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Improvement in pain interference and function by an allied health pain management program: results of a randomised trial.

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Conflicts of Interest: None.

Significance

The study is the first RCT to test effectiveness and safety of an expanded scope allied health led chronic pain program. Despite a high attrition rate the study showed reduced pain interference and increased physical function in those who completed the protocol. The results are promising and support introduction of this model as an adjunct to existing traditional chronic pain models of care, with a particular focus on improving participant retention in the program. Additionally, the model of care can be used as a standalone chronic pain model of care where no other pain management resources are available.

1 Introduction

Chronic pain) is one of the most common causes of disability worldwide (James et al., 2018). The yearly economic burden of chronic pain is estimated at $73 billion in Australia and $635 billion in the United States (Deloitte Access Economics 2019; Gaskin and Richard 2012).

Single modality treatments, especially those of a biomedical nature, may be of limited benefit or lack longevity when addressing the complexities of chronic pain (Corran et al., 2001; Davin et al., 2019). Expert consensus recommends interdisciplinary management targeting physical, psychological, and environmental factors (Pain Australia 2010; The British Pain Society 2013). Systematic reviews show that multidisciplinary biopsychosocial rehabilitation improves function and socio-economic outcomes (Bujak et al., 2019; Gatchel and Okifuji 2006; Guzman et al., 2001; Kamper et al., 2015; Peterson et al., 2018) and can also reduce pain intensity, depression and anxiety (Martinez-Calderon et al., 2020; Preis et al., 2018; van Middelkoop et al., 2011).

The growth of the biopsychosocial approach has led to the creation of specialist multidisciplinary pain centres commonly led by pain medicine physicians (Stanos and Houle 2006),. Whilst remaining the Gold Standard in pain management, there is a scarcity of pain medicine physician resources in some jurisdictions. For instance, in Australia there is only one pain medicine physician for every 100,000 Australians (Association of American Medical Colleges 2017), despite back pain accounting for more disability than any other condition (Department of Health 2016a; b; James et al., 2018). Such resource shortages have resulted in demand exceeding capacity (Hogg et al., 2012) with up to 80% of patients missing out on treatment (Pain Australia 2010). The prevalence of chronic pain is expected to increase substantially over the coming decades (Hoy et al., 2010), exacerbating pain centre access challenges and associated health status deterioration with excess wait time (Lynch et al., 2008). Contemporary models of pain management focus on matching patient needs with the most suitable practitioners within a multidisciplinary team. This may result in patients not seeing a pain medicine physician during their time with a service (Queensland Health 2020).

Whilst newer treatment models exist for community based patients in primary care (Dear et al., 2013; Furlan et al., 2019; Joypaul et al., 2019; Schultz et al., 2018; Smith et al., 2019), Australian alternatives for high complexity tertiary pain services are limited with research focusing on waitlist reduction and individual versus group assessment (Davies et al., 2011)t (Smith et al., 2016b). Internationally, research on allied health led models of care shows participants have improved functioning, improved sleep, reduced fatigue interference and better mental health (Daly-Eichenhardt et al., 2016; Smith et al., 2016a; Wiklund et al., 2018; Yu et al., 2020)

To improve service access for tertiary-referral chronic pain patients, we designed and piloted an innovative new Treatment Access Pathway (TAP). TAP is an allied health expanded scope of practice model of care with full-scope (Allied Health Professions' Office of Queensland 2014; McPherson et al., 2005) (first-contact, referring to other professionals, criteria-led discharge) and extended-scope (trans-disciplinary skill sharing assessment and discharge) clinics, in conjunction with a general practitioner (GP) shared-care model (Hayes and Hodson 2011; Pain Australia 2010) (The Allied Health Professions' Office of Queensland 2014). The TAP provided access to established, effective multidisciplinary allied health treatments as well

as innovative, untested, expanded scope clinics where allied health practitioners were delivering services traditionally undertaken by pain medicine physicians (Allied Health Professions' Office of Queensland 2014). Innovative elements of TAP were consumer engagement in shared decision making (i.e. choosing any combination of available treatments) and a group-based clinician supported self-assessment process.

Pilot feedback indicated high patient and GP satisfaction (Kennedy et al., 2015)however, a robust study to evaluate the effectiveness of this model of care was warranted.

The present randomised clinical trial aimed to provide the first comprehensive evaluation of the clinical effectiveness and safety of the TAP service delivery model. We hypothesised that patients engaged in the TAP would have significantly lower pain interference compared to a waitlist control group at 6 months. Secondary hypotheses were that patients in the TAP group would, relative to the control group, experience greater reductions in pain intensity and depression, increased pain acceptance, activity engagement, walking endurance and a positive impression of overall change.

2 Materials and Methods

2.1 Study design

The design was a randomised clinical trial (RCT) comparing an immediate treatment group (TAP) with a waitlist control group. The study was conducted as a single-centre, individually randomised trial with a 6-month follow up period. The treatment group and waitlist group were followed from the time of randomisation. Both groups completed questionnaires and objective measures at recruitment (Time 1) and again at 6 months (Time 2). At 6 months, the waitlist control group were offered the TAP. The trial recruitment commenced in July 2017. Funding restrictions mandated closure of recruitment in May 2019.

Reporting of the trial conforms to the CONSORT Statement. The study was approved by the Gold Coast Hospital and Health Service Human Research Ethics Committee (EC00160). All participants provided written informed consent.

2.2 Participants

Participants were recruited from outpatient referrals for management of chronic non-cancer pain received by the Gold Coast Interdisciplinary Chronic Pain Centre (IPPC) (a tertiary-referral public pain centre) in Queensland, Australia. Participants were required to be at least 18 years of age, have experienced chronic non-cancer pain for at least 3 months, be proficient in written and spoken English and have a referral triaged as routine. Routine referrals within Gold Coast Health are given the category number 3 and have an anticipated time-frame from referral to first visit of 12 months. In the current study participants randomised to waitlist were not disadvantaged as they were offered treatment at 6 months rather than the expected 12 months. Participants were not eligible for the study if they:

- had a medical/psychiatric condition that would prevent engagement in the TAP;
- were scheduled for surgical treatment related to their pain condition within the next 6 months; or
- had been engaged with the IPPC within the last 12 months.

A $20 gift voucher was provided to participants at the Time 1 data collection appointment and a further $20 gift voucher when attending for Time 2 data collection. The vouchers were provided to offset costs associated with participants' time and travel expenses for participation in the study and excluded purchases of alcohol or tobacco.

2.3 Recruitment, randomisation and blinding

Recruitment, data collection and randomisation were conducted by an independent research officer. A total of 442 referrals were screened for eligibility (see Figure 2) with 86 deemed ineligible and 28 not contacted during a period of inadequate staffing for the research officer role. The remaining 328 referrals were phoned by the research officer with 48 unable to be contacted. A further 72 participants declined to participate, the majority due to inconvenience of attending the site for two research appointments with transport or work-related barriers cited. Eleven referrals were excluded after failing to meet the criteria for English proficiency using two Single-Item Literacy Screening (SILS) questions (Hirsh 2016; Kirk et al., 2012; Morris et al., 2006; Nurss et al., 2001). A total of 197 referrals met eligibility criteria and agreed to attend the site for Time 1 data collection.

After completion of Time 1 data collection, participants were randomised to the intervention or control group. Participants were individually randomised using an independent automated web based clinical trials randomisation process (permuted blocks of 4-8) with allocation concealment to either the TAP or to wait list. Participants were not blinded to their allocation. Treating clinicians were blinded to their patient's research status with nil identifiers to distinguish research participants from non-research participants undergoing TAP.

Six months post randomisation, participants attended the site for Time 2 data collection.

2.4 Safety

Patients randomised to waitlist control and scoring high (severe to extremely-severe) on self-reports of emotional distress (DASS) were encouraged to visit their GP and engage with a mental health professional. Patients consented to the research officer contacting their GP to advise on levels of distress and recommendation for community-based psychological support.

2.5 Allocation groups

2.5.1 Intervention - Treatment Access Pathway (TAP)

The TAP provides an entry point for routine, non-urgent chronic pain patients who may benefit from a multidisciplinary approach to active self-management of chronic pain without needing a pain medicine physician assessment. Traditional access to multidisciplinary pain management programs required an initial assessment by a pain medicine physician whereas TAP entry is by attendance at a group education session (Pain Service Introduction), during which allied health clinicians broadly define the philosophy of self-management and patients decide if they wish to engage in the treatment program. A group-based assessment day (Choose your Path) is then scheduled at which patients are provided with education on factors that may contribute to their pain experience and information on available treatment options. Patients are prompted at key points by clinicians facilitating the group to undertake structured self-assessment and develop their individual treatment program.

Treatment options include low and medium intensity multidisciplinary pain management programs (PACE and Bounce Back), group-based aquatic physiotherapy, and a mindfulness program. Individual components include assessment and treatment with allied health clinicians (physiotherapists, occupational therapists, psychologists, pharmacists). Patients have the option to self-discharge after this group-based assessment if they do not believe the program will meet their needs. . After 6 months on the treatment program, patients are contacted to review progress (Discharge Review Clinic) and if no further treatment is required, the patient is discharged from the TAP (see Figure 1 and Table S1). In the context of a shared care model, the patient's GP maintains medical oversight of the patient for the entire treatment program.

Allied health clinicians lead the TAP and work to an expanded scope, which refers to clinical specialists with an extended scope of practice i.e. working beyond the recognised scope of practice of the profession of interest in innovative or non-traditional roles (McPherson et al., 2005). In 2014, Queensland's Department of Health recognised and prioritised the need for the health service to have a strong and modern allied health workforce (Allied Health Professions' Office of Queensland 2014). Extended scope provides the basis of recommended interdisciplinary practice in health care delivery (The Allied Health Professions' Office of Queensland 2016) and is represented in the TAP with allied health clinicians being first-contact clinicians, referring to other professionals within TAP and taking responsibility for patient discharge. Additionally, the TAP supports trans-disciplinary skill sharing in both the introductory education session and the group assessment day. From a service model perspective, the group format for education sessions and patient assessment days supports increased access to the pain management service utilising existing allied health staffing levels (program components and direct care time per clinician are provided in Table S1). Traditionally, pain management programs were prescribed for suitable patients. TAP focuses on mutually collaborating with patients to create their own individualised treatment plan and make choices throughout the program. Patients are supported to make informed decisions, choose to participate in the self-management program or make a choice to self-discharge at any time.

[Please insert Figure 1 about here]

2.5.2 Control – Waitlist group

Following the initial research appointment, participants randomly assigned to the control group were advised they will remain on the waitlist for a period of 6 months and encouraged to continue with their "usual care" pain management regime. . In Australia, most people see their GP for pain management. However, they may engage a range of health professionals in their treatment (AIHW 2020). This is consistent with the current study where GPs retained medical oversight and participants were free to engage in any treatments they chose during the waitlist period.

At the 6-month date, participants in the waitlist group were invited to attend the introductory session to commence their treatment program.

2.6 Measures

Participants completed a battery of self-report and objective performance measures immediately prior to randomisation (Time 1) and six months thereafter (Time 2). Outcome domains and measures were selected based on the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) recommendations (Dworkin et al., 2005; Taylor et al., 2016; Turk et al., 2003). Additionally a number of these measures form an essential component of the electronic Persistent Pain Outcomes Collaboration (ePPOC) data collection undertaken by specialist pain management services and reported on annually in an Australian national outcomes registry (Tardif et al., 2016; Tardif et al., 2019).

2.7 Primary outcome measure

2.7.1 Modified BPI: Pain Interference

The 7-item Brief Pain Inventory: Pain Interference (BPI-PI) scale was used to assess interference of pain with daily activities (Cleeland and Ryan 1994). The BPI-PI is an IMMPACT recommended core outcome measure for chronic pain clinical trials, with extensive evidence supporting validity and reliability in patients with chronic non-cancer pain (Mendoza et al., 2006; Turk et al., 2003). The BPI-PI ranges from 0-10, with one-point considered clinically significant change (Dworkin et al., 2008).

2.8 Secondary outcome measures

2.8.1 Modified BPI:Pain Severity scale

The 4-item Brief Pain Inventory: Pain Severity (BPI-PS) scale was used to measure the intensity of pain sensation (Cleeland and Ryan 1994). The BPI-PS is an IMPPACT recommended core outcome measure for chronic pain clinical trials, with extensive evidence supporting validity and reliability in patients with chronic non-cancer pain (Mendoza et al., 2006; Turk et al., 2003). The BPI-PS ranges from 0-10, with two-points or 30% considered to be clinically significant change (Dworkin et al., 2008).

2.8.2 DASS-Depression

The 7-item DASS- Depression scale measures dysphoric mood, including inertia and hopelessness using a rating scale from 0 –3. Higher scores on DASS-Depression subscale indicate lower mood (Lovibond and Lovibond 1996) . This scale has no somatic items, supporting its use with chronic pain patients (Taylor et al., 2005) and has strong psychometric properties (Antony et al., 1998; Henry and Crawford 2005; Wood et al., 2010). Clinical significance on the DASS subscale requires a change of 5 or more points and a move to a different severity category.

2.8.3 PGIC (Patient Global Impression of Change)

Using a 7-point numerical rating scale from 1 – Very much improved to 7 – Very much worse, the Patient Global Impression of Change (PGIC) scale quantifies patient’s perception of improvement or deterioration over time (Guy 1976). PGIC scales are an IMMPACT recommended core outcome measure for chronic pain clinical trials (Dworkin et al., 2005),

have been validated in the chronic pain population (Ferguson and Scheman 2009; Perrot and Lantéri-Minet 2019; Rampakakis et al., 2015; Scott and McCracken 2015) and are seen as a means to improve translation of research findings into clinical practice (Kamper 2009).

2.8.4 NIH Toolbox – Motor – 2MWT (2-minute walk test)

The NIH Toolbox for Assessment of Neurological and Behavioural Function is a standard set of valid and reliable tools for objectively assessing motor function (National Institutes of Health (NIH) and Northwestern University 2015). NIH Toolbox measures have been normed and validated across the lifespan in participants aged 3-85 (Reuben et al., 2013). Endurance refers to how long a person can perform an activity requiring cardiopulmonary function, biomechanical and neuromuscular function and is measured by the NIH Toolbox 2-Minute Walk Endurance Test.

2.8.5 CPAQ – Pain Willingness and Activity Engagement

The Chronic Pain Acceptance Questionnaire (CPAQ) consists of 8 items with two sub-scales, pain willingness and activity engagement. Questions are rated on a scale from 0 to 6. The validity of the CPAQ-8 has been demonstrated in cross-sectional studies (Baranoff et al., 2014; Fish et al., 2010; Vowles et al., 2016). The CPAQ-8 has also demonstrated sensitivity to change pre/post treatment in a variety of RCTs and psychometric reviews (Cederberg et al., 2016; Rovner et al., 2013; Sullivan et al., 2018). Sullivan et al., (2018) demonstrated significant patient outcomes using the CPAQ-8, 6 months post web-based pain intervention. As part of an assessment of the CPAQ-8 psychometric properties, Rovner et al., (2013) established the CPAQ's reliability, validity and sensitivity comparing pre- and post- acceptance-based rehabilitation intervention.

2.8.6 Descriptive measures

The following ancillary health status measures were collected for descriptive purposes: DASS-Anxiety (Lovibond and Lovibond 1996), DASS-Stress (Lovibond and Lovibond 1996), Pain Self-Efficacy Questionnaire (PSEQ) (Nicholas 2007), Pain Catastrophising Scale (PCS) (Sullivan et al., 1995), Tampa Scale of Kinesiophobia (TSK) (Tkachuk and Harris 2012), medication list transformed into the oral daily morphine equivalent (OMEDD) (Faculty of Pain Medicine ANZCA 2019; Svendsen et al., 2011); and self-reported health care utilisation (i.e. attending health practitioners including GP, specialists, allied health (external to IPPC) and hospital emergency) in the past 3 months.

2.9 Statistical analysis

Using a one tail t-test of independent groups at a significance level of $p<0.05$ and a power of 80% with an effect size of 0.4, G*Power (Faul et al., 2007) we estimated that a sample size of N=156 (78 in each group) was required to reject the null hypothesis.

Given the large proportion of participants without data at the 6 months follow up time point (35%) (Figure 2) we were not able to directly conduct reliable ITT comparisons. However, if we use multiple imputation to impute realistic values for participants with missing BPI pain interference and BPI pain intensity at 6 months, we obtain the following "ITT" results: BPI

pain interference: Effect size -0.47 (95% CI -1.2, 0.22), P=0.18, BPI pain intensity: Effect size -0.24 (95% CI -0.88, 0.40), P=0.46.

Consequently, to increase reliability, we performed per protocol analyses to quantify the effect sizes in participants who completed the trial. We recognised that if the trial had a positive effect the overall policy impact of the intervention may be less than we estimated from the per protocol population. Limiting analysis to this population meant that the formal statistical comparison had to be undertaken on data at the 6-month follow up time-point and included only those patients that complied with the protocol up until that time-point.

Analysis of covariance (linear regression with adjustment for baseline endpoint measures) was used to compare the primary and secondary outcome measures between groups. Results are reported as mean difference between groups with 95% confidence intervals.

Additional measures collected at baseline and 6 months were compared between groups descriptively.

3 Results

3.1 Recruitment and participant flow

The flow of patients through the study is shown in Figure 2.

Of 197 people who agreed to participate in the trial, 181 attended Time 1 data collection; the remaining 16 did not attend and did not proceed with the research study. Ninety participants were randomised to the intervention and 91 to the waitlist group. One participant was mis-randomised (with nil data collected) and was removed from the analysis.

After study commencement, a total of 46 participants (25%, intervention = 24, control = 22) withdrew from the study. A further 37 participants (20%, intervention = 25, control = 12) were lost to follow up. These participants did not attend their 6-month follow up appointment and multiple attempts to contact them were unsuccessful. At 6 months post recruitment, a full range of outcome measures were collected from 42 participants in the intervention group and 55 in the control group. A further 20 (8 Intervention and 12 Control) declined to complete the full range of Time 2 measures on site but completed the Modified-BPI over the phone.

Participants were asked to provide a reason for withdrawing if they explicitly requested removal from the study. Reasons given included improved pain management and no longer needing the service, moving away from service area /or unable to attend due to transport issues; not seeing benefit in the program; and unable to participate due to other health issues or social stressors whilst a further portion declined to provide a reason. A number of participants (intervention = 18, control = 10) withdrew from the study only and continued treatment or waitlist intervention. The time commitment (2 hours per data collection session) may have impacted on these participants withdrawing from the research component only. Available information on participants' reasons for discontinuing the study is contained in Figure 2.

[Please insert Figure 2 about here]

There was no evidence of baseline differences between the per-protocol population and the dropouts for the primary and secondary outcome measures (Table S3). In addition, the 20 patients who did not complete on site Time 2 measures but provided data via phone on the primary outcome and first secondary outcome at 6 months are described and reported by group in Table S4.

3.2 Baseline data

Table 1 shows the demographic and clinical characteristics of all per-protocol patients (see Table S2 for all included patients by treatment group allocated).

There was a 60:40 ratio of female to male patients with most married or in a relationship. Frequently identified pain locations were lower back, shoulder, neck and arm with pain lasting for more than 5 years and caused by injury or with no obvious cause. A notable proportion had comorbid depression and/or anxiety. There were no clear differences between groups except for a higher proportion of control group patients (31% compared to 17% in intervention group) who had previously been to a pain clinic.

To establish the representativeness of participants, we compared their data with those from an Australian national outcomes registry for patients attending Australian specialist pain centres (Tardif et al., 2019). A higher proportion (55%) of patients in the intervention group were unemployed compared with reference (39%) (Nicholas et al., 2019). In the intervention group, a higher number of patients reported the cause of their pain as unknown (29%) or due to illness (22%) when compared with other Australian pain patients (18% and 11% respectively) (Nicholas et al., 2019). The average number of medical conditions and pain sites in the intervention group was comparable with that documented in the data registry (Tardif et al., 2019).

[Please insert Table 1 about here]

3.3 Primary and secondary outcomes

[Please insert Table 2 about here]

Patients who remained in the TAP intervention group for 6 months experienced an average 0.9 (95% CI 0.2,1.6). unit decrease on the primary outcome measure of pain interference (Table 2). Twenty-two (52%) participants in the intervention group and 18 (33%) in the control group experienced clinically significant pain interference decreases (> 1 unit) at 6 months (Figure S1). There was evidence of an increase in walk distance over 2 minutes in the TAP intervention group by 5.4 meters (95% CI 1.7, 9.1); and 45% of participants in the intervention group reported via the Patient Global Impression of Change that they were very much or much improved compared to 8% for the control group (Figure S2 shows distribution of individual patients). Other secondary outcomes showed mean changes that were not significantly different (Table 2). The spread of OMEDD scores and health care utilisation rates at Time 1 and Time 2 is shown in Table S5.

3.4 Harms

No adverse events were recorded during the study period and a review of the service's routine risk and incident management recording system revealed no documented events linked to study participants.

4 Discussion

4.1 Main findings

This study compared an innovative expanded scope allied health model of care (TAP) for chronic pain management to a waitlist control. As hypothesised, patients engaged in TAP had a statistically significant reduction in pain interference at 6 months, with more than half reporting clinically significant improvement, compared with one third in the control group. Additionally, statistically significant improvement in walking endurance was observed in the TAP group along with significant ratings of global impressions of change compared to the waitlist group.

The study was conducted within a public tertiary pain centre, which is an "end of the road" service caring for patients who have pain that has not been satisfactorily controlled by care delivered by primary care pain services. It was a RCT with minimal exclusion criteria to enhance the sample's representativeness of tertiary care patients and maximise external validity (Glombiewski et al., 2010). Whilst an attrition rate of 20% was factored into the sample size calculation, the observed rate was much higher at 53% and 40% for the TAP and waitlist groups, respectively. These rates and the lack of follow-up data prevented meaningful estimates of the impact of the intervention in the intention to treat population. The results seen in the per protocol analyses confirmed statistically and clinically significant improvements in pain and function but the high dropout rates limit the generalizability of these results.

Systematic reviews report dropout rates in chronic pain clinical trials from 27 to 90% (Hassett and Williams 2011). Studies of routine service delivery indicate between 40%-50% of patients do not complete treatment (Angst et al., 2010; Cedraschi et al., 2004; Davies et al., 2011; Jeffery et al., 2011; Meineche-Schmidt et al., 2017) with a recent systematic review documenting between 10 and 51% dropout rates in interdisciplinary pain management (Oosterhaven et al., 2019b). Accordingly, whilst the attrition in the present study was high, it was in-line with that observed in similar patient populations. The high rates of withdrawal seen in many intervention trials in chronic pain make us question the relevance of intention to treat analysis, often viewed as the gold standard for randomised trials. Perhaps in this challenging population the focus should be more on establishing efficacy in the per protocol population and investigating methods to improve retention rates and adherence to effective programs.,

Whilst a proportion of the participants offered reasons for withdrawal, a similar proportion disengaged for unknown reasons. Research on pain program dropout rates suggests unmet patient expectations as a major cause (Turk and Rudy 1990). A comprehensive description of the intervention at recruitment as well as patient choice of treatment components and intensity were attempts to mitigate potential mismatch of patient expectations. In this study, participants' baseline characteristics indicate low self-efficacy, high depression and catastrophic thoughts which together with treatment dissatisfaction have been associated with attrition from treatment (Coughlan et al., 1995; Davis and Addis 1999; Glombiewski et al., 2010; Jack et al., 2010;

Mintz 2013; Richmond et al., 1999). The comprehensive assessment protocol involving on-site data collection, may have also contributed, despite the provision of gift vouchers to offset attendance costs (Edwards 2010). Future chronic pain clinical trials may benefit from higher attrition assumptions when estimating sample size along with patient stages of change measures (Katz et al., 2019), adherence, intensity and dose effect analyses (Amer-Cuenca et al., 2020; Nicholas et al., 2012; Samwel et al., 2009) and treatment arms based on patient characteristics (e.g., current/past compensation claim) to lessen attrition from the study (Backryd et al., 2018; Oosterhaven et al., 2019a; Westman et al., 2011).

The present study sought to examine the effectiveness and safety of an innovative model of care for tertiary-referral pain centre patients. Whilst not the specific intention to advocate for this intervention ahead of existing models, comparisons to current alternatives are useful to contextualise the intervention's merit.

Tardif et al., (2019) summarised data collected from 67 chronic pain services across Australia and New Zealand during the period of 1 July 2018 to 30 June 2019. The majority (62%) of Australian pain centres are hospital based and meet criteria for either Level 1 or Level 2 facilities, both of which require a medically trained person to monitor the services provided and a minimum of a pain medicine physician and two non-physician healthcare disciplines. (www.apsoc.org.au/Level-1-Facility, www.apsoc.org.au/Level-2-Facility). Other Australian contributors range from private multidisciplinary practices managed by pain medicine physicians to single healthcare providers. The 20 pain centres representing New Zealand are all non-hospital based. Therefore, the contributing pain services incorporate a variety of models of care. A total of 21,364 patients completed entry questionnaires during the period and 5,408 were assessed at the completion of their pain management treatment, Based on this report, patients receiving treatment from existing models of care experience BPI-PI reductions of 1.5 points on average, compared to 1.3 points for TAP (Tardif et al., 2019).

The proportion of patients experiencing clinically significant improvement is similar nationally (57%) and for TAP (52.0%). Pain interference outcomes for tertiary-care chronic pain in scientific literature are mixed. A number of reports show comparable results relative to TAP (Davies et al., 2011; Samwel et al., 2009; Scriven et al., 2019) but there is also evidence of superior reductions in pain interference (Smith et al., 2016b).

Whilst not statistically significant, TAP patients showed an average reduction in BPI-PS of 1.0 point which is consistent with the national data (Tardif et al., 2019). Nationally, 29% of patients show clinically significant improvement (>2 point changes) in pain intensity compared with 26% in the current study. Systematic reviews and meta-analyses focusing on tertiary level models of care report small, statistically significant changes in pain intensity (Du et al., 2017).

The average change of 4 points in depression score for the intervention group is similar to the national data (4.5 average change) and is trending in the same direction. Nationally, 42% of patients reduce their depression score by 5 or more points and 32% shift into a lower category of severity (Tardif et al., 2019) whilst the present study achieved 45% and 26% respectively. The between groups analysis in the present study did not find a statistically significant reduction in depression, in contrast to reported outcomes from studies of tertiary level models (Davies et al., 2011; Katz et al., 2019; Nicholas et al., 2012).

Patients suffering from chronic pain display altered spatiotemporal gait parameters (Kirmizi et al., 2019) impacting on speed and quality of walking (Clarke and Eccleston 2009) with proposed mechanisms including distorted body schema (Moreira et al., 2017) and exposure to the threat of pain in avoidance of perceived negative consequences (Asmundson et al., 1999). Additionally, aerobic function and therefore overall fitness could be impacted on by the nature of the patient's pain condition.

TAP was shown to signficantly improve objective physical function (i.e., endurance) as measured by the 2 minute walk test. Whilst previous studies have included objective measures of physical function (de C Williams et al., 1999; Williams et al., 1996), lack of consensus on core objective outcome measures limits the ability to contrast the physical functional impacts of the TAP to past research.

Close to one third of patients (31%) in the intervention group reported improved overall wellbeing. Whilst lower than normative data (74%), it is positive towards TAP when compared with 11% for the waitlist group.The statistically significant change in patient's global impression of change comparative to waitlist is consistent with existing studies, often in the absence of significant primary measures (Bourgault et al., 2015; Davies et al., 2011; Scriven et al., 2019). Patient ratings of change correlate with improved physical function (Cedraschi et al., 2004; Scott and McCracken 2015) and are useful personalised markers of patient satisfaction with program effectiveness (Birnie et al., 2012).

4.2 Implications for practice

Whilst a number of studies report positive clinical outcomes from allied health led models of care (Daly-Eichenhardt et al., 2016; Smith et al., 2016a; Wiklund et al., 2018; Yu et al., 2020), this is the only RCT to-date that tests effectiveness of an expanded allied health model of care operating at a tertiary level pain service without the oversight of a pain medicine physician. Initial evaluation compared the intervention to a waitlist control to understand the efficacy of TAP and to ensure this is a safe alternative model of care. There was no harm incurred by participants and results suggest patient gains were made, supporting potential future research comparing TAP to a parallel active intervention.

In view of the widespread burden of chronic pain and the scarce pain medicine physician resources, alternative tertiary models of chronic pain management are needed. Whilst alternatives exist in primary care and online (Dear et al., 2013; Furlan et al., 2019; Joypaul et al., 2019; Schultz et al., 2018; Smith et al., 2019), there are few Australian alternatives available for complex patients requiring tertiary level care. The intervention, TAP, has shown to be an effective alternative model of care. The innovative aspects of TAP have addressed the pain medicine specialist scarcity problems, applying a GP shared-care model, efficient use of patient group-based interventions, utilisation of allied health staffing with expanded scope, first contact and discharge responsibilities and patient self-selection of treatment.

Initial group education and assessments in tertiary-referral chronic pain clinics led by pain medicine physicians have improved access, reduced service costs, increased patient satisfaction and been shown as equivalent to resource-intensive individual assessments (Davies et al., 2011; Smith et al., 2016b). The TAP is innovative in supporting extended scope for allied health to lead these first-contact sessions. Additionally, the TAP encourages patient engagement in treatment groups which is significant as health-professional-led groups are more beneficial than

individual treatments in increasing social interaction and confidence, improved quality of life and reducing pain (Carnes et al., 2012; Meineche-Schmidt et al., 2017; Rose et al., 1997; Turner-Stokes et al., 2003).

The TAP model of care supports patient choice in treatment selection. This is recommended particularly for chronic illness where a range of different treatments, dose and intensity are available (Coulter 2010; Joosten et al., 2008). Models of patient choice in chronic pain have been associated with improved pain related function (Peterson et al., 2018). Chronic pain patients bring a unique understanding of their pain situation, whilst clinicians within the TAP program offer information on the effectiveness and benefits of specific treatments, enabling patients to make informed choices (Marshall and Bibby 2011).

Traditional shared care medical models involve a GP and medical specialist. The TAP model of care operates with GPs working in tandem with allied health practitioners to manage their patients' chronic pain whilst retaining medical oversight. Initial feedback from GPs indicated high levels of satisfaction with the model [Vandermost, unpublished] (Kennedy et al., 2015).

4.3 Limitations of this work

We have already noted several significant limitations. Importantly, ,the high attrition rate led to application of per-protocol analyses and underpowered primary outcome measure analyses based on the original sample size calculation. Accordingly, the effectiveness and safety findings need to be interpreted with caution. The reduced sample size may have contributed to non-detection of significant change in pain intensity, depression, pain acceptance and activity engagement, despite consistent trends towards improvement. Second, the lack of an active control, whilst suitable for this initial investigation, did not control for the possibility of differences in expectations between conditions and limits inferences regarding the merit of the TAP compared to pain specific care models. Third, the TAP is an individualised package of care options that reflects real-world healthcare delivery. However, the present study was not designed to ascertain whether specific components or treatment intensities were associated with improvement. Future research with a larger sample, enhanced attrition management strategies, and active treatment are warranted to extend understanding regarding the utility of TAP for patients unable to access timely traditional pain medicine physician-led tertiary care.

5 Conclusion

In summary, this study suggests that an expanded scope allied health model of care prioritising patient choice and group-based interventions may provide modest benefits for chronic pain patients. Given the findings, this model of care warrants further investigation as a viable alternative for health services where pain medicine physician resources are non-existent or scarce resulting in limited patient access The model of care can be introduced as a standalone model in health services or as an additional pathway to support existing models of care.

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Author Contributions

- Margaret Vandermost led the study conception and design, oversaw data collection, input into study analysis plan, data analysis and interpretation and prepared manuscript.
- Karl Bagraith provided input on the study conception and design, data preparation and manuscript drafting.
- Hannah Kennedy provided input on the study design and led data collection.
- Darren Doherty provided input on study design and manuscript.
- Simon Kilner provided input on study design and manuscript.
- Michele Sterling provided input on study design, participant flow and manuscript.
- David Henry provided input on study analysis plan, reviewed data analysis and interpretation of results and manuscript drafting.
- Mark Jones provided input on study analysis plan, led data analysis, interpretation of the results and manuscript drafting.
    - The manuscript was critically reviewed and approved by each author.

Conflict of interest statement

The authors have no conflicts of interest to declare.

Trial registration

The study was registered on ANZCTR (Trial ID: ACTRN12617001284358).

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