD	95%CI Low	95%CI High
Total out of pocket expenditure paid 3 months post trial initiation	$34.76	$30.44	$12.21	$57.30
Total services utilised per trial participant 3 months post trial initiation	1.27	0.63	1.01	1.54

Source: CPMC trial data

Abbreviations: CI, confidence interval; SD, standard deviation

REFERENCES

[1] Hawthorne, Graeme & Osborne, Richard. (2005). Population norms and meaningful differences for the Assessment of Quality of Life (AQoL) Measure. Australian and New Zealand Journal of Public Health. 29. 136-42. 10.1111/j.1467-842X.2005.tb00063.x.

2 Vos T, Carter R, Barendregt J, Mihalopoulos C, Veerman JL, Magnus A, Cobiac L, Bertram MY, Wallace AL, ACE–Prevention Team (2010). Assessing Cost-Effectiveness in Prevention (ACE–Prevention): Final Report. University of Queensland, Brisbane and Deakin University, Melbourne.

3 Davis JA, Robinson RL, Le TK, Xie J. Incidence and impact of pain conditions and comorbid illnesses. J Pain Res. 2011;4:331-45. doi: 10.2147/JPR.S24170. Epub 2011 Oct 10. PMID: 22090802; PMCID: PMC3215513.

4 Vos T, Carter R, Barendregt J, Mihalopoulos C, Veerman JL, Magnus A, Cobiac L, Bertram MY, Wallace AL, ACE–Prevention Team (2010). Assessing Cost-Effectiveness in Prevention (ACE–Prevention): Final Report. University of Queensland, Brisbane and Deakin University, Melbourne.

5 NSW Department of Health, 2018. Website: http://www.health.nsw.gov.au/pharmaceutical/doctors/Pages/chronic-pain-medical-practitioners.aspx#bookmark1 Accessed 15 June 2020.

6 The University of Sydney, 2018. Website: https://sydney.edu.au/news-opinion/news/2018/02/02/new-research-project-to-help-tackle-chronic-pain.html Accessed 13/2/2018

7 Painaustralia (2019). The Cost of Pain in Australia. Deloitte. Available at: https://www.painaustralia.org.au/static/uploads/files/the-cost-of-pain-in-australia-final-report-12mar-wfxbrfyboams.pdf Accessed 15 June 2020.

8 Blyth et al 2003a. Chronic pain-related disability and use of analgesia and health services in a Sydney community. MJA (173) pg84-87.

9 Deloitte. (2019). The cost of pain in Australia. Retrieved from https://www.painaustralia.org.au/static/uploads/files/the-cost-of-pain-in-australia-final-report-12mar-wfxbrfyboams.pdf

10 Tardif H, Blanchard M, White J, & Bryce M. (2018). Normative data for adults referred for specialist pain management in Australia. Retrieved from University of Wollongong: https://ro.uow.edu.au/cgi/viewcontent.cgi?article=1987&context=ahsri#page=3

[11] Hooley, J. M., Franklin, J. C., & Nock, M. K. (2014). Chronic pain and suicide: understanding the association. Curr Pain Headache Rep, 18(8), 435. doi:10.1007/s11916-014-0435-2

[12] Australian Institute of Health and Welfare. (2020). Chronic Pain in Australia. Retrieved from https://www.painaustralia.org.au/static/uploads/files/aihw-phe-267-wfkezczyrckj.pdf

[13] Painaustralia. Pain in Australia. Retrieved from https://www.painaustralia.org.au/about-pain/painful-facts

[14] Bennett, C. (2019). The impact of pain on rural and regional Australia: problems and solutions. Retrieved from http://www.ruralhealth.org.au/15nrhc/sites/default/files/B2-1_Bennett.pdf

[15] Duenas M, Ojeda B, Salazar A, Mico JA, & Failde I. (2016). A review of chronic pain impact on patients, their social environment and the health care system. J Pain Res., 9, 457-467. Retrieved from https://www.dovepress.com/a-review-of-chronic-pain-impact-on-patients-their-social-environment-a-peer-reviewed-fulltext-article-JPR

[16] National Pain Summit initiative 2010. National Pain Strategy: Pain management for all Australians. Available at: https://www.chronicpainaustralia.org.au/files/PainStrategy2010Final.pdf. Accessed on 16 May 2020

[17] Classification of pharmacies into major city/regional/remote locations is based on the Australian Statistical Geography Standard (ASGS) Remoteness Structure. Available at: https://www.abs.gov.au/ausstats/abs@.nsf/Latestproducts/1270.0.55.005Main%20Features15July%202016?opendocument&tabname=Summary&prodno=1270.0.55.005&issue=July%202016&num=&view=

[18] The PhARIA draws on previous work undertaken by the Department of Health and Aged Care and GISCA to create the Accessibility and Remoteness Index for Australia (ARIA), which quantified geographic remoteness based on the road distance people have to travel to reach a range of services.

[19] Australian Bureau of Statistics. Socioeconomic Indexes for Areas 2016. Canberra (AUST): ABS; 2016. Available from: https://www.abs.gov.au/ausstats/abs@.nsf/mf/2033.0.55.001. Accessed on 16 May 2020

[20] Nicholas MK, McGuire BE, Asghari A. A 2-item short form of the Pain Self-efficacy Questionnaire: development and psychometric evaluation of PSEQ-2. Journal of Pain. 2015;16(2):153-163. doi:10.1016/j.jpain.2014.11.002

[21] Kroenke K, Spitzer RL, Williams JB, Löwe B. An ultra-brief screening scale for anxiety and depression: the PHQ-4. Psychosomatics 2009;50:613–621

[22] Hawthorne, Graeme & Osborne, Richard. (2005). Population norms and meaningful differences for the Assessment of Quality of Life (AQoL) Measure. Australian and New Zealand Journal of Public Health. 29. 136-42. 10.1111/j.1467-842X.2005.tb00063.x.

[23] Based on mean AQoL utility score by self-reported health status, from: Hawthorne G, Osborne R. Population norms and meaningful differences for the Assessment of Quality of Life (AQoL) measure. Australian and New Zealand journal of public health. 2005 Apr;29(2):136-42

[24] Based on mean AQoL utility score by self-reported health status, from: Hawthorne G, Osborne R. Population norms and meaningful differences for the Assessment of Quality of Life (AQoL) measure. Australian and New Zealand journal of public health. 2005 Apr;29(2):136-42

[25] Youssef S, Hussain D, Upton D (2010). Do patients perceive any benefit from medicines use reviews offered to them in community pharmacies? Pharm J. 284(7589):165–166.

[26] The FPM ANZCA calculator did not include methadone (tablet) conversion calculation. The Agency Medical Directors' Group's (AMDG) calculator (http://www.agencymeddirectors.wa.gov/Calculator/DoseCalculator.htm) was used for methadone (tablet) conversions which uses higher conversion ratios that increase at higher doses (0-20 mg 4:1 ratio, 21-40 mg 8:1 ratio, 41-50 mg 10:1, over 51 mg 12:1 ratio).

[27] US Department of Health and Human Serivces, National Institutes of Health. 2017. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. Accessed 27 October 2020: https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf

[28] Gammaitoni AR, Gallagher RM, Welz M, Gracely EJ, Knowlton CH, Voltis-Thomas O. Palliative pharmaceutical care: a randomized, prospective study of telephone-based prescription and medication counseling services for treating chronic pain. Pain Med. 2000 Dec;1(4):317-31. doi: 10.1046/j.1526-4637.2000.00043.x. PMID: 15101878.

[29] Niznik, JD, He H., & Kane-Gill, SL. (2018). Impact of clinical pharmacist services delivered via telemedicine in the outpatient or ambulatory care setting: A systematic review. Research in Social and Administrative Pharmacy, 14(8), 707–717. doi:10.1016/j.sapharm.2017.10.011.

[30] Australian Institute of Health and Welfare 2020. Chronic Pain in Australia. Cat. no. PHE 267. Canberra: AIHW.

[31] Deloitte Access Economics: The cost of pain in Australia, Painaustralia, March 2019

[32] Davis JA, Robinson RL, Le TK, Xie J. Incidence and impact of pain conditions and comorbid illnesses. J Pain Res. 2011;4:331-45. doi: 10.2147/JPR.S24170. Epub 2011 Oct 10. PMID: 22090802; PMCID: PMC3215513.

[33] Coupland, C., Hill, T., Morriss, R. et al. Antidepressant use and risk of adverse outcomes in people aged 20–64 years: cohort study using a primary care database. BMC Med 16, 36 (2018). https://doi.org/10.1186/s12916-018-1022-x

[34] Cartwright C, Gibson K, Read J, Cowan O, Dehar T. Long-term antidepressant use: patient perspectives of benefits and adverse effects. Patient Prefer Adherence. 2016 Jul 28;10:1401-7. doi: 10.2147/PPA.S110632. PMID: 27528803; PMCID: PMC4970636.

[35] Patorno E, Glynn RJ, Levin R, Lee MP, Huybrechts KF. Benzodiazepines and risk of all cause mortality in adults: cohort study. bmj. 2017 Jul 6;358:j2941.

[36] Tiihonen J, Suokas JT, Suvisaari JM, Haukka J, Korhonen P. Polypharmacy with antipsychotics, antidepressants, or benzodiazepines and mortality in schizophrenia. Arch Gen Psychiatry. 2012 May;69(5):476-83. doi: 10.1001/archgenpsychiatry.2011.1532. PMID: 22566579.

[37] Independent Hospital Pricing Authority (IHPA). n.d. How much does trial participant activity cost in Australia's public hospitals?. Accessed on 7 April 2020: https://ihpa.govcms.gov.au/sites/default/files/publications/ihpa19-3899_nhcdc_infographics_overview_new.pdf

[38] IHPA 2019 National Hospital Cost Data Collection Report, Public Sector, Round 21 (Financial year 2016-17). Available at: https://www.ihpa.gov.au/publications/national-hospital-cost-data-collection-report-public-sector-round-21-financial-year. Accessed on 13 May 2020.

[39] The Centre for Clinical Governance Research in Health. 2009. Complaints and patient satisfaction: a comprehensive review of the literature. Available at: https://www2.health.vic.gov.au/Api/downloadmedia/%7BF861C026-FE97-4F4A-A52B-BA15ADCBE7A8%7D. Accessed on 13 May 2020.

[40] Hawthorne, G., & Osborne, R. (2005). Population norms and meaningful differences for the Assessment of Quality of Life (AQoL) measure. Australian and New Zealand Journal of Public Health, 29(2), 136–142.

[41] Hawthorne, G., Korn, S., & Richardson, J. (2013). Population norms for the AQoL derived from the 2007 Australian National Survey of Mental Health and Wellbeing. Australian and New Zealand Journal of Public Health, 37(1), 17–23.

[42] Nord, E. (2001). Severity of illness versus expected benefit in societal evaluation of healthcare interventions. Expert review of pharmacoeconomics & outcomes research, 1(1), 85-92.

[43] OpenEpi, accessed 6 May 2020: https://www.openepi.com/Menu/OE_Menu.htm

44 Nicholas MK, McGuire BE, Asghari A. A 2-item short form of the Pain Self-efficacy Questionnaire: development and psychometric evaluation of PSEQ-2. Journal of Pain. 2015;16(2):153-163. doi:10.1016/j.jpain.2014.11.002

[45] Battersby, M., Harris, M., Smith, D., Reed, R., & Woodman, R. (2015). A pragmatic randomized controlled trial of the Flinders Program of chronic condition management in community health care services. Patient Education and Counseling 2015: 98(11), 1367-1375.

[46] Smith, D., Lawn, S., Harvey, P., & Battersby, M. (2019). Concurrent validity of the Partners in Health scale against general self-rated health in chronic conditions: a short report. Chronic illness 2019: 15(1), 74-77.

[47] EviQ online. Opioid Conversion Calculator accessed 14 April 2020, https://www.eviq.org.au/clinical-resources/eviq-calculators/3201-opioid-conversion-calculator

[48] Western Australia Department of Health 2016. Opioid Conversion Guide. Available at: https://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/Palliative/Opioid-conversion-chart.pdf. Accessed 15 June 2020

[49] Chronic Pain MedsCheck Trial Pack. NPS Medicinewise Fact Sheet | Chronic pain: what can I do?

[50] Western Australia Department of Health 2016. Opioid Conversion Guide. Available at: https://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/Palliative/Opioid-conversion-chart.pdf. Accessed 15 June 2020

[51] Chronic Pain MedsCheck Trial Pack. NPS Medicinewise Fact Sheet | Chronic pain: what can I do?

[52] Campbell, G., Nielsen, S., Bruno, R., Lintzeris, N., Cohen, M., Hall, W., … Degenhardt, L. (2015). The Pain and Opioids IN Treatment study. PAIN, 156(2), 231–242.

[53] DoH. 2017. Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee – Service Type: Investigative (Version 3.0). Available from: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/9C7DCF1C2DD56CBECA25801000123C32/$File/InvestigativeTechnicalGuidelines-December-2016-Version-3.0.pdf

[54] Neilson, A. R., Bruhn, H., Bond, C. M., Elliott, A. M., Smith, B. H., Hannaford, P. C., Holland, R., Lee, A. J., Watson, M., Wright, D., & McNamee, P. (2015). Pharmacist-led management of chronic pain in primary care: costs and benefits in a pilot randomised controlled trial. BMJ open, 5(4), e006874. https://doi.org/10.1136/bmjopen-2014-006874

[55] Bruhn, H., Bond, C. M., Elliott, A. M., Hannaford, P. C., Lee, A. J., McNamee, P., Smith, B. H., Watson, M. C., Holland, R., & Wright, D. (2013). Pharmacist-led management of chronic pain

in primary care: results from a randomised controlled exploratory trial. BMJ open, 3(4), e002361. https://doi.org/10.1136/bmjopen-2012-002361

[56] Eckermann, Simon, "Kinky thresholds revisited: opportunity costs differ in the NE and SW quadrants" (2015). Australian Health Services Research Institute. 413. https://ro.uow.edu.au/ahsri/413

[57] DoH. 2017. Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee – Service Type: Investigative (Version 3.0). Available from: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/9C7DCF1C2DD56CBECA25801000123C32/$File/InvestigativeTechnicalGuidelines-December-2016-Version-3.0.pdf

[58] ABS, 3222.0 - Population Projections, Australia, 2017 (base) – 2066, latest issue Nov 2018

[59] ABS, 31010DO002_201612 Australian Demographic Statistics, Dec 2016, Table 8

[60] Miller, A., Sanderson, K., Bruno, R., Breslin, M., & Neil, A. L. (2017). The prevalence of pain and analgesia use in the Australian population: Findings from the 2011 to 2012 Australian National Health Survey. Pharmacoepidemiology and Drug Safety, 26(11), 1403–1410.

[61] Australian Institute of Health and Welfare 2020. Chronic Pain in Australia. Cat. no. PHE 267. Canberra: AIHW.

[62] The Pharmacy Guild of Australia. 2020. About the Guild. Accessed 15 June 2020: https://www.guild.org.au/about-us