

# Can an allied health expanded scope Treatment Access Pathway (TAP) improve health outcomes for people with persistent pain? Study protocol for a pragmatic randomised controlled trial

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## Study protocol

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## Abstract

Background Persistent pain is a public health crisis. Demand for services frequently exceeds supply and many individuals miss out on timely treatment resulting in longer than recommended wait times. The Interdisciplinary Persistent Pain Centre (IPPC) (Queensland, Australia) implemented a Treatment Access Pathway (TAP), an allied health first point of contact model of care to allow patients access to empirically supported allied health treatment without Pain Specialist assessment. The primary aim of this research project is to understand the clinical and cost effectiveness of TAP in a real-world setting. Method: Participants referred to the IPPC are randomly allocated to treatment or waitlist control groups and self-report and objective physical outcome measures are collected at baseline and 6 months' time. A total of 196 patients will be recruited for the study (treatment group, n=98 and control group, n=98) to allow a 20% attrition rate to gain 156 participants for the study. Discussion: The results of this study will determine the clinical outcomes and cost effectiveness of the TAP as a model of care to inform future clinical decision making and program development. Ethics approval was provided by the Research Governance Office at Gold Coast Hospital and Health Service (RGOGCHHS) on the 19/10/2016 (HREC/16/QGC/156).

## Background

Persistent pain (i.e. pain lasting >3 months) affects one in five Australians(1) and costs the Australian economy over \$34 billion/annum(2). Persistent pain is at the core of the Australian National Health Priority Area (Arthritis and Musculoskeletal Conditions), with low back pain alone accounting for more disability in Australia than any other health condition(3). Expert consensus and a growing body of research recommends that best-practice pain management often requires coordinated interdisciplinary assessment and management(4, 5). This biopsychosocial approach in treating persistent pain has led to the creation of multidisciplinary and interdisciplinary treatment centres(6). Traditionally, tertiary-referral Multidisciplinary Pain Centre (MPC) entry and exit is contingent on Pain Specialist assessment. However due to scarce Pain Specialist resources, demand generally exceeds capacity, resulting in up to 80% of patients missing out on MPC treatment(4) and unacceptable waiting times to access services (7).

Systematic reviews provide evidence that intensive multidisciplinary biopsychosocial rehabilitation with a functional restoration approach improves pain and function for adults with chronic pain(8). Further research has demonstrated that such programs can reduce pain intensity and disability at short term follow up compared to no treatment and usual care(9). Clinical outcomes are typically modest(10), although studies have suggested that treatment in multidisciplinary pain centres may produce billions of dollars in savings at the population level in terms of healthcare expenditure and indemnity costs(11).

To improve access for waitlisted patients the Gold Coast Interdisciplinary Persistent Pain Centre (IPPC) (Queensland, Australia) designed and piloted an innovative Treatment Access Pathway (TAP). TAP utilises allied health and nursing staffing, within the context of a GP shared care model, to provide an MPC entry point for non-urgent patients that is not contingent on receipt of a Pain Specialist assessment. TAP is an allied health and nursing expanded scope of practice model of care with full-scope(12) (first-contact, referring to other professionals, criteria-led discharge) and extended-scope (trans-disciplinary skill sharing assessment and discharge) clinics(12) (Figure. 1).

The investigators have previously reported that following TAP implementation, waitlisted IPPC referrals reduced from 950 (Apr-14) to 225 (Sep-15) with service entry waiting time reducing from 4 years to 6 months(13). It was also reported that over 95% of patients were deemed suitable for TAP by their GP. At discharge 51% and 29% of patients were 'very satisfied' or 'satisfied' with TAP, respectively. Pilot data (n=42) suggests TAP significantly ( $p<0.05$ ) improves physical function, pain, mood and HRQOL (Cohen d: 0.32 – 0.68)(14). Over 50% of TAP patients were discharged without necessitating pain specialist input. However further research is needed to address unanswered questions in the literature.

Growing evidence suggests that certain groups of patients may benefit from multidisciplinary treatment more than others(6), however there is insufficient evidence to recommend one treatment modality over another(10). Additionally, there are no recent studies on cost effectiveness of interdisciplinary rehabilitation in persistent pain (15). Accordingly, it remains unclear whether TAP as an overall model of care improves health outcomes and is a treatment the Australian public is likely to fund (i.e., is the cost of delivery below the Australian willingness to pay ratio of \$73,000/gained quality adjusted life year (QALY) (16).

### Aims, Objectives and Hypothesis

#### Aims of the Study

The primary aim of this research project is to increase understanding of the effectiveness of TAP as a multidisciplinary treatment model of care for persistent pain on a range of objective and self-reported patient measures. A secondary aim is to investigate the willingness to pay per quality-adjusted life year ratio of TAP patients for a multidisciplinary treatment model for persistent pain.

## Objectives of the Study

The proposed study has two separate study areas (see Figure 2). The first part of the project will compare treatment from day 1 of referral (*TAP without wait*) to a waitlist control (*Waitlist*) on a variety of self-report health outcomes and objective physical measures. The second part of the study will evaluate the clinical effectiveness of TAP in regard to likely real-world delivery (i.e., after waiting 6 months for treatment; *TAP with wait*). Both measures will provide data regarding cost of TAP versus the standard Australian willingness to pay rate for gains in health-related quality of life (TAP OOS x NWAU compared with willingness to pay/QALY ratio).

## Hypotheses of the Study

### Study 1

Primary Hypothesis: Treatment Access Pathway (TAP) patients at 6 months will have clinically important changes in objective physical function and self-report outcome measures (pain, mood, acceptance, self-efficacy, catastrophising and HRQOL) compared with waitlist patients.

Secondary Hypothesis: The TAP delivery cost/quality adjusted life year gained will be less than \$73,000/QALY (16, 17).

### Study 2

Primary Hypothesis: There is no significant difference in clinical outcomes (changes in pain, objective physical function, mood, acceptance, self-efficacy, and HRQOL) between patients that wait (6 months) and do not wait for TAP.

Secondary Hypothesis: There is no significant difference in cost-effectiveness (TAP delivery cost/quality adjusted life year gained) between patients that wait (6 months) and do not wait for TAP.

## Methods

### Study Design

A pre-post, waitlist control, pragmatic randomised controlled trial design will be employed. Comparison will be made with a cross over waitlist group (TAP with wait group) (18).

### Study Setting.

Participants will be patients referred to the Gold Coast Interdisciplinary Persistent Pain Centre (IPPC; a tertiary-referral public pain centre).

### Participants and eligibility criteria

Participants will be eligible to be included in the study if they are greater than 18 years of age, with persistent non-cancer pain lasting longer than 3 months, have proficient written and spoken English, non-urgent referral (i.e to be seen within 12 months), and be deemed suitable for TAP by their GP. Patients will be excluded if they have a medical/psychiatric condition that would prevent TAP engagement, be scheduled for surgical treatment related to their pain condition within next 6 months or have engaged with a pain service within the last 12 months at the time of recruitment.

### Recruitment, Blinding and Randomization

By way of a measure against research bias, an independent research assistant will be used to contact potential participants from the IPPC waitlist, consent them to the research, and complete randomization. This will ensure that clinicians who are associated with the delivery of TAP are blinded to participant group allocation. The research assistant will record socio-demographic variables and collect outcome measures (Time 1 (T<sub>1</sub>)). Participants will then be randomized to either the treatment (*TAP without wait*) or control (*TAP with wait*) group. Randomization will be achieved through independent external automated randomization service(19).

Participants are provided a \$20 AUD gift certificate for their time. Participants can withdraw from the research or from treatment at any point. At time of consent, participants are provided details to the Gold Coast Hospital and Health Service research should they wish to make a complaint independent from the study.

## Procedure

The *TAP without wait group* will enter the TAP pathway (Figure 1) from referral (bypassing waitlist) and will have access to available treatments (Appendix A). Participants allocated to the Waitlist group, will remain on the waitlist at T<sub>1</sub> and wait 6 months (standard waitlist time) before entering the TAP pathway. At six months (T<sub>2</sub>), outcome measures will be re-collected for both groups. At this point, participants in the Waitlist group will have access to the treatment program. At 12 months post T<sub>1</sub> (T<sub>3</sub>) the Brief Pain Inventory outcome measure will be re-administered to both groups (Figure 2).

## Treatment Measures

Patient outcomes at T<sub>1</sub> and T<sub>2</sub> will be recorded using a battery of objective and self-report measures that are aligned with the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) recommended core outcome domains for clinical trials investigating the efficacy and effectiveness of treatments for persistent pain(20). The Brief Pain Inventory outcome measure will be recorded at T<sub>3</sub>.

## Objective Measures

This study will use the National Institutes of Health (NIH) Toolbox for Assessment of Neurological and Behavioural Function, a standard set of valid, reliable and royalty-free tools for objectively assessing cognitive, emotional, motor and sensory function (Table 1)(21).

## Self-Report Measures

Data will be collected and stored using REDCap (Research Electronic Data Capture)(22). REDCap is a secure web application designed to support data capture for research studies. Self-report measures collected at T<sub>1</sub> and T<sub>2</sub> are listed in Table 2. Only the Brief Pain Inventory will be collected at T<sub>3</sub>.

DASS(23) PCS(24) PGIC(25) PSQ(26) CPAQ(27) PROMIS(28)

## Statistical Considerations and Data Analysis

### Power analysis

The G\*Power statistical package was used to complete A-priori power analysis to determine the necessary sample size (*N*) of the study(29). Preliminary clinical data (unpublished) of the outcome measures shows a range of effect size between 0.3 (Depression) and 0.68 (Pain Acceptance) (Figure 3). 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 (moderate range) a sample size of  $N = 156$  (78 in each group) will be required to reject the null hypothesis. A total of 196 patients will be recruited for the study (treatment group,  $n=98$  and control group,  $n=98$ ) to allow a 20% attrition rate to gain 156 participants for the study.

## Statistical Methods

The analyst will be masked to group allocation. Comparisons will be made between pre-post changes in outcomes (see pre/post measures) for the two groups (i.e. 'TAP without wait' vs 'TAP with wait'). Measures at 6 months will be analysed using a linear mixed model(30) (choice based on Akaike Information Criteria),(31) with group, subjects and baseline measures as fixed factors, a random effect and covariate, respectively. SPSS (v22) will be used to analyse by intention to treat with two-tailed alpha set at 0.05 (32). A t-test ( $\alpha=0.05$ ) will be used to test whether mean pre-post changes in outcome variables are different between groups (i.e. TAP without wait' vs 'TAP with wait'). A t-test of independent groups will be used to examine whether the mean TAP costs/QALY gained is significantly different to \$73,000 (inflation adjusted value). REDCap and the NIH tool box require complete data sets from participants as a measure against missing data.

## Discussion

In this era of high demand for persistent pain services, alternate models of care are required to ensure patients have greater access to treatment(1, 2) . TAP represents a novel model of care with the ability to reduce waitlist times, decrease demand for pain specialist resources, while also maintaining patient satisfaction(13). The data provided from this study aims to establish patient outcomes after accessing treatment from TAP and assess its cost effectiveness.

It is hoped that the results will provide relevant stakeholders and policy makers evidence for such models of care, as we continue to see growth in demand. By advancing treatment options, patients will ultimately benefit by gaining hassle free access to empirically supported persistent pain treatments.

A pragmatic randomised control protocol has been proposed to gather data for this study as TAP is a model of care rather than a single prescriptive treatment. TAP provides a truly patient centred approach, allowing the individual to choose their own path through the program and the resources they wish to access. Furthermore, the array of treatments accessed by patients are rarely achieved in isolation, consisting of an inter-disciplinary approach. More traditional research paradigms would risk losing the pragmatic aspects of program delivery which exists in real world settings. As such, the results obtained will be directly relatable to established clinic operations.

While efforts will be made to maintain standardised delivery of services, natural variation in presenting styles and staff turnover are expected to occur during the data collection period. It is unclear how such alternations may affect participant engagement or outcomes. However, this variability adds to the pragmatic nature of this study as service delivery is usually provided by multiple services providers.

TAP represents an innovative approach to a common and ever-expanding problem for health services in Australia and abroad. This study will evaluate the clinical and cost effectiveness of an allied health and nursing expanded scope practice model of care to improve access to persistent pain management services. To the authors' knowledge this is the first formal evaluation of this kind of model of care in an Australian pain population. The burden persistent pain places on consumers and health services is only outweighed by its complexity. Further research is needed to establish a variety of treatments to improve access and improve patient quality of life.

## Abbreviations

IPPC – Interdisciplinary Persistent Pain Centre

TAP – Treatment Access Pathway

QALY – Quality Adjusted Life Year

MPC – Multidisciplinary Pain Centre

HRQoL – Health Related Quality of Life

OOS – Occasion of Service

NWAU – National Weight Activity Unit.

REDCap – Research Electronic Data Capture

RGOGCHHS - Research Governance Office at Gold Coast Hospital and Health Service

HPRS – Health Practitioner Research Scheme

AHPOQ – Allied Health Professions' Office of Queensland

## Declarations

Ethics approval and consent to participate

Ethics approval was provided by the Research Governance Office at Gold Coast Hospital and Health Service (RGOGCHHS) on the 19/10/2016 (HREC/16/QGC/156). Informed consent will be obtained from all study participants.

Protocol amendments

Protocol amendments if required, will be communicated in writing to the RGOGCHHS in the first instance for ethical clearance. Once approval has been received site approval and protocol publication updates will be submit notifying publisher of amendments made to this protocol.

Consent or assent

Informed consent will be obtained from all study participants. See recruitment section (Appendix B-D).

#### Confidentiality/ Access to data

Study data will be collected and managed using REDCap and NIH Toolbox(21, 22). Information will be initially collected in an individually identifiable manner while the participant is on the waitlist and while receiving IPPC treatment, as the information is used for clinical management. Participants will be assigned a participant number once they have consented to be recorded alongside their name and unit record number. Once all the participant's data has been collected, their data will be downloaded to a separate spreadsheet and referred to by participant number only. This spreadsheet will be stored on a secure shared network and only accessible by the research assistant. Data presented in any publication or presentation will be in a non-identifiable form.

REDCap was developed by a multi-institutional consortium which includes Griffith University and was initiated at Vanderbilt University. REDCap is installed within the Griffith University data centre. Griffith University data centres are secure facilities that are restricted areas with higher levels of security measures than standard facilities. Access to these facilities is governed by access policies.

Data recorded on electronic spreadsheets will be password protected with access to the research team only. After completion of the research project, both hard copy and electronic records (on USB) will be kept in a locked filing cabinet. Only the research team and IPPC manager will have access to the research filing cabinet. Records will be kept for the required period as mandated by Queensland Health records management.

#### Dissemination strategy

Following submission and acceptance of a manuscript for publication in a peer-reviewed journal (e.g. Clin.J.Pain), results will be disseminated via local media and local hospital and health service professional streams.

#### Competing interests

Authors confirm no competing interests that would unduly/unethically influence clinical objectivity or decision making.

#### Ancillary and post-trial care

While on the waitlist and completing TAP, a patient's GPs remain responsible for their medical care. At discharge the patient's GP is notified and care continues to be managed by the GP. At entry to the study, if a patient's scores on self-report measures indicate a high level of emotional distress, they will be encouraged to access support from their GP/mental health professional in the community.

#### Trial status

This trial is currently in the process of recruiting and collecting T<sub>1</sub> data. The protocol version number 2.3 dated October 2017. Recruitment commenced on 11/09/2017 and is expected to be finalised by 10/05/2019. T<sub>2</sub> and T<sub>3</sub> data collection is anticipated to continue through to 30/10/2019.

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## Figures

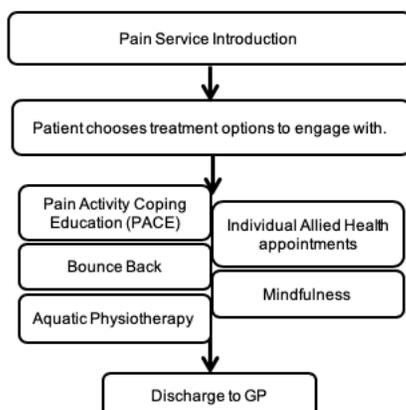


Figure 1

Treatment Access Pathway (TAP). An explanation of the various components of the pathway are detailed in Appendix I

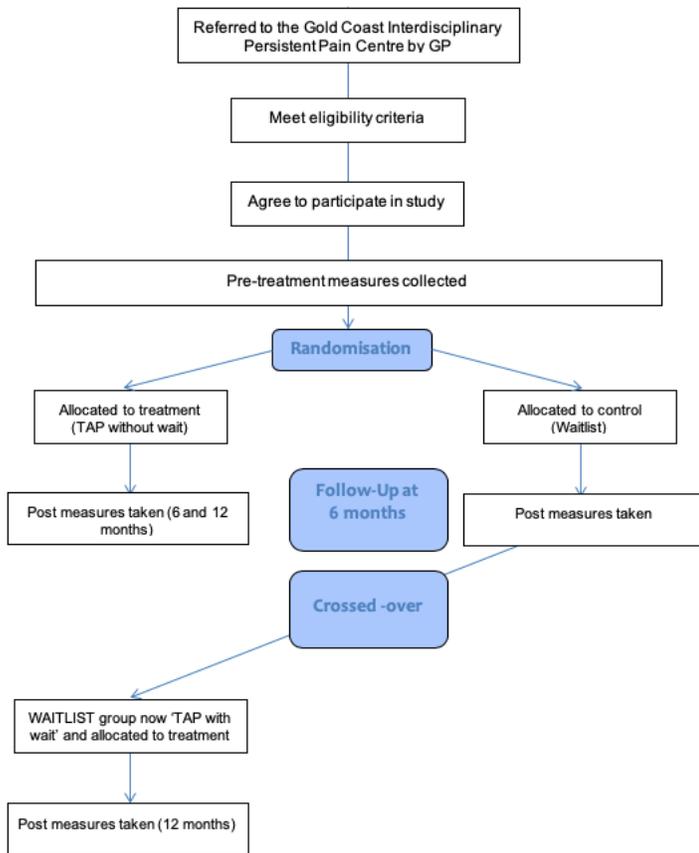


Figure 2

Participant flow diagram.

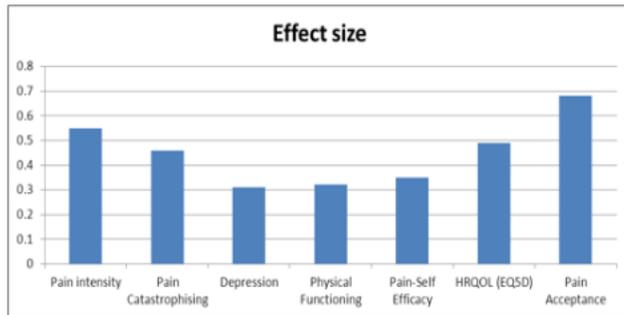


Figure 3

Effect size of relevant self-report measures determined by unpublished clinical data.

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Appendix A Components of the TAP treatment program.docx](#)
- [TAP RCT SPIRIT Figure.docx](#)
- [SPIRIT fillable checklist 15 Aug 2013.doc](#)