Nutrition's role in the management of chronic pain

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Statement of originality

I hereby certify that the work embodied in the thesis is my own work, conducted under normal supervision.

The thesis contains published scholarly work of which I am a co-author. For each work a written statement, endorsed by the other authors, attesting to my contribution to the joint work, has been included.

The thesis contains no material which has been accepted, or is being examined, for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made. I give consent to the final version of my thesis being made available worldwide when deposited in the University of Newcastle's Digital Repository, subject to the provisions of the Copyright Act 1968 (Cth) and any approved embargo.

Signed:

Name: Katherine Brain

Date: 31/12/2018

Thesis by publication

I hereby certify that this thesis is in the form of a series of papers. I have included as part of the thesis a written declaration from each co-author, endorsed in writing by the Faculty Assistant Dean (Research Training) attesting to my contribution to any jointly authored papers.

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Publications arising from this thesis

Brain K, Burrows TL, Rollo ME, Chai LK, Clarke ED, Hayes C, Hodson FJ and Collins EC. A systematic review and meta-analysis of nutrition interventions for chronic noncancer pain. Journal of Human Nutrition and Dietetics: The official journal of the British Dietetic Association. 2019; 32(2):198-225.

Brain K, Burrows TL, Rollo ME, Chai LK, Hayes C, Hodson FJ and Collins CE. The association between nutrition and chronic pain: a systematic review. PROSPERO 2019 CRD42017055420. Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017055420 (Appendix 1 & 2)

Brain K, Burrows T, Rollo ME, Hayes C, Hodson FJ, Collins CE. Population characteristics in a tertiary pain service cohort experiencing chronic non-cancer pain: Weight status, comorbidities, and patient goals. Healthcare (Basel). 2017;5(2).

Brain K, Burrows TL, Rollo ME, Thompson DI, Hayes C, Hodson FJ and Collins CE. Perceptions of tertiary pain staff on including nutrition support within current treatment: A qualitative study. SAGE Pathway [Under Review]

Brain K, Burrows TL, Rollo ME, Thompson DI, Hayes C, Hodson FJ and Collins CE. Exploring the attitudes and beliefs of nutrition's role in pain management through semi-structured focus groups with patients experiencing chronic pain. Healthcare [Under Review]

Brain K, Burrows TL, Rollo ME, Hayes C, Hodson FJ, Collins CE. The Effect of a Pilot Dietary Intervention on Pain Outcomes in Patients Attending a Tertiary Pain Service. Nutrients. 2019;11(1)

Presentations arising from this thesis

During my candidature, I presented results arising from this thesis at eight conferences. This has resulted in one topical session, three oral presentations, two rapid communication presentations and four poster presentations.

1. **Brain K**, Burrows T, Rollo M, Chai LK, Hayes C, Hodson F, Collins C. A systematic review and meta-analysis of nutrition intervention for chronic non-cancer pain. Australian Lifestyle Medicine National Conference. August 2018. Brisbane, Australia. Oral presentation.
2. **Brain K**, Burrows T, Rollo M, Chai LK, Hayes C, Hodson F, Collins C. A systematic review and meta-analysis of nutrition intervention for chronic non-cancer pain. Dietitians Association of Australia National Conference. May 2018. Sydney, Australia. Oral presentation.
3. **Brain K** (chair & presenter), Burrows T, Hayes C, Collins C. The why, what and how of nutrition for people experiencing chronic pain. Australian Pain Society and New Zealand Pain Society Annual Scientific Meeting. April 2018. Sydney, Australia. Topical session.
4. **Brain K**, Burrows T, Rollo M, Chai LK, Hayes C, Hodson F, Collins C. Nutrition interventions for chronic pain: A systematic review and meta-analysis. Australian Pain Society and New Zealand Pain Society Annual Scientific Meeting. April 2018. Sydney, Australia. Poster presentation.
5. **Brain K**, Rollo M, Burrows T, Hayes C, Hodson F, Collins C. The feasibility of including nutrition support within current tertiary pain services: A staff perspective. Dietitians Association of Australia National Conference. May 2017. Hobart, Australia. Poster presentation.
6. **Brain K**, Rollo M, Burrows T, Hayes C, Hodson F, Collins C. Perceptions of tertiary pain service staff on including nutrition support within current treatment. Australian Pain Society Annual Scientific Meeting. March 2017. Adelaide, Australia. Poster and rapid communication presentation.
7. **Brain K**, Rollo M, Burrows T, Hayes C, Hodson F, Collins C. The nutrition status of patients attending Hunter Integrated Pain Service. Dietitians Association of Australia National Conference. May 2016. Melbourne, Australia. Oral presentation.
8. **Brain K**, Rollo M, Burrows T, Hayes C, Hodson F, Collins C. Nutritional status of patients experiencing chronic pain: What do we know? Australian Pain Society Annual Scientific Meeting. March 2016. Perth, Australia. Poster and rapid communication presentation.

Additional publications co-authored during candidature

Chai LK, Burrows T, May C, **Brain K**, Wong See D, Collins C. Effectiveness of family-based weight management interventions in childhood obesity: an umbrella review protocol. JBI database of systematic reviews and implementation reports. 2018:14 32-39.

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Contribution statement

I was the sole PhD candidate responsible for this body of work presented in this thesis. I was involved in all aspects of this work and a summary of my contribution is outlined below.

Chapter 2: A systematic review and meta-analysis of nutrition interventions for chronic non-cancer pain

I was responsible for managing all stages of the systematic review. With the support of my supervisors I created the systematic review protocol. I then developed and ran the search strategy with the support of Ms Debbie Booth (Senior Research Librarian). My co-authors and I participated in: the title and abstract screening, full text screening, data extraction and risk of bias assessment. Using the results from the data extraction and risk of bias assessment, I synthesised the narrative results. I also prepared the data for meta-analysis and undertook the meta-analysis with the assistance of A/Prof Tracy Burrows. I drafted the full manuscript which was reviewed and approved by my supervisors and all co-authors.

Chapter 3: Population characteristics in a tertiary pain service cohort experiencing chronic non-cancer pain: Weight status, comorbidities, and patient goals

I drafted, submitted and obtained ethics approval from Hunter New England Health (15/07/15/5.01) and the University of Newcastle (H-2015-0266) with the support of my supervisors. I extracted and collated de-identified patient data from medical records. I then undertook data analysis and drafted the full manuscript where I presented the results I found from the analysis. The manuscript was reviewed and approved by my supervisors and co-authors.

Chapter 4: Perceptions of tertiary pain service staff on including nutrition support within current treatment: A qualitative study

I drafted, submitted and obtained ethics approval from Hunter New England Health (16/07/20/5.04) and the University of Newcastle (H-2016-0248) with the support of my supervisors. I developed the recruitment materials, questionnaire and focus group

protocol with the support of my supervisors and co-authors. I managed the recruitment and organisation of the focus groups. I acted as the primary moderator for the focus groups. I managed the transcription of the audio files which was conducted by an independent transcriber. I then analysed the quantitative and qualitative results and drafted the manuscript where these results were presented. The manuscript was reviewed and approved by my supervisors and co-authors.

Chapter 5: Exploring the attitudes and beliefs of nutrition's role in pain management through semi-structured focus groups with patients experiencing chronic pain

I drafted, submitted and obtained ethics approval from Hunter New England Health (16/07/20/5.04) and the University of Newcastle (H-2016-0248) with the support of my supervisors. I developed the recruitment materials, questionnaire and focus group protocol with the support of my supervisors and co-authors. I was actively involved in the recruitment process by disseminating the recruitment materials directly to patients at Hunter Integrated Pain Service. I organised and facilitated all focus groups. I managed the transcription of the audio files which was conducted by an independent transcriber. I then analysed the quantitative and qualitative results and drafted the manuscript where these results were presented. The manuscript was reviewed and approved by my supervisors and co-authors.

Chapter 6: The effect of a pilot dietary intervention on pain outcomes in patients attending a tertiary chronic pain service (ReJUICE your pain study)

I drafted, submitted and obtained ethics approval from Hunter New England Health (17/07/19/4.04) and the University of Newcastle (H-2017-0295) with the support of my supervisors. As part of this process I developed all the recruitment materials, information statement, consent forms, participant screening procedures, data collection protocols, data collection questionnaires and intervention protocols and materials.

I distributed the recruitment materials to patients at Hunter Integrated Pain Service in consultation with the clinical and administrative staff at Hunter Integrated Pain Service. I also undertook the screening process with all patients who returned an expression of interest.

I organised and conducted all data collection sessions with the assistance of a research assistant. Prior to this I developed a data collection protocol and trained the research assistants to ensure the protocol was followed and all measures were taken consistently. After the data collection session I entered, de-identified and cleaned data for all participants.

As an Accredited Practicing Dietitian I also delivered the personalised dietary consultations for the intervention study. I managed and organised the scheduling and reminders for all consults.

I conducted the quantitative analysis of the data using a statistical software program, SPSS. I interpreted and presented the results with the support of my supervisors.

I drafted the full manuscript which was reviewed and approved by my supervisors and all co-authors. In addition, as part of the 2018 Australian Pain Society and New Zealand Pain Society Annual Scientific Meeting I was invited to develop a media release (Appendix 3 & 4) in consultation with the Australian Pain Society to advocate for nutrition's role in chronic pain management and in particular this intervention study. As a result, I was interviewed on both ABC radio and NBN news. I was also invited to write an article for 6minutes, an online platform providing medical and health information and news to health care professionals (Appendix 5).

Table of contents

List of tables

List of figures

Abbreviations

Abbreviation	Meaning
ABS	Australian Bureau of Statistics
APD	Accredited Practicing Dietitian
ARFS	Australian Recommended Food Score
BMI	Body Mass Index
BPI	Brief Pain Inventory
CI	Confidence Interval
DAA	Dietitians Association of Australia
ePPOC	Electronic Persistent Pain Outcomes Collaboration
FFQ	Food Frequency Questionnaire
HIPS	Hunter Integrated Pain Service
HNELHD	Hunter New England Local Health District
IASP	International Association for the Study of Pain
NSW	New South Wales
OR	Odds Ratio
PCS	Pain Catastrophising Scale
PSEQ	Pain Self-Efficacy Questionnaire
SD	Standard Deviation

Thesis abstract

Chronic pain is a debilitating condition which affects 20% of adults or more worldwide. These individuals live with pain on a daily basis which affects their ability to work and socialise. Chronic pain also impacts an individual's mood, movement and the foods and drinks that they consume. Chronic pain has important implications for long-term health and risk and severity of chronic diseases. Given the complexity of chronic pain, current treatment focuses on the whole-person with the approach often involving a multidisciplinary team of clinicians, including pain specialists, nurses, psychologists, psychiatrists and pain physiotherapists. These clinicians provide education about the whole-person approach and active strategies for patients to utilise to help manage their pain. The whole-person approach comprises the biopsychosocial and lifestyle factors which modulate the pain experience. Traditionally nutrition has been underrepresented as a component of pain management, despite associations between chronic pain and elevated weight status, increased risk of chronic diseases and sub-optimal dietary intake and overall poor diet quality. Given the association demonstrated in previous research suggesting a relationship between chronic pain and poor diet-related health, and the current lack of nutrition support for people within clinical services experiencing chronic pain there is a need to explore the role of nutrition in the management of pain. This thesis presents five individual studies which work synergistically to address the gap in the current evidence base on nutrition in pain management and to answer the overall research question: *How can people experiencing chronic pain use nutrition to manage their pain experiences?*

To my knowledge, this thesis is the first body of work to comprehensively explore the role of nutrition in pain management using a collaborative approach involving both quantitative and qualitative research. The body of work presented in this thesis involves a collaboration between dietetic researchers from the University of Newcastle and clinicians from Hunter Integrated Pain Service (HIPS), a tertiary pain service in Newcastle, New South Wales. The primary aim of this thesis is to generate new evidence to address gaps in the literature exploring the role of dietary intake and nutrition in the management of chronic pain. The second aim is to develop, implement and assess the effectiveness of a personalised dietary intervention at HIPS. The thesis

also presents six secondary aims which are addressed in the five studies and are presented in the following order:

Secondary aim 1: Systematically review nutrition interventions for chronic non-cancer pain

A systemic review was conducted to investigate the impact of nutrition interventions on participant self-reported pain severity and intensity in people with chronic pain or a chronic pain related condition. In total 71 studies were identified which were categorised by their intervention: altered overall dietary intake (n=16), altered a single nutrient (n=5), prescribed a nutrition supplement (n=46) or prescribed fasting therapy (n=4). Of these studies, 23 were eligible for meta-analysis. Findings from the meta-analysis showed that, when combined, all nutrition interventions had a significant effect on pain reduction. Those studies which altered overall dietary intake or a single nutrient had the greatest effect.

Secondary aim 2: Describe weight status, comorbidities and patient treatment goals of patients attending a pain service

A cross-sectional study was undertaken using data from patients who attended the HIPS between July – December 2014. Data were collected from the Electronic Persistent Pain Outcomes Collaboration (ePPOC) referral questionnaire and the Pain Assessment and Recovery Plan (PARP), both tools are used as part of the standard care provided at HIPS. One-hundred and sixty six patients completed the ePPOC referral questionnaire and 153 patients completed the PARP. Body Mass Index was calculated using self-reported weight and height. The average BMI was 31.7 kg/m^2 (ranged from 18.52-54.46 kg/m^2). Thirty-three percent of patients were in the overweight BMI category and 45% were in the obese category. Eighty-seven percent of females and 77% males reported a waist circumference that placed them ($\geq$ 80 cm and $\geq$ 94 cm, respectively) at risk for developing chronic disease. Of the comorbidities patients could choose from the top two answers were osteoarthritis/degenerative arthritis (25%) and depression/anxiety (22%). Nearly two thirds of the patients (64%) reported having $\geq$ 2 comorbidities. Patients listed and prioritised treatment goals when completing the PARP. In descending order of frequency participants chose the following areas from the whole-person approach to

focus on as part of their recovery plan: physical activity, nutrition, connection, mindbody and biomedical.

Secondary aim 3: Identify nutrition-related goals reported by patients at this service

Using the same cross-sectional study outlined above the patients nutrition-related treatment goals were further categorised with 47% choosing a specific nutrition-related goal (e.g. reduce soft drink intake or increase vegetable consumption), 27% of patients stating that they wanted to improve their overall diet and 27% of patients stated that they wanted to lose weight or reduce their waist circumference.

Secondary aim 4: Collect and collate opinions of staff employed at two pain services about incorporating nutrition into practice

Qualitative focus groups (n=3) were held with staff (n=13) from HIPS and Tamworth Integrated Pain Service in order to gather the opinions of staff regarding the integration of nutrition support into current practice. Staff from all disciplines attended including: nurses, administrative staff, psychologists, physiotherapists and one pain specialist. On average, staff had been working in their respective fields for 18.4±12.8 years and specialising in chronic pain for 6.5±6.6 years. Staff discussed the benefits of nutrition intervention acknowledging patients would receive an increase in knowledge and skills and the service would gain a more comprehensive whole-person approach to pain management. Key barriers which would impact patients included comfort eating, lack of motivation and access to dietetic services. Key barriers for the service included time limitations and access to dietetic services. Preferences for intervention content were: evidence-based, simple education and skill development with practical strategies and visual incentives, with a focus on nutritional benefits for pain experiences, not weight management. The overall preferred intervention delivery method was a flexible combination of face-to-face and technology-based resources with the intervention ideally developed and/or delivered by an Accredited Practicing Dietitian.

Secondary aim 5: Explore attitudes and beliefs of patients in relation to the role of nutrition in pain management

Qualitative focus groups (n=5) were also held with patients (n=21) from HIPS in order to explore the opinions of patients regarding the integration of nutrition support into current practice. Patients were asked how they perceived the meaning of 'healthy eating' with most participants identifying fruits and vegetables as the main component of healthy eating. Patients also discussed how accessing and preparing food can lead to an exacerbation of pain and therefore many patients rely on convenience foods. Medication and mental health issues were also identified as contributing to the difficulty of maintaining a healthy weight. Patients identified that the main benefits of participating in a nutrition intervention would be improved overall health, increased knowledge, skills and self-efficacy. The significant barrier which most patients discussed was the cost of food and health care in general. The ideal intervention from a patient perspective, would include easy and practical ideas which are delivered using a combination of in-person and technology components to enhance flexibility. There were mixed responses with regard to patients' use and confidence about using technology with some patients promoting the use and others preferring in-person.

Secondary aim 6: Investigate the effectiveness of a personalised dietary intervention and dietary supplement in patients attending a pain service

The final study in this thesis explores the efficacy of a six-week 2x2 dietary intervention study on pain scores, quality of life and dietary intake of patients attending HIPS. This intervention was informed by the results of all previous studies to increase the acceptability and success of the intervention. Two intervention components were tested and these included personalised dietary consultations provided using telehealth and a dietary supplement, a fruit juice high in antioxidants (active fruit juice). Sixty participants were randomised into four groups with each group receiving either the personalised dietary consultations or waitlist control and the active fruit juice or placebo fruit juice. Forty-two participants completed the study and results showed one group-by-time effect where the group receiving the personalised dietary consultations and active fruit juice had a significant reduction in percentage energy from total fat ($p=0.024$). Other results demonstrated that overall, all groups had a statistically significant improvement in the following pain scores: pain interference (-0.9±0.3 points,

p=0.003), pain self-efficacy (+6.2±2.2 points, p=0.004) and pain catastrophising (-3.8±1.8 points, p=0.046). There were also statistically significant improvements for all groups in six of the eight quality of life categories post intervention and for the percentage energy coming from nutrient-dense foods (+5.2±1.4%, p<0.001). There were also clinically important improvements in pain scores (visual analogue scale, pain interference and pain self-efficacy) in those randomised to the personalised dietary consultations compared to the waitlist control groups.

Discussion

The body of work presented in this thesis identified that people who are experiencing chronic pain reported a reduction in their pain experiences and improvement in their overall health by changing and making improvements to their dietary intake. The studies that comprise this thesis have all contributed to addressing the gap in the evidence relating to the role of nutrition in the management of chronic pain. These studies have also informed the development of an intervention study. The systematic review confirmed that changing dietary intake can reduce pain experiences. The cross-sectional study provided further support for the need and want for a nutrition intervention. The qualitative studies provided important insight and views from staff and patients regarding a nutrition intervention, the potential barriers which may affect the success of this intervention and preferred delivery method. This thesis, which addresses a complex health condition, has demonstrated the potential benefits to both people experiencing pain and the clinicians who treat them of incorporating a nutrition intervention into current service. Future research should test the efficacy of the nutrition intervention within a larger, fully-powered high quality randomised control trial with a longer follow-up period to further establish the most effective and sustainable approach to incorporating nutrition into the management of chronic pain.

Chapter 1: Thesis Introduction

1.1 What is pain?

1.1.1 A brief history of pain science

The science behind pain is evolving and understanding of the concept of pain is continuing to be refined from both a scientific and clinical perspective (1). Pain is a fundamental necessity required to protect and ensure evolution and survival of humans (2). It is an unpleasant experience designed to act as an alarm system to warn of danger, allow escape and prevent injury or illness (2, 3). Over time, and through the development of new techniques and research, the understanding of pain has increased and the explanation for pain has become much more complex (1, 4-6). Early theories perceived pain as an emotional or spiritual experience rather than a sensation. In the 17th Century, Rene Descartes proposed the first scientific explanation for pain, whereby pain was produced by a disturbance which was carried via tubes (nerves) to the brain (7). It was not until the mid-1960s when Melzack and Wall published the Gate Control Theory (8) that there was acknowledgement of the effect of neural modulation on the pain experience whereby thoughts, emotions and cognition amplify or reduce the intensity of the pain experience (1). The gate control theory takes into account the psychological and social factors which influence pain and as such the biopsychosocial approach to pain management was established (9).

1.1.2 Definition of pain

The International Association of Pain defines pain as: “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (10, p.S17). However, in 2016, a new definition was proposed by Williams et al.: “pain is a distressing experience associated with actual or potential tissue damage with sensory, emotional, cognitive and social components” (11, p. 2420). This definition acknowledges pain as a subjective experience, rather than a sensation experienced by humans. This definition also incorporates the psychological, social and environmental aspects associated with the pain experience.

Currently, pain is recognised as a “lived experience associated with a brain interpretation of threat or danger” (5). This is a contemporary neuroscience view of the

biopsychosocial approach (5). The brain receives multiple information inputs and is more likely to make an interpretation of pain in the context of perceived danger (5). Pain is a subjective and unique experience. Every individuals experience of pain is different and influenced by a range of psychological, social, cultural and lifestyle factors which modulate the severity of pain (4).

1.1.3 Pain classifications

There are several ways that clinicians and researchers classify pain (12). However the two main classifications are: duration-based classification and mechanism-based classification. However there are aspects of overlap in the mechanism based classification as it is not uncommon for different mechanisms to co-exist and contribute to one pain presentation (13).

1.1.3.1 Duration-based classifications

- ***Acute pain*** is defined as pain of less than three months duration (14). It is usually associated with tissue damage such as a broken bone, trauma or surgery (14). Acute pain is often described as 'normal' pain and can at one level be seen as a physiological mechanism designed to protect the body from serious harm and promote survival behaviours in humans (14). The purpose of pain is to capture the individual's attention so that they can prioritise escape from harm or protect from injury, therefore it is an unpleasant experience (2, 14). However, the interpretation of this experience, i.e. if seen as a threat or not, is dependent on the context (14).

- ***Chronic non-cancer pain*** is defined as pain that persists beyond three months which is the amount of time it typically takes for tissues to heal (15). It excludes pain which is caused by active cancer and/or active cancer treatment. Chronic non-cancer pain and chronic pain are interchangeable terms and from this point forward in the thesis will be referred to as chronic pain (14). Cancer survivors who experience persisting pain triggered from their cancer and/or treatment would be considered to have chronic pain as the cancer is no longer active (14). Chronic pain is also characterised by changes to the nervous system, endocrine and immune systems (3, 14). These systems typically become hypersensitive and more able to produce pain sensations with less stimulus (3, 14). Chronic pain is described by some as a pathological pain which is no longer helpful in keeping the body safe

from physical injury (5, 6). Others consider that chronic pain may have meaning at psychological or social levels (4). In this context chronic pain is not pathological and can be seen to be just as meaningful as acute pain.

1.1.3.2 Mechanism-based classifications

Nociceptive pain is associated with physical tissue injury. This is best seen in the setting of acute pain (13). The peripheral nerves responsible for identifying injury, the nociceptors, are found throughout the body. Nociceptors respond to damaging or potentially damaging stimuli and when activated send 'danger' messages using action potentials along primary afferents to the dorsal horn in the spinal cord (5, 6). These messages are then relayed to the brain to interpret the level of danger. If the brain perceives the level of danger as sufficient it will produce pain. (Figure 1.1) (12). Primary motor efferents then send a message back to the region the stimulus was originally felt (6, 12). This allows the body to respond, for example by withdrawal of a threatened limb. In processing pain the brain relies on various areas to assist in interpreting potential 'danger' of which vision and memory are two major components. Vision helps the brain to put the situation into context allowing a better interpretation of danger (3, 5). Memory identifies if this situation has happened before and if it has, was it a positive (less likely to produce pain) or negative (more likely to produce pain) outcome (3, 5). In the early phase nociceptive pain is helpful and protects the body from serious danger. However, in some situations pain persists and transitions through the sub-acute to the chronic phase (16). Typically where this happens there are associated changes in the nervous system including sensitisation and loss of descending inhibition (16). This is described further under nociplastic pain below. Nociceptive pain can be further categorised as somatic pain (driven primarily by nociceptors found in skin or muscle tissues) and visceral pain (driven primarily by nociceptors found in the internal organs) (13).

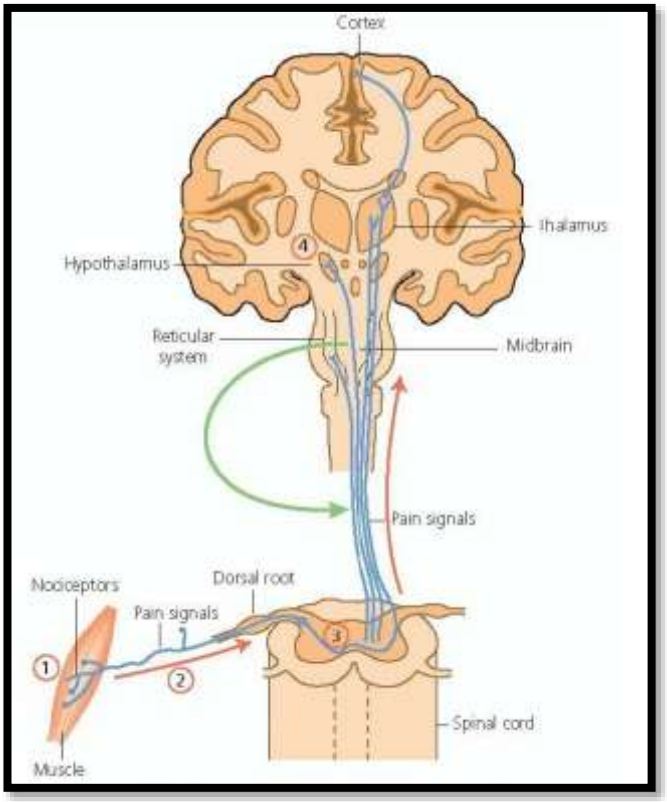

Figure 1.1. Nociceptive pathway between the periphery and central nervous system

Source: Michael J Cousins and Rollin M Gallagher, Fast Facts: Chronic and Cancer Pain 4th edn. © 2017, S. Karger Publishers Limited.
www.karger.com/fastfacts

- ***Neuropathic pain*** is defined as "pain caused by a lesion or disease of the somatosensory system" (17, p. 2204). This pain results from abnormal responses within an injured nervous system which can occur in diabetic neuropathy, post herpetic neuralgia and phantom limb pain (13, 18).

- ***Nociplastic pain*** describes pain that exists in the absence of clear nociception or nerve injury (16). It describes abnormal neural processing and is commonly implicated in the development of chronic pain (Figure 1.2) (16). The abnormal processing can be due to increased facilitation (wind up or sensitisation) or reduced inhibition in the nervous system (16). Sensitisation can occur in the peripheral or central nervous system or both. There are many aspects such as mood, diet, physical movement and isolation which can modulate the wind up or down of the pain sensations (19). This type of pain provides an explanation as to why two different people, with the same injury may experience different levels of pain (5, 16). The

brain's ability to be neuroplastic can have both positive and negative effects on the pain experience. From a positive perspective, it indicates that the brain can be retrained and learned activities or thoughts perceived to be dangerous are, in reality, not dangerous (5). Conversely, the longer the brain produces pain, the more efficient it becomes at producing pain, which worsens the experience for individual (5).

It should be noted that nociceptive, neuropathic and nociplastic mechanisms may co-exist (13).

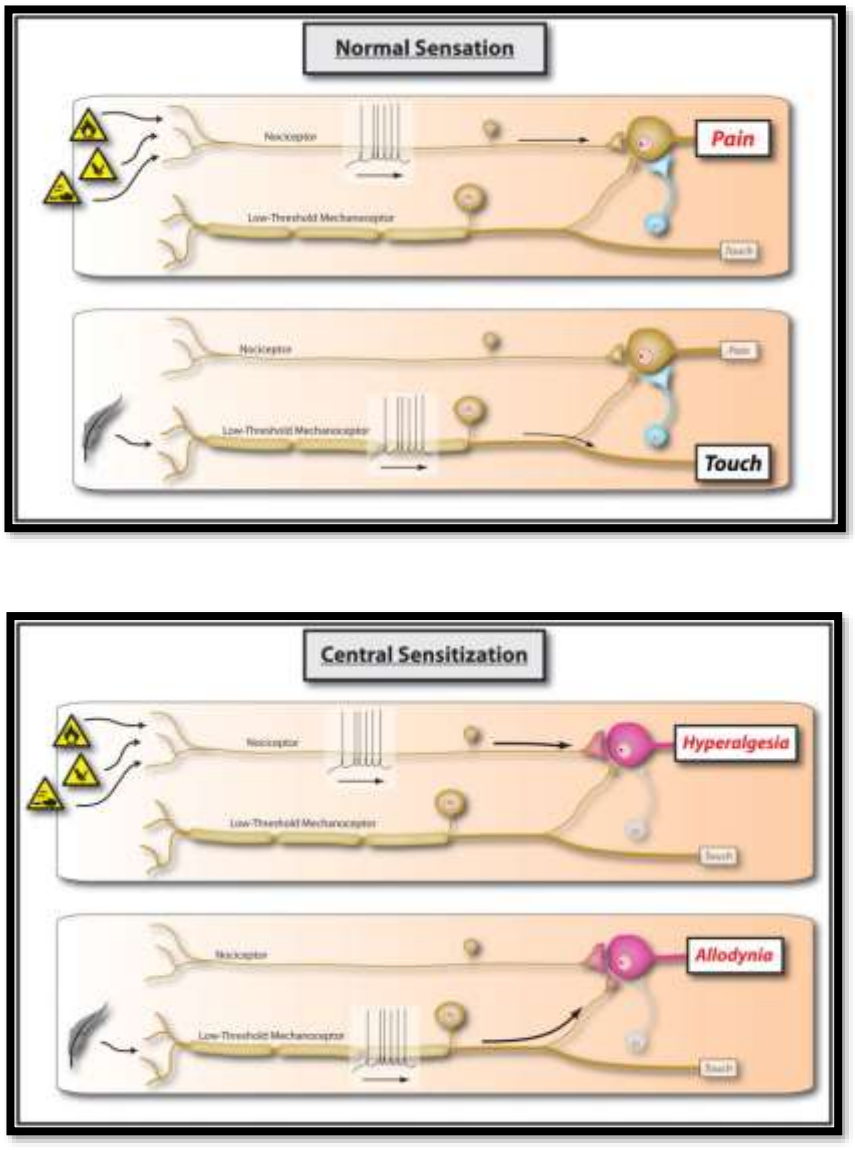

Figure 1.2. The difference between normal nociception and sensitised nociception

Woolf CJ. Central sensitization: implications for the diagnosis and treatment of pain. Pain. 2011;152(3 Suppl):S2-15.

1.2 Chronic pain

1.2.1 Chronic pain: A symptom or disease

The International Association for the Study of Pain (IASP) and European Federation of IASP Chapters put forward a declaration to the European Parliament in 2001 stating that chronic pain should be considered a disease in its own right (20). Most recently the IASP established the Task Force for the Classification of Chronic Pain with the intention of including chronic pain in the 11th revision of the International Classification of Diseases of the World Health Organisation (21). However this stance is controversial. Others put the view that the experience of pain is essentially a brain interpretation and hence should be considered as a condition rather than a disease (2). They make the point that changes in somatosensory pathways may be more or less hard-wired and amenable to therapeutic retraining (2). While hard-wired neural changes come closer to the definition of a disease, softer-wired changes do not (2).

Proponents argue that chronic pain meets the definition of a disease, namely a disease has its own pathology with its own signs and symptoms (6). When pain persists the nervous system undergoes abnormal pathological change leading to peripheral and central sensitisation (6). In addition endocrine and immune system changes contribute to low level chronic inflammation, also known as metaflammation (9). Chronic pain can be triggered by an injury (accounting for 38%), disease (30%) or in the absence of a physical problem (30%) (22). Despite the trigger, if the initial nociceptive signals are sustained over time, this causes peripheral and central hypersensitivity (6). The multifaceted physical, psychological, social and lifestyle changes caused by chronic pain can also be considered symptoms of chronic pain (20). These symptoms modulate pain experiences by producing excitatory (glutamate) or inhibitory neurotransmitters (GABA) which modulate the intensity of the pain experience (6).

The biopsychosocial and lifestyle changes which occur as part of chronic pain are the same factors which are incorporated into the biopsychosocial or whole-person approach to pain management. Factors such as decreased mobility, poor sleep and appetite, reliance on medication, overuse of health care systems, reduced productivity and increased absenteeism, anxiety and social isolation are all consequences of chronic pain (20, 23) on one hand, yet on the other they can be contributors to pain. Addressing these factors is a focus of treatment at interdisciplinary pain services (24).

1.2.2 Prevalence of chronic pain

Internationally, the prevalence of chronic pain varies, however most reports state that on average, 20 to 25% of the population experience moderate to severe chronic pain (25, 26). On average 37% percent of people living in developed countries (range from 20-55%) and 41% (range from 41-47%) in developing countries experience chronic pain of any severity, when defined as pain persisting beyond three months (25). Globally, approximately 12% of those with chronic pain experience severe disability as a result of their chronic pain (ranges 6-14%) (25).

The rates of chronic pain in Australia reflect these global statistics. Using NSW Health Department statistics from 1999, self-reported prevalence rates from Blyth et al and Australian Bureau of Statistics population data, it was calculated that in 2007 one in five Australian adults (aged 25-64) experience chronic pain and this prevalence increases to one in three in adults over the age of 65 years (22). In parallel with the ageing population, and a rise in cancer survivorship, prevalence rates of chronic pain are expected to rise. In 2007 approximately 3.2 million Australians reported having chronic pain and this is likely to increase to 5 million by 2050 (22). The expected rise in chronic pain is supported by data from the Australian Bureau of Statistics which reported that in 1995, 57% Australian adults' experienced bodily pain in the last four weeks. This had risen to 68% in 2007-2008 (27). The percentage of people experiencing severe or very severe pain has also increased over this time, from 7% to 10% (27). Compared to other conditions, in 2016, back pain and arthritis, were ranked third and fourth in terms of prevalence, after cardiovascular disease and mental health conditions (28). Approximately 64% of those with back pain and 53% with arthritis report limitations due to chronic pain (29).

1.2.3 Burden of chronic pain

1.2.3.1 Global burden of pain

Chronic pain conditions have a significant impact on the global burden of disease. To assess the global burden of chronic pain the reports are limited to musculoskeletal pain, including back and neck pain, osteoarthritis and rheumatoid arthritis (30). In the Global Burden of Disease Report 2010, musculoskeletal pain-related conditions were first recognised as one of the leading causes of global disability with low back pain the most common of these conditions (30). Conditions which are also associated with chronic

pain such as mental health and behavioural conditions such as depression and anxiety are also leading causes of the global burden of disease (30). In 2016, lower back pain was the most frequent specific cause of years lived with disability and lower back and neck pain the third highest contributor to the number of disability adjusted life years, preceded by ischaemic heart disease and cerebrovascular disease (30).

1.2.3.2 Economic burden of pain

Chronic pain is also associated with a substantial economic cost and healthcare burden. People who experience chronic pain are more likely to be high users of the health care system (31). In Australia, the economic cost of chronic pain is estimated to be $34 billion; this includes $11 billion in productivity losses and $7 billion in direct medical costs (22). In 2000-2001, chronic pain was ranked third behind cardiovascular and musculoskeletal conditions in terms of health expenditure (22). This is also reflected in more recent data from the percentage of expenditure for those who were admitted to hospital in 2012-2013. The top conditions which contributed to these costs were: cardiovascular disease (11%), injuries (9%), reproductive and maternal conditions (8%), gastrointestinal disease (8%) and chronic musculoskeletal disorders (8%) (32).

1.2.3.3 Personal burden of pain

At a personal level, living with pain day in and day out can significantly affect mood, ability to work and socialise, often impacting on family relationships. People who experience chronic pain report a decreased quality of life, reduced social contact and poorer mental health compared to those without chronic pain. Ninety percent of those experiencing severe or very severe pain reported that their pain moderately or extremely interfered with paid work and housework over the last four weeks (27). Of the 20% who experience moderate to severe chronic pain, one third are unable to live independently due to their pain (26). Activities such as exercise, normal sleep, household chores, social activities, and driving, walking and sexual activities are impacted with half to two thirds of those experiencing pain having difficulty with these activities. Furthermore, chronic pain impacts on relationships with one in four reporting strained or broken family or friend relationships (26).

1.2.4 Risk factors for chronic pain

Age and gender are two main risk factors for experiencing chronic pain. Internationally, a higher proportion of those experiencing chronic pain are women (25, 33, 34). Pain is more likely to be experienced as age increases, especially pain that interferes with function and quality of life (25). In Australia, those aged over 45 years are twice as likely to experience severe or very severe pain than those less than 45 years (27). The highest rates of severe or very severe pain are seen in those aged 75 years and above (27). Other social and environmental factors which also increase the risk of chronic pain include low socio-economic status, geographical and/or cultural backgrounds, employment demands and history of abuse (35).

1.2.5 Healthcare use and chronic pain

Chronic pain is the leading reason for visiting a general practitioner (GP), with one in five of all GP appointments related to chronic pain (36). Several studies conducted in Europe have reported similar rates of health care use for those with chronic pain in various countries (25). A study in Sweden examining the reasons for GP visits in approximately 14,000 patients found that 30% were seeking advice about chronic pain, predominately related to musculoskeletal conditions (37). This is supported by a study conducted in Italy where 89 GP's provided data on patients attending their practice over a two week period (38), where one third of consultations were related to chronic pain, in particular musculoskeletal and chronic abdominal pain. In two thirds of these visits GP's prescribed an analgesic of some sort (38). In Australia a similar study with approximately 6000 patients who visited 197 GP's found that 19.2% of visits were related to chronic pain, of these 48% related to pain associated with osteoarthritis and 29.4% related to back pain (39). The percentage of patients that were categorised into one of four pain severity categories as graded by the Von Korff Pain Grades where one is the lowest and four the highest pain grade, was 25.2%, 37.1%, 28.3% and 9.4% respectively (39). Eighty-six percent of patients were already using some sort of medication to relieve their pain (39). Of these, one third were using opioids and this was most frequent in the highest pain severity category (39). One third of patients were also using non-pharmacological strategies to manage their pain (39). Another study conducted by Blyth et al. where 17500 New South Wales residents aged over 16 years were contacted by a computer assisted telephone interview found that despite age, gender, self-rated health, psychological distress and access to care, having chronic pain

predicted health care use (31). It was found that those with chronic pain and pain related disability were higher users of primary care, hospital admissions and emergency department visits than those with chronic pain and no or limited pain-related disability (31). This was the case for primary care visits over the last two weeks and 12 months (adjusted mean number of visits 0.59 vs 0.40 and 10.72 vs 4.81, both p=0.005), hospital admissions (0.46 vs 0.18, p=0.005) and emergency department visits (0.85 vs 0.17, p=0.005) (31).

1.2.6 The health status of people experiencing chronic pain

People experiencing chronic pain have poor health as there is a bidirectional association between chronic pain and presence of comorbidities. The number of comorbidities each person has also contributes to their overall health. In Australia, almost one third of patients have self-reported having three or more comorbidities concurrent to their pain (23). Chronic pain increases the risk of developing comorbidities, however comorbidities can also contribute to the development of chronic disease.

1.2.6.1 Depression and anxiety

The most prevalent comorbidity associated with chronic pain is depression and anxiety. A population based cohort study conducted in 2017 with 24,000 participants found that those with depression were more than twice as likely to have chronic pain as well, compared to those without depression (40). The adjusted odds ratio was 2.64 (95% confidence interval 2.34, 2.97) (40). Another study conducted in Germany where 3000 citizens were interviewed by phone found that 18.4% had non-neuropathic chronic pain and 6.5% had neuropathic chronic pain (41). Of these, major depressive disorder as defined by the Diagnostic and Statistical Manual of Mental Disorders IV was three times more likely and six times more likely in non-neuropathic chronic pain and neuropathic chronic pain respectively (41). In a clinical setting, where depression was measured using the 9-item Patient Health Questionnaire, 61% of chronic pain participants met the criteria for probable depression and 34% met the cut off for severe depression (42). In Australia, 60% of chronic pain patients have self-reported being diagnosed with depression or anxiety (43). These patients also completed the Depression Anxiety and Stress Scale (DASS) 21, with the average score for each subscale: depression, anxiety and stress categorising patients as moderate for all subscales (43).

1.2.6.2 Other chronic diseases

Other chronic diseases, as defined by the ICD-10, including obesity, heart disease, diabetes, hypertension, hypercholesterolemia and cerebrovascular diseases are also highly prevalent in people experiencing non-neuropathic and neuropathic chronic pain (41). Angina is more than four times more likely in people with chronic pain (OR 4.19 [3.64, 4.82]) compared to those without (40). Data from almost 12,500 New Zealand residents was extracted from the 2006-2007 New Zealand Health Survey to explore the association between chronic pain and comorbidities (44). Of the 16.9% of survey respondents who self-reported chronic pain, 30% also self-reported that their general practitioner had diagnosed them with diabetes, 34% heart disease and/or bowel disease and 49% osteoporosis (44). Adjusted odds ratios showed that diabetes was 1.4 (1.1, 1.8, $p=0.0132$), heart disease 1.6 (1.3, 1.9, $p<0.0001$), bowel disease 1.4 (1.1, 1.8, $p=0.002$) and osteoporosis 2.2 (1.6, 3, $p<0.0001$) times more likely in those with chronic pain compared to those without (44). There was also a significant difference between the number of comorbidities reported and the presence of chronic pain. Six percent of participants without a comorbid condition also reported chronic pain compared to 36% who had two or more comorbid conditions, $p<0.0001$(44).

Globally, dietary intake is the top modifiable risk factor for morbidity (45) and is a key risk factor for these chronic diseases along with other lifestyle behaviours such as sedentary behaviour and lack of sleep (45).

1.3 Pain management in Australia

1.3.1 Pain Management Organisations and the National Pain Strategy

The International Association for the Study of Pain (IASP) has 90 national chapters and each chapter represents a country which upholds the vision of IASP (46). The Australian Chapter of the IASP is the Australian Pain Society which represents all disciplines associated with pain research, education and treatment (47). In Australia there is also the Australian and New Zealand College of Anaesthetists, Faculty of Pain Medicine, Painaustralia and Chronic Pain Australia. The Australian and New Zealand College of Anaesthetists is the professional organisation for specialist anaesthetists and anaesthetist fellows in training (48). The Faculty of Pain Medicine is the professional organisation which, when formed in 1998, was the first multidisciplinary medical

academy for both pain medicine physicians and pain medicine physicians in training (49). Painaustralia is an independent advocacy body which is supported by its founding members Australian and New Zealand College of Anaesthetists, Faculty of Pain Medicine and Australian Pain Society with support of other consumer and industry stakeholders (50). Chronic Pain Australia was established in 2001 with the aim to represent consumers and provide a place for people to get support from others with similar pain experiences (51).

In NSW, the Agency for Clinical Innovation (ACI) Pain Management Network was established in 2010 for both consumers and health care professionals as a one stop shop for education and resources on pain science and pain management (52).

The first national framework which was developed for pain management, including acute, chronic and cancer pain was launched in 2010, called the National Pain Strategy (NPS) (53). Over 150 stakeholder organisations (including Australian and New Zealand College of Anaesthetists, Faculty of Pain Medicine, Australian Pain Society and Chronic Pain Australia) met at the National Pain Summit in Canberra in 2010 to develop the NPS (53). There are six key goals of the NPS, detailed as follows (53):

- People in pain as a national health priority
- Knowledgeable, empowered and supported consumers
- Skilled professionals and best-practice evidence based care
- Access to interdisciplinary care at all levels
- Quality improvement and evaluation
- Research

1.3.2 Pain Management Services

Based on IASP classifications pain facilities can be grouped into three levels depending on their purpose and the staff employed (54). IASP have also recently defined interdisciplinary and multidisciplinary services with interdisciplinary referring to services which have all clinical disciplines functioning in an integrated way at the same location and multidisciplinary referring to services which have serial input from all disciplines, however the clinicians work in separate locations (54). The Australian Pain Society have classified the services listed in their facility directory using these

classifications (55). In total, there 82 facilities which provide pain management services to the Australian community. Of all the states and territories in Australia, NSW has the most facilities (n=26) (55). The majority of pain services are based in metropolitan settings. For example, in NSW, only six of the 26 services are located in regional areas (55). NSW also has additional classifications which indicate whether a pain service is funded to operate part-time (typically 3 days per week) (Tier 2) or full-time (typically with Faculty of Pain Medicine accreditation to train and supervise pain medicine physicians) (Tier 3) (56).

The long standing IASP classification recognises:

Level 1: Multidisciplinary Pain Centre (n=29 in Australia) (24, 55)

- Treat a wide variety of patients with painful conditions
- Staff must be qualified to treat all aspects of pain (medical, physical, psychosocial & vocational)
- Minimum three medical specialities including psychiatrist (or psychologist) and minimum two non-physician disciplines represented on the staff (e.g. nursing, physiotherapy, psychology etc.)
- If analgesic procedures are conducted must have a registered nurse, if the service uses cognitive behavioural therapy must have a psychologist.
- Must have an appointed director or coordinator who is medically trained and a Fellow of the Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists
- Should have designated space and adequate staff to undertake its activities, maintain clinical records to assess individual outcomes and evaluate overall program effectiveness
- Schedule minimum fortnightly multidisciplinary meetings regarding individual patients and the overall programs offered
- Must be active in education and research

Level 2: Multidisciplinary Pain Clinic (n=36 in Australia) (55, 57)

- Treat variety of patients with painful conditions
- Staff must be qualified to treat all aspects of pain (medical, physical, psychosocial & vocational)
- Minimum one medical specialist and one psychiatrist (or psychologist) and minimum two non-physician disciplines represented on the staff (e.g. nursing, physiotherapy, psychology etc.)
- If analgesic procedures are conducted must have a registered nurse

- Must have an appointed director or coordinator who is medically trained and a Fellow of the Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists
- Should have designated space and adequate staff to undertake its activities, maintain clinical records to assess individual outcomes and evaluate overall program effectiveness
- Schedule minimum fortnightly multidisciplinary meetings regarding individual patients and the overall programs offered

Level 3: Pain Practice or Single Modality/Body Region Clinic (n=17 in Australia) (55, 58)

- Single health care provider licensed to specialise in pain
- Must be knowledgeable about all aspects of pain (medical, physical, psychosocial & vocational)
- Must have a means for obtaining consultation from other health care professionals as needed
- The health care professional should refer patients to a multidisciplinary pain clinic if the patient's issues exceed the professionals capabilities
- If specialising in a single modality, body region or pain type it must be specified (e.g. biofeedback clinic or spinal pain)
- Must maintain clinical records and engage in quality improvement activities
- Access to these services is by referral from a general practitioner or medical specialist

1.3.3 Access to services

Access to pain services is by referral which is often provided by a general practitioner or medical specialist. However there are often long waiting times which can worsen mood, decrease quality of life and increase disability (59). Fifty-seven Australian pain services were systematically surveyed between 1 December 2008 and 31 January 2010 to identify the wait times experienced by patients (60). It was found that the median wait time between referral and initial assessment in public services was 150 days compared to private services which was 38.5 days (60). Of those who experience pain, <0.2% will obtain access to a specialist pain service in any given 12 month period (60). Since then, national data collected and analysed by ePPOC (outlined in section 5 below) has found that the median wait time for services in Australia and New Zealand between referral and initial assessment between July 2017 – June 2018 has reduced to approximately 48 days (43).

1.4 Hunter Integrated Pain Service

Hunter Integrated Pain Service (HIPS), located in the Hunter New England Local Health District of New South Wales, Australia is a Level 3 Centre provider who use an interdisciplinary approach to treat chronic pain. HIPS use a standard pain assessment and care pathway with over 1000 patients referred to the service each year (61). Treatment pathways, consistent with evidence based treatments and international practice, focus on weaning opioid medication and adopting self-management strategies (9, 62). The HIPS team (n=16, with fractional appointments) includes nurses, physiotherapists, psychologists, psychiatrists and medical specialists with expertise in pain medicine (Table 1.1). As part of a brief social media based chronic pain intervention created by the HIPS team and Hunter Medicare Local (HML) which began in 2011, the HIPS team identified five fundamental areas that relate to self-supported pain management (63). These five areas encompass the whole-person approach and have become standardised components of HIPS assessment and treatment (63). Interdisciplinary pain services all use a biopsychosocial approach. However the emphasis differs between teams resulting in significant clinical variation. For example some teams weight the biomedical aspects of treatment much more heavily than others. HIPS whole-person approach aims to use client friendly language and encourage the transition from biomedical to active self-management treatments. The 'mindbody' word emphasises the view that psychological processes impact physical state. 'Connection' focuses on the social aspects along with connection to the natural world and purpose. The nutrition aspect is specifically recognised. This is not the case with traditional pain management approaches. Since 2011, HIPS and HML have produced and published, on YouTube, three short videos which translate and collate evidence based pain management strategies into concise and easy to understand videos for clients. These videos are called *Understanding pain and what to do about it in less than five minutes* (64); *Understanding pain: Brainman chooses* (65) and *Understanding pain: Brainman stops his opioid*s (66). These videos have been translated into at least 15 different languages and each video receives approximately 1500 views each month (63). To date, HIPS still use these five essential areas to underpin their assessment and treatment approach towards pain management. These areas have been summarized in Figure 1.3,

where the HIPS team chose to pictorially represent these areas using five fingers on a hand and further explained in Table 1.2.

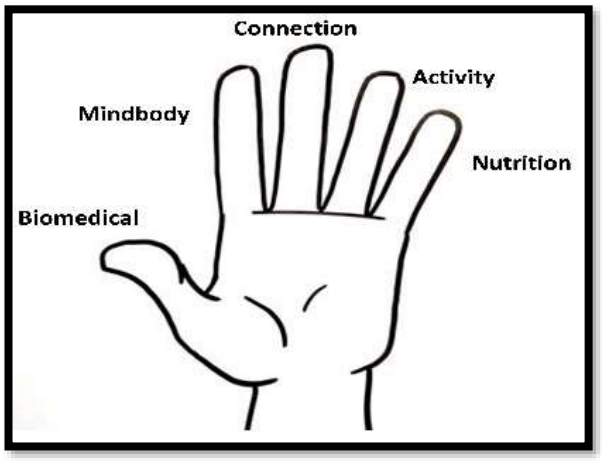

Figure 1.3. The whole-person approach to pain management (63)

Table 1.1. Staffing at Hunter Integrated Pain Service

Position	**Full Time Equivalent (1 FTE = 40 hours/week)**
Specialist pain medicine physicians	1.6
Pain medicine trainee fellows	1.0
Clinical nurse consultants/specialists	2.1
Psychiatrists	0.4
Clinical psychologists	1.4
Pain physiotherapists	1.6
Administrative staff	2.2

Table 1.2: Five key treatment areas at Hunter Integrated Pain Service

Key treatment area	**Explanation**
Biomedical (67)	• Addresses the biological and structural issues/illnesses that may contribute to chronic pain • Biomedical treatments are also included; medication is a component of this • Over the past decade there has been a gradual shift to reduce and cease the use of opioids (e.g. morphine) and transition to supported self-management • Opioids become less effective over time and the risk associated with long term use outweighs the benefits for those who experience chronic pain • De-prescribing and weaning from opioids is the main focus for many patients who attend HIPS • Other drugs include: Non-steroidal anti-inflammatory drugs (NSAIDS), paracetamol, antidepressants and anticonvulsants
Mindbody (68-70)	• A person's life events and reactions to them can impact their pain experience • Thoughts and emotions are also involved and can alter physical state • Negative thinking significantly impacts upon people who experience chronic pain, it can perpetuate a state of frustration or sadness, with depression and anxiety often associated with chronic pain • At times, this can be inappropriate e.g. an experienced bushwalker who has been bitten by a snake while bush walking, may experience excruciating pain if they scratch their leg on a branch while bushwalking after the snake bite. In an acute setting this response aims to protect us, but in a chronic pain setting this reaction is unhelpful • Addressing negative thinking is one aspect of retraining the brain with a view to reduce the experience of pain over time
Connection (71)	• Relates the people (family, friends, colleagues and health professionals), place (environment we live and work in, how we travel) or purpose (meaning and existence) • Loss of and withdrawal from connections is commonly associated with pain and can significantly contribute to their pain experience

	• Also, a person's connection, or lack of, before their pain begins may impact on how they experience their pain • The focus of this section is to break down barriers to social isolation and reconnect them to people, place and purpose
Activity (72)	• In situations of acute injury, rest is recommended. However, this is not the case for chronic pain • A sedentary lifestyle can lead to reduced muscle mass and stiff joints which can worsen pain. Inactivity can also lead to chronic diseases such as obesity, diabetes, heart disease and depression • As part of the whole person approach people learn about activity tolerance and working within their limits to prevent flare-ups • People who are physically active have fewer problems with their pain and therefore providing practical strategies to increase activity is a main component of this section • Sleep disturbances is one of the most common complaints from people who experience chronic pain. There is a reciprocal relationship between sleep and chronic pain in that poor sleep leads to worse pain and experiencing pain can make sleep difficult
Nutrition (73)	• Nutrition can influence the nervous, immune and endocrine systems • Promoting healthy eating and focusing on low glycaemic index, high fibre, antioxidants and high quality fats is important for those who experience chronic pain • Weight status is also important, with weight maintenance and loss the main focus • Current Western eating habits include consumption of high energy dense and nutrient poor foods. These foods can lead to conditions such as obesity, heart disease, diabetes and cancer • It can also exacerbate lifestyle induced inflammation which contributes to pain experiences by sensitising the nervous system.

The majority of patients follow a standard treatment pathway through HIPS which is predominately group-based. Triage to individual appointments occurs if needed (see Figure 1.4).

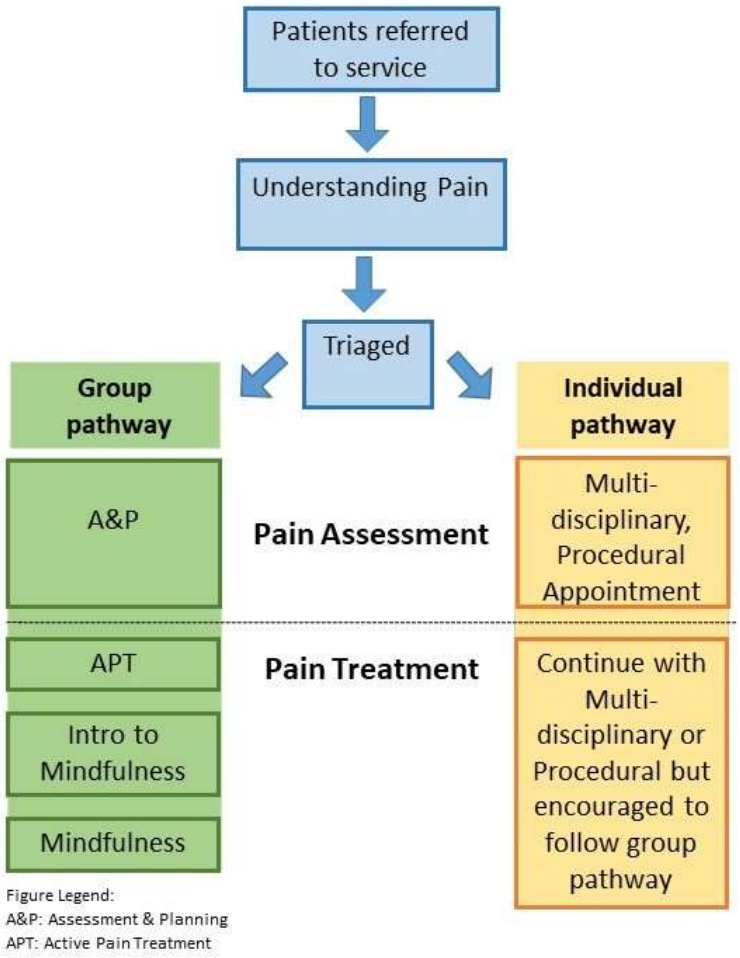

Figure 1.4. Standard treatment pathway at Hunter Integrated Pain Service

All sessions are voluntary and patients are given a choice at the end of each session whether to continue with the service or be discharged back to their general practitioner (GP). Patients are referred to HIPS by their GP or another medical specialist (e.g. neurosurgeons or rheumatologist) and then invited to attend an introductory seminar called Understanding Pain (UP) (see Table 1.3). For those who decide to continue they are triaged by the nursing staff to either the group pathway or individual pathway. The group pathway is preferred as it is more resource efficient, reduces the wait time for patients to access care and promotes patient engagement with self-management (74). The pathway is constantly evolving as evidence is updated and resources altered. Assessment and Planning (A&P) is the first workshop patients attend (Table 1.3). Here, patients are assisted by clinicians to create a patient centred goal plan to manage their pain based on their individual circumstances. This plan is broken down into the five areas previously identified by the HIPS team (see Figure 1.3). Following A&P there are

a series of group based workshops called Active Pain Treatment (Table 1.3). Patients are given strategies and resources to help them make appropriate lifestyle changes aimed at improving their pain, again based on the five key treatment areas.

Table 1.3: Groups sessions at Hunter Integrated Pain Service

Session name [average wait time]	**# sessions (hours)**	**# patients**	**Clinicians involved**	**Session content**
Understanding Pain (UP) [from referral: 6-8 weeks]	1 (2)	Max 30	Facilitator: Nurse or Physiotherapist Presenter: Medical Specialist	- Orientation seminar - Explain the current science behind chronic pain - Whole person approach to pain management (see Fig 4) - Introduce services offered by HIPS
Assessment and Planning (A&P) [from UP: 4 weeks]	1 (5)	Max 12	Pain Specialist Clinical Psychologist Pain Physiotherapist	- Guided by clinicians, patients self-assess their pain using the whole-person approach to pain management (Fig 4)
Active Pain Treatment (APT) [from A&P: 4 weeks]	1/week for 6 weeks (3.75)	Max 12	Clinical Psychologist Pain Physiotherapist Nurse	- Patients learn active strategies to manage their pain - Strategies related to the whole-person approach to pain (Fig 4)
Intro to Mindfulness	1 (4)	Max 12	Clinical Psychologist Pain Physiotherapist	- Provide evidence of the role of mindfulness in managing chronic pain and associated mental health issues - Participate in mindfulness practices
Mindfulness	1/week for 8 weeks (3.5)	Max 12-15	Clinical Psychologist Pain Physiotherapist	- Practice mindfulness skills to calm the mind and nervous system

1.5 Evaluating Australian Pain Services: ePPOC

The electronic persistent pain outcomes collaboration (ePPOC) is an initiative of the FPM and is monitored and coordinated by the Australian Health Services Research Institute (AHSRI) at the University of Wollongong (75). Development of ePPOC began in 2011 and the first national annual report was published in 2014 with 12 services providing data (23, 75). The most recent report, the 2018 mid-year report included data from 30,193 active patients from 64 adult services (43). There is also additional data presented in the 2016 annual report with 17,000 patients from 46 adult services (23). The aim of ePPOC is to improve services and outcomes for people experiencing chronic pain by developing a national benchmarking system for Australia and New Zealand (75). Data is collected from participating services every six months. This data is analysed and reports are generated at a national level and service level.

A minimum data set (86 items) which was established by members of the FPM who worked with the APS and New Zealand Pain Society to ensure a standardised assessment tool was developed to capture outcomes of interest (75). Measures had to incorporate the multidimensional aspects of pain, as well as be clinically relevant (75). Nine domains were created including patient characteristics (14 items), pain (5 items), physical disability (1 item), cognition (2 items), mood (1 item), health care utilisation (1 item), medication use (3 items), service activity (3 items), and treatment (1 item) (75). Several validated tools were included within these items which included the Brief Pain Inventory (pain and physical disability) (76), Depression Anxiety and Stress Scale (mood) (77), Pain Self Efficacy Questionnaire (cognition) (78) and Pain Catastrophizing Scale (cognition) (75).

The ePPOC report also compares services to benchmark targets which are set to reflect best practice (43). This benchmark is set by the proportion of patients who achieve a clinically significant improvement (79) from referral to the end of their active treatment (43). The number of services who met the benchmark for reduction in average pain severity and interference were 25 (out of 49) and 42 (out of 49) (43). Thirty-three percent and 65% of patients made clinically significant improvements in these outcomes (43). For depression, anxiety and stress 39/47, 13/46 and 35/44 services met the benchmark with 60%, 45% and 59% of patients making a clinically significant improvement (43). Thirty-four (out of 47) and 30 (out of 49) services met the

benchmark for pain catastrophising and pain self-efficacy, respectively (43). Fifty-six percent and 52% of patients made a clinically significant improvement (43). For patients taking opioids as measured by oral morphine equivalent daily dose at referral, a total of 44% of patients reduced their intake by ≥50% (43).

With the establishment of ePPOC, pain services can now evaluate their own clinical practice compared to clinical benchmarks determined by ePPOC Clinical and Management Advisory Committee. However, there are still limitations as it is not common practice to undertake clinical audits to identify patients' individual goals and needs, in particular in the domain of nutrition. Furthermore, due to resource limitations in clinical services, they do not routinely undertake qualitative research to investigate patients' goals and needs and how implementing new treatment approaches might affect the current service provision. With the complexity of chronic pain, its treatment and requisite clinical resources it would be useful to explore the opinions of staff and patients before changing current practice.

1.5.1 Patient demographics: Summary from 2018 mid-year & 2016 annual ePPOC report for all services

Analysis of adult data from all services (n=30193) in the 2018 mid-year report found 57% of patients were female, the average age at the time of referral was 50.3 years . Fifty-two percent of patients were born in Australia and 3.8% identified as being Aboriginal and/or Torres Strait Islander origin (43). A small percentage of patients needed assistance with written or spoken communication (8.3%) or required an interpreter (4.4%) (43). Thirty-nine percent of patients were unemployed due to their pain condition (43). The top three comorbidities reported by patients were depression/anxiety, arthritis and heart/circulation problems including high blood pressure and high cholesterol (43). Data in the 2016 annual report shows that over 90% of patients reported that pain affected the number or hours and type of work they were able to do and 78% of patients reporting one or more comorbidity (23). The average BMI was 29.3±7.7 kg/m^2 (overweight category) with 2% of patients' underweight, 28% normal weight, 31% overweight and 39% obese (23).

1.5.2 Pain: Summary from 2018 mid-year & 2016 annual ePPOC report for all services

For 26% of patients, their pain was triggered by injury at work or school, 39% had experienced their pain for more than five years and in 2016, 88% described their pain as always present (23, 43). The back was the top reported main pain site (43%) and 36% patients reported having pain in 4-6 body regions or sites (43). Average pain severity at referral was 6.1 which falls into the moderate category and average pain interference was 6.9 which is categorised as severe (43).

1.5.3 Mood and cognition: Summary from 2018 mid-year ePPOC report for all services

On average, patients reported moderate depression (18.7), anxiety (12.9) and stress (20.1) (43). Patients' self-efficacy in relation to pain management, on average was rated as moderate (43). Pain catastrophising was rated as moderate (i.e. exaggerating a negative mental state due to pain (80)) over their pain experiences and how it affected their day to day activities (43).

1.5.4 Medication use and health service utilisation: Summary from 2016 ePPOC annual report for all services

Over half of patients were taking opioids (57%) on more than two days per week (43). On average, in the last three months patients visited a GP and/or allied health professional 4.7 times (23). This was followed by a medical specialist and/or diagnostic test (1.5 times), an emergency department visit (0.5 times) or hospital admission (0.3 times) (23).

1.6 Relationship between nutrition and chronic pain

The five key areas outlined in the whole-person approach to pain management (Figure 1.3) interrelate with each other and Figure 1.5 shows the interaction between nutrition and each area.

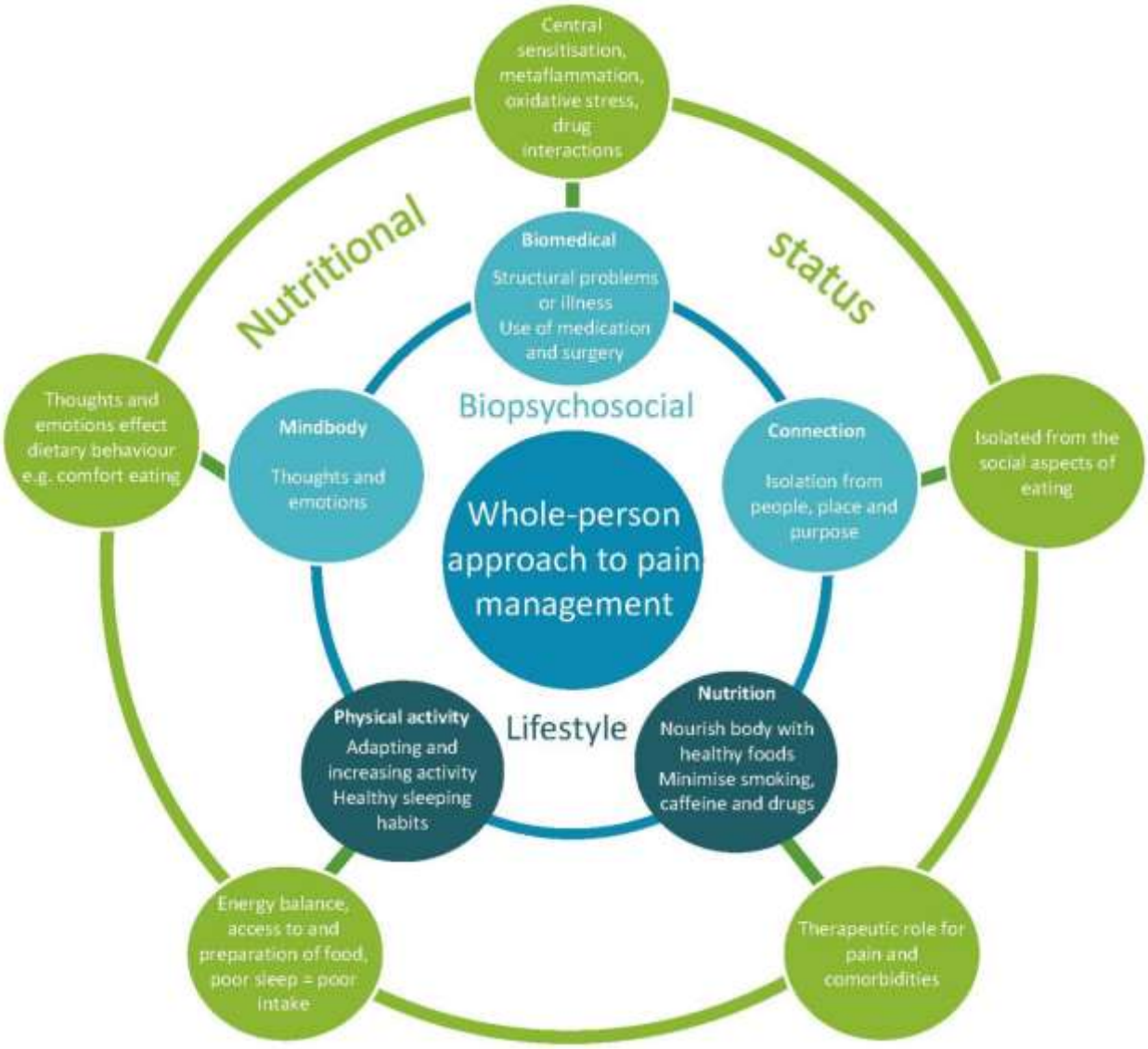

Figure 1.5. Interaction between the whole person approach to pain management and nutrition

The relationship between chronic pain and nutrition has been intermittently acknowledged throughout the evolution of pain science and pain management (9, 20). At an international level, in 2001, the International Association for the Study of Pain (IASP) and European Federation of IASP Chapters recommended that the world adopt the concept that chronic pain is a disease in its own right (20). A declaration and rationale to support this was put to the European Parliament in 2001. The rationale acknowledged the fundamental and complex physical and psychosocial changes that are associated with chronic pain (20). Eleven examples of how chronic pain burdens an individual were outlined which included *poor appetite and nutrition* (20). In Australia,

in 2015, the Faculty of Pain Medicine also recognised nutrition as one component in an active interdisciplinary approach to pain management (81). The Faculty of Pain Medicine also listed a number of health care professionals who should be considered to provide input in patient care, if necessary (81). A dietitian was listed as one of the health professionals. This can also be seen in *Guidelines for Units Offering Training in Multidisciplinary Pain Medicine*, also published by the Faculty of Pain Medicine in 2013 where dietetics is listed as a profession which should be consulted if needed (82). In 2016, dietetics was also added to the list of disciplines to select from when becoming a member of the Australian Pain Society (83). The ACI Pain Network also acknowledged the importance of nutrition by including a page on their website which was established in 2014 called *Pain: Lifestyle and Nutrition* which is presented by an Advanced Accredited Practicing Dietitian (84).

Since the commencement of this PhD more evidence and support for the role of nutrition has been generated. Most recently, in early 2018, the Australian Pain Society collaborated with several experts to publish *Pain in Residential Aged Care Facilities: Management Strategies*, 2nd edition (85). Compared to the first edition published in 2005, this internationally recognised document now contains a chapter on nutrition which was written by four Accredited or Advanced Accredited Dietitians (86). This highlights that nutrition is now being recognised as an important component to pain management. The Australian Pain Society is also advocating for nutrition issues in the elderly which have been highlighted as an important issue in the Aged Care Royal Commission and Senate enquiry into aged care (87). Another recent acknowledgement of the importance of nutrition was its inclusion in the Consortium Pain Task Force White Paper published by Tick et al. in 2018 (88). This paper discusses the role of nutrition from an anti-inflammatory perspective with reference to vegetables, fruits, legumes, nuts, seeds, healthy oils, wholegrains and low levels of animal protein as well as the role of antioxidants (88). Micronutrient deficiencies are also highlighted as contributing to pain experiences (88). Common deficiencies include Vitamin D, Vitamin B12 and magnesium (88). Vitamin D functions as an antioxidant and is associated with muscle fatigue risk factors, therefore deficiencies may exacerbate pain experiences (88). Vitamin B12 plays a role in a number of neurological processes related with pain and magnesium is associated with muscle spasm, inflammation and

neuropathic pain (88). Tick et al. also discusses the role of turmeric and omega-3 in pain management, particularly due to their anti-inflammatory properties (88).

From the patient perspective, a 2013 qualitative study conducted by Chronic Pain Australia, an organisation which represents individuals experiencing pain, reported that the individuals who took part in the focus groups explicitly noted diet as an area for which they would like more information in relation to pain management (89). This helped to inform the content for the ACI pain management website (84).

Despite this, to date, consideration of nutrition has been limited. Van Hecke et al. acknowledges the lack of high quality human studies exploring nutrition interventions in people experiencing chronic pain (90). The NPS states that those with chronic pain require support for ongoing self-management (53). This requires health education strategies which emphasises the: *recognition that a healthy lifestyle is still possible despite chronic pain* (53). Healthy lifestyle includes healthy eating, however clinically, there is limited nutrition education and support available due to limited resources, and when it is provided it is not developed or delivered by an Accredited Practicing Dietitian.

At present, when pain services identify patients who should have a consultation with an Accredited Practicing Dietitian (APD) they are either referred to an outpatient clinic, available in some public hospitals, however they commonly have long waiting lists (91). APDs can also be accessed via private service which have costs in the range of $50 to $150 (91). Individuals with a chronic health condition can get financial assistance if they are referred to an APD by a general practitioner under the Medicare Benefits Scheme, although there can still be a gap payment (92). Alternatively, those with private health insurance may be able to receive financial assistance for appointments with an APD (91). For rural and remote communities there are additional barriers such as the availability of APD's or long travel times to reach an APD.

More recently, lifestyle factors such as nutrition, physical activity and sleep have been suggested as important factors contributing to low grade systemic inflammation or metaflammation which in turn can influence pain experience. As with pain, inflammation is a necessary and appropriate response to injury (93). However, when the body is constantly under physical, psychological or environmental stress this leads to

alterations in the function of the nervous, endocrine and immune systems leading to the production of pro inflammatory cytokines (9). This low grade, chronic and systematic inflammation is known as metaflammation and is very different to the classic and acute inflammation (94). Metaflammation is associated with abnormal changes to the vascular endothelium, increasing the risk of cardiovascular disease and metabolic syndrome (93). However, more recently it has been identified that this metaflammation can extend to the nervous system and activate the non-neural cells which protect the nervous system, glial cells (95, 96). This further contributes to the hypersensitivity of the peripheral and central nervous system (96, 97). Lifestyle based intervention such as changes to dietary behaviours and intake, physical activity and sleep help to reduce metaflammation in the vascular endothelium. The role of such interventions in helping to reduce the neurovascular inflammation contributing to chronic pain needs consideration (9).

Traditionally the biopsychosocial approach to pain management has focused on accepting and managing pain, however by emphasising lifestyle factors as part of a whole person approach there is potential to go beyond managing pain to provide a chance to reduce or resolve pain experiences (9) .

1.6.1 Obesity and chronic pain

Overweight and obesity is defined as excessive accumulation of fat which may impair overall health and wellbeing (98). Body Mass Index (BMI) is a weight-for-height index (kg/m^2) which is commonly used to classify weight status in adults (99). The BMI categories are: Underweight (<18.5 kg/m^2); Healthy weight range (18.5-24.9 kg/m^2); Overweight (25-29.9 kg/m^2); Obese Class I (30-34.9 kg/m^2); Obese Class II (35-39.9 kg/m^2); and Obese Class III (>40 kg/m^2) (99).

Fundamental causal relationships between obesity and chronic pain currently remain unclear. While evidence supports that obesity is a risk factor for chronic pain, other evidence provides support for chronic pain as a risk factor for obesity. There are several studies (100-102) which explore the relationship between obesity and pain, with some studies reporting that a higher BMI is associated with a higher level of pain. Two studies conducted in the United States of America (n=3637 and n=1,062,271) found that those with a higher BMI self-reported moderate and severe pain (100, 102). Hitt et al reported that participants who were classified as class I or class II obese were twice as likely to report severe pain as measured using two short answer questions when

compared to participants who were underweight or who had a normal weight (100). This increased to 2.3 times more likely in participants who were classified as class III obese (100). Stone et al found that those who had obesity (class I-III) were approximately 1.3 to 2 times more likely to experience pain (102). In both studies, after controlling for demographic and lifestyle confounding factors the association was still substantial between pain and those who were in the obese groups (100, 102).

Obesity is associated with several pain-related conditions with low back pain, headache, fibromyalgia, abdominal pain, pelvic pain and neuropathic pain associated with a higher BMI (41, 103). Data from a twin registry in the United States was analysed and found that twins with overweight or obesity were 1.3-3 times more likely to report back pain, abdominal pain, headache and fibromyalgia (103). Another study exploring additional clinical measures such as metabolic syndrome, insulin resistance and inflammation markers found that central obesity was the strongest independent association with pain and other aspects of the metabolic syndrome, insulin resistance and inflammation markers were not significantly influential in contributing to pain experiences (104).

The coexistence of chronic pain and obesity amplifies the interference with performing daily activities and quality of life. A cross-sectional population based study conducted in Australia (n=2600) found that there was a strong association between obesity and patients reporting *pain that interfered moderately or extremely with day-to-day activities*, when compared to those without pain (OR 2.25, 95% confidence interval 1.57, 3.23, $p<0.001$) (105).

1.6.2 The effect of chronic pain on dietary intake

Few studies have explored the association between dietary intake and chronic pain. Of those that have, one study compared the dietary intake in people with chronic pain to those without. Using data from the British Birth Cohort Study (n=89573, aged ≥45 years, 12% with chronic pain), a series of diet-related questions were extracted from a larger questionnaire for analysis (106). These questions aimed to determine the frequency of consumption of the following food items of groups: fruit and vegetables, foods high in fat, hot chips and alcohol (106). Analyses indicated that the fruit and vegetable consumption of women with chronic pain was more likely to decrease over time when compared to women with no pain, with participants transitioning from high consumption to low/rare consumption (106). Diet quality was also lower in women with

chronic pain. This was measured by fruit and vegetable consumption less than once per week [OR 2.0; 95% CI 1.3 to 3.1] and fatty foods [OR 1.7; 95% CI 1.1 to 2.7] and chips consumed at least once per day [OR 1.5; 95% CI 1.0 to 2.4] (106). These findings are supported by a study which compared bodily pain scores, as measured using the SF-36, where a higher score represents less pain to quintiles of diet quality (107). Diet quality scores were divided into quintiles with the 1st quintile representing the lowest diet quality and the 5th quintile representing the highest dietary quality (107). The pain score, measured by SF-36, where a higher score represents lower pain, of those in the lowest quintile was 66.6/100 compared to those in the highest quintile 71.8/100 (107). This indicates that those with a higher diet quality have less pain (107). Another study conducted by Meleger et al. found that the dietary intake of people experiencing chronic pain was suboptimal (108). The study found that one third of male and approximately half of the female participants were consuming more than the recommended energy intake (108). The percentage of energy coming from fat was moderate, contributing to 34.1% of energy intake, while the percentage energy coming from saturated fat exceeded the recommendations of 10% at 12.1% (108).

Not only is there a relationship between dietary intake and chronic pain, there is also a relationship between dietary behaviours and chronic pain. Dietary choices are often influenced by pain. Focus groups were conducted with people who experienced pain at a level of $\geq 4/10$ for minimum 3 months, and with a diagnosis of chronic pain condition and had a BMI ≥ 25 kg/m^2 (overweight or obese) (109). Many participants expressed emotional eating or binge eating behaviours as a response to pain, this often coincided with depression and negative feelings such as guilt (109).

1.6.3 The impact of dietary intake and behaviours on chronic pain

In 2002, a review found that the current 'Western diet' which is low in fruit and vegetables and high in refined foods, sugar and meat contributes a pro-inflammatory state which in turn, contributes to the pain experience (110). This eating pattern leads to low levels of antioxidants, phytochemicals and essential fatty acids, which are conducive to promoting an inflammatory state (110).

1.6.4 Dietary supplements and pain management

Various dietary supplements have been the focus of many studies which aim to reduce pain experiences. One of the most popular has been fish oil supplements and/or omega-3 fatty acid for relieving pain, particularly in arthritic conditions such as rheumatoid arthritis and osteoarthritis. This is due to the effect omega-3 fatty acids have on the inflammatory process as they help to reduce pro-inflammatory prostaglandins (111). A 2017 systematic review found 18 randomised control trials where patients with rheumatoid arthritis (n=1143) were prescribed >2 g omega-3 per day or a control (either capsules containing air or a vegetable oil) (112). Ten of these studies found a statistically significant reduction in patient reported or physician assessed pain (112). Eight studies found no difference (112). Another systematic review and meta-analysis collated data from 42 randomised control trials which prescribed a marine oil (fish, seal or mussel) or a control (air filled capsule, vegetable oil or unspecified) to patients (n=2751) with arthritic conditions (113). Doses of DHA ranged between 0.01-2.7 g/day and EPA ranged between 0.013-4.05 g/day (113). Of the 42 studies, 30 contained data on pain outcomes including patients with rheumatoid arthritis (n=22), osteoarthritis (n=5) and other (n=3) (113). Overall the quality of these studies were low and highly heterogeneous (I^2 = 63%), however the standardised mean difference (SMD) was -0.24 (95% CI: -0.42, -0.07, p = 0.007) (113).

More recently, there has been growing interest and research into the effect of non-nutritive bioactive compounds such as polyphenols. Polyphenols are a type of antioxidant and they help to reduce inflammation and reduce oxidative stress (114). Polyphenols can be further categorised into flavonoids and anthocyanins (114). Anthocyanins are found in plants with red, purple and blue pigments (115). Cherries have been identified as containing high concentrations of anthocyanins and have been tested in vitro (116-120), animal (121-123) and human studies (124-126) to investigate if it can reduce inflammation and pain.

A recent review published in 2018 explored the health benefits of cherries in human studies (127). Twenty-nine studies were identified where participants consumed between 45-270 cherries/day which is equivalent of 55-720 mg anthocyanins/day (127). Various health benefits were included with the majority of studies finding positive results (i.e. reduction of the symptom or improvement in outcome) (127). The health

conditions included: oxidative stress (8/10 studies had a decrease in oxidative stress); inflammation (11/16 studies had reduction in inflammation); exercise-induced muscle soreness and loss of strength (8/9 studies found improvements in soreness and strength); arthritis (5/5 studies found reduction in frequency of flare ups) (127). Other improvements were reported with hypertension and sleep (127). Women with diabetes also had improvements with haemoglobin A1C and people with obesity had improvements with cholesterol (127).

Previous studies have provided participants with various doses of cherry juice based on what is feasible for someone to consume but also due to a lack of empirical research it is difficult to determine the dose requirements of anthocyanins. A randomised control trial testing the effect of anthocyanins on memory, blood pressure and inflammation in older adults provided participants with 200ml/day of cherry juice (intervention group) compared with 200ml/day of apple juice (control group) . This study found a significant improvement in memory and blood pressure, however no changes in inflammatory markers (128). Another randomised control trial provided participants with 480ml/day of cherry juice vs 480ml/day of a control drink prepared using cherry flavoured cordial (129). This study investigated the effects of the cherry juice on blood lipids, blood pressure and inflammation in older adults (129). Findings showed that there was a significant improvement in C-reactive protein and LDL cholesterol (129). A recent systematic review has also found that dietary polyphenols (from a range of foods including strawberries and tart cherry juice) may slow the progression of osteoarthritis and decrease inflammation, however the heterogeneity among the included studies means it is difficult to make any definite conclusions about the effect of polyphenols on osteoarthritis (130).

1.7 Providing dietary advice to people with chronic disease: What is best practice?

At the core of dietetic practice is the Nutrition Care Process (NCP) which clearly states that its purpose is not to standardise care but to provide consistent and high quality individualised care (131). The NCP includes four steps: Nutrition Assessment; Nutrition Diagnosis; Nutrition Intervention; and Nutrition Monitoring and Evaluation (131). Each of these steps include a framework and standardised terminology to ensure consistent practice (131). The framework constantly refers to an individualised approach or

tailored to the client's needs emphasising that each individual has different circumstances and a one size all approach is not appropriate in dietetic care (131). Accredited Practicing Dietitians use the NCP to translate evidence-based nutrition information into individualised and practical dietary advice in a number of conditions (e.g. cardiovascular disease and metabolic syndrome) and life stages. The effectiveness of dietitians providing individualised scientific advice has been demonstrated in a number of chronic diseases which is essential given that, worldwide, dietary intake is the top modifiable risk factor for morbidity (45). An essential component for the management of many highly prevalent chronic diseases such as overweight and obesity, cardiovascular disease and type 2 diabetes is modifying dietary intake and behaviours through individualised medical nutrition therapy provided by a dietitian (132-135).

A systematic review synthesised data from randomised control trials which tested diabetes prevention interventions to control groups (136). Overall it was found that providing nutrition education led to significant weight loss of 2.07 kg in 12 months ($p<0.001$) (136). Interventions delivered by dietitians compared to non-dietitians also found that there was a larger relative weight loss (overall sample -1 kg, USA subsample -2.4 kg) (136). A second systematic review identified 26 randomised control trials which examined the effect of nutrition care provided by a dietitian to patients in primary health care (137). Of the 26 studies included, 18 studies showed a statistically significant improvement favouring the intervention group particularly in the following outcomes: dietary quality, weight loss and glycaemic control (137).

Despite the demonstrated benefits of using a personalised approach to nutrition care, very few pain services employ an Accredited Practicing Dietitian and when nutrition advice is provided it is often broad and generic (56).

1.8 Use of technology in treatment

Technology is becoming more readily available to both the community and the health care system (138). The use of technology in health care also addresses many access barriers, making care easier to access for those who are physically housebound or who have a mental health condition where they would prefer to stay home. In particular, telehealth is currently being used by pain services to provide care to patients. Dietitians also use telehealth to provide effective care in people with chronic disease. However, to

date, the use of telehealth to provide dietary advice to patients at pain services is limited/non-existent.

1.8.1 Definition of telehealth

Telehealth, also known as telemedicine, is defined as remote delivery of health care through the use of telecommunication and information technology (139). Telehealth is delivered using telephone or video conferencing software via the internet. Video conferencing allows for real time one on one consultations between a clinician and patient. Both the audio and video are streamed to each party which allows both the clinician and patient to act as though they were attending an in-person consultation. People experiencing chronic pain have difficultly mobilising and travelling long distances. Travelling to appointments can also add significant financial burden to patients.

1.8.2 Accessibility of technology and telehealth

Eighty-six percent of Australian households are connected to the internet and 88% of individuals own a smartphone (138, 140). The percentage of internet users who accessed health information online more than doubled from 22% (2014-15) to 46% (2016-17) in recent years (138). There is potential to use this medium to reach people experiencing pain who may have difficulty mobilising and travelling long distances to reach in-person care.

1.8.3 Telehealth in pain management

1.8.3.1 Telehealth use in Australian Pain Services

Telehealth has only become more common in recent times and currently it is used by some pain management services in Australia, including Hunter Integrated Pain Service, Orange Base Hospital Chronic Pain Telehealth, St George Pain Management Unit Telehealth Clinic, Concord Hospital Chronic Pain Telehealth, Illawarra and Shoalhaven Chronic Pain Service and Nepean Hospital Pain Management Unit Murrumtele Chronic Pain Telehealth (NSW) (52) and Gold Coast Interdisciplinary Persistent Pain Centre (Qld) (141). The Agency for Clinical Innovation (ACI) has also developed a chronic pain telehealth toolkit available to all services wanting to implement telehealth (97).

1.8.3.2 Benefits of using telehealth in pain services

One of the main benefits of using telehealth to provide pain management services is that it helps to reduce the long wait times associated with accessing care. IASP recommend that wait times for uncomplicated pain should be no longer than eight weeks (142). However, in reality, wait times range from 3-6 months (43, 60). Wait times which exceed 6 months which have consequences such as decreased mood, quality of life and increased disability (59). It also extends reach to patients who have to travel long distances to access in-person care (143).

Services using telehealth to deliver care will also benefit from the cost effectiveness of using telehealth. While the initial set up is more expensive, the ongoing costs are less expensive than in-person care. This was found in a study conducted by Pronovost et al. where the start-up costs were approximately $60,000 (144). However, after using telehealth for five years the cost savings for telehealth appointments ($133 per patient) outweighed the in-person appointments ($433 per patient) (144).

1.8.3.3 Effectiveness of delivering treatment using telehealth

Herbert et al. conducted a randomised controlled trial with 128 chronic pain participants who were randomised into either video teleconferencing or in person acceptance and commitment therapy (145). Both groups had a statistically significant reduction in the primary outcome, pain interference as measured using the Brief Pain Inventory (145). The video teleconferencing group had a mean reduction of -1.37 (-1.75, -0.98) $p<0.001$ and the in-person group had a mean reduction of -1.17 (-1.5, -0.85) $p<0.001$ (145). Another randomised control trial with 118 participants with fibromyalgia were randomised to a web based exercise and behavioural self-management program or standard care for eight weeks (146). A greater percentage of those in the web-based group (29%) reported a 30% mean reduction pain severity as measured by the Brief Pain Inventory compared to the standard care group (8%), $p<0.008$ (146). Similar results were seen with physical function (SF-36), with 31% in the web based group with a 0.5 standard deviation improvement compared to 6% in the standard care group, $p<0.002$ (146).

1.8.4 Providing dietary advice via telehealth in chronic disease

A recent systematic review has analysed the effect of dietary interventions provided via telehealth to adults with a chronic disease (147). Twenty-five randomised controlled trials were included with participants (n=7384) diagnosed with either of the following: obesity, diabetes, heart disease, hypertension, stroke or kidney disease (147). Dietary interventions had to involve changing overall dietary patterns, ≥2 nutrients or food groups (147). The review found that providing this advice via telehealth was effective for both dietary and clinical outcomes. Diet quality improved by a standardised mean difference (SMD) of 0.22 (95% CI: 0.09, 0.34, p = 0.0007), fruit and vegetable intake increased by 1.04 servings/day (95% CI: 0.46, 1.62 servings/day, p=0.0004) and dietary sodium intake reduced -0.39 (95% CI: -0.58, -0.20, p = 0.0001) (147). Clinical outcomes which also significantly improved included (mean difference): systolic blood pressure (-2.97 mm Hg, 95% CI -5.72, -0.22 mm Hg, p=0.05); total cholesterol (-0.08 mmol/L, 95% CI: -0.16, -0.00 mmol/L, p=0.04); triglycerides (-0.10 mmol/L, 95% CI: -0.19, -0.01 mmol/L, p=0.04); weight (-0.8 kg, 95% CI: -1.61, 0 kg, p=0.05) and waist circumference (-2.08 cm, 95% CI: -3.97, -0.2 cm, p=0.03) (147).

The increased use of telehealth in dietetic practice has also led to the development of guidelines for dietetic video consultations for weight management (148). These guidelines also incorporate the recommendations and frameworks outlining in the NCP to ensure that a personalised approach is not lost by delivering nutrition care through video consultations (148). The guidelines outline the requirements for several components of consideration for using telehealth including: privacy and security standards, administrative requirements, technical requirements and clinical factors as per the NCP which includes nutrition assessment, nutrition diagnosis, nutrition intervention and nutrition monitoring (131, 148).

Despite the successful use of telehealth to provide care to those experiencing chronic pain and the successful use of telehealth to provide dietary advice to those with chronic diseases, the use of telehealth to provide dietary advice to those with chronic pain has not been explored previously.

1.9 Theoretical domains framework and behaviour change wheel

Behaviour change at a service and personal level can be difficult. Utilising evidence based principles of behaviour change theories is more effective as these theories conceptualise potential barriers so that they can be incorporated into proposed changes or interventions.

From a service perspective, implementing evidence-based practice requires health care professionals to change their practices and behaviours. The theoretical domains framework addresses the potential barriers to changing health care professionals' behaviours (149). The TDF is made up of 14 constructs which include:

- Knowledge: Awareness and understanding of scientific, procedural and task environment (149).
- Skills: Skill development, competency, ability, practice and interpersonal skills (149).
- Social/professional role and identity: Acquiring and maintaining social/professional identity, role, confidence, boundaries and organisational commitment (149).
- Beliefs about capabilities: Acceptance and validity regarding self-confidence, self-efficacy, behavioural control and empowerment (149).
- Optimism: Confidence that tasks will be achieved and goals attained (149).
- Beliefs about consequences: Acceptance of truth and expected outcomes (149).
- Reinforcement: Use of rewards, incentives or punishments to increase the probability of a response (149).
- Intentions: Stability of conscious decisions to perform a behaviour, intrinsic motivation and goal setting (149).
- Goals: Planned outcomes that an individual wants to achieve and related to goal setting, action planning and implementation intention (149).
- Memory, attention, decision processes: Ability to retain information and make decisions or choose between alternatives (149).
- Environmental context and resources: Environment can encourage or discourage action such as environmental stressors, resources and organisation culture (149).
- Social influences: Includes social pressures, group conformity and conflict (149).
- Emotion: Interaction between experimental, behavioural and physiological elements leading to feelings such as anxiety, stress, burn-out (149).

- Behaviour regulation: Actively managing or changing behaviour such as self-monitoring, breaking a habit or action planning (149).

The Behaviour Change Wheel allows researchers to design behaviour change interventions by taking into consideration aspects which influence the behaviour of individuals and subsequently impact on the success of the intervention (150). The sources of behaviour can be categorised into three main concepts: capability, motivation and opportunity (150). Capability refers to an individual's psychological and physical ability to engage in a particular activity, it refers to the knowledge and skills individuals need to complete a task or activity (150). Motivation involves the brain processes that encourage or direct a particular behaviour beyond goals and conscious decision making, it includes emotional responses and analytical decision making (150). Opportunity includes all the factors that lie outside the control of the individual such as the environment they are in (150). The corresponding intervention functions for each of these include: education, persuasion, incentives, coercion, training, enablement, modelling, environmental restructuring and restrictions (150). Researchers can identify any gaps individuals might have in their behaviour and utilise the corresponding intervention to increase their capability, motivation and opportunity to change their behaviour (150).

1.10 Limitations of current research

Traditionally, comprehensive nutrition treatment options have been underrepresented within pain services. However, patients with chronic pain want nutrition addressed more frequently. This thesis will unite these areas and provide a comprehensive explanation and assessment of the role nutrition has in chronic pain management

Given the effectiveness of personalised dietary consultations exceeds that of a one-size fits all approach, this thesis will develop and evaluate an evidence based personalised dietary intervention which will be delivered using existing telehealth infrastructure available at HIPS.

This thesis will combine evidence based personalised dietary consultations with existing telehealth infrastructure currently being used at HIPS.

1.11 Summary

Tertiary pain services provide access to and support for patients in active self-management of chronic pain and aim to address aspects of a person's lifestyle. This includes healthy eating, physical activity, patterns of thinking and sleeping habits. Nutrition is an important component of lifestyle behaviours that influence health outcomes and is a leading risk factor contributing to morbidity and mortality in Australia (45). Despite this, dietetic services are not routinely provided within chronic pain services, due in part to budgetary limitations and because nutrition has not been forefront on the clinical radar. This PhD will investigate the role of dietary intake and nutrition in chronic pain management in the context of usual treatment.

The research projects in this thesis will generate new knowledge about the relationship between nutrition and chronic pain and are likely to have a broad range of applications when translated to the 4.6 million Australians who suffer chronic pain (22). This PhD was completed as part of a collaboration between nutrition researchers at the University of Newcastle (UON) and clinicians at Hunter Integrated Pain Service (HIPS) within the Hunter New England Local Health District in NSW, Australia. Ultimately, the aim of this PhD is to develop, implement and evaluate the effectiveness of a tailored web-based nutrition treatment pathway relevant to current practice at HIPS.

1.12 Research question

The overall research question for this thesis is:

How can people experiencing chronic pain use nutrition as part of their pain management approach?

1.13 Research aims

The aims of this PhD thesis are to:

1.13.1 Primary aims

1. Generate new evidence to address gaps in the literature exploring the role of dietary intake and nutrition in the management of chronic pain.

2. Develop, implement and assess the effectiveness of a personalised dietary intervention at HIPS

1.13.2 Secondary aims

The secondary aims of this thesis are summarised in Figure 1.6 below:

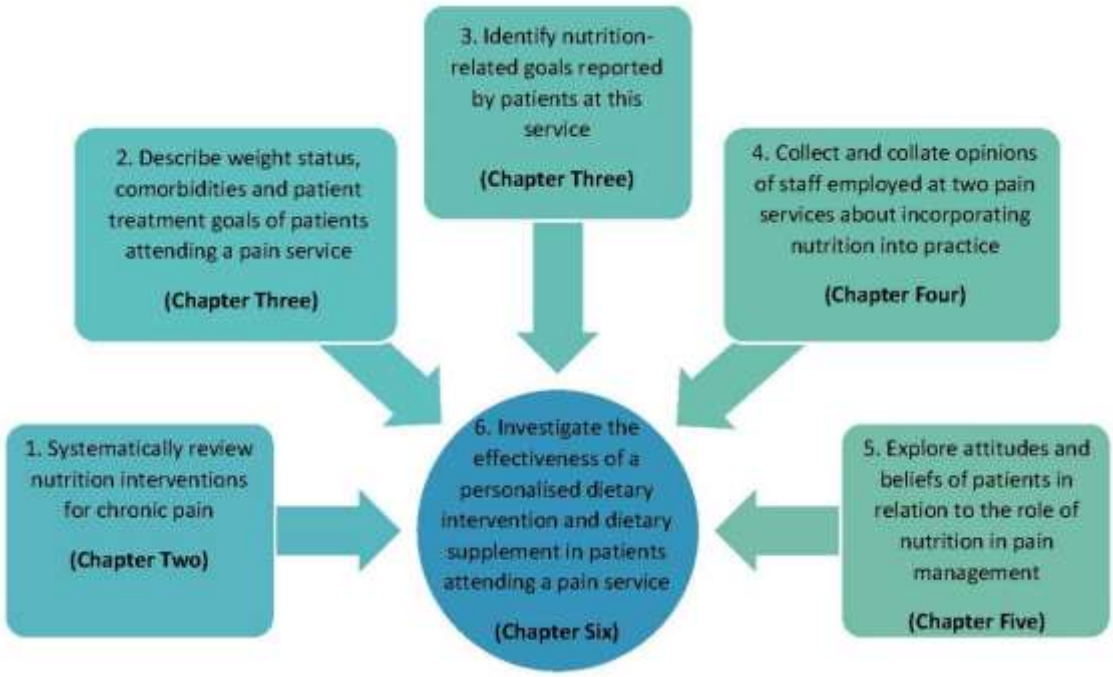

Figure 1.6. Relationship between the secondary aims and chapters in this thesis

1.14 Thesis structure

This thesis is comprised of seven chapters, which are outlined below.

1.14.1 Chapter 1: Thesis Introduction

This chapter provides background information which defines and describes chronic pain as well as the limited existing literature exploring nutrition in pain management. This chapter also provides rationale for focusing on incorporating nutrition interventions into current pain management services. The research aims are presented in this chapter.

1.14.2 Chapter 2: A systematic review and meta-analysis of nutrition interventions for chronic non-cancer pain

This chapter addresses both Primary Aims as well as Secondary Aim 1.

Brain K, Burrows TL, Rollo ME, Chai LK, Clarke ED, Hayes C, Hodson FJ and Collins CE. A systematic review and meta-analysis of nutrition interventions for chronic noncancer pain. Journal of Human Nutrition and Dietetics: The official journal of the British Dietetic Association. 2019;32(2):198-225.

This chapter systematically reviews the features and effectiveness of nutrition interventions on self-reported pain in populations with pain related conditions.

1.14.3 Chapter 3: Population characteristics in a Tertiary Pain Service Cohort Experiencing Chronic Non-Cancer Pain: Weight Status, Comorbidities and Patient Goals

Chapter 3 addresses both Primary Aims as well as Secondary Aims 2 & 3.

Brain K, Burrows T, Rollo ME, Hayes C, Hodson FJ, Collins CE. Population Characteristics in a Tertiary Pain Service Cohort Experiencing Chronic Non-Cancer Pain: Weight Status, Comorbidities, and Patient Goals. Healthcare (Basel). 2017;5(2).

This chapter systematically collates all nutrition intervention studies conducted since 1980 in populations with chronic pain or chronic pain conditions.

In addition, the protocol for this systematic review was registered with PROSPERO, ID number CRD42017055420. This is not included in the body of the thesis and is instead included as Appendix 2.

1.14.4 Chapter 4: Perceptions of tertiary pain service staff on including nutrition support within current treatment: A qualitative study

Chapter 4 addresses both Primary Aims as well as Secondary Aims 4.

Brain K, Burrows TL, Rollo ME, Thompson DI, Hayes C, Hodson FJ and Collins CE. *Perceptions of tertiary pain staff on including nutrition support within current treatment: A qualitative study.* SAGE Pathway [Under Review]

This chapter explores the opinions of staff employed at two tertiary pain services in Australia in relation to implementing a nutrition intervention into current service.

1.14.5 Chapter 5: Exploring the attitudes and beliefs of nutrition's role in pain management through semi-structured focus groups with patients experiencing chronic pain

Chapter 5 addresses both Primary Aims as well as Secondary Aims 5.

Brain K, Burrows TL, Rollo ME, Thompson DI, Hayes C, Hodson FJ and Collins CE. Exploring the attitudes and beliefs of nutrition's role in pain management through semi-

structured focus groups with patients experiencing chronic pain. Healthcare [Under Review]

This chapter explores the thoughts and experiences of patients attending Hunter Integrated Pain Service in relation to the role of nutrition within pain management.

1.14.6 Chapter 6: The effect of a pilot dietary intervention on pain outcomes in patients attending a tertiary chronic pain service (ReJUICE your pain study)

Chapter 6 addresses both Primary Aims as well as Secondary Aims 6.

Brain K, Burrows TL, Rollo ME, Hayes C, Hodson FJ, Collins CE. The Effect of a Pilot Dietary Intervention on Pain Outcomes in Patients Attending a Tertiary Pain Service. Nutrients. 2019;11(1).

This chapter presents the findings of the effectiveness of a dietitian-led nutrition intervention on pain experiences of patients from Hunter Integrated Pain Service.

1.14.7 Chapter 7: Thesis Discussion and Conclusion

This chapter presents a synthesis of the overall findings from the research presented in this body of work. The strengths and weaknesses are outlined and the recommendations for research and implications for practice are discussed.

Chapter 2: A systematic review and meta-analysis of nutrition interventions for chronic non-cancer pain

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2.1 Abstract

This systematic review aimed to evaluate the impact of nutrition interventions on participant reported pain severity and intensity in populations with chronic pain. Eight databases were systematically searched for studies that included adult populations with a chronic pain condition, a nutrition intervention and a measure of pain. Where possible, data were pooled using meta-analysis. Seventy-one studies were included, with 23 being eligible for meta-analysis. Studies were categorised into four groups: (i) altered overall diet with 12 of 16 studies finding a significant reduction in participant reported pain; (ii) altered specific nutrients with two of five studies reporting a significant reduction in participant reported pain; (iii) supplement-based interventions with 11 of 46 studies showing a significant reduction in pain; and (iv) fasting therapy with one of four studies reporting a significant reduction in pain. The meta-analysis found that, overall, nutrition interventions had a significant effect on pain reduction with studies testing an altered overall diet or just one nutrient having the greatest effect. This review highlights the importance and effectiveness of nutrition interventions for people who experience chronic pain.

2.2 Introduction

Chronic non cancer pain (hereafter referred to as chronic pain) is defined as pain that continues beyond the typical tissue healing time of 3 months (15). Nervous system sensitisation, brain perception and psychosocial factors play an important role in the experience of persisting pain. There are also associated changes in immune and endocrine systems (5). Neural sensitisation can be triggered following injury or disease of the nervous system itself or of bodily tissues (e.g. peripheral nerve injury or

osteoarthritis). At times, altered nervous system processing can generate pain in the absence of any identifiable structural contributors (22, 39). Multiple additional factors such as adverse childhood experiences, emotional dysregulation, unhelpful beliefs, stress, social isolation, low physical activity and poor nutrition can also contribute. Internationally, 20% of adults (18–65 years) and ≥33% of older adults (>65 years) have chronic pain. This is associated with disability, reduced function, poor quality of life, mental health issues and higher healthcare utilisation and costs (20, 26, 31, 39). The variability and complexity of chronic pain means that no individual person's pain experience is exactly the same as another person's. No objective tests for pain are available; hence, the many measurement tools available are all based on self-report. These include visual analogue scales and numeric rating scales (151), the Western Ontario and McMaster Universities Osteoarthritis Index Pain Score (WOMAC) (152), and the Short Form (SF-36) Health Survey, Bodily Pain subscale (153).

Comorbid conditions such as obesity, depression, anxiety, type 2 diabetes and cardiovascular disease are associated with chronic pain (40). Many of these conditions share a bidirectional relationship with chronic pain, where pain increases the risk of the condition, whereas the condition can exacerbate pain. For example, overweight and obesity rates are much higher in those with chronic pain (80%) compared to the general population (63%) (154, 155). A large proportion of people who experience chronic pain also have nutrition-related comorbidities such as high blood pressure, diabetes and heart disease (154). Dietary intake is among the top modifiable risk factors for the global burden of disease (156). Positive or negative dietary change can either lower the risk or increase the severity of all of the above mentioned conditions (157-160). Diet has a complex relationship with the experience of chronic pain itself. Dietary change has also been identified by those attending a clinical pain service for chronic pain as their highest treatment priority (154).

With a greater risk and prevalence of chronic disease in people who experience chronic pain and the acknowledged importance of diet, the inclusion of a comprehensive nutrition component to chronic pain treatment should be considered. Guidelines such as the European Pain Federation acknowledge nutrition as being important; however, the current available treatment options for pain do not recommend a nutrition service that

includes a review or consultation with a registered or accredited dietitian or a health professional with nutrition qualifications (20).

The current literature exploring the role between dietary intake and pain severity is quite heterogeneous and includes a variety of nutrition interventions and/or specific pain-related conditions (161-164). Several systematic reviews exist; however, these are limited by having focused on supplement usage, including alpha lipoic acid in those with diabetic neuropathy (164) and omega-3 fatty acid supplements in those with inflammatory joint pain (162). Both of these reviews found significant reductions in self-reported pain scores following supplement use over a time period of 3 weeks and 3–4 months, respectively (162, 164). Other systematic reviews have examined the effect of specific dietary pattern interventions (vegetarian, vegan and the Mediterranean diet) on self-reported pain in populations with fibromyalgia or arthritis, suggesting some beneficial results post-intervention with statistically significant differences in pain scores (161, 163). Hagen et al. (163) also explored the effect of a 3-week elemental diet (Elemental 028 Extra, Nutricia, Ireland) and use of an elimination diet on self-reported pain scores in arthritis, with neither demonstrating significant reductions in pain. These previous systematic reviews have only included single population groups, often with small samples sizes, single trials with moderate to high risk of bias, populations experiencing only one pain-related condition (i.e. arthritis or fibromyalgia), and limited aspects of diet. No previous review has considered chronic pain within community-based population samples, nor has total diet relative to control interventions been evaluated.

Therefore, the present systematic review aimed to summarise the available current literature evaluating the impact of nutrition interventions in participants experiencing a chronic pain condition, specifically focusing on participant reported pain severity, or intensity of pain.

2.3 Methods and materials

This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and the PRISMA 2009 checklist (Table S1) (Appendix 11) is provided in the Supporting information.

2.3.1 Search Strategy

A systematic literature search was conducted to identify studies published from 1980 to December 2017 that examined the effectiveness of nutrition-based interventions conducted in adults (>18 years old) who experience chronic pain. Eight electronic databases were used to search for relevant studies, and these included: MEDLINE, The Cochrane Library, EMBASE (Excerpta Medica Database), CINAHL (Cumulative Index to Nursing and Allied Health), Scopus, PsycINFO, Informit Health Collection and AMED (Allied and Complementary Medicine Database). A copy of the search conducted in MEDLINE can be found in Table S2 (Appendix 12). A preliminary search of the literature was used to inform the choice of key words. The final search comprised of the following key words used individually and in combination: chronic pain, persistent pain, pain, back pain, neuralgia, trigeminal neuralgia, hyperalgesia, fibromyalgia, phantom limb, complex regional pain syndromes, nociceptive pain, headache, endometriosis, migraine, arthritis, food, diet, eating, appetite, food habits, food preferences, nutrition, nutrient and diet therapy. The search was limited to results published in English only and study participants were adults aged ≥18 years. The protocol for this search was registered with PROSPERO, ID number CRD42017055420 (Appendix 2).

2.3.2 Screening process

All of the titles and abstracts of included studies were examined by one author (KB), whereas the second examination was shared by reviewers (CC, TB, MR, CH, LKC and MM) to determine whether the studies were eligible for inclusion. The full texts for studies meeting the inclusion criteria were retrieved. If the study's eligibility was unclear from the abstract, it was retrieved to be included in the full-text screening. The full text of included studies was examined by two independent authors (KB and LKC) to ensure the studies were eligible for inclusion. Any discrepancies between reviewers were resolved through discussion or a third reviewer.

2.3.3 PICOS criteria

2.3.3.1 Types of participants

Adults, aged ≥18 years, who reported experiencing chronic pain, were included in the review. Chronic pain was defined as pain that persists beyond the typical healing time

of 3 months (15). More detailed information regarding the PICOS criteria can be found in Table 2.1.

2.3.3.2 Types of interventions

Intervention studies that aimed to or included a dietary strategy to reduce pain were included. For the purposes of the current review, studies were classified by the authors into one of four categories: (i) altered overall diet (e.g. prescribed a specific diet such as vegetarian, vegan or Mediterranean); (ii) altered specific nutrients (e.g. altered the intake of a single nutrient at the same time as maintaining a usual diet); (iii) prescribed supplements (e.g. prescribed a supplement at the same time as maintaining a usual diet; and (iv) used fasting therapy (e.g. restricted total intake to 300– 350 kcal day^{-1}).

Table 2.1 PICOS criteria for inclusion and exclusion of studies

Criteria	Definition
Participants	Participants were adults, aged ≥18 years, who reported experiencing chronic pain. Chronic pain was defined as pain that persists beyond the typical healing time of 3 months
Intervention	Intervention studies that aimed to or included a dietary strategy to reduce pain were included. For the purposes of the current review studies were classified by the authors into one of four categories: (i) altered overall diet (e.g. prescribed a specific diet such as vegetarian, vegan or Mediterranean); (ii) altered specific nutrients (e.g. altered the intake of a single nutrient at the same time as maintaining a usual diet); (iii) prescribed supplements (e.g. prescribed a supplement at the same time as maintaining a usual diet; and (iv) used fasting therapy (e.g. restricted total intake to 300–350 kcal day^{-1})
Comparator	Any comparator was considered for inclusion. Hence, studies with no intervention control groups and standard care control groups were included

Outcome	Primary outcome: Studies were only included if they measured a change in chronic pain, either as a primary or secondary outcome. Changes in chronic pain included pain frequency, intensity or severity and could be measured using any pain assessment tool (e.g. visual analogue scale; VAS). Secondary outcomes: There were several secondary outcomes included in this review. These included but are not limited to changes in diet, quality of life, chronic disease risk and mental health (e.g. anxiety and depression)
Study design	All experimental studies were included in the review. Case studies, letters, reviews and conference abstracts were excluded

2.3.3.3 Types of comparators

Studies with no intervention control groups, standard care control groups or placebo groups were included.

2.3.3.4 Types of outcomes

Primary outcome. Studies were only included if they measured a change in chronic pain, either as a primary or secondary outcome. Changes in chronic pain included pain frequency, intensity or severity and could be measured using any pain assessment tool, such as the visual analogue scale (VAS).

Secondary outcomes. There were several secondary outcomes included in this review. These included, but are not limited to, changes in diet, quality of life, chronic disease risk and mental health (e.g. anxiety and depression). These outcomes were chosen to explore the comorbidities associated with chronic pain. Chronic disease risk incorporates blood lipids, blood sugars and blood pressure as makers for heart disease, diabetes and high blood pressure, which are all associated with chronic pain.

2.3.3.5 Types of studies

All experimental studies were included in the review. Case studies, letters, reviews and conference abstracts were excluded.

2.3.4 Data extraction

Relevant data, including participant demographics [e.g. age, gender, body mass index (BMI)], study methodology (e.g. design, setting, recruitment, inclusion/exclusion criteria, retention and intervention description), description of primary and secondary outcomes (e.g. measurement tool used, pre–post measures, *P*-value) and conclusions and limitations, were extracted by one reviewer (KB). The heterogeneity of nutrition interventions was categorised based on the type of nutrition intervention to assist with analysis. A second reviewer (LKC or EC) checked the data for consistency.

2.3.5 Risk of bias

Four reviewers (KB, LKC, EC and DC) independently assessed the risk of bias using the Academy of Nutrition and Dietetics Criteria Checklist for primary research (165). This tool includes 10 questions exploring the quality of each study by examining aspects such as participant selection, withdrawals, blinding, intervention and outcome descriptions and author affiliations. Four questions [(i) Selection of study subjects; (ii) Comparable study groups; (iii) Intervention description; and (iv) Outcomes] are considered of higher importance, which affect the classification of each study. If the study is not remarkably strong in these categories, the study is considered neutral; if all four of these criteria have been met and at least one other criterion, the study is considered positive. A study is considered negative if six or more criteria are not met.

2.3.6 Meta-analysis

Where available, results were pooled for meta-analysis to determine the overall effect of nutrition interventions on pain outcomes. The following data were collected: reported number of participants, mean (SD) for the pain outcome measure. There were a wide variety of outcome measures; however, the most consistently reported across studies was the VAS, and therefore, only studies using this measure were included in the meta-analysis. For these studies, all VAS data were converted where required and entered as a score out of 100. Meta-analysis was undertaken by overall nutrition intervention and also by each nutrition category: supplement, altered dietary pattern, altered nutrient and fasting therapy. If there was significant heterogeneity, the random effects model was used. Meta-analysis was conducted using COMPREHENSIVE META-ANALYSIS PROFESSIONAL, version 2 (Comprehensive Meta-Analysis, Engle- wood, NJ, USA).

2.4 Results

2.4.1 Study selection

Figure 2.1 summarises the selection process. After the removal of duplicates, a total of 7080 studies was identified in the search. Following full-text screening, 71 studies (124, 125, 166-234) were identified for inclusion, with 23 (167, 171, 174, 175, 180, 181, 183-185, 193, 199-204, 207, 216, 219, 221, 226, 230, 234) eligible for meta-analysis. The abstracts for the majority of the papers were not sufficiently detailed to determine whether the full text should be retrieved. As such, there were a large number of papers excluded when screening the full texts. Most of these papers were not experimental studies (*n* = 225), did not measure pain as an outcome (*n* = 112) or did not include appropriate nutrition intervention (*n* = 110).

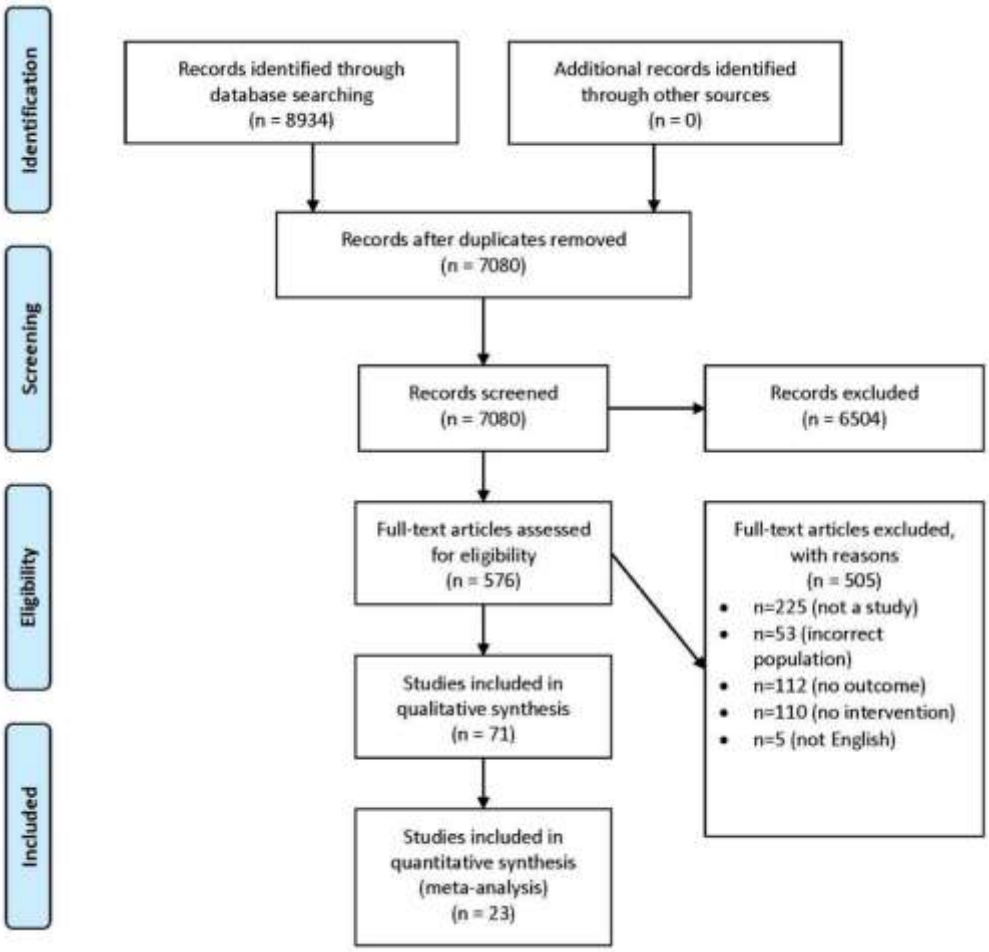

Figure 2.1. Systematic review flow chart.

2.4.2 Study characteristics

Characteristics of the included studies are reported in Table 2.2. Approximately 30% (n = 21) of the studies were conducted in the USA (124, 125, 170, 176-178, 180, 181, 184, 185, 187, 190, 197, 199, 206, 212, 214, 215, 224, 229, 231), with five undertaken in Australia (183, 186, 195, 218, 234), four conducted in each of Germany (167, 191, 216, 217), Japan (201-203, 211) and Spain (168, 182, 228, 233), and three conducted in each of Denmark (194, 196, 220), Finland (193, 200, 219), Sweden (225-227), Iran (192, 205, 221) and the Netherlands (222, 230, 232). Of the included studies, 47 were randomised controlled trials (RCT) (166, 168-171, 173-175, 179, 181-186, 190-192, 194-199, 201, 202, 204, 205, 207-209, 214, 218, 219, 221-228, 230, 232, 234), eight were nonrandomised trials (167, 193, 200, 203, 206, 213, 216, 217), nine were pre–post studies (176-178, 187, 211, 212, 215, 229, 231), six were randomised cross-over trials (124, 125, 172, 180, 188, 189) and one a longitudinal study (210).

2.4.3 Pain condition

The most common pain-related condition experienced by study participants was rheumatoid arthritis (n = 19 studies) (167, 172, 173, 183, 194, 196, 204, 206, 212, 213, 219, 220, 222, 225-227, 229, 232, 233), followed by osteoarthritis (n = 16) (124, 170, 174, 175, 184-186, 190, 192, 195, 198, 201, 202, 204, 205, 209) and fibromyalgia (n= 13) (125, 171, 178, 187, 188, 193, 200, 210, 214-216, 228, 233), migraine (177, 180, 189, 191) (n=4), chronic pain (199, 217, 234), joint pain (176, 179, 182), back pain (207, 223, 224), diabetic neuropathy (166, 181, 231) (n = 3), chronic pancreatitis (203), irritable bowel syndrome (IBS) (168), neuropathy (169) and headache (230) (n = 1). Two studies had participants with two pain-related conditions: rheumatoid arthritis and osteoarthritis (211) and fibromyalgia and IBS (197).

2.4.4 Risk of bias

Assessment of study quality rated 31 studies as of positive quality (124, 169, 181, 195, 202, 205, 208, 209, 211-220, 222-234), 36 as neutral (125, 167, 168, 170, 172-176, 178-180, 182-190, 192-194, 196-201, 203, 204, 207, 210, 221) and four studies were classified as being of negative study quality (166, 171, 191, 206). Of the 33 studies classified as neutral, information regarding the randomisation process (n = 29) or the intervention description (n = 13) was lacking. Outside of the four main criteria, blinding

was used in 37 studies and adequate information on the statistical analysis was available for 35 studies. More detailed information about the risk of bias is reported in Table 2.3.

2.4.5 Participant characteristics

Studies included a median of 48 (range 12-2121) participants. Of those that did report participant sex (68 out of 71 studies), 10 included female participants only (125, 178, 188, 200, 205, 210, 213, 221, 233, 234) with no studies exclusively in males. The remaining 58 studies included a mixture of male and female participants, with most of these studies reporting more than half the participants being female. From studies reporting age (n = 67), the variation in mean reported age was from 32.7 to 65.7 years. Of those that reported mean BMI (n = 38) the range was 18.3–36 kg m^{-2}, with 58% of study population samples having a mean BMI that fell in the overweight category (BMI25.0–29.9 kg m^{-2}).

Table 2.2: Study and intervention characteristics by nutrition category

Study characteristics				**Participant characteristics**		**Intervention description**		
Author (year) ***Country***	Study type (number of study groups)	Pain condition (duration)	Subcategory	N (% retention)	Sex (% female) age* BMI*	Study length (f/u) (weeks)	Intervention (i)	Control (c)
Altered dietary pattern								
Allison et al. (2016) ***Canada***	RCT (n=2)	Neuropathic pain (4-37 years post injury)	Anti-inflammatory	20 (100)	50 Total: 49 (14) NR	12	Anti-inflammatory diet: eliminate pro-inflammatory foods (e.g. high GI & hydrogenated oils) and include foods & supplements with anti-inflammatory properties (e.g. omega-3 & antioxidants). Info seminar and one-on-one consults with nutritionist	Usual diet
Azad et al. (2000) ***Bangladesh***	RCT (n=2)	FM (G1†: 67 (46), G2: 64 (79) months)	Vegetarian	78 (100)	78 Total: 40 (12) NR	4	Vegetarian diet: Provided prescription	Amitriptyline: 20-25 mg day^{-1}, dose dependent on insomnia. Titrated ≥100 mg if needed.
Bunner et al. (2014) ***USA***	RCT CO (n=2)	Migraine [24 (13) years]	Vegan	42 (90)	93 Total: 46 (13) Total: 28 (6)	6	Vegan diet: Provided prescription, then eliminate trigger food and reintroduce	Placebo supplement: Capsule containing 10 mcg ALA and 10 mcg Vitamin E
Bunner et al. (2015) ***USA***	RCT (n=2)	Diabetic neuropathy	Vegan	35 (97)	56 Total: 57 (6)	20	Low fat, plant based diet: Low GI foods, limit fat to 20-30 g day^{-1}, no animal products. 1000 mg B12	Usual diet: Plus 1000 mg B12 supp day^{-1}

		[diabetes 14 (10) years]			Total: 36 (6)		supp day^{-1}. Weekly nutrition classes	
Clinton et al. (2015) ***USA***	RCT (n=2)	OA (NR)	Vegan	40 (93)	84 G1: 56 (8), G2: 60 (6) G1: 29 (7), G2: 28 (5)	8	Whole food, plant based diet: Lecture and online material. 90% E from plants, no E restriction.	Usual diet
Donaldson et al. (2001) ***USA***	Pre-post (n=1)	FM (NR)	Vegetarian	30 (90)	7 NR NR	11	Raw vegetarian diet: written instruction, provided with juicer, barley grass juice powder, laxative herb and psyllium	
Hanninen et al. (2000) ***Finland***	NR exp (n=2)	FM (NR)	Vegan	75 (NR)	All NR	12	Vegan diet: Education on how to prepare diet	Omnivorous diet
Hansen et al. (1996) ***Denmark***	RCT (n=2)	RA [G1: 7 (6), G2: 11 (8) years]	Adjusted AMDR, ↑ fish oil	109 (74)	72 G1: 59 (10), G2: 54 (11) NR	12	Specialised diet: Prescription, financial support, n-3 capsules if couldn't reach 800 g fish per week and specific foods provided	Usual diet
Kaartinen et al. (2000) ***Finland***	NR exp (n=2)	FM (5 years)	Vegan	33 (85)	100 G1: 51, G2: 52 G1: 28, G2: 28	12 (20)	Vegan diet: Education on how to prepare 'living food'	Omnivorous diet
Kjeldsen-Kragh et al. (1991) ***Norway***	RCT (n=2)	RA (G1: 6, G2: 8 years)	Vegetarian	53 (64)	85 G1: 53, G2: 56 NR	13	Diet group: 7 day fast, prescription gluten free vegan diet then lactovegetarian diet	Usual diet

Marum et al. (2017) ***Portugal***	Longitudinal (n=1)	FM (10 years)	Low FODMAP	38 (100)	100 51 27.4 (4.6)	8	Low FODMAP: Reduce/remove all fermentable oligo-di-mono saccharides and polyols. Provided with verbal and written instructions/recipes	
McDougall et al. (2002) ***USA***	Pre-post (n=1)	RA (NR)	Vegan	24 (92)	92 Total: 56 (11) NR	13	Vegan diet: Face to face and written education & resources, provided with specific foods	
McKellar et al. (2007) ***Scotland***	NR exp^ (n=2)	RA (G1: 9, G2: 10 years)	Mediterranean	130 (100)	100 G1: 55, G2: 53 G1: 27, G2: 28	13 (12 & 26)	Med diet: Cooking classes, written info and resources	Control: Provided readily available written info on healthy eating only
Nenonen et al. (1998) ***Finland***	RCT (n=2)	RA [G1: 13 (10), G2: 16 (14) years]	Vegan	43 (91)	95 G1: 49 (7), G2: 56 (11) G1: 26 (4), G2: 24 (4)	26 (12)	Vegan diet: Provided pre-packaged 'living' food and education and supervision	Omnivorous diet
Skoldstam et al. (2003) ***Sweden***	RCT (n=2)	RA (G1: 17, G2: 10 years)	Mediterranean	56 (91)	80 G1: 58, G2: 59 G1: 28, G2: 26	30	Mediterranean diet: Served Cretan Mediterranean Diet and provided education in hospital. At home: resources, specific food and phone/face to face contact	Control: Served standard hospital food, then usual diet at home
Slim et al. (2016) ***Spain***	RCT (n=2)	FM	Gluten free diet	75 (100)	97 Median age; G1: 52, G2: 53 G1: 27 (5.6), G2: 30 (5)	24	Gluten free diet: Given explanation and lists of gluten containing foods and gluten free foods. No calorie restriction	Placebo: Hypocaloric diet (5 small meals/day, max 1500 kcal/day). Given dietary program and meal options

Altered macro- /micronutrients

Aller et al. (2004) ***Spain***	RCT (n=2)	IBS (NR)	Fibre	56 (100)	63 G1: 47 (12), G2: 4 (1) G1: 25 (4), G2: 25 (4)	1.8	High fibre: 30.5 g fibre (4.11 g sol, 25.08 g insol) = ↑ breakfast cereal 60 g day^{-1} and 2X apples per day	Low fibre: 10.4 g fibre (1.97 g sol, 8.13 g insol)
Bic et al. (1999) ***USA***	Pre-post (n=1)	Migraine (Median: 3yrs)	Fat	54 (100)	78 (Median) Total: 41 NR	4 (4)	Low fat: ≤20 g fat per day. One on one nutrition counselling, handouts, reading material. No caloric restriction imposed. Advised to use F/V and legumes for hunger.	
Ferrara et al. (2015) ***Italy***	RCT CO (n=2)	Migraine (Mean monthly attacks: G1: 16.1±11, G2: 17.7±11)	Fat	128 (65)	76 G1: 33 (12), G2: 37 (11) G1: 25 (4), G2: 27 (5)	12	Low fat: <20% total daily energy intake from fat. 77 g prot, 32 g fibre, 330 g (63% total E) CHO. 14% MUFA, <8% sat fat	Normal fat: 25-30% energy intake from fat. 75 g prot, 32 g fibre, 307 g (56% total E) CHO. 19% MUFA, <8% sat fat
Kawaguchi et al. (2015) ***Japan***	NR exp^ (n=2)	Chronic pancreatitis [1.39 (15.3) years]	Elemental diet	30 (100)	7 Total: 63 (15) G1: 18 (4), G2: 17 (3)	12	Elental ®: 80 g day^{-1} - low fat elemental diet, fat content 100 kcal is as low as 0.17 g.	Usual diet
Spigt et al. (2005) ***Netherlands***	RCT (n=2)	Headache (NR)	Water	18 (83)	78 Total: 44 NR	52	High water: Advised to drink 1.5 L water day^{-1} in addition to normally consumed beverages.	Placebo capsule: 1 cap day^{-1}

Fasting therapy

Abendroth et al. (2010) ***Germany***	NR exp (n=2)	RA (NR)	Fasting therapy	50 (100)	94 G1: 56 (7), G2: 60 (12) G1: 27 (4), G2: 26 (6)	1.7	i1) Buchinger fasting method: 2 pre fasting days (800 kcal), followed by fasting 300-350 kcal day^{-1} i2) Mediterranean diet: Leitzmann method, 2000 kcal day^{-1} Both groups: not allowed alcohol or caffeine	
Michalsen et al. (2005) ***Germany***	NR exp (n=2)	Chronic pain (NR)	Fasting therapy	2121 (25)	80 G1: 54 (12), G2: 52 (16) NR	26	Buchinger fasting method: 2 pre fasting days (800 kcal), followed by fasting 300-350 kcal day^{-1}	Usual diet
Michalsen et al. (2013) ***Germany***	NR exp (n=2)	FM (NR)	Fasting therapy	48 (88)	96 G1: 52 (10), G2: 54 (11) G1: 30 (7), G2: 28 (5)	26 (12)	Buchinger fasting method: 2 pre fasting days (800 kcal), followed by fasting 300-350 kcal day^{-1}	Usual diet
Skoldstam et al. (1981) ***Sweden***	RCT (n=2)	RA (G1: 12, G2: 13 years)	Fasting therapy	26 (96)	73 G1: 52, G2: 54 NR	36	Fast 7-10 days: E=800 kJ from 3 L F/V juice. Lactoveg diet introduced after fasting. No alcohol, tobacco, coffee or tea. Recommended to restrict salt, sugar, white flour.	Usual diet
Supplements								
Abbas et al. (1997) ***Tanzania***	RCT (n=2)	Diabetic neuropathy (NR)	Vitamin	200 (84)	47.3 NR NR	1.7	High dose: 1cap = 25 mg thiamine & 50 mg pyridoxine Prescription: 2cap day^{-1} for 3 days, then 1cap day^{-1} for 25 days	Low dose: 1cap = 1 g thiamine & 1 g pyridoxine

Arjmandi et al. (2004) ***USA***	RCT (n=2)	Knee OA (NR)	Protein	88 (100)	48 Total: 61 (2) G1: 32 (1), G2: 31 (1)	2	Soy protein: 40 g (1400 mg Ca, 200 IU vitamin D. Total 88 mg soy isoflavones)	Milk protein: 40 g (1400 mg Ca, 200 IU vitamin D. Nil isoflavones)
Bae et al. (2009) ***Korea***	RCT CO[#] (n=3)	RA [10.2 (5.9) years]	Antioxidant	20 (100)	95 Total: 52 (10) Total: 22 (3)	4	i1) Quercetin (500 mg) + vitamin C (400 mg) i2) α-lipoic acid (600 mg)	Placebo: corn starch
Belch et al. (1988) ***Scotland***	RCT (n=3)	RA (Median, all groups: 5 yrs)	Omega-3	49 (100)	88 (Median) G1: 46, G2: 53, G3: 48 NR	4	i1) Evening primrose oil (EPO): 540 mg y-linolenic acid (GLA) + 120 mg vitamin E i2) EPO + fish oil: 450 mg GLA & 240 mg EPA + 120 mg vitamin E	Placebo: Liquid paraffin + 120 mg vitamin E
Bellare et al. (2014) ***India***	RCT (n=2)	Knee OA (NR)	GlucChron	117 (76)	77 G1: 60 (9), G2: 61 (8) G1: 27 (4), G2: 26 (3)	4	Wt loss diet + glucosamine (1500 mg) & chondroitin (1200 mg)	Wt loss diet only
Benito-Ruiz et al. (2009) ***Ecuador***	RCT (n=2)	Knee OA [G1: 2.1 (1.7), G2: 2 (1.7) years]	Protein (AA)	250 (83)	93 G1: 59 (10), G2: 59 (12) G1: 27 (4), G2: 28 (5)	4	Collagen hydrolysate: 10 g	Placebo: 10 g lactose
Benson et al. (2012) ***USA***	Pre-post (n=1)	Joint pain (NR)	Combination	12 (100)	50 Total: 53 (8) Total: 26 (4)	4	Ergoflex: glucosamine, hyaluronic acid, glycosaminoglycan, collage, acai, cats claw, willow bark and 500 µg ergotheioneine	

Bramwell et al. (2000) ***USA***	Pre-post (n=1)	FM (NR)	Dietary Indole	16 (75)	100 Total: 44 NR	6	Ascorbigen/broccoli powder: 100 mg	
Bruyere et al. (2012) ***Belgium***	RCT (n=2)	Joint pain (NR)	Protein (AA)	200 (72)	69 G1: 66 (8), G2: 64 (9) G1: 28 (5), G2: 28 (5)	6	GENACOL: 1200 mg collagen hydrolysate	Placebo
Caturla et al. (2011) ***Spain***	RCT (n=2)	Joint pain (NR)	Omega-3 + Antiox	45 (69)	35 [median (SD)] G1: 39 (12), G2: 40 (12) (median) G1: 26, G2: 26	6	Fish oil (370 mg, EPA: DHA, 10:8) and standardised lemon verbena extract (230 mg)	Placebo
Cleland et al. (1988) ***Australia***	RCT (n=2)	RA (G1: 8y, G2: 8.5y)	Omega-3	60 (77)	70 G1: 51, G2: 50 NR	7 (4)	Fish oil: 3.2 g EPA & 2 g DHA	Olive oil: 1 g
Colker et al. (2002) ***USA***	RCT (n=2)	OA (NR)	Combination	31 (100)	65 G1: 52 (19), G2: 59 (21) NR	8	Milk supp beverage (355 ml): 90 kcal, 19 g CHO, 9 g protien, IgG 90 mg, 195 mg Ca, 240 g Na, 90 mg vitamin C, 9 µg vitamin B_{12}, 45 IU vitamin E, 27 mg Fe, 23 mg Zn. Fortified with B12, C, E, Fe and Zn. Nil fat or cholesterol	Grape juice (355 ml): isocaloric, 90 kcal, 19 g CHO, 38 mg Na, Nil protein, vitamins, Fe or Zn. Nil fat or cholesterol

Coulson et al. (2013) ***Australia***	RCT (n=2)	Knee OA [G1: 7.5 (5.9), G2: 11.4 (9.5)]	Combination	40 (95)	74 G1: 57 (9), G2: 60 (9) G1: 31 (6), G2: 30 (5)	8	GlycOmega PLUS: 3000 mg	Glucosamine sulphate: 3000 mg
Edwards et al. (2000) ***UK***	RCT CO# (n=4)	FM [4.2 (2.3) years]	Antioxidant	12 (75)	100 Total: 46 (6) NR	11	i1) Anthocyanidins (AC): 120 mg, i2) AC: 80 mg, i3) AC: 40 mg. Including grape seed, bilberries & cranberries	Placebo
Elliot et al. (2010) ***USA***	RCT CO# (n=2)	FM (8.25 years)	Antioxidant	15 (93)	100 Total: 51 NR	12	Cherry juice: 10.5 oz, 600 mg phenolic compound & 40 mg anthocyanins	Placebo: 10.5 oz taste and calorie matched fruit punch
Frestedt et al. (2009) ***USA***	RCT (n=2)	OA (NR)	Algae	22 (64)	59 G1: 63 (5), G2: 63 (11) NR	12	Aquamin: 2400 mg Lithothamnion corallioides (34% Ca, 2.4% Mg + <1% of other minerals)	Placebo: 3900 mg maltodextrin
Gaul et al. (2015) ***Germany***	RCT (n=2)	Migraine (NR)	Combination	130 (86)	87 G1: 40 (13), G2: 36 (11) G1: 23 (4), G2: 23 (4)	12	Multivit/mineral: 400 mg B2, 600 mg Mg, 150 mg Q10, 750 ug vitamin A, 200 mg vitamin C, 134 mg vitamin E, 5 mg B_1, 20 mg B_3, 5 mg B_6, 6 µg B_{12}, 400 µg B_9, 5 µg vitamin D, 10 mg B_5, 165 µg B_7, 0.8 mg Fe, 5 mg Zn, 2 mg Mn, 0.5 mg Cu, 30 ug Cr, 60 µg Mo, 50 µg Se, 5 mg bioflavonoids	Placebo: identical with active components

Ghoochani et al. (2016) ***Iran***	RCT (n=2)	Knee OA	Antioxidant	39 (97)	87 G1: 57 (10), G2: 54 (12) G1: 32 (4), G2: 29 (6)	6	Pomegranate juice: 200 ml day^{-1} (sugar and additive free)	Usual diet
Hill et al. (2015) ***Australia***	RCT (n=2)	OA	Omega-3	202 (83)	50 Total: 61 (10) G1: 29 (4), G2: 29 (5)	104	High dose fish oil: 15 ml day^{-1} (4.5 g omega-3)	Low dose fish oil: 15 ml day^{-1} (fish:sunola, 1:9, 0.45 g omega-3)
Holst-Jensen et al. (1998) ***Denmark***	RCT (n=2)	RA (median: G1: 9, G2: 13 years)	Protein (AA)	30 (90)	80 (median) G1: 46, G2: 56 (median) G1: 23, G2: 25	12 (12 & 26)	Top up™: Hydrolysed soy protein (37.5 g L^{-1}). Dose = 30 kcal kg^{-1} body weight day^{-1}	Usual diet
Holton et al. (2012) ***USA***	RCT (n=2)	FM & IBS [G1: 18.1 (11), G2: 18.8 (10)]	MSG challenge	37 (81)	92 G1: 53 (13), G2: 43 (16) G1: 31 (6), G2: 26 (7)	12	MSG challenge: eliminate all MSG and then challenge with beverage containing 5 mg MSG	Placebo challenge: fruit beverage without MSG
Hughes et al. (2002) ***UK***	RCT (n=2)	Knee OA [7.62 (8.06) years]	Glucosamine	80 (94)	68 Total: 62 (9) NR	12	Glucosamine: 1500 mg potassium chloride free glucosamine sulphate, 900 mg vitamin C, 900 mg Ca, 15 mg manganese	Placebo: Ca (quantity NR)
Jensen et al. (2015) ***USA***	RCT (n=2)	Chronic pain (NR)	Protein	25 (100)	54 G1: 54, G2: 50, G3: 52, Gr4: 47	12	Water soluble egg membrane: 450 mg	Placebo: microcrystalline cellulose (quantity NR)

					G1: 29, G2: 32, G3: 27, Gr4: 30			
Kanzaki et al. (2012) ***Japan***	RCT (n=2)	Knee OA (NR)	GlucChronAntiox	40 (100)	83 G1: 55 (11), G2: 58 (7) G1: 22 (3), G2: 23 (3)	12	GCQ: 1200 mg glucosamine hydrochloride, 60 mg chondroitin, 45 mg quercetin	Placebo
Katayoshi et al. (2017) ***Japan***	RCT (n=2)	Knee OA	GlucChron & others	16 (100)	81 G1: 50 (7), G2: 53 (8) G1: 22 (4), G2: 23 (6)	6	Supplement: 1200 mg GS hydrochloride, 420 mg MSM, 50 mg type II collagen, 90 mg collagen peptide, 12 mg olive extract, 6 mg bovine protein	Placebo: Starch, calcium stearate
Kolahi et al. (2015) & Mahdavi et al. (2015) ***Iran***	RCT (n=2)	Knee OA [G1: 4 (4), G2: 6 (6)]	Protein (AA)	72 (96)	100 G1: 52 (6), G2: 52 (7) G1: 32 (3), G2: 32 (3)	8	L-carnitine: 750 mg day^{-1}	Placebo: 750 mg day^{-1} inactive ingredients
Kremer et al. (1987) ***USA***	NR exp (n=2)	RA (12.8 years)	Omega-3	40 (83)	76 Total: 57 NR	13	Fish oil: 2.7 g EPA, 1.8 g DHA	Control: 10.3 g oleic acid, 2.1 palmitic acid, 1.8 g linoleic acid
Letizia Mauro et al. (2000) ***Italy***	RCT (n=2)	Back pain (NR)	Vitamin	60 (100)	82 G1: 49 (13), G2: 50 (14) NR	13	B12 injection: 1000 mg	Placebo
Lugo et al. (2016) ***India***	RCT (n=3)	Knee OA	Protein (AA)	191 (86)	51	26	Type II collagen: 1.2 mg day^{-1}	GlucChron: 1500 mg + 1200 mg

					G1: 53±1, G2: 53±1 G1: 25, G2: 26		Placebo: Excipients only	
Li et al. (2015) *China*	RCT (n=3)	Chronic cervical pain (3m to >10years)	Protein & Antioxidant	260 (90)	35 Male – G1: 61 (16), G2: 61 (17), G3: 62 (15). Female – G1: 60 (18), G2: 59 (17), G3: 59 (16) Male – G1: 24 (6), G2: 25 (6), G3: 24 (6) Female – G1: 24 (6), 24 (6), 23 (7)	24	Soy bean: i1) 3 g day^{-1}, i2) 5 g day^{-1}, i3) 10 g day^{-1}	
Matsuno et al. (2009) ***Japan***	Pre-post (n=1)	RA [7.9 (10.3) years) and OA (8.5 (6.7) years]	GlucChronAntiox	68 (100)	87 G1: 58 (10), G2: 63 (9) NR	13	GCQ: 1200 mg glucosamine 75-111 mg chondroitin and 45 mg quercetin	
Merchant et al. (2000) ***USA***	Pre-post (n=1)	FM (NR)	Algae	20 (90)	94 Total: 47 NR	16	Chlorella: 10 g single cell green algae, plus 100 ml Wakasa Gold (chlorella growth factor, CGF)	
Merchant et al. (2001) ***USA***	RCT (n=2)	FM (NR)	Algae	43 (86)	97 Total: 47 (9) NR	17	Chlorella: 10 g + 100 ml Wakasa Gold. Each capsule: 60%, 20% CHO, 11% unsat fat. Each microorganism 28.9 g/kg chlorophyll + essential AA, vitamin and minerals	Placebo: identical capsules and liquid without active components

Myers et al. (2010) ***Australia***	RCT (n=2)	Knee OA (NR)	Algae	13 (92)	42 G1: 62±11, G2: 57±9 NR	26	i1) Low-dose Maritech extract: 75 mg fucoidan, brown algae i2) High-dose Maritech extract: 1875 mg fucoidan	
Nielsen et al. (1992) ***Denmark***	RCT (n=2)	RA (median 5 years, range 1-41 years)	Omega-3	57 (86)	NR (median) Total: 61 NR	26	n-3 PUFA: 68.3 g (34 g EPA, 3.5 g DPA, 19 g DHA, 5 g Sat, 17 g PUFA)	Fat composition like normal diet: 0 g FA, 41 g Sat fat, 59.7 g PUFA
Pirouzpanah et al. (2017) ***Iran***	RCT (n=2)	RA [G1: 11 (2), G2: 9 (2)]	Antioxidant	44 (100)	100 G1: 49 (2), G2: 46 (3) G1: 27 (1), 27 (1)	6	Camomile: 6 g day^{-1} via teabags	Placebo: placebo teabags
Remans et al. (2004) ***Netherlands***	RCT (n=2)	RA [G1: 13.6 (11.9), G2: 11.7 (11.1) years]	Combination	66 (83)	82 G1: 60 (11), G2: 53 (11) G1: 26 (3), G2: 26 (5)	26	Liquid nutritional supp (200 ml): E 150 kcal, EPA 1400 mg, DHA 211 mg, DPA 40 mg, ALA 16 mg. GLA 500 mg, linoleic acid 440 mg, fibre 3 g. Includes: vitamin & minerals, Coenzyme Q10, Flavonoids, Carotenoids	Placebo supp (200 ml): Identical without active components
Reme et al. (2016) ***Norway***	RCT (n=4)	Low back pain (10-12.5 years)	Omega-3	414 (99)	53 G1: 45 (10), G2: 44 (9), G3: 44 (10), G4: 43 (10)	12 (36)	Seal oil: 56.6 g/100 g MUFA, 1 µg vitamin D, 85.4 g/100 g vitamin E (20 caps day^{-1})	Soy oil: Considered placebo, minimal vitamin D, vitamin E
Schumacher et al. (2013) ***USA***	RCT CO[#] (n=2)	Knee OA (NR)	Antioxidant	58 (79)	24 Total: 57 (11) Total: 32 (6)	26	Cherry juice: 8 oz, 450 mg phenolic compounds, minimum 30 mg anthocyanins	Placebo juice: matched for taste and colour

Shell et al. (2012) ***USA***	RCT (n=3)	Back pain (NR)	Protein (AA)	129 (98)	All NR	30	i1) Theramine (AAF), i2) AAF & naproxen (250 mg). Amount of AAF not specified	Naproxen only (250 mg)
Skoldstam et al. (1992) ***Sweden***	RCT (n=2)	RA	Omega-3	46 (100)	74 G1: 58, G2: 55 NR	36	Fish oil: 10 g (18% EPA, 12% DHA, 10 mg tocopherol)	Control oil: 10 g (maize, olive and peppermint)
Sperling et al. (1987) ***USA***	Pre-post (n=1)	RA [98.3 (3.5) m]	Omega-3	14 (86)	92 Total: 47 (12) NR	52	MAX EPA capsules: 3.6 g EPA, 2.4 g DHA	
Trippe et al. (2016) USA	Pre-post (n=1)	Diabetic Neuropathy (23% <1year, 34% 1-3yeasr, 35% >3years, 9% unsure)	Vitamin	544 (100)	50 Total: 66 (11) NR	12	Metanx: Medical food containing folic acid, Vitamin B12, Vitamin B6	
Tulleken et al. (1990) ***Netherlands***	RCT (n=2)	RA (G1: 18, G2: 20 years)	Omega-3	28 (96)	89 G1: 52, G2: 58 NR	56	Fish oil: 20.4 g EPA, 1.32 g DHA, 6 g a-tocopherol	Coconut oil: 8:0 octanoic acid and 10:0 decanoic acid. 10.3 mg A-tocopherol, fish flavour added to prevent ID of capsules
Vellisca et al. (2014) ***Spain***	RCT (n=2)	FM [G1: 7.42 (4.23), G2: 7.21 (3.89) years]	Elim MSG/aspartame	72 (100)	100 Total: 41 (8) NR	60	Elimination: MSG and aspartame (provided instruction on how detect these and not allowed to eat out during study)	Waitlist control
Wong et al. (2017) ***Australia***	RCT (n=2)	Chronic pain post menopause [11 (1.3) years	Antioxidant	80 (90)	100 Total: 62 (1)	14	Resveratrol: 75 mg 2X per day, maintain diet and medication	Placebo: inert excipients

	since menopause]	Total: 27 (1)

*Reported as mean (SD) unless otherwise stated. †G1, G2, G3 = Group 1, Group 2 or Group 3.

BMI, Body Mass Index; RCT, Randomised Control Trial; NR, Not Reported; GI, Glycemic Index; FM, Fibromyalgia; CO, Cross-over; ALA, Alpha Lipoic Acid; OA, Osteoarthritis; NR exp, Non Randomised Experimental Study; RA, Rheumatoid Arthritis; AMDR, Acceptable Macronutrient Distribution Range; IBS, Irritable Bowel Syndrome; sol, soluble; insol, insoluble; F/V, fruit & vegetables; CHO, carbohydrates; MUFA, monounsaturated fatty acids; PUFA, polyunsaturated fatty acids; IU, International Units; AA, amino acid; EPA, eicosapentaenoic acid; DHA, docosahexaenoic acid; MSM, methylsulfonylmethane.

Table 2.3: Risk of bias

Study	Research Question	Selection criteria	Comparable groups	Follow up/ withdrawal	Blinding	Intervention	Outcomes	Statistics	Conclusion	Funding	Overall rating
Abbas et al. (1997)	Y	UC	N	N	N	N	Y	N	UC	N	Negative
Abendroth et al. (2010)	Y	UC	N	N	N	N	Y	N	UC	N	Neutral
Aller et al. (2004)	Y	UC	N	N	N	UC	Y	N	UC	N	Neutral
Allison et al. (2016)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Arjmandi et al. (2004)	Y	UC	N	UC	N	UC	Y	N	UC	N	Neutral
Azad et al. (2000)	UC	N	N	N	N	N	N	N	N	N	Negative
Bae et al. (2009)	Y	UC	N	UC	N	UC	Y	N	UC	UC	Neutral
Belch et al. (1988)	Y	UC	N	UC	N	UC	Y	N	UC	UC	Neutral
Bellare et al. (2014)	Y	UC	N	UC	N	UC	Y	N	UC	UC	Neutral
Benito-Ruiz et al. (2009)	Y	UC	NA	UC	N	UC	Y	N	UC	UC	Neutral
Benson et al. (2012)	Y	Y	NA	UC	N	UC	Y	N	UC	UC	Neutral

Bic et al. (1999)	Y	Y	NA	UC	N	UC	Y	N	UC	UC	Neutral
Bramwell et al. (2000)	Y	Y	NA	UC	N	UC	Y	N	UC	UC	Neutral
Bruyere et al. (2012)	Y	Y	NA	UC	N	UC	Y	N	UC	UC	Neutral
Bunner et al. (2014)	Y	Y	NA	UC	N	UC	Y	N	UC	UC	Neutral
Bunner et al. (2015)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Caturla et al. (2011)	Y	Y	NA	UC	N	UC	Y	N	UC	UC	Neutral
Cleland et al. (1988)	Y	Y	NA	Y	N	Y	Y	N	UC	UC	Neutral
Clinton et al. (2015)	Y	Y	NA	Y	N	Y	Y	N	UC	UC	Neutral
Colker et al. (2002)	Y	Y	NA	Y	N	Y	Y	N	Y	UC	Neutral
Coulson et al. (2013)	Y	Y	UC	Y	N	Y	Y	N	Y	UC	Neutral
Donaldson et al. (2001)	Y	Y	UC	Y	N	Y	Y	N	Y	UC	Neutral
Edwards et al. (2000)	Y	Y	UC	Y	N	Y	Y	N	Y	UC	Neutral
Elliot et al. (2010)	Y	Y	UC	Y	N	Y	Y	N	Y	UC	Neutral
Ferrara et al. (2015)	Y	Y	UC	Y	UC	Y	Y	N	Y	UC	Neutral

Frestedt et al. (2009)	Y	Y	UC	Y	UC	Y	Y	N	Y	UC	Neutral
Gaul et al. (2015)	UC	UC	N	N	N	N	N	N	UC	N	Negative
Ghoochani et al. (2016)	Y	Y	UC	Y	N	Y	Y	Y	Y	UC	Neutral
Hanninen et al. (2000)	Y	Y	UC	Y	UC	Y	Y	N	Y	Y	Neutral
Hansen et al. (1996)	Y	Y	UC	Y	UC	Y	Y	N	Y	Y	Neutral
Hill et al. (2015)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Holst-Jensen et al. (1998)	Y	Y	UC	Y	UC	Y	Y	N	Y	Y	Neutral
Holton et al. (2012)	Y	Y	UC	Y	UC	Y	Y	N	Y	Y	Neutral
Hughes et al. (2002)	Y	Y	UC	Y	UC	Y	Y	N	Y	Y	Neutral
Jensen et al. (2015)	Y	Y	UC	Y	Y	Y	Y	N	Y	Y	Neutral
Kaartinen et al. (2000)	Y	Y	UC	Y	Y	Y	Y	UC	Y	Y	Neutral
Kanzaki et al. (2012)	Y	Y	UC	Y	Y	Y	Y	UC	Y	Y	Neutral
Katayoshi et al. (2017)	Y	Y	Y	Y	Y	Y	Y	Y	Y	UC	Positive

Kawaguchi et al.(2015)	Y	Y	UC	Y	Y	Y	Y	UC	Y	Y	Neutral
Kjeldsen-Kragh et al. (1991)	Y	Y	UC	Y	Y	Y	Y	UC	Y	Y	Neutral
Kolahi et al. (2015)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Kremer et al. (1987)	UC	UC	N	N	N	N	Y	N	UC	N	Negative
Letizia Mauro et al. (2000)	Y	Y	UC	Y	Y	Y	Y	Y	Y	Y	Neutral
Li et al. (2015)	Y	Y	Y	Y	Y	Y	Y	Y	Y	UC	Positive
Lugo et al. (2016)	Y	Y	Y	Y	Y	Y	Y	Y	UC	UC	Positive
Marum et al. (2017)	Y	Y	NA	UC	N	Y	Y	Y	UC	UC	Neutral
Matsuno et al. (2009)	Y	Y	UC	Y	Y	Y	Y	Y	Y	Y	Positive
McDougall et al. (2002)	Y	Y	UC	Y	Y	Y	Y	Y	Y	Y	Positive
McKellar et al. (2007)	Y	Y	UC	Y	Y	Y	Y	Y	Y	Y	Positive
Merchant et al. (2000)	Y	Y	UC	Y	Y	Y	Y	Y	Y	Y	Positive
Merchant et al. (2001)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive

Michalsen et al. (2005)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Michalsen et al. (2013)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Myers et al. (2010)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Nenonen et al. (1998)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Nielsen et al. (1992)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Pirouzpanah et al. (2017)	Y	Y	N	Y	Y	Y	Y	Y	UC	UC	Neutral
Remans et al. (2004)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Reme et al. (2016)	Y	Y	Y	Y	Y	Y	Y	Y	Y	UC	Positive
Schumacher et al. (2013)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Shell et al. (2012)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Skoldstam et al. (2003)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Skoldstam et al. (1981)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive

Skoldstam et al. (1992)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Slim et al. (2016)	Y	Y	Y	Y	Y	Y	Y	Y	Y	UC	Positive
Sperling et al. (1987)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Spigt et al. (2005)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Trippe et al. (2016)	Y	Y	NA	Y	N	Y	Y	Y	Y	UC	Positive
Tulleken et al. (1990)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Vellisca et al. (2014)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive
Wong et al. (2017)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Positive

Y, yes; N, no; UC, unclear; NA, not applicable.

2.4.6 Description of outcomes

Pain severity was explicitly stated as the primary outcome by 12 of the included studies (169, 175, 179-181, 195, 198, 203, 208, 209, 233, 234). In addition to pain, 53 studies had several primary outcomes listed, including other disease-related symptoms such as stiffness, tender and swollen joints, function, fatigue and blood biomarkers such as erythrocyte sedimentation rate and C-reactive protein. Six studies explicitly listed pain as a secondary outcome (186, 191, 201, 216, 223, 226).

Pain assessment: The most common measurement tool used to assess pain severity was the VAS, which was used in 46 studies. Within those using a VAS, 18 studies used a 100-mm scale (125, 167, 172, 175, 176, 198, 199, 205, 207-209, 212, 213, 216, 222, 226, 230), 14 did not specify the units of the scale (171, 174, 183, 185, 194, 201-204, 210, 211, 219, 221, 232), 11 used a 10-cm scale (173, 180, 181, 184, 193, 200, 214, 215, 218, 231, 234), one each reported using a 20-cm scale (197) and a 15-cm scale (225), and one used ‘arbitrary units’ (220). The VAS was followed by a pain score or pain scale (n = 10) (168, 177, 186, 188, 189, 196, 206, 223, 227, 233). The WOMAC was used in 10 studies (124, 174, 175, 182, 186, 190, 192, 195, 205, 209) and the SF-36 Bodily Pain subscale was used in three studies (184, 187, 216). The remaining measurement tools were a mixture of validated questionnaires, count of painful joints, intensity of maximal pain and threshold pain values (166, 169, 170, 178, 182, 187, 191, 224, 228, 229).

Secondary outcomes: These were highly variable among the included studies. The most common in descending order were: diet quality (n = 31), quality of life (n = 20), chronic disease risk (n = 30) and mental health (n = 13). Dietary intake was measured in 31 studies (166-169, 172, 174, 175, 177, 181, 184, 185, 187, 189, 192-194, 197, 200, 202, 204, 206, 210, 212, 213, 217, 219, 221, 225, 230, 232, 233). However, of these, six did not report diet-related outcomes (184, 200, 204, 219, 232, 233). Dietary intake was assessed in several ways, with four studies using two assessment tools, these included a 2, 3, 4, 5 or 7 day food diary (n = 10) (168, 169, 175, 181, 189, 200, 206, 212, 225, 230), food frequency questionnaire (n = 7) (166, 167, 177, 187, 189, 197, 213), unspecified food diary (n = 6) (177, 204, 210, 219, 232, 233), a single 24 h recall (n = 5) (174, 177, 184, 185, 192) and multiple 24 h recalls (n = 2) (205, 221), with the following being used once: a checklist (212), weight of food (g) (194), food behaviour

questionnaire (193), food models (172) and one not reported (217). Quality of life was reported in 20 studies with a range of tools used to measure this, including the SF-36, disease-specific questionnaires and The Health Assessment Questionnaire (167, 175, 181, 184, 185, 187, 188, 194, 195, 197, 201, 204, 208, 215-217, 226, 230, 234). Thirty studies reported one or more chronic disease risks including weight, blood cholesterol, blood pressure and glycated haemoglobin. Twenty-five studies measured weight (kg) or BMI (168, 174, 177, 180, 181, 184, 189, 194-197, 200, 202-204, 210, 212, 213, 219, 221, 222, 225-228). Other measures of chronic disease risk included blood cholesterol (n = 9), blood pressure (n = 6) and glycated haemoglobin (n = 2). In total, 13 studies reported mental health outcomes including anxiety and depression. The SF-36, The Hassles Score, The Hospital Anxiety and Depression Scale and the Beck Depression Inventory were used to measure this (181, 184, 187, 200, 208, 210, 214-217, 223, 226, 228).

2.4.7 Nutrition intervention details

All studies reported on a nutrition intervention. Average intervention duration was 17 weeks (range 1.7–104 weeks), with nine (177, 183, 196, 200, 213, 216, 217, 219, 223) providing some type of follow-up period post-intervention (range 4–36 weeks). In terms of the health professionals involved in study delivery, 23 studies reported who delivered and/or collected measurements for the intervention. Of these, a dietitian delivered and/or undertook data collection in 12 studies (167-169, 181, 185, 189, 194, 197, 204, 212, 219, 227), a physician in four studies (216, 217, 222, 229), the lead researcher in three studies (184, 200, 215), a mixed team in four studies (i.e. in one study a nutritionist, an occupational therapist and teaching staff were listed and in the second study a dietitian, nurse and physician were listed and finally the last two a dietitian and physician) (167, 206, 210, 213) and a nurse in one study (196).

Altered dietary pattern (n = 16): Participants were prescribed either a vegan (n = 7) (180, 181, 184, 193, 200, 212, 219), vegetarian (n = 3) (171, 187, 204), Mediterranean diet (n = 2) (213, 226) or anti-inflammatory diet (n = 1) (169), a low FODMAP diet (n = 1) (210) and a gluten-free diet (n = 1) (228). In one study, the participants were prescribed a diet with reduced energy intake (i.e. fat contributed 20–30% of total energy, with a ratio of saturated:unsaturated 1:1, protein 1.5 g kg^{-1} body weight per day

and fish oils in either food or supplement form increased to 800 g fish per week or 1.2 g n-3 oils per day) (194).

Altered specific nutrients (n = 5): Of these, two studies included reduction in total fat intake (<20 g day $^{-1}$ and <20% total E intake) (177, 189), whereas changes to fibre (30.5 g day^{-1}) (168), water (1.5 L day^{-1}) (230) and protein (80 g day^{-1}) (203) composition were each the focus in one study.

Supplements (n = 46): For these studies, the supplements investigated included omega-3 fatty acids (doses ranging from 0.7 to 6 g day^{-1}) (n = 9) (173, 183, 195, 206, 220, 223, 225, 229, 232), antioxidant (doses ranging from 40 to 640 mg day^{-1}) (n = 7) (124, 125, 172, 188, 192, 221, 234) amino acid (doses ranging from 1200 mg to 10 g day^{-1}) (n = 6) (175, 179, 196, 205, 209, 224), multivitamin and/or mineral supplements (doses ranging from 500 lg to 5600 mg day^{-1}) (n = 5) (176, 185, 186, 191, 222), algae (doses ranging from 0.1 to 10 g day^{-1}) (n = 4) (190, 214, 215, 218) and glucosamine/chondroitin/antioxidant (doses 1200 mg glucosamine, 60–111 mg chondroitin and 45 mg quercetin per day) (n = 3) (201, 202, 211), protein (doses ranging from 88 to 450 mg day^{-1}) (n = 3) (170, 199, 208) and vitamin B (doses ranging from 75 to 100 mg day^{-1}) (n = 3) (166, 207, 231) and dietary indole (500 mg day^{-1}) (178), glucosamine (1500 mg day^{-1}) (198), glucosamine/chondroitin (1500 and 1200 mg day^{-1}) (174), monosodium glutamate (MSG) challenge (5 mg day^{-1}) (197), omega-3/antioxidant (370 and 240 mg day^{-1}) (182) and MSG/aspartame elimination (233) (n = 1).

Fasting studies (n = 4): Three studies stated that the Buchinger method was used for fasting, which included two pre-fasting days (800 kcal day^{-1}) where consumption was limited to either fruit or rice or potatoes, followed by 7 days of fasting with laxatives, a total of 300–350 kcal day^{-1} and 2–3 L of fluid each day. Food was reintroduced gradually over 4 days before returning to an isocaloric intake (167, 216, 217). The fourth study did not explicitly refer to the Buchinger method and did not include a pre-fasting period. The caloric restriction during the fasting period (7–10 days) was 800 kcal day^{-1} (227).

2.4.8 Effect of nutrition intervention type on pain

The outcomes for all studies are summarised in Table 2.4. Only six out of the 57 studies reported an effect size (180, 181, 185, 217, 228, 230). When studies were combined in a meta-analysis, it was found that, overall, there was a statistically significant difference in change in pain score, -0.905 [95% confidence interval (CI) = -0.537 to -1.272] (P = 0.000). Studies that altered the overall dietary pattern [-1.415 (95% CI = -2.698 to -0.133), P = 0.030] or intake of one specific nutrient [-1.415 (95% CI = -2.071 to -0.759), P = 0.000] had greater reductions in pain scores than studies that prescribed a supplement [-1.213 (95% CI = -1.921 to -0.505), P = 0.001] or fasting diet [-0.056 (95% CI = -0.690 to 0.578), P = 0.863]. All approaches were statistically significant in the meta-analysis, except for fasting therapy (Fig. 2.2). The following results were found within each of the categories:

2.4.8.1 Altered dietary pattern

Three studies in this category reported an effect size. Bunner et al. (180) reported effect size by measuring mean (SD) change in pain and reported -1.4 (4) change in pain, rated by VAS, which was also statistically significant (P = 0.03). Bunner et al. (181) and Slim et al. (228) reported effect size as mean (95% CI). Bunner et al. (181) reported a 0.8 (-1.3 to 2.8) change in pain, rated by VAS, which was not statistically significant. An effect size was also calculated for change in pain as rated by The McGill Pain Questionnaire, which was -8.2 (-16.1 to -0.3) and statistically significant (P = 0.04) (181). Slim et al. (228) reported a small effect size for both pain severity [-0.008(-0.74 to 0.72)] and pain interference [-0.404 (-0.43 to1.24)], which was measured using the Brief Pain Inventory. Neither were statistically significant (228). Twelve out of 16 studies reported statistically significant between group differences, in favour of the intervention group (with P-values ranging from P < 0.0001 to P = 0.049) (169, 181, 184, 187, 193, 194, 200, 204, 210, 212, 213, 226), with two studies reporting no significant difference between the groups (219, 228). The other two studies (171, 180) only reported within-group differences, not between-group differences, with Bunner et al. (180) showing a significant reduction in pain within the intervention group (P < 0.0001) and Azad et al. (171) showing a significant reduction within both groups (P = 0.025 and P < 0.001), with the magnitude higher in the control group. A total of nine studies were eligible for meta-analysis in this category. Overall, the meta-analysis showed a large effect size that is statistically significant, -1.415 (95% CI = -2.698 to -0.133) (P =

0.030). Azad et al. (171) and Bunner et al. (181) both showed a negative effect and Nenonen et al. (219) showed no change, whereas the remaining studies ranged from -0.034 to -7.276.

2.4.8.2 Altered specific nutrient

Spigt et al. (230) reported an estimated effect size (95% CI) for mean headache intensity on a VAS, -13 (-32 to 5). Two studies, one lowering overall fat intake and the other altering protein composition, reported statistically significant between-group differences: $P < 0.0001$ and $P = 0.018$, respectively, with one study exploring the role of water in headache pain showing no statistically significant results (177, 203). Ferrara et al. (189) reported mixed results, with the cross-over study showing a significant between-group difference ($P < 0.01$) when participants crossed from the control to the intervention but no significant results for the opposite group. Aller et al. (168) reported within-group differences, finding that the intervention group was significantly different at study completion compared to baseline. Overall, the meta-analysis showed a large effect size of -1.415 (95% CI = -2.071 to -0.759) ($P = 0.000$).

2.4.8.3 Supplements

One study reported an effect size for the overall WOMAC score, which includes pain (185). This study found a moderate effect in the intervention group of 0.55 (185). Eleven studies reported statistically significant between-group differences ($P < 0.0001$ to $P = 0.044$) in pain (175, 176, 179, 191, 195, 205, 207-209, 220, 224), whereas 22 studies showed no significant differences between groups. Two studies had mixed results (125, 229). Elliot et al. (125) showed no significant difference overall; however, there was a significant difference ($P < 0.001$) in those patients who reduced their VAS score by >25 mm; this is also considered clinically important. Sperling et al. (229) showed a significant difference in joint pain index ($P \leq 0.03$) but not in number of painful joints. The remaining 10 studies (166, 170, 182, 183, 185, 201, 202, 211, 214, 231) only reported within-group differences; of these, the intervention group for nine studies (166, 170, 182, 185, 201, 202, 211, 214, 231) had a significant change over time, whereas the control group did not have a significant change over time. Matsuno et al. (211) found a significant within-group difference in the osteoarthrosis population ($P < 0.05$) but not the rheumatoid arthritis population. Ten studies provided enough information for meta-analysis, which was significant with an overall effect size of -

1.213 (95% CI = -1.921 to -0.505) (P = 0.001). Cleland et al. (183) and Katayoshi et al. (202) showed a small negative effect, whereas the remaining studies had effect sizes ranging from -0.379 to -3.437.

2.4.8.4 Fasting

Only one study reported the effect size for both the intervention group (0.62) and the control group (0.53) post intervention (216). One study reported between-group differences; however, this was not significant (216). Michalsen et al. (217) demonstrated that the within-group difference for both the intervention and control was the same (P < 0.001), whereas Skoldstam et al. (227) showed a difference in the intervention group, although only immediately after fasting. Abendroth et al. (167) found that there was only a significant difference in the intervention group at 7 days, although it was not significant at 8 days. The meta-analysis that included two studies showed a small effect, although this was not statistically significant, -0.056 (95% CI = -0.690 to 0.578) (P = 0.863).

Table 2.4: Outcomes for pain

Author (year)	Measurement tool	Baseline*		Study completion*		P value		
Altered dietary pattern								
Allison et al. (2016)	NPQ (sensory)	i)** 32.8±23.4	c)*** 18.1±17.2	i) 19.8±15.8	c) 21.3±20.1	b/n†	p<0.01	
	NPQ (affective)	i) 34.7±28.6	c) 27.5±24.4	i) 21.2±19	c) 23.7±25.3		p=0.18	
	NPQ (sensitivity)	i) 26.8±26.1	c) 29.7±32.9	i) 22.6±32.9	c) 32.6±		p=0.19	
Azad et al. (2000)	VAS (not specified)	i) 5.7±1.8	c) 6.2±1.9	i) 5±1.8	c) 2.3±1.3	W/in#	i) p=0.025	c) p<0.001
Bunner et al. (2014)	VAS (10 cm)	i) 6.1±2.4	c) 6.7±1.9	i) 3.6±3	c) 4.1±2.8	Effect size: −1.4 (4.0)		
						W/in	i) p<0.0001	c) NS^^
Bunner et al. (2015)	VAS (10 cm)	i) 5.3±2.7	c) 5.8±2.4	i) 4±2.4	c) 3.8±2.7	b/n	Effect size 0.8 (-1.3, 2.8) p=0.45	
	McGill Pain Q	i) 22.6±11	c) 21±10	i) 13.5±10	c) 20.1±12.2		Effect size -8.2 (-16.1, -0.3) p=0.04	
Clinton et al. (2015)	VAS (10 cm)	i) 5.06	c) 3.56	i) -2.85^	c) -1.18^	b/n	p<0.001	
	SF-36	i) 39.18	c) 40.13	i) 8.61^	c) 5.41^		NS	
Donaldson et al. (2001)	FIQ pain	6.6±1.9		3.6±2.5		Sig @ 2m (p<0.0001) but not 7m		
	SF-36 pain	32.6±20.2		48.5±28.8		Sig @ all time points (p<0.01)		
Hanninen et al. (2000)	VAS (0-10)	i) 6	c) 5.7	i) 4.2	c) 5	b/n	p=0.003	
Hansen et al. (1996)	VAS (not specified)	Δ†† during 6m: i) -0.2±1.2 c) 0.2±1				b/n	p=0.01	
Kaartinen et al. (2000)	VAS (0-10)	i) 6	c) 5.8	i) 3.2	c) 6.5	b/n	p=0.005	
Kjeldsen-Kragh et al. (1991)	VAS (not specified)	i) 5.5	c) 5	i) 3.5	c) 6	b/n	p<0.02	

Marum et al. (2017)	Generalised pain (VAS)	Time 1) 6.6	Time 2) 4.9	Time 3) 5.4		b/n	Time1-2) p<0.01, Time2-3) NS
McDougall et al. (2002)	VAS (100 mm)	49±20		34±20		p < 0.004	
McKellar et al. (2007)	VAS (100 mm)	i) 50	c) 55	3m: i) 50 6m: i) 50	3m: c) 62 6m: c) 63	b/n	3m) p=0.011 6m) p=0.049
Nenonen et al. (1998)	VAS (not specified)	i) 25	c) 25	End: i) 15 F/U: i) 20	End: c) 15 F/U: c) 20	NS	
Skoldstam et al. (2003)	VAS (100 mm)	i) 32±20	c) 31±20	i) 20±13	c) 34±21	b/n	p=0.006
Slim et al. (2016)	Brief Pain Inventory (BPI) (severity)	i) 6.7±1.7	c) 6.9±1.4	i) 6±2.2	c) 6.3±2.1	b/n	Effect size -0.008 (-0.74, 0.72) p=0.982
	BPI (interference)	i) 7.1±1.7	c) 7.2±1.6	i) 6.7±2	c) 6.3±2.3		Effect size 0.404 (-0.43, 1.24) p=0.339
Altered macro- /micronutrients							
Aller et al. (2004)	Pain score (not specified)	i) n=9	c) n=9	# improve from BL: i) 8, c)1		W/in	: i) p<0.001 c) NS
Bic et al. (1999)	6 pt scale (0= no pain to 5= worst pain)	Median (range): 2.9 (0.8-4.5)		Median (range): 0.5 (0-4.8)		p<0.0001	
Ferrara et al. (2015)	Pain score (1= mild, 2= moderate, 3= very severe)	i. first) 1.2±0.9	c. first) 1.7±0.9	i.1st) 1.2±0.9 c.2nd) 1.6±1	c.1st) 1.8±0.9 i.2nd) 1.2±0.8	c. first) p<0.01, others NS	
Kawaguchi et al. (2015)	VAS (not specified)	i) 5.8±3.1	c) 5.5±2.5	i) 2.5±2.1	c) 5.6±2.1	b/n: p=0.018	
Spigt et al. (2005)	VAS (100 mm)	i) 45±17	c) 39±12	i) 39±16	c) 50±16	Effect size: -13 (95% CI: -32, 5) NS	
Fasting therapy							
Abendroth et al. (2010)	VAS (100 mm)	i) 4	c) 3.5	Day 7: i) 3 Day 8: i) 2.8	Day 7: c) 3.5 Day 8: c) 3.6	W/in	Day 7: i) p=0.049 c) NS Day 8: i) NS c) NS

Michalsen et al. (2005)	SF-36 Pain	i) 29.9	c) 34.4	i) 43.5	c) 48	W/in	p <0.001	p <0.001
Michalsen et al. (2013)	VAS (100 mm)	i) 64.4±25.7	c) 48.8±26.1	Mean diff b/n time point 1-3 (95%CI): -13 (-28, 2.1).		Effect size: i) 0.62, c) 0.53 P=0.091		
Skoldstam et al. (1981)	Pain Rating Scale (0-10)	i) 3.5±1.9	c) 2.7±1.7	Fasting i)-2±1.7	c)+0.5± 1.4 c) -0.3± 2.1	Diet group (after fasting, compared to BL): p<0.001, all others NS		
				LV diet i)-1.2± 3.2				
Supplements								
Abbas et al. (1997)	# pts select worst symptom (pain, numbness, paraesthesia)	i) n=9	c) n=9	# improve from BL: i) 8, c)1		W/in	i) p<0.001	c) NS
Arjmandi et al. (2004)	Self-administered questionnaire (validated and adapted from SF36, McGill pain questionnaire and Medical College of Wisconsin non cancer pain questionnaire)	i) 17	c) 18	i) 14	c) 17	W/in	i) p<0.05	c) NS
Bae et al. (2009)	VAS (100 mm)	i1) 31.25	i2) 25.37 c) 31.75	i1) 30	i2) 30 c) 40	b/n	p=0.34	
Belch et al. (1988)	VAS (10 cm)	Median (range) i1) 3.6 (0-9.5), i2) 3 (0-7.3), c) 2.3 (0-8)		% change: i1) 50%, i2) 115%, c) 130%		b/n	NS	
Bellare et al.(2014)	VAS (not specified)	i) 8±0.91	c) 8.05±0.98	i) 1.9±0.5	c) 3.6±0.81	b/n	NS	
	WOMAC pain	i) 14±1.84,	c) 13.68±2.11	i) 16.2±1.04	c) 9.3±1.65	b/n	NS	
Benito-Ruiz et al. (2009)	VAS (100 mm)	i) 43.1±7.4	c) 42.1±7.5	i) 10.5±13.1	c) 14.1±16	b/n	p=0.024	
	WOMAC pain	i) 7.6±3.5	c) 7.2±3.4	i) 2.8±2.8	c) 3.3±3.3	b/n	p=0.044	
Benson et al. (2012)	VAS (100 mm), measured at rest and in use, at primary and	%Δ from BL: Primary pain at rest: 6 weeks -20%, 12 weeks -18%. At use: 6 weeks -58%, 12 weeks 50%. Secondary pain at rest: 6				p<0.005		

	secondary pain sites and at 6 & 12m	weeks -25%, 12 weeks -10%. At use: 6 weeks -50%, 12 weeks -70%							
Bramwell et al. (2000)	Threshold pain values (lbs /0.5 cm2)	2.22±0.64		2.42±0.732			p=0.059		
Bruyere et al. (2012)	VAS (100 mm)	% clinical responders: i) 51.6%, c) 36.5%					b/n	p=0.036	
Caturla et al. (2011)	WOMAC pain	Δ from BL: i) -7, c) +1					W/in	i) p≤0.001	c) NS
	Lequesnes questionnaire	Δ from BL: i) -6.5, c) 0						i) p≤0.01	c) NS
Cleland et al. (1988)	VAS (not specified)	i) 9.6±5.8	c) 9.8±4.6	i) 7±4.6	c) 7.1±5.1		W/in	i) NS	c) p<0.01
Colker et al. (2002)	VAS (not specified) (Mean±SE)	i) 4.42±0.45	c) 4.18±0.42	i) 3.17±0.41	c) 3.77±0.72		Effect size (overall WOMAC): 0.555		
							W/in	i) p=0.02	c) p=0.76
Coulson et al. (2013)	WOMAC pain	Δ BL-12w (95%CI): i) -4.9 (3.4, 6.3), c) -3.3 (1.5,, 5.1)					NS		
	Daily pain score (Likert)	BL: i) 1.75, c) 1.73. 12w: i) 1.1, c) 1.1					W/in	i) p<0.001	c) p=0.001
							b/n	p=0.157	
Edwards et al. (2000)	5 point scale (0= no symptoms to 4= very severe)	2.25±0.79		i1) 2.38± 0.95	i2) 2.29± 0.81	i3) 2.20± 0.89	c) 2.49± 0.77	b/n	p=0.39
Elliot et al. (2010)	VAS (100 mm)	Δ BL: i) -4.9±16.3, c) -3.9±19.3. Five pt Δ>25 mm (considered clinically sig change)					b/n	p=0.1, >25 mm: p<0.001	
Frestedt et al. (2009)	WOMAC pain	i) 54±17	c) 60±15	Mean Δ over time of study: i) 10.83±8.3, c) 5.38±2.8			b/n	p=0.63	
Gaul et al. (2015)	Intensity of maximal pain/migraine day (mild=1, mod=2, sev=3)	i) 2.71±0.458 (0% mild, 29.1% mod, 70.9% sev)	c) 2.7±0.533 (3.5% mild, 22.8% mod, 73.7% sev)	i) 2.47±0.639 (7.3% mild, 36.5% mod, 52.7% sev)	c) 2.64±0.52 (1.8% mild, 31.6% mod, 64.9% sev)		b/n	p=0.03	
Ghoochani et al. (2016)	WOMAC pain	i) 8±5	c) 9.6±5.4	i) 7.3±5	c) 10±5.2		b/n	NS	
Hill et al. (2015)	WOMAC pain	i) 16±9	c) 15±9	i) 13	c) 8		b/n	p<0.01	

Holst-Jensen et al. (1998)	Pain score (/30) = Pain now (/10) + Worst pain last week (/10) + Ave pain last week (/10)	Median: i) 17, c) 15			Median 4w: i) 12, c) 16			b/n	NS	
Holton et al. (2012)	VAS (20 cm)	FM: 13.3±3, IBS: 10.4±5			Diet (Δ4w) FM: 5.4±5.7, IBS: 4.6±6.3. Challenges (score): i) FM: 10.6±4.8, IBS: 8.4±5.3, c) FM: 8.1±4.2, IBS: 6.3±4.9			Diet - FM&IBS: p<0.0001. Challenges - FM: p=0.07, IBS: p=0.19		
Hughes et al. (2002)	VAS (100 mm)	i) 51	c) 55		i) 45	c) 40		p=0.89		
Jensen et al. (2015)	VAS (100 mm)	Upper back @ rest: i) 15, c) 14. Lower back @ rest: i) 25, c) 17			UB @ rest: i) 5, c) 9. LB @ rest: i) 8, c) 12			b/n	UB) NS	LB) p<0.071
Kanzaki et al. (2012)	VAS (not specified)	i) 40.9±14	c) 32.5±7.4		i) 8.6±15.1	c) 20.2±28.6		W/in	i) GCQ p<0.01	c) NS
Katayoshi et al. (2017)	VAS (not specified)	i) 6.5±1.6	c) 7.0±0.9		i) 2.5±1	c) 3.6±2.3		W/in	i) p<0.001	c) p=0.009
Kolahi et al. (2015) & Mahdavi et al. (2015)	WOMAC pain	i) 10.6±3.6	c) 9.2±4.9		i) 4.9±3.4	c) 7.2±4.4		b/n	P<0.001	
	VAS (0-100 mm)	i) 43	c) 42		i) 25	c) 40			P<0.001	
Kremer et al. (1987)	5 point scale (0=absent, 1=mild, 2=mod, 3=severe, 4=very severe)	2.6±0.17			Mean w/in patient Δ b/n supp and placebo after 14w: -0.28 (95%CI -0.69 to 0.13)			NS		
Letizia Mauro et al. (2000)	VAS (100 mm)	i) 75.5±8.9	c) 70.6±7.9		i) 9.53±16.5	c) 36.83±27.4		b/n	p<0.0001	
Lugo et al. (2016)	WOMAC pain	i) 58.1 ±1	c1) 57.5 ±1.3	c2) 56.9 ±1.4	i) 24.0 ±1.2	c1) 19.2 ±1.2	c2) 17.0 ±1.3	b/n	i) vs c2): 95%CI -11.1 to -2.8, p=0.00003	
	VAS (100 mm)	i) 58.4 ±0.99	c1) 59.1 ±0.97	c2) 58.2 ±0.97	i) 37	c1) 42	c2) 44		i) vs c2): 95%CI -9.5 to -1.8, p=0.002	
Li et al (2015)	VAS (100 mm)	i1) 43.1 ±5.5	i2) 42.9 ±11.2	i3) 42.2 ±11.3	i1) 43.6 ±5.2	i2) 34.6 ± 14.3	i3) 30.3 ± 13.3	b/n	p=0.01	

Matsuno et al. (2009)	VAS (not specified)	RA: 60, OA: 62		RA: 55, OA: 37		W/in	RA) NS	OA) p<0.05
Merchant et al. (2000)	VAS (10 cm)	# pts that felt better: 10, # pts worse: 4, Δ from BL: 21% (+'ve % = improvement)				NS		
Merchant et al. (2001)	VAS (10 cm)	7±2		i) Ave ↓ 21%	c) Ave ↓ 8%	W/in	i) p=0.011	c) NS
Myers et al. (2010)	COAT pain score (VAS 10 cm)	i) 4.786	c) 4.903	i) 2.122	c) 3.827	p=0.088		
Nielsen et al. (1992)	VAS (arbitrary units)	i) 120 (90-143)	c) 118 (81-142)	i) 104 (78-143)	c) 136 (86-170)	b/n	p=0.002	
Pirouzpanah et al. (2017)	VAS (not specified)	i) 3.4±0.4	c) 3.1±0.3	i) 2.7±0.2	c) 2.9±0.3	b/n	NS	
Remans et al. (2004)	VAS (100 mm)	i) 50±18	c) 55±18	Δ from BL: i) 5±18, c) -4±17		NS		
Reme et al. (2016)	Numeric rating scale (0-10) Pain during rest (last wk)	i) 4.36	c) 3.83	i) 3.75	c) 3.39	b/n	p=0.77	
Schumacher et al. (2013)	WOMAC pain	i) 42.1±22.9	c) 41.5±24.4	i) 36.3±27	c) 40±26.6	b/n	p=0.24	
Shell et al.(2012)	Roland-Morris Pain Questionnaire	i1) 10.97±5.42	i2) 12.38±5.31	c) 12.90±5.14	Δ from BL: i1) -44, i2) -65, c) 2.95	b/n	p<0.05	
Skoldstam et al. (1992)	VAS (15 cm)	i) 1.46±1.13	c) 1.29±0.14	Δ BL to 6m: i) 0.02±0.14, c) 0.17±0.17		NS		
Sperling et al. (1987)	# painful joints & joint pain index	25.7±3.2/34.6±5.1		20.4±3.2/25.8±4.3		# painful joints: NS, joint pain index: ≤0.036		
Trippe et al. (2016)	VAS (1-10)	5.8		4		W/in	p<0.05	
Tulleken et al. (1990)	VAS (not specified)	i) 4	c) 4.4	i) 2.4	c) 3.8	NS		
Vellisca et al. (2014)	7 point numerical rating scale	i) 5.58±0.91	c) 5.63±0.86	i) 5.15±0.95	c) 5.31±0.88	NS		

Wong et al. (2017)	VAS (10 cm)	i) 17.4±2.9	c) 19.6±3.1	i) 11.2±2.9	c) 13.1±2.8	b/n	p<0.001
	Persistent Pain Intensity	i) 19.4±2.8	c) 20.6±2.9	i) 13.1±2.8	c) 23.0±2.9		p=0.011

*Reported as mean ±SD unless otherwise stated. †b/n = between-group difference. ‡w/in = within-group difference. §Reported as change from BL. **i) = intervention group. ††Δ = change. ‡‡c) = control group.

NPQ, Neurophysiology of pain questionnaire; VAS, Visual analogue scale; NS, Not significant; BL, Baseline; CI, Confidence interval; pts, patients;

FM, Fibromyalgia; IBS, Irritable bowel syndrome; UB, Upper back; LB, Lower Back; RA, Rheumatoid arthritis; OA, Osteoarthritis.

Study name	Subgroup within study	Comparison	Std diff in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Azad 2000*	Altered diet	Vegetarian	2.055	0.280	0.078	1.506	2.604	7.336	0.000
Bunner 2014*	Altered diet	Vegan	-0.034	0.325	0.106	-0.671	0.602	-0.106	0.916
Bunner 2015*	Altered diet	Vegan	0.667	0.358	0.128	-0.035	1.368	1.863	0.062
Clinton 2015*	Altered diet	Vegan	-5.041	0.672	0.452	-6.358	-3.724	-7.501	0.000
Hanninen 2000**	Altered diet	Vegan	-0.645	0.237	0.056	-1.110	-0.181	-2.724	0.006
Kaartinen 2000**	Altered diet	Vegan	-2.605	0.474	0.225	-3.534	-1.675	-5.491	0.000
Kieldsen-Kragh 1991*	Altered diet	Vegetarian	-7.276	0.751	0.564	-8.748	-5.804	-9.686	0.000
Nenonen 1998*	Altered diet	Vegan	0.000	0.320	0.103	-0.628	0.628	0.000	1.000
Skoldstam 2003*	Altered diet	Med	-0.864	0.319	0.102	-1.489	-0.238	-2.707	0.007
			-1.415	0.654	0.428	-2.698	-0.133	-2.164	0.030
Abendroth 2010**	Fasting therapy	Fasting therapy	-0.366	0.287	0.083	-0.929	0.197	-1.275	0.202
Michalsen 2013**	Fasting therapy	Fasting therapy	0.281	0.316	0.100	-0.338	0.900	0.891	0.373
			-0.056	0.324	0.105	-0.690	0.578	-0.172	0.863
Kawaguchi 2015**	Specific nutrient altered diet	Elemental diet	-1.619	0.421	0.177	-2.444	-0.794	-3.848	0.000
Spigt 2005*	Specific nutrient altered diet	Water	-1.063	0.553	0.305	-2.146	0.021	-1.922	0.055
			-1.415	0.335	0.112	-2.071	-0.759	-4.226	0.000
Bellare 2014*	Supplement	GlucChron	-2.494	0.283	0.080	-3.050	-1.939	-8.799	0.000
Benito-Ruiz 2009*	Supplement	Protein (AA)	-0.317	0.140	0.020	-0.592	-0.042	-2.260	0.024
Cleland 1988*	Supplement	Omega-3	0.021	0.295	0.087	-0.557	0.599	0.070	0.944
Colker 2002*	Supplement	Combination	-0.379	0.363	0.131	-1.090	0.332	-1.045	0.296
Jensen 2015*	Supplement	Protein	-1.539	0.456	0.208	-2.432	-0.646	-3.378	0.001
Kanzaki 2012*	Supplement	GlucChronAntiox	-0.875	0.331	0.110	-1.523	-0.226	-2.642	0.008
Katayoshi 2017*	Supplement	Combination	0.338	0.504	0.254	-0.649	1.325	0.672	0.502
Letizia Mauro 2000*	Supplement	Vitamin	-1.424	0.289	0.084	-1.990	-0.857	-4.925	0.000
Pirouzpanah 2017*	Supplement	Antioxidant	-2.021	0.418	0.175	-2.841	-1.201	-4.831	0.000
Wong 2017*	Supplement	Antioxidant	-3.437	0.371	0.138	-4.164	-2.710	-9.265	0.000
			-1.213	0.361	0.130	-1.921	-0.505	-3.359	0.001
			-0.905	0.187	0.035	-1.272	-0.537	-4.828	0.000

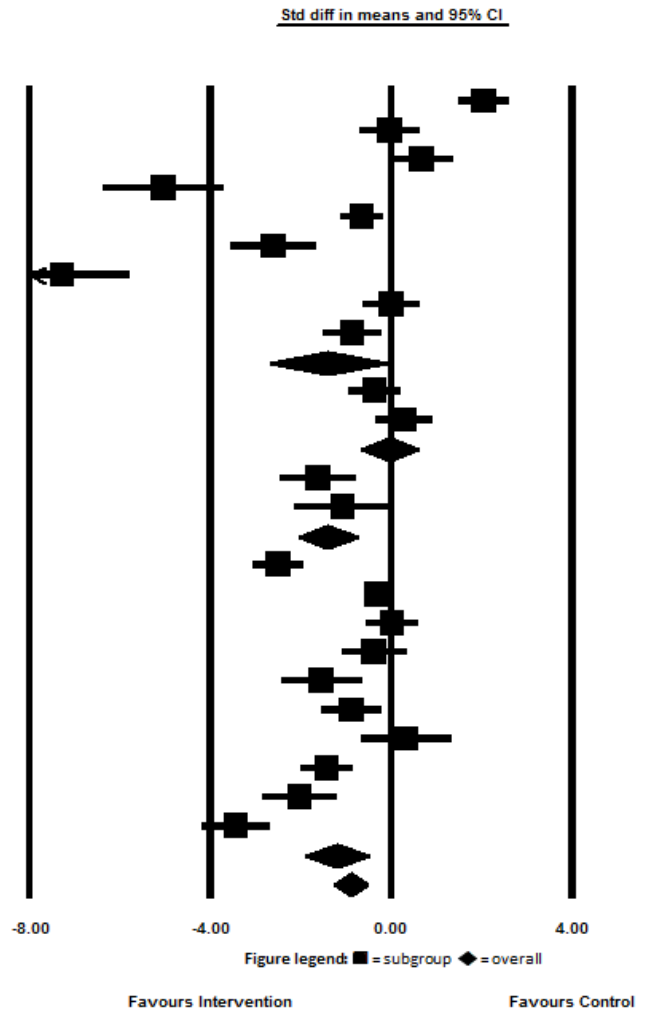

Figure legend
* = Randomised control trial
** = Non randomised experimental trial

Figure 2.2. Meta-analysis of overall effect of dietary intervention

2.4.9 Effect of nutrition interventions on secondary outcomes

There were also mixed results with the secondary outcomes: dietary intake, quality of life, chronic disease risk and mental health status. Changes in dietary intake were statistically significant in four (174, 177, 212, 213) out of nine studies (172, 174, 177, 194, 197, 210, 212, 213, 225). There were an additional six studies (167, 168, 187, 189, 206, 221) that measured dietary intake for adherence purposes and, of these, only one reported 100% adherence to their intervention (189), the remaining four stated that the majority adhered to the intervention. Another five studies measured dietary intake but did not report an analysis of these data (166, 175, 193, 217, 230). Physical and/or mental quality of life was statistically significant in eight (184, 185, 187, 188, 197, 204, 208, 231) of the 20 studies (167, 175, 181, 184, 185, 187, 188, 194, 195, 197, 204, 208, 215-217, 219, 226, 230, 231, 234) that measured this outcome. There was no clear pattern as to which type of nutrition intervention contributed to this result. A statistically significant change was seen for weight and/or BMI in 13 studies (177, 180, 181, 184, 195-197, 200, 204, 212, 219, 226, 227). Of these, seven included a vegan or vegetarian dietary intervention (180, 181, 184, 200, 204, 212, 219). Twelve studies (168, 174, 189, 194, 202, 203, 210, 213, 221, 222, 225, 228) did not have statistically significant results, of these five (174, 202, 221, 222, 225) prescribed a supplement without changing dietary intake. Of the studies that measured cholesterol, blood pressure and glycated haemoglobin, six (177, 180, 183, 202, 213, 225) out of 14 studies (167, 177, 180, 181, 183, 184, 189, 202, 203, 209, 213, 218, 225, 226) reported statistically significant outcomes. Of those that were significant, four were related to serum cholesterol levels (vegan, omega-3and fat) (177, 180, 183, 225) and two to blood pressure (Mediterranean diet and glucosamine, chondroitin and other bioactives) (202, 213). In terms of mental health, five (187, 208, 210, 214, 216) out of the 13 (181, 184, 187, 200, 208, 210, 214-217, 223, 226, 228) studies measuring this showed statistically significant results. Similar to quality of life, there was no clear pattern as to which type of nutrition intervention was more effective in this result.

2.5 Discussion

This systematic review investigated the impact of different nutrition interventions in individuals with chronic pain on participants' pain severity and/or intensity. For each of the four nutrition intervention categories (altered dietary pattern, altered specific nutrients, supplements and fasting therapy), varying impacts on participants' self-reported pain were reported. Only six studies reported an effect size (180, 181, 185, 217, 228, 230). The meta-analysis identified significant reductions in pain scores (-0.905 on a VAS) for all nutrition interventions combined (P = 0.000). Within subcategories of intervention type, the altered dietary pattern and altered specific nutrient had the largest statistically significant reductions (-1.415 on a VAS, P = 0.030and P = 0.000, respectively), followed by supplements (-1.213 on a VAS, P = 0.001). The fasting therapy intervention had a very small nonsignificant reduction (-0.056 on a VAS, P = 0.863).The intervention category having the largest number of studies with a positive effect comprised those interventions that aimed to move a person's overall dietary pattern to a more healthful eating pattern, with 12 (169, 181, 184, 187, 193, 194, 200, 204, 210, 212, 213, 226) of the 16 studies (169, 171, 180, 181, 184, 187, 193, 194, 200, 204, 210, 212, 213, 219, 226, 228) having a positive effect on pain score. Altering intakes of a specific nutrient such as fat or fibre, led to mixed results. Only two intervention studies found a statistically significant improvement in pain score when either total fat or protein intakes were altered (177, 203). Among the studies that prescribed a supplement to participants, only 11 out of 46 had statistically significant results (175, 176, 179, 191, 195, 205, 207-209, 220, 224). The supplement type that most consistently had statistically significant results was the use of amino acids (n = 5), in the form of collagen, carnitine and theramine, as studied in knee osteoarthritis (n = 3) (175, 205, 209), joint pain and back pain (179, 224). Overall, this review identified six studies (175, 179, 196, 205, 209, 224) that supplemented participant's diets with various combinations of amino acids, with the five previously mentioned studies achieving statistically significant reductions in pain scores post-intervention. This warrants further investigation in well-designed trials. The 'fasting therapy' intervention category, where total daily energy intake is very low, did not demonstrate a consistent reduction in pain scores, with the only statistically significant result found immediately after the fasting therapy had been completed by participants' (167). For community-based population groups with chronic pain, fasting usually

provides only a short-term benefit and repeated use may negatively affect nutritional status and overall health. Despite the positive results narratively, the meta-analysis did not identify any statistically significant weighted effects, which may be a result of the heterogeneity of the included studies. The majority of participants in the included studies were in the overweight BMI category (BMI 25.0–29.9 kg m^{-2}), predominately being women and aged over 50 years. This is similar to the clinical chronic pain population. For example, in 2015, the Australian tertiary pain clinics collectively reported that 30% of patients were in the overweight BMI category and 37% in the obese BMI category (BMI > 30 kg m^{-2}) with 59% being female, and with an average age of 52.4 years (95). All the tools used in the included studies to measure pain are subjective and the majority (n = 61) were single item measures (e.g. VAS, pain scale or pain score). The experience of pain is fundamentally subjective and self-reported measures are the gold standard for assessment (235). However, chronic pain is complex and influenced by multiple factors, such as physiology, psychology and sociocultural status. Therefore, multidimensional measures are required that incorporate sensory, behavioural and social factors (236). In the current systematic review, 19 studies used multidimensional pain measurement tools, including WOMAC (n = 10) (124, 174, 175, 182, 186, 190, 192, 195, 205, 209), SF-36 Pain Score (n = 3) (184, 187, 217), Brief Pain Inventory (228), McGill Pain Questionnaire (181), Roland-Morris Pain Questionnaire (224), Fibromyalgia Impact Questionnaire (187), Neuropathic Pain Questionnaire (169) and Lequesne Questionnaire (182) (n = 1). Interestingly, of the studies that used WOMAC, half used a single-item measure, the VAS, in conjunction with the WOMAC (174, 175, 186, 205, 209). By contrast, a single-item measure of pain has been recommended to determine pain intensity in clinical trials, with the VAS, numerical rating scale (NRS) and verbal rating scale all being considered as reliable and valid (235). However, the NRS was ranked as the optimal tool to use because the VAS can be difficult to complete in participants with very low literacy levels (235).This is supported by another study where test–retest reliability of the VAS in a rheumatology population was calculated (151). Findings demonstrated that the VAS had good test–retest reliability, although it was better in patients with high literacy levels ($r = 0.94$, $P < 0.001$) compared to those of lower literacy ($r = 0.71$, $P < 0.001$) (151).The variety of pain-related conditions, in addition to the wide range of nutrition-related interventions, has contributed to the large heterogeneity among the studies included in the current

review. Chronic pain can be sub-classified in a number of ways, including mechanism-based classification or by pain syndrome (3), as well as by diagnostic frameworks such as the International Classifications of Disease 11th Revision, as constantly being developed (21).The lack of a precise methodology to categorise a number of the broad pain-related conditions identified in the current review makes comparisons difficult. Only two studies (199, 217) have included a population who experienced chronic pain; all other studies have specified a pain-related condition (e.g. rheumatoid arthritis, fibromyalgia, degenerative arthritis). Beyond the complexity of pain is the complexity and diversity of therapeutic interventions trialled and their potential mechanisms of action. Some interventions seek to directly modify the experience of pain, whereas others act indirectly through improvement in comorbid conditions. From changing overall dietary patterns to supplementing dietary intake with a specific nutrient, it is difficult to compare the interventions directly. Although the authors have categorised the studies based on the type of nutrition intervention, there is still a wide variety of interventions within each category. Less than one-quarter of the studies reported changes in dietary intake (n = 15), and only nine studies (177, 183, 196, 200, 213, 216, 217, 219, 223) had follow-up periods beyond the completion of the intervention. Only 15 studies included a dietitian as part of the intervention and/or data collection research team (167-169, 181, 185, 189, 194, 197, 204, 206, 210, 212, 219, 227). These limitations add to the disparity between the recognition of nutrition-related issues as key treatment goals and the availability of good-quality, dietetic-led, nutrition-related treatment options for people who experience chronic pain. Further research is needed to investigate the relationship between nutrition and nutrition interventions and chronic pain. There are several limitations to this review. These include the age and quality of the studies. Almost half of the studies are ≥10 years old and 56% of the studies were of poor or neutral methodological quality. Over this time span, chronic pain treatments have changed, as pain science has developed and the evidence base has grown. The search was limited to studies published in English, with 30% published in the USA, which limits the generalisability of results. Only 13% of studies assessed the impact of the intervention on pain outcomes at any follow-up beyond the completion of the intervention, making it difficult to determine the long term effectiveness of nutrition interventions on people who experience chronic pain (Table 2.4).The main strength of the current review is that it acknowledges chronic pain as a condition, despite the pain-

related condition that may trigger it. In this review, chronic pain is the outcome reported and not a secondary outcome of an underlying disease or illness. The study also combines categories of nutrition interventions into one review that has allowed the authors to summarise studies that aim to treat chronic pain using a nutrition intervention.

2.6 Conclusion

The present review examines the impact of nutrition-related interventions on chronic non cancer pain severity. This review found that nutrition interventions can have a positive effect on the pain experience. However, the included studies are of limited quality and explore a range of nutrition interventions in those with chronic pain. This highlights the need for more rigorous nutrition intervention studies where chronic pain is the primary outcome. High-quality studies testing nutrition advice and support in populations with chronic pain and where pain is the primary outcome would be of benefit to researchers and clinicians. Particularly in a clinical setting as a successful nutrition intervention could be implemented into practice and improve the quality of life for people experiencing chronic pain. Studies could also go further by not only addressing pain itself, but also overweight, obesity and other comorbidities experienced by those living with chronic non cancer pain

Chapter 3: Population characteristics in a tertiary pain service cohort experiencing chronic non-cancer pain: Weight status, comorbidities and patient goals

This chapter has been reproduced from: **Brain K**, Burrows T, Rollo ME, Hayes C, Hodson FJ, Collins CE. Population Characteristics in a Tertiary Pain Service Cohort Experiencing Chronic Non-Cancer Pain: Weight Status, Comorbidities, and Patient Goals. Healthcare (Basel). 2017;5(2).

3.1 Abstract

We describe the characteristics of patients attending an Australian tertiary multidisciplinary pain service and identify areas for nutrition interventions. This cross-sectional study targets patients experiencing chronic pain who attended the service between June–December 2014. Self-reported data was captured from: (1) an Electronic Persistent Pain Outcomes Collaboration (ePPOC) referral questionnaire, incorporating demographics, pain status, and mental health; (2) a Pain Assessment and Recovery Plan (PARP), which documents patients' perceived problems associated with pain and personal treatment goals. The ePPOC referral questionnaire was completed by 166 patients and the PARP by 153. The mean (SD) patient age was 53 ± 13 years, with almost 60% experiencing pain for >5 years. Forty-five percent of patients were classified as obese (BMI ≥ 30 kg/m^2, mean (SD) BMI was 31 ± 7 kg/m^2), with a mean waist circumference of 104 ± 19.4 cm (SD). The most frequent patient nominated treatment goals related to physical activity (39%), followed by nutritional goals (23%). Traditionally, pain management programs have included physical, psychosocial, and medical, but not nutritional, interventions. By contrast, patients identified and reported important nutrition-related treatment goals. There is a need to test nutrition treatment pathways, including an evaluation of dietary intake and nutrition support. This will help to optimise dietary behaviours and establish nutrition as an important component of multidisciplinary chronic pain management.

3.2 Introduction

Chronic pain is defined as pain that persists beyond the usual time for tissue healing, or pain that continues beyond three to six months (15). Musculoskeletal conditions and neurological injuries are commonly associated with chronic pain (39). In Australia, osteoarthritis is the most common structural condition associated with chronic pain (39). However approximately 30% of those who experience chronic pain have no obvious structural contributors and a large body of pain research has sought an explanation for this (22). Neuroscience research has helped to provide answers with important insights into the contribution of nervous system sensitisation and brain interpretation in the expression of chronic pain (3).

Approximately 3.2 million Australians experience chronic pain and this is estimated to rise to 5 million by 2050 as the population ages (22). Chronic pain often occurs with other physical and mental health comorbidities including depression and anxiety, heart disease, and diabetes (75). Current treatment services in Australia include over 50 public and private multidisciplinary pain management services, which typically provide a range of interventions including group-based pain management programs (55). Treatments commonly include reducing the reliance on medication (such as opioid de-prescribing) and lifestyle-based interventions, including cognitive approaches and physical activity. In contrast, nutritional expertise is commonly lacking within multidisciplinary teams. Of the 20 services located in NSW, Australia, three list nutrition as part of the program content provided to patients, but none have a nutrition expert employed as part of their team (56).

Research has only partially explored the relationship between nutritional status and chronic pain. Some evidence suggests an association between chronic pain and poor diet quality with higher intakes of energy-dense, nutrient poor foods (106, 108). There are a number of studies that explore the association between obesity and chronic pain, including a recent systematic review summarising the evidence which supports the notion that there is a higher prevalence of chronic pain in people who are obese, compared to a normal weight population (237). This review further emphasises the importance of including weight reduction in chronic pain management (237). Other studies have also reported a link between greater pain perception and a higher weight status, with individuals classified as obese twice as likely to experience pain (100, 102).

Stone et al. present the results from a large US-based population study (n > 1,000,000) and when controlling for age, gender, race, education, smoking, and the presence of health care coverage, the associated risk for experiencing pain was 3.5 times greater for those who were in the obese III (BMI 40/m^2) category compared to those in the normal BMI (18.5–24.99 kg/m^2) category (102). It has been suggested that the relationship between a poor nutrition status and chronic pain may in part be mediated by nervous and immune system sensitisation (5, 9). In addition, excess body weight can contribute to pain through a direct mechanical load on specific joints (101). Both Okifuji et al. and Ding et al. outline a number of issues, including: the association between a higher BMI and pain and a significant association between a higher BMI and the prevalence of defective knee cartilage (101, 238).

The current study aims to summarise and describe the demographics, pain characteristics, weight status, comorbidities, and treatment goals of patients attending an Australian multidisciplinary chronic pain service. This study will identify the prevalence of overweight and obesity and explore patient treatment goals in a real-world clinical population. This will enable the identification of major nutrition-related issues, as reported by patients that could be used to inform appropriate treatment and the future development of tailored interventions.

3.3 Materials and methods

This descriptive cross sectional study was undertaken at Hunter Integrated Pain Service (HIPS), which provides a person-centred approach to pain management incorporating aspects of biomedicine, mindbody, connection, physical activity, and basic nutrition education (Figure 3.1) (63). In practical terms for patients experiencing chronic non-cancer pain, this involves a shift from the passive receipt of medical treatment toward active lifestyle changes. Opioid de-prescribing is an important part of this approach. The treatment programs offered at HIPS are currently facilitated by pain medicine specialists, nursing staff, psychologists, and physiotherapists. However there are no dietetic staff within the service. Referrals to the service for chronic non-cancer pain are generally made by the patient's general practitioner or medical specialist. Patients are then invited to attend a seminar, Understanding Pain (UP), which outlines current pain science and an overview of the service. Patients then have a choice to either leave the service (where they continue with their GP and community services) or be triaged into

one of two pathways. The first pathway is the group-based pathway and this is the path that the majority of patients follow; it begins with a group-based assessment and planning workshop (A&P), followed by a six week group-based treatment program called Active Pain Treatment (APT). Patients then have the choice to attend a follow up session called Progress Review Group and/or a Mindfulness Group. The second pathway involves individual management. Patients may be triaged to attend an individualised multidisciplinary appointment or one-on-one appointment with a specific clinician. Other patients may attend a procedural appointment. Those who attend an individualised or procedural appointment are strongly encouraged to follow up by attending the group-based treatment options.

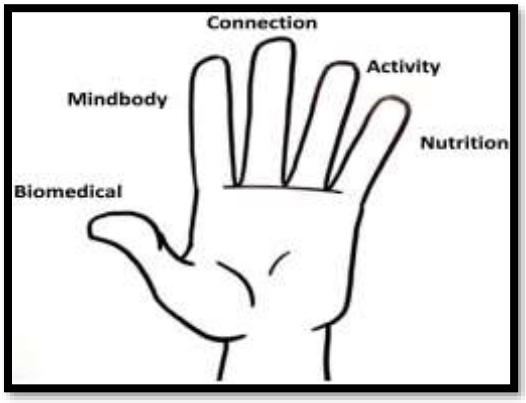

Figure 3.1. Whole person approach to pain management, Hunter Integrated Pain Service.

Patients who attended HIPS between June–December 2014 were identified by searching the Electronic Persistent Pain Outcomes Collaboration (ePPOC) database (75). The Medical Record Numbers (MRN's) were extracted and used to search Digital Medical Records (DMR) to find patients eligible for inclusion in the study. To be eligible for inclusion, patients had to have: (1) a completed ePPOC referral questionnaire (Appendix 15-20), which patients complete before attending UP; (2) a Pain Assessment and Recovery Plan (PARP) (Appendix 21 & 22), completed at A&P, on file; and (3) have provided consent for their data to be used in research projects via the ePPOC referral questionnaire, which included a consent statement. During data extraction, it was identified that a portion of these patients had completed an earlier version of the PARP which could not be merged due to the qualitative nature of the data. These PARPs were excluded from the analysis.

The ePPOC referral questionnaire consists of eight sections and was completed by patients before they entered the pain service. Section 1 covers demographic questions (21 items), including: gender, date of birth, country of birth, ethnicity, and work status (where possible answers (n = 11) ranged from retired to full time work). In addition, Section 1 asked general questions relating to pain status such as the cause of pain (where participants could nominate their perception of the cause of their pain, choosing from eight pre-defined categories ranging from injury to cancer) and the main pain site on the body. The ePPOC survey also asked for details on height, weight, and comorbidities (where participants could choose from one or more responses (n = 13) and the possible answers ranged from kidney disease to osteoarthritis). The ePPOC survey also included a question asking if patients required assistance filling out the form with the option of a yes/no answer. Sections 2 and 3 relate to the use of health services (six items) and current medication (one item). Sections 4–7 include standardised, validated pain assessment tools including the Brief Pain Inventory (BPI) (76, 239), Pain Self Efficacy Questionnaire (PSEQ) (78), Pain Catastrophising Scale (PCS) (240), and the Depression Anxiety Stress Scale 21 (DASS-21) (77). The BPI, PSEQ, and PCS describe pain severity and interference, confidence in carrying out activities despite pain, and thoughts and feelings associated with pain, respectively. The BPI severity and interference score is rated on a scale of 0–10 for severity, where a score of 0–4 indicates mild pain, 5–6 moderate pain, and 7–10 severe pain. An average of the seven interference questions is calculated as a score out of 10, with the higher the score, the higher the interference. The PSEQ total is a sum of the scores (0 = not confident at all to 6 = completely confident) from 10 questions. A higher score indicates a higher level of self-efficacy: severe < 20, moderate 20–30, mild 31–40, and minimal impairment > 40. The PCS measures pain catastrophising by measuring three sub-categories: rumination, magnification, and helplessness. A score of <20 indicates mild catastrophising, high is 20–30, and severe is >30. The DASS-21 provides a score for each domain of depression (normal 0–9, mild 10–13, moderate 14–20, severe 21–27, extremely severe 28+), anxiety (normal 0–7, mild 8–9, moderate 10–14, severe 15–19, extremely severe 20+), and stress (normal 0–14, mild 15–18, moderate 19–25, severe 26–33, extremely severe 34+), and classifies each patient from normal to extremely severe. Where possible, survey data (BPI, PSEQ, and DASS-21) was scored according to pre-specified author instructions. Section 8 (10 items) includes additional information such as other health

professionals involved, previous medication use, smoking, and alcohol and caffeine consumption.

As a patient centred treatment plan that facilitates goal setting, the PARP questionnaire was developed by the HIPS team to encourage the use of active self-management skills to treat pain. This tool allows patients to select perceived problems associated with their pain experiences, set individualized goals, and nominate the solutions that they would like to pursue. Problems and solutions can be selected from five areas: biomedical, mindbody, connection, physical activity, and nutrition. The biomedical domain considers the balance of body structure and nervous system contributions to pain along with medication use, mindbody addresses thoughts and emotions related to pain, and connection explores the linkage with people, places, and purpose. The activity domain covers the patient's ability to undertake physical activity and reduce sedentary behaviour. The nutrition section provides an opportunity for patients to self-report waist circumference and patients are provided with a tape measure and brief instructions on how to do this. Patients can also list any intention to focus on a balanced diet and/or other strategies (e.g., reduce sugar intake and increase water and/or fruit and vegetable consumption) to improve diet quality.

Ethics approval for the current study was obtained from Hunter New England Health (HNEH) (15/07/15/5.01) and the University of Newcastle (H-2015-0266).

3.3.1 Data analysis

Data were extracted from each survey and linked via patient MRNs. The date of birth was obtained to calculate the age of the participants and this was subsequently collapsed into 20 year age brackets. Height and weight were used to calculate BMI using standardized equations. Where patients were able to list "other" comorbidities, the answers were collated and those which fell under one of the pre-existing comorbidities were moved to that group. Patient goals were categorized and collated based on the five domains in the PARP. A patient's BPI severity, BPI interference, PSEQ, PCS, and nutrition-related goals were collated for those patients with adequate data to allow a BMI calculation. This data was then compared based on the BMI category (normal weight, overweight, and obese). Sample statistics were used to explore associations between these variables. BPI severity and PCS were analysed using ANOVA, while

BPI interference and PSEQ were analysed using a non-parametric Kruskal Wallis test. A chi-squared test was used to compare BMI categories and the % patients who selected a nutrition-related goal. For those results which were statistically significant ($p < 0.05$), post-hoc testing was carried out. All statistics were generated using Stata13 (241) and descriptive statistics were reported as mean ± standard deviation or response frequencies and sample statistics reported using p-values.

3.4 Results

A total of 166 patients consented for their data to be used in research and had a complete ePPOC referral questionnaire at the time of entry to the service, which was subsequently included in the study. This is just over one third of the total patient cohort that HIPS would see, at any stage of treatment, in a six month period. Of these, 93% (*n* = 153) of patients also completed the appropriate PARP, which was analysed separately. Thirteen patients had insufficient data due to the completion of an earlier version of PARP that could not be merged.

3.4.1 Patient demographics

Information provided via the ePPOC referral questionnaire identified that 57% of patients were female (Table 3.1), with a mean age of 53 ± 13 years (SD) (range 21–89 years) and no differences in the demographic characteristics by gender. The major age group was 41–60 years, incorporating 55% of patients. Ninety percent of patients were born in Australia, with 5% identifying as being Aboriginal or Torres Strait Islander (*n* = 8) and 1% being of Maori descent (*n* = 1). Thirty seven percent described their work status as *unemployed (due to pain)* and listed *osteoarthritis/degenerative arthritis* (25%) and *depression/anxiety* (22%) as the top two most common comorbidities experienced in addition to pain. Twelve percent chose the comorbidity category "*other, please specify*", with 40% specifying a pain-related condition, and of this, 28% listed fibromyalgia. Other comorbid conditions included asthma (8%) and sleeping difficulties (8%). Thirty six percent of patients reported having < 2 comorbidities (from the 13 listed categories), and 64% of patients reported ≥ 2 comorbidities (242). On average, each patient reported taking eight medications (range 0–31), with a total of 1356 medications listed by the 166 patients. Seventy-one percent of patients reported ≥1 opioid, 69% paracetamol, 51% antidepressant, 42% anticonvulsant, 31% non-steroidal anti-

inflammatory (NSAID), and 28% a nutrition related supplement. Approximately one quarter of the patients were taking ≥1 medication for hypertension and hypercholesterolemia and 10% were taking ≥1 laxative, with one patient reporting four laxatives. Of the 1356 medications listed, 33% related to pain relief, 9% were a nutritional supplement, 9% were antidepressants, 7% were anticonvulsants (which may or may not be directed toward the treatment of neuropathic pain), 6% were for treating hypertension, 3% were for treating high cholesterol, and 2% were laxatives.

Table 3.1. Patient Demographics.

Patient demographics					
Characteristic	**N**	**%**	**Characteristic**	**N**	**%**
Gender			**Comorbidities[1]**		
Male	71	43	Osteoarthritis/ degenerative arthritis	116	25.2
Female	95	57	Depression and anxiety	102	22.1
Work status[1]			Other	56	12.2
Unemployed (due to pain)	76	36.5	High blood pressure	54	11.7
Retired	44	21.2	Stomach/ulcer	27	5.9
Home duties	30	14.4	Diabetes	22	4.8
Paid work (part time)	10	4.8	Blood disease	15	3.3
Unemployed (not due to pain)	9	4.3	Heart disease	17	3.7
Studying (school/university)	9	4.3	Lung disease	14	3.0
On leave from work (due to pain)	9	4.3	Rheumatoid arthritis	14	3.0
Paid work (full time)	8	3.9	Neurological condition	13	2.8
Voluntary work	7	3.4	Cancer	8	1.7

Working (limited hours/duties)	4	1.9	Kidney	3	0.7
Retraining	2	1.0			

[1] Patients could select more than one answer.

Based on the data provided by the DASS-21 tool, 81% of patients had some degree of depression (9% mild, 20% moderate, 16% severe, and 36% extremely severe). The anxiety component of the DASS-21 showed that 57% of patients had some degree of anxiety (7% mild, 14% moderate, 12% severe, and 24% extremely severe). Similarly, the stress component showed that 76% of patients had some level of stress (9% mild, 20% moderate, 24% severe, and 23% extremely severe). The average (SD) score for each component was 21.75 ± 12.57, 14.62 ± 10.60, and 20.67 ± 11.44, respectively.

3.4.2 Patients' description of pain experience

A total of 185 answers to the question "what was the cause of your pain?" were selected by the 166 patients. The top answer for patient perceived causes of pain was injury at work/school (24%) and the main pain site selected by patients was the back (40%) (Table 3.2). Just under half of the patients (48%) stated that they had pain in one to three body sites. Eighty four percent of patients described their pain as always present, but at varying intensity. The majority (58%) of patients stated that they had experienced pain for more than five years. The majority of patients (71%) reporting taking ≥1 opioid-based medication. Of the total medications listed by patients, 33% were related to pain relief: 16% were opioids, 6% paracetamol, 5% NSAIDS, and 5% combination analgesic (paracetamol/NSAID and codeine). The BPI was completed by 161 patients with the pain severity score: 21% mild, 42% moderate, and 35% severe. The mean BPI severity score was 6.32 ± 1.72 (range 1.3–10) and the BPI interference score was 7.32 ± 2 (range 0.3–10) out of a possible 10. The PSEQ categorizes pain self-efficacy and the average (SD) score was 19.59 ± 12.01, with 6% rated as having minimal impairment, 13% mild, 26% moderate, and 55% severe. The average PCS score was 30.07 ± 13.10, which just falls into the severe category. Just over half (51%) of patients fell into the severe category, with 25% falling into the high category and 24% into the mild category.

Table 3.2. Patients' description of pain experience.

Patients' Description of Pain Experience					
Characteristic	**N**	**%**	**Characteristic**	**N**	**%**
Cause of pain[1]			**Main pain site[1]**		
Injury (work/school)	44	23.8	Back	65	40.1
Motor vehicle accident	24	13.0	Legs	28	17.3
No obvious cause	23	12.4	Neck	19	11.7
Other (not specified)	21	11.4	Arms/shoulder	12	7.4
Injury (other setting)	20	10.9	Head	8	4.9
Other illness	19	10.3	Feet	7	4.3
Surgery	19	10.3	Abdomen	5	3.1
Injury (home)	11	6.0	Knee	5	3.1
Cancer	4	2.2	Pelvis	4	2.5
Frequency of pain[1]			Buttocks	3	1.9
Always present (varying intensity)	135	84.4	Hands	3	1.9
Always present (same intensity)	14	8.8	Chest	2	1.2
Often present	5	3.1	Whole body	1	0.6

Occasionally present	3	1.9		**Number of pain sites[1]**		
Rarely present	3	1.9	1-3		76	47.5
Time experiencing pain[1]			4-6		59	36.9
<3 months	3	1.9	7-9		21	13.1
3-12 months	11	6.9	>10		4	2.5
1-2 years	18	11.3				
2-5 years	34	21.4				
>5 years	53	58.5				

[1] Patients could select more than one answer.

In terms of health service use over the preceding three months, patients had visited their GP a mean of 4.5 times and saw a health professional (other than a doctor) three times due to pain. There were 280 professionals listed by 107 patients in response to the question "*What health professionals are you seeing?*" These professionals can be categorized into 43 professions. The top professionals (excluding "other") that were listed included general practitioners, physiotherapists, psychologists, and surgeons (12.5%, 11%, 10%, and 7% respectively). The least commonly reported was a dietitian, which was listed by one patient.

3.4.3 Patients' nutrition-related health and treatment goals

A total of 117 patients had anthropometric data recorded. The mean BMI was 31±7 kg/m^2 (range 18.52–54.46 kg/m^2) (Figure 3.2). According to WHO classifications, 21% of patients were in the normal BMI category (18.5–24.99 kg/m^2), 33% were in the overweight category (25–29.99 kg/m^2), and 45% were in the obese category (≥30 kg/m^2). The average BMI of those taking opioids (30.96 kg/m^2) and not taking opioids (29.71 kg/m^2) was similar. The mean waist circumference (reported by n = 138) was 104

± 19.40 cm (range 66–165 cm). Of these, 82 females reported a waist circumference with a mean of 101.21 ± 19.70 cm (range 66–150 cm) and males (*n* = 56) 108.61 ± 18.23 cm (range 82.5–165 cm). Eighty seven percent of females and 77% of males recorded waist circumferences that categorized them (≥80 cm and ≥94 cm respectively) as at risk of developing chronic disease (243). Of the 1356 medications listed by the patients, 9% were either a vitamin, mineral, omega-3, or combination of the three.

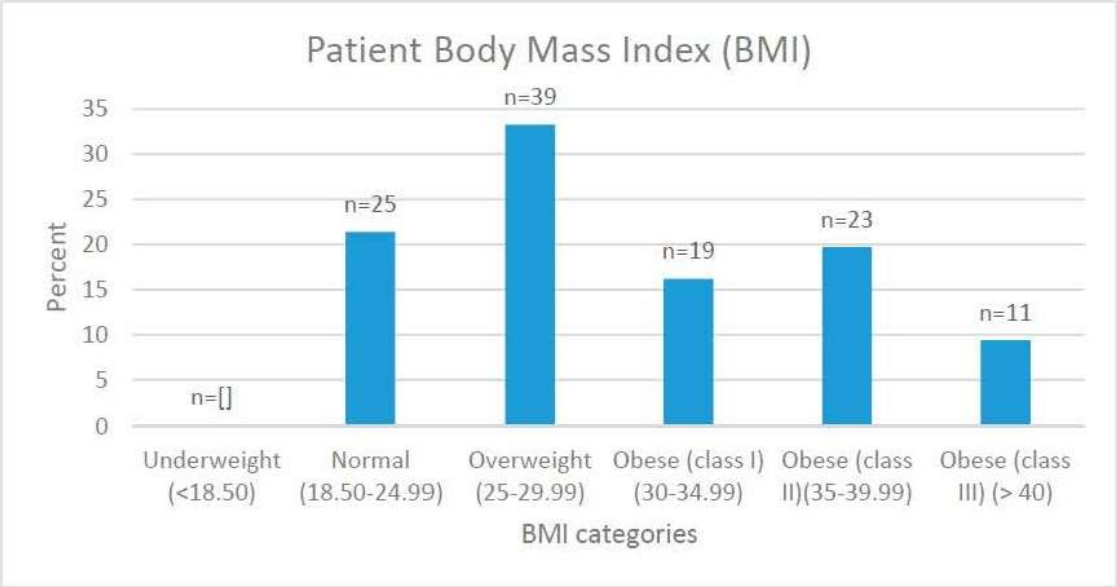

Figure 3.2. Body Mass Index (BMI) of patients attending the Hunter Integrated Pain Service.

Most patients reported that they drank alcohol less than one day per week (70%), with 3% stating that they drank every day of the week. Of those who did drink alcohol, 57% indicated that they consumed one to two drinks per day and 6% reported having eight to 15 drinks per day. Fourteen percent of patients reported that they used alcohol to relieve pain, 42% said that they did not, and 44% did not answer this question. The majority of patients (54%) reported that they consumed one to three caffeinated drinks (coffee, cola, energy drinks) per day, with 2% stating that they had >8 per day.

Based on the data provided from the PARP, 34–39% of patients chose to make a nutritional change. These changes included: reducing the sugar intake, and increasing the intake of water, fruit, and vegetables. In addition, 13% of patients selected “referral

to a dietitian" as a service needed to assist them with changes to their nutrition-related health.

Patients were able to list and prioritize a treatment goal which could be selected from the five PARP domains (i.e., biomedical, mindbody, connection, physical activity, and nutrition). Of the 153 patients who completed the PARP, 141 set one or more goal(s). In a descending order of frequency, patients chose the following: physical activity (e.g., increase walking and strengthening exercise), nutrition (e.g., improve diet and lose weight), connection (e.g., to family, work and community), mindbody (e.g., seek psychological help), and biomedical (e.g., reduce opioid use) (Figure 3.3). Ten percent of goals could not be categorized into a domain (e.g., "improve what I am already doing" or "become pain free"). From those who listed nutrition, 27% stated that they wanted to improve their overall diet/nutrition, 47% chose a specific nutrition-related goal (e.g., reduce soft drink or sugar consumption, reduce portion size, and increase vegetable or water intake), and 27% stated that they wanted to reduce their weight or waist circumference.

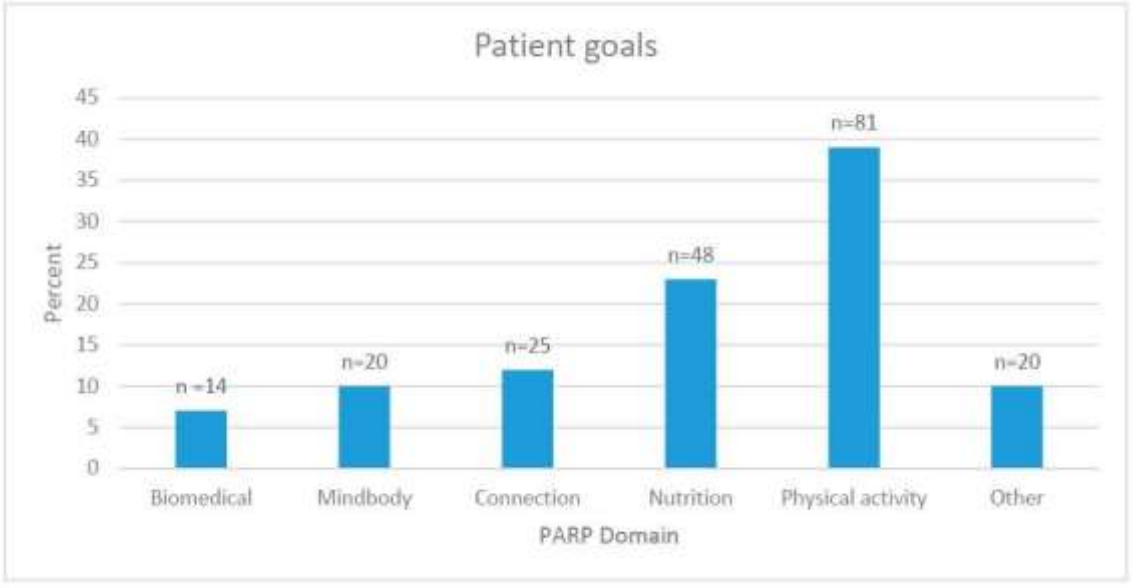

Figure 3.3. Patient goals, as defined by the five domains of treatment, Hunter Integrated Pain Service.

Patients who had a normal weight BMI (18.5–24.99 kg/m^2), overweight BMI (25–29.99 kg/m^2), and obese (>30 kg/m^2) were compared in terms of their pain-related scores (BPI severity, BPI interference, PSEQ, and PCS) and nutrition-related goals (Table 3.3).

There were no statistically significant differences in BPI severity ($p = 0.79$), PCS ($p = 0.93$), or number of nutrition-related goals ($p = 0.84$) selected by patients by weight category. Statistically significant differences were found for BPI interference ($p = 0.02$) and PSEQ ($p = 0.04$) by weight status group. However, a post-hoc analysis indicated that the only significant difference in BPI interference was between those in the overweight versus obese groups ($p < 0.001$).

Table 3.3. Patients' pain-related scores and nutrition-related goals, based on the BMI category.

	Normal BMI (n=23)	**Overweight BMI (n=39)**	**Obese BMI (n=51)**
BPI (severity) (mean ± SD)	6.2 ± 2.0	6.0 ±1.7	6.3 ±1.7
BPI (interference) (mean ± SD)	7.3 ±1.8	6.3 ±2.3	7.6 ±1.8
PSEQ (mean ± SD)	23.3 ±10.9	22.5 ±12.2	17.2 ±12.0
PCS (mean ± SD)	28.0 ±14.6	29.3 ±12.8	28.8 ±13.8
Nutrition-related goals (%)	30.4	25.6	31.4

3.5 Discussion

This study has summarized the demographic data, pain characteristics, and nutritional status of patients attending HIPS. It was identified that almost 60% patients were female and the most common age group was middle aged adults aged 41–60 years. Almost 40% of patients stated that they were unemployed due to the impact of their pain experiences. This data reflects the same patient characteristics from a national database collected using the ePPOC tool in 21 pain services across Australia and presented in a 2014 report, where 57% of patients were female, with an average age of 53 years, and 36% reported that they were unemployed due to pain (244). In a population of healthy young adults, unemployment was associated with a poor quality of life and inequality in terms of health status (245). Considering the high level of unemployment in the current population, as well as complex health issues, it is highly likely that this cohort also have a poorer quality of life.

Just under a quarter (22%) of patients in this study reported depression and anxiety as a comorbid condition. When compared to data provided by the DASS-21, there is a large difference, with 81% and 57% of patients experiencing a degree of depression and anxiety, respectively. The discrepancy between these two results may be explained by the way in which the data was collected. Patient comorbidity is a self-reported measure which relies on the patient's awareness and honesty, whereas the DASS-21 is a validated objective tool which is more accurate in identifying levels of depression and anxiety. In addition, those who were categorized with depression or anxiety via the DASS-21 may not have been formally diagnosed and therefore did not list these conditions as a comorbidity. When compared to national data, a similar trend exists, where over one third (34%) reported depression and anxiety as a comorbid condition (244) while 76% recorded a degree of depression and 67% anxiety on DASS-21 findings (244). A literature review exploring the coexistence of chronic pain and depression found 15 studies where data was analysed from pain clinics and inpatient pain programs (number of patients ranged from 37–900) (246). The percentage of patients with depression ranged from 1.5% to 100%, with six out of 15 studies having >40% of their patients reporting depression (246). The high numbers of people who experience both chronic pain and depression contributes to poorer treatment responses and higher health care costs (247).

The most common pain site listed by patients attending HIPS reflects national data, with 43% in both populations selecting back pain (75). Nationally, the second most common site was the shoulder region, whereas at HIPS, it was reported by patients as being leg pain. There was a greater proportion of HIPS patients who had experienced pain for more than five years (58%) compared to 48% of national patients (75). Slightly more HIPS patients (55%) found that pain interfered with their self-efficacy compared to national data (52%). BPI scores were similar across both groups, with most patients describing pain intensity and interference as moderate or severe, respectively (244).

A large percentage (71%) of patients at HIPS reported taking ≥1 opioid medication, compared to the national cohort in 2014, where 61% patients were taking opioids on ≥2 days/week. The frequency of opioid consumption in the HIPS population is unable to be determined in this study, which is a limitation. There was also no difference between the BMI in those taking opioids and those not taking opioids, which suggests that there is

no linear relationship between weight status and opioid consumption. It also suggests that there may not be a difference in the dietary status based on opioid consumption. The results found in Meleger et al. may apply to patients who experience chronic pain and do not take opioids (108). Interestingly, after pain-related medication, nutrition supplements were the next highest group of medications to be consumed by patients. This highlights that further investigation is required to identify the potential benefits that nutrition and nutritional supplements can play for people who experience pain.

The average BMI and percentage of patients who fell into the overweight or obese category was higher at HIPS compared to the national pain service data (244) and the general population in Hunter New England Health Local Health District (HNELHD) (248). However the data is based on self-report measures, so bias may exist. The average BMI of patients in this study was 31 ± 7 kg/m^2 (obese category) compared to 28.9 ± 7.4 kg/m^2 (overweight category) for the national pain services cohort in Australia. The study showed that 78% of the patients were overweight or obese, which is 115% higher than the national pain service data and 124% higher than HNELHD data. A wider gap exists between these populations when looking at obesity alone. Forty five percent of patients were obese, which is 122% higher than the national pain service data and 167% higher than HNELHD data. This study found that 21% of patients were in the normal (18.5–24.99 kg/m^2), 33% in the overweight (25–29.99 kg/m^2), and 45% in the obese (30 kg/m^2) BMI category. In comparison, the national ePPOC report states that 3% patients fell into the underweight BMI category (<18.5 kg/m^2), 29% in the normal, 31% in the overweight, and 37% in the obese category (244). In 2014, in the Hunter New England Health Local Health District, 36% of the general population was overweight and 27% was obese (248). When comparing these three populations, the difference in the percentage of people who are overweight is narrow, whereas the difference when focusing on those who are obese is significant. When comparing pain-related outcomes by BMI category, those in the obese category reported higher pain interference compared to those who were overweight ($p < 0.001$). All other results were not significant, suggesting that in this cohort, body weight is not significantly associated with the severity of most pain-related outcomes. The results from the current audit of a clinical population are not consistent with the current literature, where studies have shown a direct relationship between an increasing weight status and poorer pain

experience (102, 105, 249). A limitation of the current study is that it was not powered to detect statistically significant differences in outcomes by weight status, and hence, further research to explore the relationship between weight status and the characteristics of pain experiences in greater depth is warranted. Interestingly, there was no difference by the weight status group in the percentage of patients who chose a nutrition-related goal based on weight status. This suggests that patients consider nutrition an important part of their pain experience and treatment, irrespective of weight. Further research is needed to explore this outcome.

There is a substantial difference in the waist circumference between patients at HIPS and the general population of HNELHD. The average waist circumference for females attending HIPS compared to HNELHD was 101.2 cm and 87.5 cm, respectively. For males, the mean waist circumference was 108.6 cm at HIPS and 97.5 cm at HNELHD. The percentage of females considered "at risk" of developing chronic disease based on their waist circumference from the HIPS cohort and the HNELHD is 87% and 65.4% respectively. For males, 77% of the HIPS cohort and 59% of the HNELHD cohort had a waist circumference over the guidelines. In both females and males, the HIPS cohort had a higher percentage "at risk", compared to the HNELHD.

The relationship between obesity and chronic pain is complex, with a higher weight status being a risk factor for developing chronic pain (101). Conversely, overweight and obesity can be a result of pain, in association with limited mobility and poor eating habits (101). This relationship needs to be investigated further in order to develop effective strategies to address the concurrence of these conditions. Patients at HIPS reported multiple and complex comorbidities, with almost two-thirds of patients reporting two or more comorbidities. There are many inter-relationships between comorbidities and chronic pain, which increases the complexity of the experience and the challenges faced when treating it. Most commonly, chronic pain is linked to mental health disorders and sleep disorders (250, 251). Mood and poor sleep play a huge role in a person's experience of chronic pain (250, 251), and in this study, both depression and sleep disorders have been reported by patients. There is also a high prevalence of the co-occurrence of chronic pain, depression, and cardiovascular disease (40). Approximately one-fifth of the patients in this study reported having high blood pressure, diabetes, and heart disease, all of which contribute to cardiovascular disease and all of which are

mediated by diet. Chronic pain can be considered a disease in its own right, with changes in the nervous system often becoming more important contributors than the original pain-related condition or injury (6). As such, the initial pain-related condition or injury could be considered a comorbid condition. While some patients may be unaware of this differentiation, a proportion (14%) reported a specific pain-related condition when asked about their other medical conditions. This further emphasizes the complexity of chronic pain and the need for tailored education. HIPS patients report poorer health and are more likely to be socially disadvantaged compared to national data, which may explain why they have higher rates of overweight and obesity.

The study results indicate that dietary strategies that address personal nutrition-related problems were commonly chosen by patients, along with other lifestyle-related goals. Lifestyle-related goals comprised 62% of the goals chosen by patients, with nutrition selected as a target for one quarter of these patients. In contrast, only one patient had ever been referred to a dietitian. This highlights that there is a major disparity between the expressed needs of the patients and resources currently available within the health system to support those needs. This could be due to lengthy waiting lists for public dietetic services, a lack of awareness of alternative dietetic services in the community, and/or perceived expense for private health services. This disparity is also present in current literature as there is limited, yet growing support to include nutrition in chronic pain management services, particularly to support and complement physical activity in weight management (237, 252). However, this has yet to be followed up with feasibility and efficacy studies. Regardless of the reason, these disparities support prioritizing the integration of nutrition-related intervention into multidisciplinary pain services.

There are several limitations of the current study. Firstly, this was a one-off measure which limits the validity of drawing causal relationships. Secondly, the use of self-reported measures may be a source of bias. Height and weight data are self-reported by the patients as they fill in the questionnaire. However, self-report has been previously shown to be valid in other studies, including in a population of young adults (253). Patients also measured their own waist circumference and therefore the results should be interpreted accordingly. In addition, this study was conducted at a single site with a relatively small number of patients. Hence the results may not be representative of other pain services in Australia. The strengths of this study include the use of clinical data

routinely collected within a multidisciplinary pain service, which includes a questionnaire with validated tools for pain and mental health.

Behaviour change can be challenging to achieve, especially in a population with chronic pain whom have complex health issues and diverse social backgrounds. In practice, multi-modal behavioural strategies (e.g., using a biopsychosocial approach) are used to maximize the likelihood of achieving treatment benefit. It is also important to consider that personalized interventions are important for populations such as those with chronic pain. The current study highlights the need for testing a comprehensive nutrition-based intervention as part of the overall treatment package for chronic pain and its comorbidities. Future research should evaluate the feasibility and effectiveness of such an approach.

3.6 Conclusions

The current study has identified that patients attending a chronic pain management service report nutrition as an area of need that is currently not met within the treatment of chronic non-cancer pain. Patients referred to HIPS were more likely to be overweight or obese compared to community norms or patients referred to other pain services across Australia. In addition many patients expressed a desire to make nutrition-related lifestyle changes. Within a self-management approach, patients are able to initiate such changes themselves. However, the dietetic staff required to address this in a comprehensive way and support the nutritional change process are currently lacking. The addition of dietetic expertise to the routine workforce of a multidisciplinary pain team could support patient self-management in the area of nutrition and enable the development of pain specific, appropriate resources and outcome measures.

Chapter 4: Perceptions of tertiary pain service staff on including nutrition support within current treatment: A qualitative study

4.1 Abstract

Evidence-based clinical practice for chronic pain uses a whole-person approach which includes nutrition. Currently, pain services have limited resources for nutrition education, and when provided it is rarely delivered by an Accredited Practising Dietitian. The aim was to summarise opinions of staff from two Australian chronic pain services regarding integration of nutrition support. Three semi-qualitative focus groups were conducted and data analysis was conducted using Leximancer. Themes identified from including nutrition in pain management were benefits for and barriers to patients and the service. Interventions suggestions included simple practical strategies and the preferred mode of delivery was a group setting but considering technology to ensure flexibility. Staff use and confidence in using technology in service delivery for nutrition was also discussed. Findings suggest there is interest in including a dietetic-led nutrition intervention into current service. Key barriers must be addressed to ensure the intervention is successful and accessible utilising technology.

4.2 Introduction

People experiencing chronic pain have poor nutrition-related health (102, 108, 154). Given that dietary intake is the leading modifiable risk factor for all-cause morbidity in developed countries, this is of concern (156). Sub-optimal dietary patterns, characterised by high intakes of energy-dense, nutrient poor foods is common in population groups but often more apparent in those with chronic pain (108), with saturated fat intakes exceeding recommendations (108), and lower fruit and vegetable intakes compared to those without chronic pain (106).

In addition to poor dietary intakes, nutrition-related health comorbidities are prevalent in people with chronic pain, including obesity, hypertension, type 2 diabetes and heart disease (23, 154). Eighty-percent of patients attending a tertiary pain service in New South Wales (NSW), Australia were overweight or obese compared to 63% of the general Australian population (154). High body-mass index (BMI), which is also a

modifiable risk factor (156), has a strong relationship with the prevalence of chronic pain. Those who are classified as obese using the World Health Organisation's BMI categories (98), are over two times more likely to experience pain compared with those of normal weight (100, 102). High blood pressure, high fasting plasma glucose and high plasma total cholesterol are also prevalent nutrition-related modifiable risk factors in people experiencing chronic pain (41, 156).

In addition to the relationship between dietary intake, BMI, nutrition-related modifiable risk factors and chronic pain, a recent clinical audit of 166 patient records at a tertiary pain service in NSW, Australia identified that patients frequently set personal nutrition-related goals as part of their treatment plan (154). Despite this, pain services often have limited and generalised nutrition education available and largely do not employ dietitians.

The role of nutrition within an individual's experience of a pain service is a topic of increasing interest among pain clinicians (254). Evidence shows that chronic pain is best managed using a multidisciplinary approach (255). This recognises the complexities of chronic pain and incorporates biopsychosocial aspects associated with the condition (1). These aspects include: physiological changes to the nervous system; increased prevalence of depression, anxiety and unhelpful beliefs; limited social interactions (e.g. isolation); and lifestyle factors such as impaired physical activity, sleep patterns and poor nutrition (20). In Australia 2010, the National Pain Summit Initiative published The National Pain Strategy which outlines ways to improve the assessment and treatment of all forms of pain. (53). The National Pain Strategy recognises the importance of a healthy lifestyle and states: "*a healthy lifestyle is still possible despite chronic pain"* (53, p. 27). Despite acknowledging the importance of a healthy lifestyle and the established efficacy of using a multidisciplinary approach for pain management, dietetic services are not routinely provided at pain services.

The practical implications of introducing a comprehensive nutrition intervention into tertiary pain services have not been explored. Therefore, the aim of this study was to canvass the opinions of staff employed in two tertiary pain services, one metropolitan and one rural, in NSW, Australia about incorporating a nutrition intervention within current multidisciplinary services.

4.3 Methods

Semi-structured focus groups were conducted by researchers with staff working at both urban (Hunter Integrated Pain Service; HIPS), and rural (Tamworth Integrated Pain Service; TIPS) sites during August and September 2016. The assessment and treatment programs provided by HIPS (receive ≥1000 referrals per year) and TIPS (receive ≥300 referrals per year) follow a whole-person approach which address five categories of pain management. These are represented as five fingers on a hand (Figure 4.1) with the thumb being the biomedical aspect, the first finger the mindbody, the next connection, followed by physical activity and nutrition.

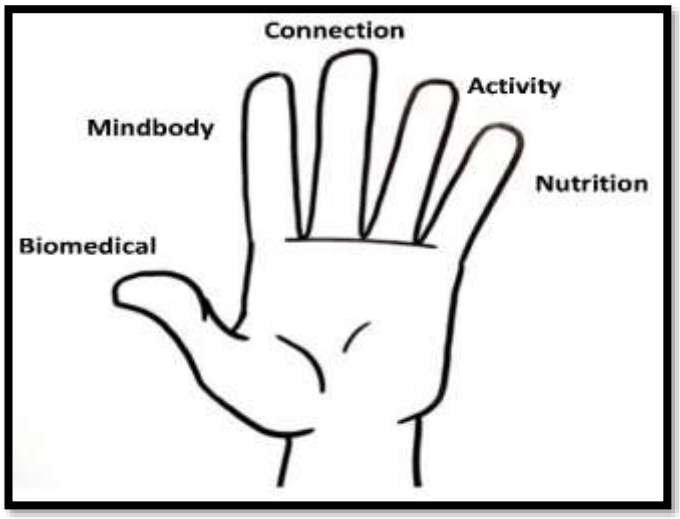

Figure 4.1. Whole-person approach to pain management, Hunter and Tamworth Integrated Pain Services

The focus group protocol (Appendix 24) was developed in consultation with an expert in qualitative research (DIT) and informed by the Theoretical Domains Framework (149, 256) and the Behaviour Change Wheel (150). The Theoretical Domains Framework is comprised of 14 framework domains (256). The key domains included in the protocol included: knowledge, skills, professional role identity, beliefs about capability, goals and environmental context and resources. The Behaviour Change Wheel identifies key behavioural components which include capability (individual's psychological and physical capacity to engage), opportunity (external factors that make the behaviour possible) and motivation (brain processes that excite and direct behaviour) (150). The questions were based on the following categories: the influence

of chronic pain on nutrition, nutrition behaviours and weight; benefits of and barriers to implementing a nutrition intervention for both patients and the service; preferred intervention inclusions/exclusions, delivery methods and the ability/confidence to use technology for both patients and staff.

Recruitment was initiated by sending an email invitation to staff employed at HIPS (n=16) and TIPS (n=6). The email was disseminated on behalf of the research team by the administrative coordinator with HIPS (Appendix 25) and the clinical nurse consultant at TIPS (Appendix 26). Staff were asked to respond to the focus group moderator (KB) via email to indicate if they were interested in participating. Two focus groups were scheduled at HIPS and one with TIPS. No further focus groups were scheduled as the two focus group moderators (KB & LKC) determined that data saturation had been met after these groups had been conducted.

Each focus group contained 4 to 5 participants comprised of clinicians and administrative staff from HIPS and TIPS. All groups were conducted by the first author (KB) with the help of an assistant moderator (LKC) who organised paper work, took notes and managed time. Both moderators received training in focus group methodology from a qualitative research expert (DIT). All focus groups were audio-recorded. Participants were asked to fill out a short questionnaire prior to the discussion which consisted of two questions related to relevant work history and one question asking participants to rate perceived usefulness of having a nutrition intervention within their respective clinical service teams, on a scale of 1 (not very useful) to 10 (extremely useful) (Appendix 27). All participants provided written consent (Appendix 28) and used pseudonyms during the focus group discussion to ensure confidentiality was maintained.

Ethics approval for this study was obtained from Hunter New England Human Research Ethics Committee (16/07/20/5.04) and the University of Newcastle Human Research Ethics Committee (H-2016-0248).

The short questionnaire was analysed using descriptive statistics with Stata/IC 13.1 for Windows (Stata Corp LP, College Station, TX, USA). Digital recordings from focus groups were transcribed verbatim by an independent transcriber, which were merged and analysed using the software tool, Leximancer v4.5 (Leximancer Pty Ltd).

Leximancer uses automated content analysis to scrutinize qualitative data (257-259). Compared to manual text analysis, automated content analysis uses statistical algorithms to identify patterns which may have otherwise been overlooked in manual text analysis (259, 260). Automated content analysis also reduces human error and pre conception bias (259, 260). The protocol was used as a guide to form themes from the data which arose from the focus groups. The transcripts were then divided up so that all relevant data for each theme was in a separate document. From there, Leximancer uses unsupervised concept seeding to identify key concepts for each theme by analysing word-association information using algorithms to elicit word-like and name-like concepts from the text (259, 260). The frequency and relationship of these concepts was also identified (259). Researchers were able to modify the software's parameters to suit the data and manually identify any additional concepts relevant to the data (260). The next step involved defining the concepts through building a thesaurus using concept mapping algorithms (259, 260). After these steps were completed, the results were presented in the form of an interactive concept map, with each map representing a theme (260). The concepts were clustered, and heat-mapped to indicate importance (261). The most important concept appeared in red, followed by orange and continues to follow the colour wheel with blue and purple being least important (261). The location of concepts on the map indicates how strongly they relate with one another, the closer they are the stronger the relationship (261). The researchers were able to manipulate the size and number of concepts which appear on the map (261).

4.4 Results

A total of 13 staff volunteered to participate (60% of all staff employed at both sites) in three focus groups (HIPS, n=2 groups; TIPS, n=1 group), comprised of 5 nurses, 3 administrative staff, 2 psychologists, 2 physiotherapists and 1 medical specialist. Staff had worked in their respective fields for 18.4±12.8 years (range 2-36 years), with 6.5±6.6 years (range 1-20 years) working in the area of chronic pain. Participants perceived providing a nutrition intervention to patients with chronic pain would be very useful with a mean score of 9.2±1.6 (on a scale from 1 (not very useful) to 10 (extremely useful)). Six themes were identified from the qualitative data, including: expected patient benefits from a nutrition intervention; expected barriers faced by patients in participating in a nutrition intervention; expected service benefits; expected

service barriers; intervention inclusions and use and confidence with technology. Themes were comprised of related concepts with each theme and the related concepts described below.

4.4.1 Expected patient benefits from a nutrition intervention

The content analysis and concept map (Figure 4.2) identified that the expected benefits for patients with chronic pain of providing nutrition support in tertiary healthcare settings included: whole person wellness, the perceived ease of implementing dietary changes, improved knowledge, increased skill development and self-confidence.

Whole person wellness

Many participants expressed the importance of whole person wellness, and that nutrition goes beyond pain management. One participant said: "*you feel vital when you eat well, you feel happy"* and another participant stated: "*The benefits extend beyond any potential winding down of pain"*. Specifically related to other chronic diseases *"its prevention of further disease and its making people feel better"*.

Perceived ease of implementing dietary change

Participants also perceived that changing one's diet appeared to be easier for patients, than other aspects of pain management as exampled by: "*I think it's a benefit for the clients because nutrition is often less obtrusive I suppose, in terms of pain management … , for a lot of people it's something that they can change right now to improve their health"* and "*one of the things that probably more people change … it's one of the things people will often identify …whether they maintain it I don't know".*

Improves knowledge

Participants provided examples of patients' inaccurate and mistaken nutrition-related beliefs such as: *"a lot of people still come to the groups believing that potato chips are a vegetable"* and *"I had someone tell me they do really well because they have corn flakes in the morning because it's not covered in chocolate"*.

Participants also gave examples of patients habits such as *"I can think of one man that only ate white food"* and *"we also had a gentleman who said I don't drink anything but coke, I don't like water"*

These were given as examples of areas where knowledge and education can help to improve the beliefs and habits of participants. One participant stated *"yeah about knowledge and skill, I think often the people that do change their diet are better educated"*.

Skill development and self confidence

The other main perceived benefit for patients participating in a nutrition intervention that arose from the focus group discussions was the improvement they are likely to gain in their skills and self-confidence, both within themselves and their ability to change their diet, and subsequently other aspects of pain management.

One participant described patients as: "*they see themselves as unhealthy and non-capable anyway so they don't expect themselves to change"*.

Following on from this another participant stated "*what they're looking for as much as anything is not so much information about what food to eat, but information about how to build their confidence"*.

A nutrition intervention would be beneficial as it would help patients to *"build up their confidence"* and it *"would be good and give them some skills instead of just giving them some really basic things and hoping they'll go off and run with it".*

One participant stated that she already uses nutrition as a conversation starter and as a way to empower patients *"I often use it [nutrition] as a conversation around medication you know like start off with the food side of things and then once they're feeling a little bit empowered I can go onto the hard conversation".*

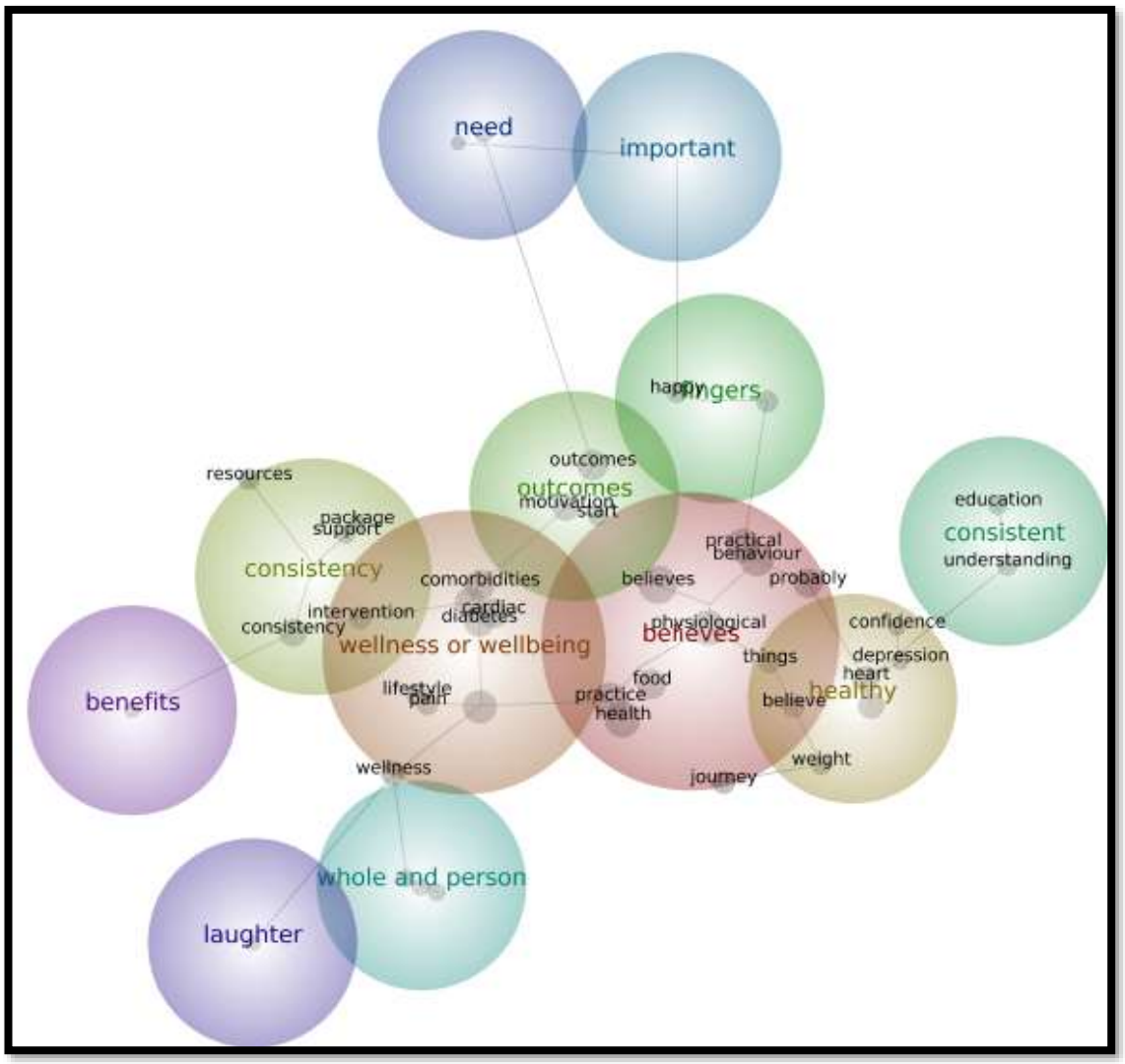

Figure 4.2. Concept Map: Expected patient benefits from a nutrition intervention

Figure legend: Heat map, where red, orange and yellow represent more important concepts and green, blue and purple indicate less important concepts

4.4.2 Expected barriers faced by patients in participating in a nutrition intervention

Four main barriers were identified from the analysis and concept map (Figure 4.3). These were: the food environment, its relationship to health literacy, psychological relationship with food and access to dietetic services.

The food environment and its relationship to health literacy

Many aspects of the food environment were discussed in the focus groups, including the impact of a patients' early home environment and the food habits developed in childhood "*if people have been brought up in generations of processed things, they don't know that it's actually not healthy"*.

Food marketing and media was also discussed "*what's in each food…I think it's become more and more apparent in the media"*.

The link between the food environment and low health literacy was also raised as an issue with one participant following on from the above comments with: "*still comes back to low health literacy across the board"*. This was supported by another participant with: "*I reckon that health literacy in general can be something of a barrier"*.

The psychological relationship with food

Many participants raised the issue of patients' sense of control and pleasure, with food being the only aspect of life that many of them can control or find joy in.

One participant stated: "*I think heaps of it is still about control…food is something that you have to control yourself every day as an adult".* With another expressing: "*people see those sometimes foods as the good things and the treats and that's my only pleasure in life"*.

This idea was explored further with discussion around comfort eating and food as a reward. One participant stated: "*they're comfort eating and I think the addictive reward processes that kick in on a lot of the sweet foods is a huge barrier".*

Access to dietetic services

The availability and funding for Accredited Practicing Dietitians, either through outpatient dietetic services or community dietitians was raised by several participants.

One participant stated: "*it depends whether there's something available that we can refer them to …so there was initially the diet clinic at the Uni that people were going to and then the funding for that was cut"*.

Another participant stated: "*I think there's barriers just in general for people in the community around access and cost to see dietitians and even in our own outpatient department*".

Issues relating to service access were more apparent in the focus group conducted at TIPS, where distance to services was also a barrier to accessing services: *"access to support is probably one, we don't have a lot of appointments with dietitians available in the area, there's not a lot of private dietetic support"* and "*barriers with travel and that sort of thing, the distances to come to a major centre where there is that support in terms of dietetics".*

This issue extends beyond access to professional services and also includes services which are in place to provide nutrition support: *"access to those community services like Meals on Wheels or home delivered groceries and that kind of thing is a barrier"*

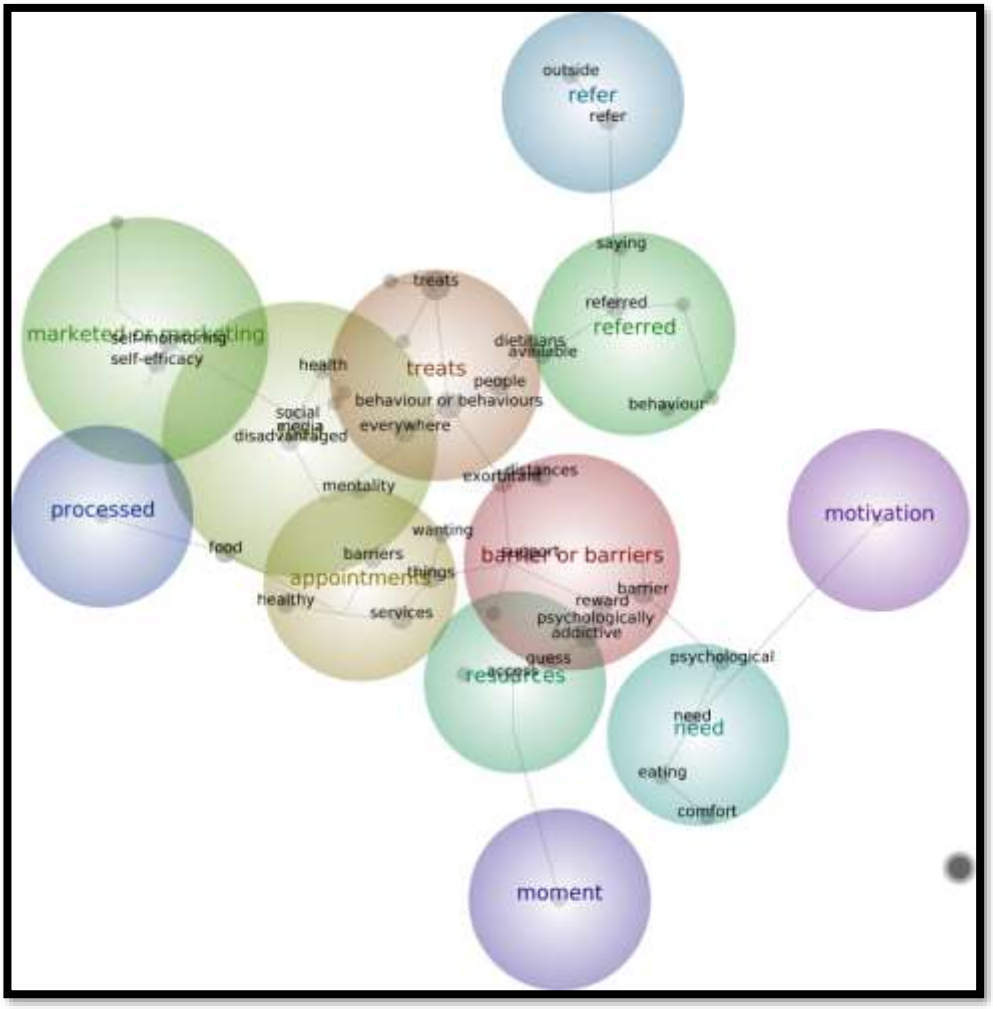

Figure 4.3. Concept Map: Expected barriers faced by patients in participating in a nutrition intervention

Figure legend: Heat map, where red, orange and yellow represent more important concepts and green, blue and purple indicate less important concepts

4.4.3 Expected service benefits from a nutrition intervention

From a service perspective, it was identified that by including nutrition it would complete the whole-person approach to pain management. Figure 4.4 displays the concept map.

Whole person wellness and client satisfaction

Participants discussed that by including a structured nutrition intervention the service would more closely align its staff resources with its professed whole-person approach to pain management. The inclusion of nutrition would also allow the service to be more closely aligned with management strategy for other chronic conditions.

When asked what benefits would you expect the service to get from incorporating a nutrition intervention one participant replied by saying *"be more holistic".*

Another participant's response was *"it's more in line with general health promotion too, chronic disease management or prevention of diseases".*

Other participants stated: *"recognizing its importance as one of the fingers in the holistic approach"* and *"it's [nutrition] a fifth of what we're trying to sell them, you know I think it's equally as important as the others ….. we recognize that we just haven't quite managed to implement it".*

4.4.4 Expected service barriers for a nutrition intervention

Many barriers were discussed (Figure 4.4) including limited time and resources, current beliefs and confidence surrounding nutrition and lack of dietetic expertise.

Time

Many participants expressed concern about adding more time to the existing programs in order to increase the nutrition component. This was both from a resource perspective and concern in terms of increasing the burden on patients *"people really struggle to last the distance"*. Comments such as *"dare I say we'd have to blow out our program times"*, *"comes back to time as well"* and *"we don't have much time in our calendars to be able to do that"* also demonstrate that time is a limiting factor.

However, it was acknowledged that nutrition should be covered equally with the other four components *"we say we rate it as a fifth of the recovery but we don't give it a fifth of the time and we don't do real practical applications".*

Another participant referred to this *"the barrier at the moment is that we haven't actually scheduled it in fully and I think that we're a bit remiss in that….it should get more time, I mean it's a fifth of it".*

There was also discussion surrounding potential solutions to this barrier such as utilizing the lunch break during group sessions to discuss nutrition and encourage participants and staff to share a meal where staff can role model by bringing in a healthy meal.

One participant stated *"you could always think about do you want to stay an extra half hour and have a shared meal where we focus on nutrition"* and another, after asking how much time patients get for lunch, *"we could actually use that as their eating time together".*

There were many pros and cons raised regarding this idea such as food hygiene and patients feeling judged: *"my germ phobia side just bothered me"* and *"people might feel threatened".*

Staff beliefs and confidence

Another barrier raised during these focus groups was staff beliefs relating to nutrition and their confidence in providing nutrition advice to patients with chronic pain.

One participant stated *"maybe it [nutrition] needs more time added to it, more importance"* which was followed by another participant "*I don't know that the evidence base supports that though…we certainly don't have any meta-analysis and we don't have any RCTs [randomized controlled trials] and we don't have a case series written up of people that have done well with a nutritional component to a pain management program, so how can we stand there with hand on heart and say we've got the evidence to support it".* Another participant rebutted with *"well there is [evidence] around inflammation and general health".* There was also acknowledgement that regardless of the evidence, nutrition must be important as it has been longstanding inclusion in the current model with one participant asking the rhetorical question *"so why do we have it?"*

Staff also acknowledged that their own knowledge and confidence in providing nutrition advice was lacking *"I think the staff probably need more education"* and *"It's true the staff are not confident".* Another participant stated *"I just don't think we've got the skills, we don't know how to hold people and guide them through getting sorted out with their food"* and *"I've never done, I don't think, …what do you call it, like a continuing education thing…on learning what to tell patients about food".*

Lack of dietetic expertise

Many participants acknowledged that not having a dietitian employed is another barrier to providing evidence-based nutrition advice.

One participant stated that it would enhance the credibility of the service *"so if I was going to use nutrition as a selling point, to say that we had a clinician, a dietitian, nutritionist involved then when you educate, in that respect they know that they're getting the best advice".*

Others described the difficulty in accessing dietetic services *"we don't have dietitian/nutritionist support …not funded in a lot of pain services", "we don't have a lot of appointments with dietitians available in the area, there's not a lot of dietetic support in our region"* and *"it depends whether there's something available that we can refer them to".*

Access and funding, particularly due to location and travel was particularly prevalent in the focus group held at TIPS and one of the major differences between the responses given at TIPS compared to HIPS.

One participant stated: *"the distances to come to a major center where there is support in terms of dietetics … people find that difficult to get to a major center in this region".*

The other issue for TIPS was the availability of dietitians in the area; *"we don't have a lot of appointments available in the area, there's not a lot of private dietetic support in our region either so there's a big burden on public health for that kind of stuff if they want professional assistance with nutrition. There's no funding in our pain service for that either to be able to provide that level of intervention".*

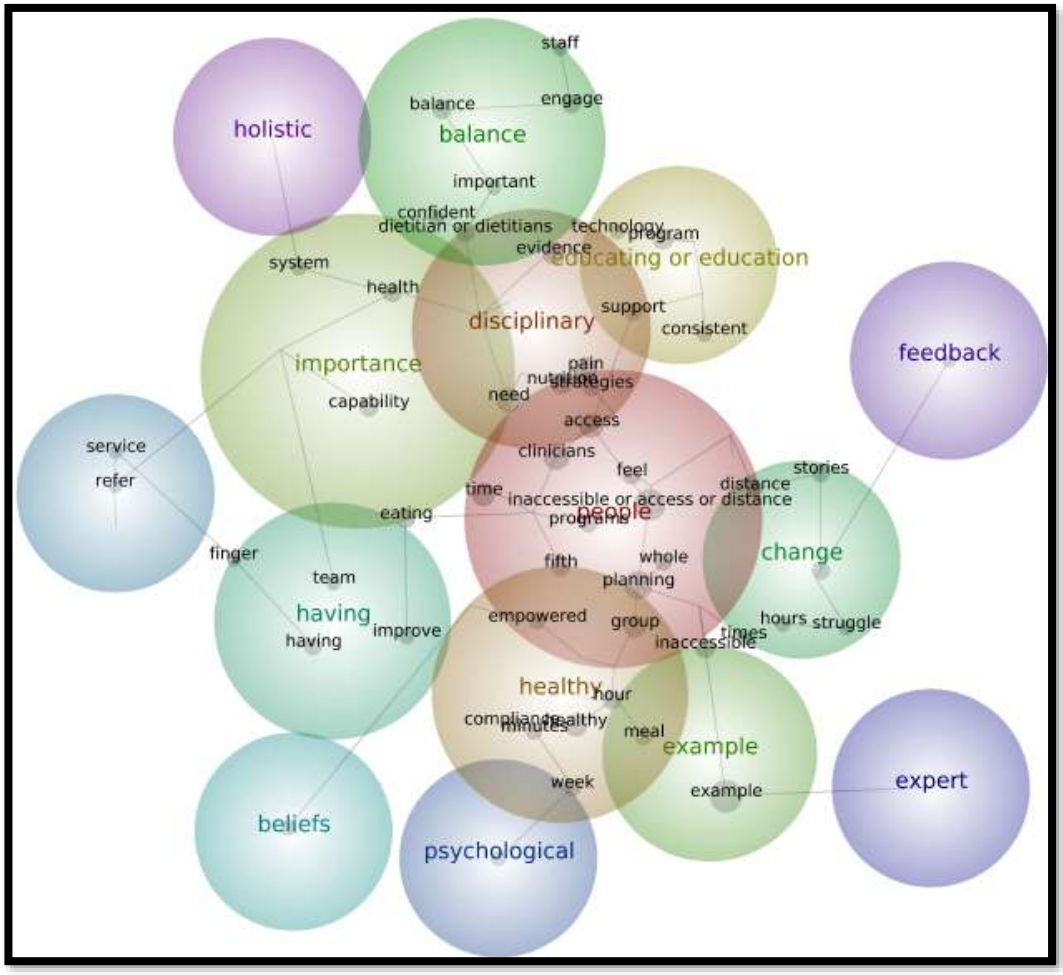

Figure 4.4. Concept Map: Expected service benefits from and barriers for a nutrition intervention

Figure legend: Heat map, where red, orange and yellow represent more important concepts and green, blue and purple indicate less important concepts

4.4.5 Intervention inclusions

The main findings from the concept map (Figure 4.5) and content analysis highlighted: topics for education, intervention inclusions and delivery methods.

Topics for education

Staff opinions were that a nutrition intervention should target eating for pain, not weight management as this would be more of an incentive for patients *"keep the focus back on pain though rather than weight", "include education on what is actually healthy food and the importance on why we would be asking them to follow a healthy diet"* and

"people are going to want to see the benefits are for them for pain, that is an incentive".

Participants in the focus group discussed the negative effect on patients when discussing weight loss, particularly by general practitioners (GPs). *"A lot of people struggle with the focus at the moment of obesity … the only thing they're being talked to about, in their appointments [with their GP], is weight loss and the need to do it but not how to go about it. At the moment people are quite in the resistive phase …, my doctors' talks to me about it all the time but I don't have the resources or the confidence.* Another participant stated *"some patients take offence, they [GPs] are not targeting anything else"*.

Another education topic discussed was inflammatory foods "*inflammatory foods, like the foods which we know now through science cause metaflammation".*

Intervention inclusions

When asked about preferred intervention inclusions the majority of conversation centred on practical skills. The overall and recurring discussion point was to ensure that any intervention, despite its inclusions/exclusions was simple.

Participant comments included: *"it'll have to be simple"* and *"I like that idea of keeping it simple"*.

Specific ideas and suggestions included: *"recipes is probably really important", "links or resources on easy meal prep like how to prep easy and healthy foods"* and *"information on how to navigate the supermarket and food labels".*

Participants also discussed the use of visual examples and patient success stories as incentives for patients.

One participant spoke about a helpful personal learning experience where she learnt that certain foods equal a certain amount of minutes of exercise. This was taken further with another participant stating: *"I liked it actually that one Tim Tam [chocolate coated biscuit] equals this much exercise so that you've got that visualization I think that's*

really good, but even that Tim Tam has got sugars in it and those sugars aren't great for pain despite the fact that you're going to have to walk it off no matter what".

Other examples of visualization focused on how participants felt when they saw 'disgusting' things such as fake fat replicas and how that was an incentive to follow healthy eating patterns. One participant stated: *"those shows on TV that plonk on the table….like the whole kilo or three kilos of fat with blood vessels…you just kind of go that's revolting"* and another participant: *"rethink that sugary drink to me is repulsive".*

Patient success stories and role modelling was also discussed with one participant stating: *"we want to try the success stories of people in groups"* and another: *"role modelling it has been mentioned but it would be a good thing to incorporate".* Specific suggestions were also given: *"role modelling could be as simple as providing nutritious options for morning tea…the people presenting it having a bottle of water with them…it doesn't need to be formalised really, it's that kind of subtle suggestive stuff as well".*

Delivery methods

Participants in all the focus groups expressed that the intervention should be delivered through a combination of mediums and be flexible: *"A range of options is good"* and *"I think a combination of all is what is required"*.

Participants suggested that where possible in-person would be best with either a website or email follow up: *"I mean our programs are face to face so we probably need something that slots into that, but maybe there could be other things that you know people could go on with afterwards that aren't necessarily face to face".*

This was supported by another participant stating that: *"Where it can be done in group I think that's beneficial because they get information from each other and they can share tips…but I know we have a lot of clients who can't attend groups so having something that could be done by telehealth or online or that kind of thing would be a nice option as well".*

Participants stated that online resources and email may be preferred over telehealth: *"I mean an online resource rather than telelink of something where they could check*

in…because video link is good but hard to organise and tend to be limited to fewer participants" and *"maybe this could be done by like an email thing"*

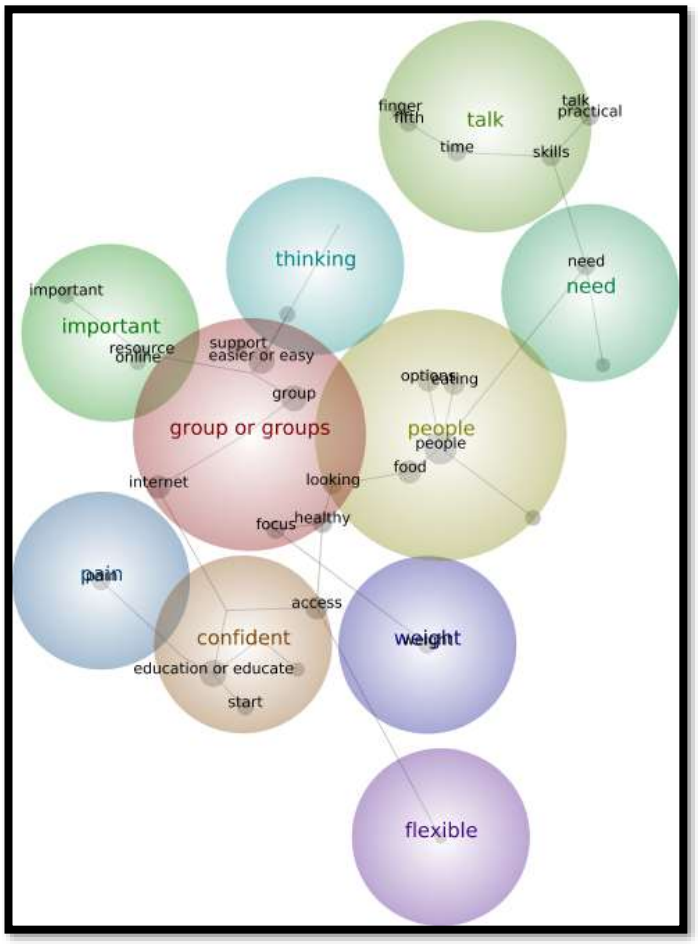

Figure 4.5. Concept Map: Intervention inclusions and delivery

Figure legend: Heat map, where red, orange and yellow represent more important concepts and green, blue and purple indicate less important concepts

4.4.6 Use and confidence with technology

The concept map (Figure 4.6) outlines the various types of technology which were discussed for delivery of a nutrition intervention as well as the benefit of being able to use devices as a way to monitor and reward success.

The general consensus regarding the use of technology for nutrition support was that it needs to be used in combination with in-person strategies and other delivery tools. One

participant stated: *"technology is a great thing but I think at this stage in human life where we are with technology, I think it's secondary to face to face.*

In contrast other participants discussed the benefits of technology: *"technology is becoming more reliable"* and *"I think our access is good"*. There was discussion surrounding different forms of technology such as the internet, smartphones, and wearable devices such as a Fitbit and how technology can be used as a way to monitor and reward success.

Example of comments made include: *"people will say oh no I don't have internet but they've got a smartphone"* and *"some kind of built in reward, I have a Fitbit and it gives me this amazing little thing when I hit my 10,000 steps"*.

Specific comments related to nutrition included: *"You could even use bits of technology … even for those people who aren't completely computer literate you can still use things … I'll take a photo of my meal and that could be my log, I'm going to photograph the three meals and two snacks I have over the day rather than write it out"*.

The majority of the discussion revolved around patient use and examples of how technology could be used. There was only one comment made on the staff's confidence with technology: *"I think the staff are probably reasonably comfortable in using that stuff, but that comes back to time as well, so the staff would need it to be simple and fairly timely to support people"*

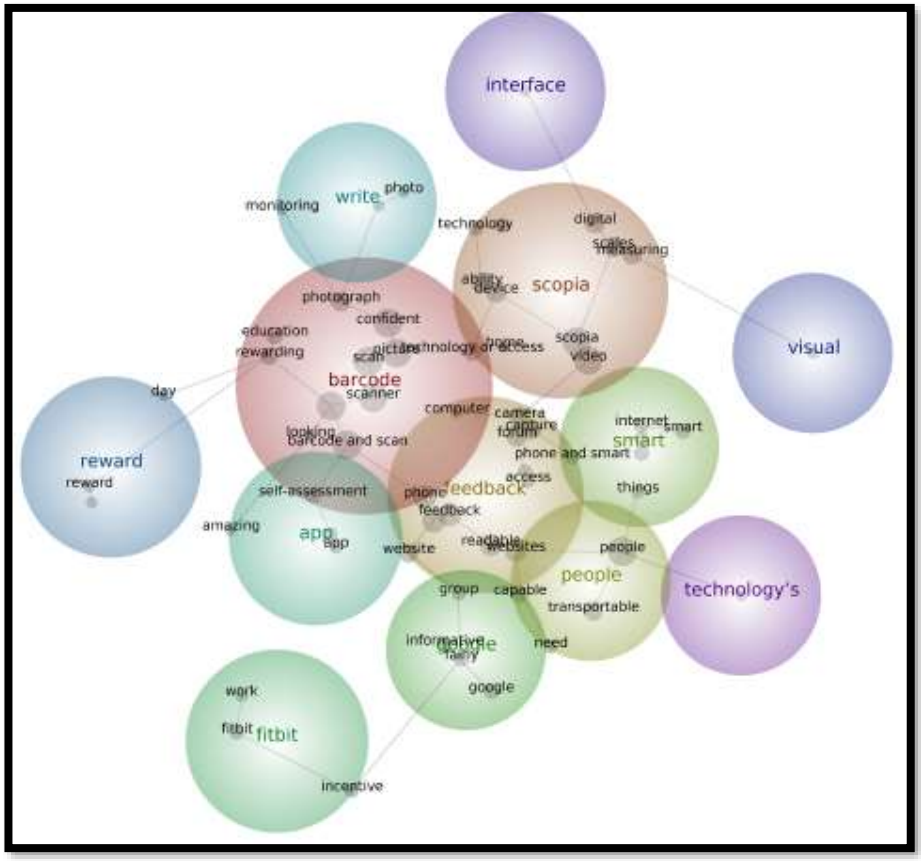

Figure 4.6. Concept Map: Staff and perception of patient use and confidence with technology

Figure legend: Heat map, where red, orange and yellow represent more important concepts and green, blue and purple indicate less important concepts

4.5 Discussion

In chronic pain services, nutrition is not routinely addressed by staff with qualifications in nutrition and dietetics, despite patients having poor nutrition-related health and setting personal nutrition-related goals for treatment (154). The current study aimed to gain comprehensive insights into staff views on incorporating nutrition interventions within tertiary pain services in two locations in NSW. The predominant concepts arising included anticipated improved health and wellness patients may gain and the potential issues surrounding behaviour change, such as food being perceived as a treat or reward. From a service perspective distance, access to dietitians and time were raised as major barriers to implementing nutrition interventions. The main concepts arising when asked about intervention inclusions and delivery were education, support and group-based

sessions. Finally, concepts arising from discussion around use and confidence of technology were feedback and monitoring.

The focus groups acknowledged the need to include dietitians in chronic pain treatment programs, with health professionals acknowledging that a healthy diet benefits an individual's pain perception and overall health. APDs are qualified to undertake nutrition assessments, provide and monitor nutrition interventions within the nutrition care process (131) to optimise patient health and provide evidence-based nutrition education to help patients manage their pain. Staff felt that changing nutrition and dietary patterns may be easier initially than changing other behaviours, hence the importance of ensuring evidence-based advice is accessible. This aligns with findings from a previous clinical audit which demonstrated that patients report being interested in changing their dietary habits, with 25% selecting a nutrition related goal in their treatment plan (154).

These views are supported by interviews with general practitioners and practice nurses on their experiences with giving weight loss advice in primary care to patients with obesity (262). Health professional participants identified that weight loss can be a sensitive topic and negative consequences may arise when discussing the topic with some patients, with limited understanding, time and resources to address this issue appropriately (263). While obesity is a major contributor to the pain experience (102), nutrition education can focus on benefits for pain management and a healthy lifestyle generally. Dietary management for chronic pain overlaps with the dietary management of weight loss, hence implementing strategies for one is likely to benefit both. A recent systematic review found that consuming a diet rich in vegetables, fruit, wholegrains and healthy fats, while avoiding highly processed foods helps to reduce pain (264) which for most people, would lead to a reduction in energy intake and therefore weight loss. APDs can address the gap left by GPs and provide vital information (e.g. how to implement dietary changes to improve health) so that patients can achieve their goals in both pain management, and if appropriate, weight loss.

Another point arising from discussion was use of visual cues to illustrate the impact of excess body weight. Evidence for the use of graphic images using negative health consequences associated with a specific behaviour is most common for tobacco

smoking. In quit smoking campaigns, the use of graphic health warnings leads to changes in smoking behaviour. The Australian Government Department of Health and Ageing commissioned a report in 2008 which states that when current smokers saw a graphic health warning, 28% stated they would stop smoking, without any prompts (265). As the focus groups highlight issues of low self-esteem and self-confidence for patients, use of graphic health images or props would need evaluation before routine use so as not to adversely impact on self-esteem and confidence.

One of the major strengths of the current study is the inclusion of both urban and rural tertiary pain services. A key difference which arose in discussions at Tamworth Integrated Pain Service was nutrition service access and out of pocket expenses, particularly due to location and limited availability of dietitians. Another main component of these focus groups was discussion around the use of technology. Utilising technology, including telehealth and in consultations would help overcome the need to travel long distances to access services in rural communities.

eHealth technologies, including web-based programs, smartphone apps, wearable devices for tracking sleep and activity levels, are becoming more accessible resulting in alternative and complementary delivery modes for the treatment of chronic health conditions (138). In Australia, 86% of households are connected to the internet and 88% of individuals own a smartphone (138, 140). Between 2014-2015 and 2016-2017 the percentage of internet users who accessed health services or health information online more than doubled from 22% to 46% (138). The majority of Australians have access to the internet and are increasingly interested in using this medium to access health services and information, indicating there is potential to extend reach of dietetic services for chronic pain management. Participants in the focus group also suggested a solution for the small percentage of patients without access or who lack confidence in using technology, was utilise telehealth services at their local GP practice. The publically funded universal health care system in Australia, Medicare, currently provides a number of telehealth items under the Medicare Benefits Schedule (MBS). This provides patients with financial assistance towards the cost of these services. In terms of the telehealth items included in the MBS, it is limited to certain health professionals including specialists, medical and nurse practitioners, midwives and Aboriginal Health workers (266). Patients can have a health care professional with them to provide clinical support

if the health care professional has a Medicare provider number (266). While the MBS partially supports the costs associated with telehealth and subsequently makes it more accessible, it is limited to a small number of health care professionals and does not include dietetic services.

Technology can address the issue of access as well as effectiveness, as demonstrated in a systematic review and meta-analysis of effectiveness of eHealth programs in overweight and obesity (267). This review identified that participants who received an eHealth weight loss program compared to a control (-2.7 [-3.33, -2.08], $p<0.001$) or minimal intervention (-1.4 [-1.98, -0.82], $p <0.001$) had greater weight loss (267). Not only are eHealth interventions effective, they are also cost effective. Establishing eHealth can be more costly when compared to in-person ($1394 vs $90), however the recurring costs ($561 vs $390) are lower, leading to lower costs long-term (268). Using technology can be an effective way to overcome some of the barriers raised in the focus groups.

4.5.1 Implications for research and practice

Public health services commonly lack resources and time. The focus groups have provided important insights which can be used to ensure appropriate translation of a nutrition intervention into current models of care. Issues raised by participants should be considered when incorporating a nutrition intervention. Barriers, such as distance and limited resources can be overcome by utilising technology. This has been demonstrated in America and Australia, where the use of video consultations has improved the reach and outcomes for those living in rural communities (269, 270). In the context of weight management, practical considerations and implications for using telehealth in nutrition care have been published (148), with a summary and checklist developed for dietitians, incorporating frameworks such as the American Telemedicine Association standards, Nutrition Care Process and guidelines for adult obesity management (148). This could be adapted to chronic pain management. APDs are qualified to provide medical nutrition therapy (271) and hence can provide accurate and evidence-based education and practical strategies to patients. Participants perceived that patients' psychological relationship with food and the food environment are barriers to change. APDs utilise many strategies such as motivational interviewing (272) to address these issues.

4.5.2 Strengths and limitations

A strength of the current study is the variety of clinical and administrative backgrounds of participants, which captures the views of a multidisciplinary team. Collectively, the participants were highly experienced in the area of chronic pain management. To the authors knowledge this is the first study gathering in-depth qualitative information to inform development and implementation of a unique nutrition component into existing chronic pain management services. Inclusion of a rural tertiary pain service allows additional insight into the challenges of distance and location.

Despite theme saturation being reached in the few focus groups conducted, the insights gained may not be generalizable to all types of pain services across the spectrums from public to private and primary to intermediate to tertiary care. Another limitation is the exclusion of patients from the focus groups. The perceptions of patients may be different to those of staff and need to be explored to capture a comprehensive insight.

4.6 Conclusion

The current study provides unique insights into staff opinions on provision of nutrition education and support for the treatment of chronic pain, from two tertiary pain clinics. Findings recognize the importance of nutrition and the need for dietetic services to be included in chronic pain management services, recommending that interventions include realistic and practical strategies to improve dietary behaviours. Key barriers, including patients' emotional connection with food, time and health literacy need to be addressed to optimise intervention outcomes. Future research to test feasibility and acceptability for both patients and staff of pilot interventions is warranted.

Chapter 5: Exploring the attitudes and beliefs of nutrition's role in pain management through semi-structured focus groups with patients experiencing chronic pain

5.1 Abstract

Perceptions of individuals experiencing chronic pain towards nutrition have rarely been reported. The aim was to investigate the thoughts and experiences of patients attending a tertiary pain service in regard to the role of nutrition within chronic pain management. Five semi-quantitative focus groups were conducted with patients attending Hunter Integrated Pain Service, New South Wales, Australia. The focus groups were audio recorded and transcribed. The focus group protocol acted as a guide for themes which were analysed using the program, Leximancer. Twenty-one patients participated (62% female and mean age 53.0±9.9 years). Seven themes were supported by the analysis. The first was the perceived meaning of 'healthy eating'. The second theme was the influence of pain on dietary intake and dietary behaviours and the third theme was the influence of pain on weight management. The fourth theme related to the main benefits regarding possibly participating in a nutrition intervention. The fifth theme were the key barriers to possibly participating in the intervention. The sixth theme related to the preferred intervention inclusions and delivery method. The final theme was participant's use and confidence in using technology. These findings should be considered when developing a nutrition intervention for patients with chronic pain.

5.2 Introduction

Chronic pain is defined as pain that persists beyond three months or beyond the usual time it takes for tissues to heal(15). Regardless of the trigger, whether it be an injury or a disease process such as arthritis, the primary pathophysiological characteristic of chronic pain is abnormal changes to the central nervous system leading to central sensitisation (16). On average, one in five adult Australians experience chronic pain and this increases to one in three with age (≥65 years old) (22). The consequences of chronic pain are major and include an increased risk of comorbidities such as depression, anxiety, obesity, cardiovascular disease and type-2 diabetes (154). Activities of daily

living are also affected with increased social isolation, reduced physical activity and sub-optimal dietary patterns (20). In addition to the personal burden of chronic pain, the 2007 total economic impact of chronic pain in Australia was estimated to be more than $34 billion (22). Current best-practice treatment for chronic pain includes a multidisciplinary team with a holistic and patient centred approach to pain management (53). This means moving away from a pure medical model and instead focusing on a biopsychosocial and healthy lifestyle approach to treatment which addresses patients' mental health, isolation, physical activity levels and dietary intake (273).

The relationship between pain and nutrition is bidirectional with pain leading to poor appetite and sub-optimal dietary intake and poor dietary intake leading to exacerbated pain experiences (20, 106, 108). Meta-analysis has shown that modifying dietary intake can lead to a reduction in pain, as expressed on a visual analogue scale in a number of pain related conditions (264). Pain also coexists with a number of nutrition-related comorbidities such as obesity, cardiovascular disease and metabolic syndrome (44, 154). Independent of pain, dietary intake is the top modifiable risk factor for morbidity in the developed world and has a direct role in managing chronic pain and these comorbidities (45, 133-135). Rates of obesity are higher in those with chronic pain compared to those without (102) and those classified as obese are more than two times more likely to experience pain, compared to those of normal weight (100, 102). The relationship between dietary intake and chronic pain is complex but there is potential to improve pain and overall health by intervening with an appropriate dietary intervention. Despite this, the inclusion of nutrition as part of the treatment for chronic pain has been limited and Accredited Practicing Dietitians (APDs) are not routinely employed within pain services in Australia.

Studies have utilised qualitative methods to include patient perspectives in developing appropriate and acceptable multidisciplinary treatments for chronic pain (274, 275). However, few have used a social or behavioural theory framework such as the Behaviour Change Wheel (150) to formulate their protocols. Despite the benefits of using qualitative studies to collect in-depth data from users of the healthcare system (276), qualitative studies aimed at eliciting discussion around nutrition and pain have not been conducted.

Chronic Pain Australia has utilised focus groups to inform the development of pain management resources for the Agency for Clinical Innovation. In 2013 focus groups were used to ask participants experiencing chronic pain what they wanted in pain treatment and management strategies (89). Within these focus groups, participants specifically listed diet as an area they had found helpful and one which they would like more information about (89). Despite this, nutrition and dietary intake and patient perceptions of its relationship with the pain experience has not been explored further. This expressed need for more nutrition assistance is supported by a recent clinical audit at a tertiary pain service in New South Wales (NSW), Australia, where data was compiled for 166 patients (154). Among this data were the treatment goals set by patients where approximately 25% of patients selected a nutrition-related goal e.g. lose weight, consume more vegetables and/or reduce sugar intake (154). This highlights that nutrition is something patients are interested in and want more information about and while qualitative studies are common to develop programs and resources for people experiencing pain, none have specifically explored the perceived implications and opinions of patients on a nutrition intervention and how that might fit in with current practice.

Therefore, the current study aimed to address the gap between the expressed need (89, 154) and current service provision for nutrition advice and the preferences for the provision of nutrition advice amongst individuals experiencing chronic pain. This will be achieved by summarising the attitudes and beliefs of patients at a tertiary pain service in NSW, Australia in relation to the role nutrition plays in pain management.

5.3 Methods

Participants were recruited from Hunter Integrated Pain Service (HIPS), NSW, Australia. HIPS is a tertiary multidisciplinary service providing a whole-person approach to pain management for adults experiencing chronic pain. This service receives > 1000 referrals by general practitioners or medical specialists every year. From these referrals, approximately 600 patients attend the service and of these, the majority, 85% July 2017- June 2018 (43), are triaged to the group pathway, which is preferred, by clinicians, over the individual pathway. The group pathway includes progression through a series seminars and workshops including: Understanding Pain seminar (UP), Assessment and Planning Workshop (A&P) and Active Pain Treatment

Workshop (APT). These seminars and workshops are delivered by the multidisciplinary team of clinicians at HIPS including medical specialists, nurses, psychologists, psychiatrists and physiotherapists. Understanding Pain is an orientation seminar and the first point of contact with the service where patients are introduced to the science behind chronic pain and the whole-person approach to pain management. The whole-person approach to pain management acts as a framework for the subsequent assessment and treatment workshops. It incorporates the biopsychosocial and lifestyle factors which influence pain experiences and includes: biomedical, mindbody, connection, physical activity and nutrition. In the Assessment and Planning workshop, patients self-assess their pain with the assistance of clinical staff using the whole-person approach. Active Pain Treatment is a series of six workshops where patients are taught how to actively manage their pain by going through each of the factors which comprise the whole-person approach.

The recruitment process for the current study occurred using a two-step approach. Firstly, information statements (Appendix 30) and research flyers were included in the appointment letters posted to all patients who were invited to UP and APT during August-December 2016. Secondly, a verbal invitation was presented by the researcher or a HIPS clinician, to patients at UP (n=6 sessions) and APT (n=3 sessions). At this time, expression of interest forms (EOI) were disseminated to those in attendance. Patients had the option to select one of three options listed on the EOI: “yes I would like to participate”, “Please contact me for more information” or “I do not wish to participate”. The name and contact information from each patient was recorded in a database and the student researcher phoned and/or emailed the respondents that selected “yes” or “please provide more information”. Dates and times for the focus groups was then organised based on availability of respondents. Separate focus groups were held with patients recruited from UP and APT.

Upon arrival to the focus group, participants provided written consent (Appendix 31). Participants were asked to complete a brief questionnaire (Appendix 32) which collected data on four items: participant demographics (e.g. age, gender and comorbidities), pain experiences (e.g. cause of pain, length of time experiencing pain), shopping and cooking habits (e.g. who in the household does the shopping and/or cooking), and use of technology (e.g. number of devices participants owned and

confidence in finding and using health information on the internet). Some questions such as those asking participants to select the comorbidities they have, allowed participants to provide more than one answer. All focus groups were conducted by the student researcher (KB), with the help of an assistant moderator (LKC) who took notes and managed time. Both moderators undertook training in qualitative methodology with an expert (DIT). The focus groups were audio recorded and participants used pseudonyms during this time to ensure confidentiality. Participants were reimbursed for their parking or travel costs and refreshments were provided during the focus group.

The protocol used for these focus groups was developed using the Behaviour Change Wheel (150) with input from an expert in qualitative research (DIT). This was chosen because The Behaviour Change Wheel incorporates a model (COM-B model) which allows researchers to better understand behaviour and account for this in intervention studies (150). It incorporates three key aspects which influence behaviour including: capability, motivation and opportunity (150). Capability refers to an individual's psychological and physical ability to engage; opportunity encompasses the external factors that make the behaviour possible and motivation which involves the brain processes that excite and direct behaviour (150). These key aspects were incorporated into focus group protocol as described below.

The questions included in the focus group protocol (Appendix 33) were designed to elicit discussion around the following seven themes: participants' perception of the term "healthy eating"; the influence chronic pain has on dietary intake and dietary behaviours; the influence chronic pain has on weight; perceived benefits from participating in a nutrition intervention; perceived barriers to participating in a nutrition intervention; the usefulness of a nutrition intervention for people experiencing chronic pain; what participants want (or do not want) in a nutrition intervention, preferred modality of delivery, and their own current use of and ability for using technology. Probes and prompts were included in the protocol and used when needed to keep the discussion on topic.

The COM-B model was used to form the questions surrounding two of the main themes in the focus group protocol: the perceived benefits for and barriers to participating in a nutrition intervention. It was anticipated that each aspect of the COM-B model;

capability (e.g. increased dietary knowledge or lack of dietary knowledge), opportunity (e.g. having the time to change dietary behaviours) and motivation (e.g. feeling you want or not want to change dietary behaviour) would be the overarching benefits and/or barriers identified and as such prompts and probes focused on these.

Ethics approval for the current study was obtained from Hunter New England Human Research Ethics Committee (16/07/20/5.04) and the University of Newcastle Human Research Ethics Committee (H-2016-0248).

Quantitative data from the questionnaires was analysed using descriptive statistics using Stata/IC 13.1 for Windows (Stata Corp LP, College Station, TX, USA). The audio recordings were transcribed verbatim by an independent transcriber. The transcripts were divided by the seven themes in the protocol and the transcript from each of the five focus groups pertaining to each theme was merged together for analysis. A structured analytic approach was used where the emerging concepts are presented based on the themes in the protocol. Leximancer v4.5 (Leximancer Pty Ltd) was used for qualitative analysis. This analysis package uses an automated concept analysis and has been shown to be more reliable than manual text analysis as it is able to identify patterns in the text and prevent bias (259, 260). Nunez-Mir et al. has shown that both automated and manual text analysis are effective but automated concept analysis is superior as it has the ability to identify trends which may have otherwise been overlooked (259). Automated concept analysis uses strategies based on ‘grounded theory’ and is inductive by nature (259). Grounded theory is defined as the discovery of emerging patterns in data (277). Leximancer does this this by searching for and collecting data until prominent concepts emerge (259).

Leximancer uses algorithms to identify word-association information to collate relevant word-like and name-like concept as well as their frequency and relationships, from the text (259, 260). Once the concepts have been identified, a thesaurus is generated so that similar terms are grouped together under each concept (259, 260). Some words may appear in more than one concept if they are identified depending on their frequency and relationship to each concept. This is then presented in the form of a concept map with each concept colour coded (260, 261). The colour indicates the importance of the concept, with red being most important and indicates greater concept strength, followed

by orange which indicates a concept of mid-strength and continues through the colour wheel, finishing with blue and purple which are the least important and show the lowest strength (261). The relationship between the words displayed on the concept map are shown by the distance and location of the concepts with closer concepts indicating a stronger relationship (261). There are also lines which are used to link words together between concepts, the closer the lines the stronger the relationship (261). Leximancer has a default setting for the size (33%) of each concept displayed on the map and this was used throughout the analysis (261).

5.4 Results

Of the 71 patients who returned an EOI, 21 patients from HIPS (mean age 53.0±9.9 years; 62% female) participated in 5 focus groups (average 4.2 participants per group). Despite the flexibility of the focus group sessions, many patients could not attend during business hours due to work commitments. The majority of participants described their pain as *always present, at varying intensity*, 52% had experienced their pain for more than 5 years and 22% stated their pain was caused after surgery. Depression and anxiety was the most commonly reported comorbidity (32% of participants). Just over half of participants reported that they completed the household food shopping and cooking themselves. Twenty-four percent and 33% reported their partner did the food shopping and cooking, respectively; while 24% and 14% shared the food shopping and cooking with another family member, respectively.

All participants owned at least one device which could access the internet for the purpose of finding and using health information, with six participants stating they owned two devices, five owned three and four owned four devices. The most commonly owned device was a smartphone (n=16), followed by laptop (n=12), tablet (n=9) and desktop (n=6). The smartphone (n=10) was the device which was most commonly used to access the internet, this was followed by a laptop or tablet computer (n=8), and desktop (n=4). Two participants stated they did not access the internet on their device(s). When asked how often they used technology (including internet, website, email, social media and apps) to access personal and/or health related activities the top answers reported by participants were “once/day” and “2-4 times/day” (n=5). This was followed by “once/week” (n=4), “once/month”, “5-10 times/day” and “never” (n=2). Responses

given in relation to questions assessing confidence in accessing and interpreting health information found on the internet can be found in Table 5.1**.**

Table 5.1: Participants reported confidence from focus groups in accessing and interpreting health information on the internet

Statement	**Strongly disagree (n)**	**Disagree (n)**	**Undecided (n)**	**Agree (n)**	**Strongly agree (n)**
I know **what** health resources are available on the internet	4	5	8	2	0
I know **where** to find helpful resources on the internet	3	3	9	5	0
I know **how** to find helpful resources on the internet	3	2	9	7	0
I know **how to use** the internet to answer my questions about health	2	3	5	11	0
I know how to use the **health information** I find on the internet to help me	1	4	6	9	0
I have the skills I need to **evaluate** the health resources I find on the internet	1	6	5	8	1
I can tell **high quality** health resources from **low quality** health resources on the internet	2	5	9	4	0
I feel **confident** in using health information from the internet to make health decisions	2	6	9	3	1

(n) = number of participants who selected this answer

5.4.1 Qualitative results

5.4.1.1 Theme 1: Perceived meaning of "healthy eating"

The concept map shows that the two major concepts which arose when participants were asked to state what comes to mind when they think of the term "healthy eating" were (1) vegetables and (2) drinking [water] as indicated by the red and orange concepts in Figure 5.1.

Under the concept "vegetables", participants commonly reported *"salad"*, *"fruit and vegetables"* and *"vegetables"* with some participants specifying certain vegetables such as *"beetroot"* and *"capsicum"*. The concept "drinking" related to water. While the question asked participants how they perceived "healthy eating", one participant answered by saying *"water, even though that's not eating, well drinking, but water".* Discussion followed with some participants identifying they do not like water *"I'm a terrible water drinker"* and "*I only drink it with my pills".* Additional concepts were also identified and demonstrated on the concept map such as the idea of healthier options such as: *"low salt/low fat", "low carb/low GI"* and *"low sugar"*. Another common concept that arose was the idea of moderation and portion size with participants making comments such as *"healthy eating is eating smaller meals isn't it, not big meals", "that's a big thing portion control, isn't it?"* and *"yeah moderation is a key word"*. Participants also discussed the perceived expense associated with healthy eating, particularly in relation to organic foods *"all your healthy things are expensive"* and *"my daughter's trying to feed her little one who's just turned 12 months organic food, can't afford it"*. Other barriers to healthy eating included time, busy lifestyles and planning *"but to do healthy preparation, it's time consuming and I don't have the time for it"*. Participants also made suggestions on perceived foods which would improve healthy eating *"use cold pressed oils"* and *"coconut items from oils"*. Two participants interpreted this question in the reverse, i.e. what is unhealthy and stated takeaways and deli meats as being unhealthy choices *"all those deli foods and the salamis and things, yeah how bad they are for you, a lot of salt and a lot of curing and that".*

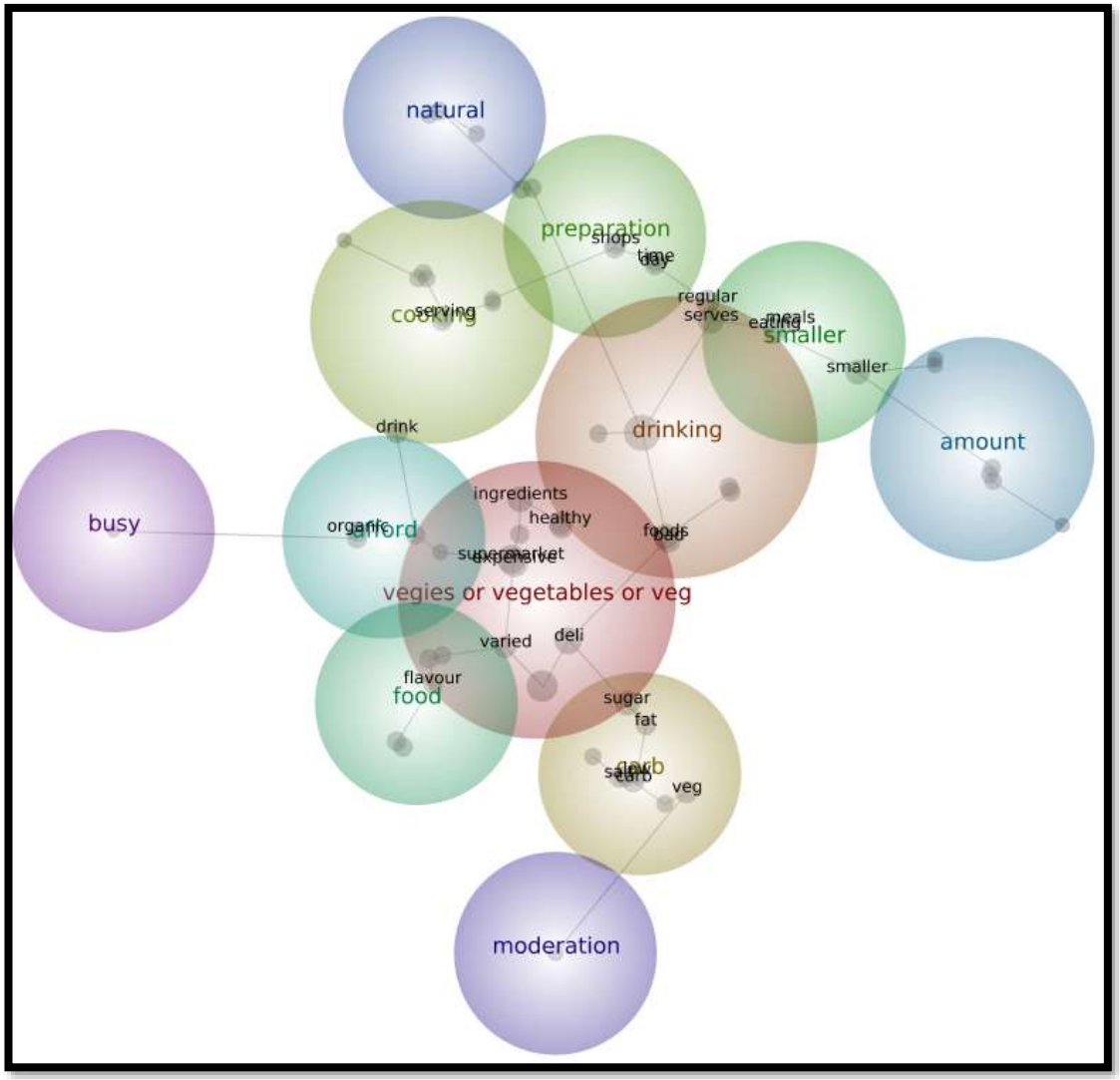

Figure 5.1. Patients perceived meaning of healthy eating

5.4.1.2 Theme 2: The influence of chronic pain on dietary intake and dietary behaviours

The concept map (Figure 5.2) highlights that the primary concept that emerged regarding how pain influences dietary intake was "food choice". Reasons for this included increased difficulty shopping and cooking when in pain, mood and motivation, and ability to prepare and shop for food.

Participants stated that they prefer foods that are easy and quick to prepare such as pre-packaged or takeaway with one participant stating: *"If you're in pain your selection of food wanes quite a bit. You go for quick and easy foods".* Another participant stated *"I cook less, it hurts too much standing in the kitchen".* While another stated *"basically*

whatever's easiest when you're in agony and you can't be bothered". Participants reported consuming certain foods in higher amounts due to pain such as chocolate and sweets. One participant stated: *"pizzas and all that already cooked"* and *"you tend to get more lollies and biscuits".* Other foods which were identified included chips, alcohol, doughnuts, coffee, frozen pies and sugary drinks. In contrast, participants also spoke about eating less when in pain *"yeah I skip a lot of meals", "you tend to live more on fluids than solids"* and *"when I'm in agony I just can't be bothered and whatever's there gets eaten. Toast for tea, that's a regular".* One participant identified that *"sugary things increase the pain".* Other habits as a consequence of pain included grazing *"I tend to graze"* and eating at night time *"you eat at the wrong time, late at night…and then you can't go to sleep"*.

Participants also discussed the impact pain has on preparing and/or shopping for food. One participant stated *"you don't want to stand in the kitchen, just going shopping and pushing the trolley is hard for me but you have to do it…it makes me irritable and grumpy and you just chuck stuff in"*. There was also discussion on how participants made food shopping easier by utilising trolleys or having their partner come to help them. One participant stated *"I hold onto the trolley a bit harder…the trolley is a good crutch"* which was followed by another participant who said *"yep, until it gets too heavy and it won't turn the corners, then my husband takes over".* Another participant stated *"I've got to go and do the shopping but I drag my husband along to give me a helping hand"*.

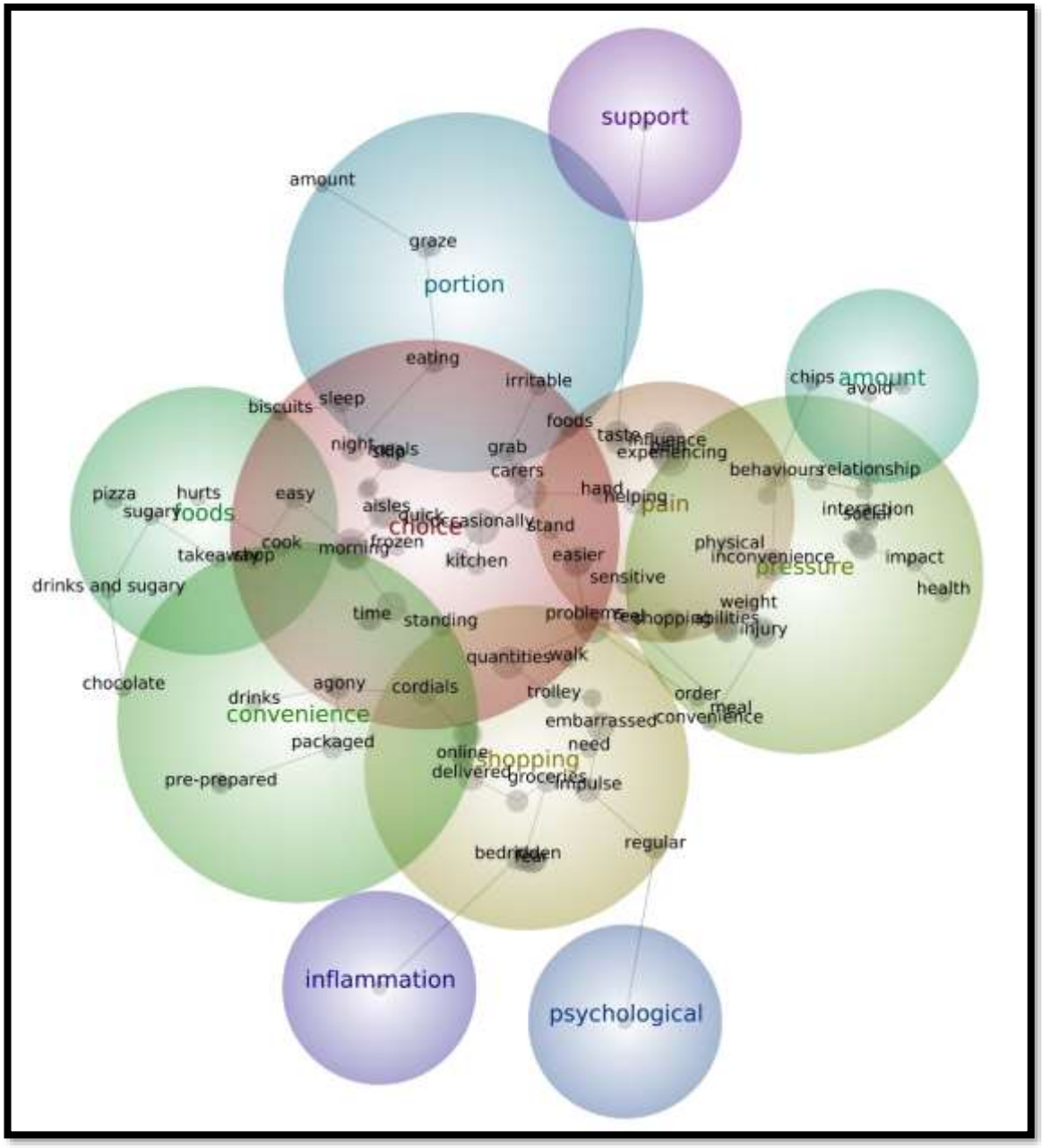

Figure 5.2. The influence of chronic pain on dietary intake and dietary behaviours

5.4.1.3 Theme 3: The influence of chronic pain on weight management

There were several ways in which chronic pain was thought to influence weight management as shown in the concept map (Figure 5.3). The predominant concept highlighted on the concept map is appetite which is influenced by other concepts such as: food consumption, medication and mental health. The amount and types of foods consumed leads to increased weight *"I eat more because of the pain"* and *"you don't*

eat healthy the weight piles on". Another contributing factor raised is the side effects associated with medication *"my medications bring a lot of my weight issues on".* Depression was identified as a consequence of increased weight *"you get depressed because your size keeps going up"* and *"not being able to do what I want to do to lose the weight causing the depression and mental health issues".* One person identified that increased weight led to an increase in pain *"have more pain because you're adding weight to whatever is wrong with you either your back or your legs"*. Feelings of exhaustion was also discussed with one participant describing their feelings associated with the thought of exercise: *"you just can't exercise"* and *"not being able to exercise"* while others said they didn't want to *"don't want to exercise"*.

When asked what would be helpful to achieve a healthy weight many participants discussed professional help to educate and support them and having a fall back or flare up plan which is reflected in the concept map (Figure 5.3) with 'flare' being one of the major concepts. Participants expressed a desire for education and support, particularly from professionals. One participant stated: *"teach us, mainly teach us"* while another: *"having someone to help them and having support there that is a big issue, if you don't have that support".* One participant made the comment *"talking to the correct people…yeah people in the field and that to get you motivated"* another participant responded by saying *"nutritionist, dietitians"* which was followed up with *"yeah will help you…give you suggestions and that and gives you a bit of peace of mind"*. Participants also stated that having a meal plan would also be helpful *"you need a meal plan".* There were also some barriers discussed which included food cravings *"I need somebody who can tell me how to stop craving that food"* and the cost of commercial weight loss programs *"if I had the money, excess money, I would live on Lite n Easy or whatever you call that".*

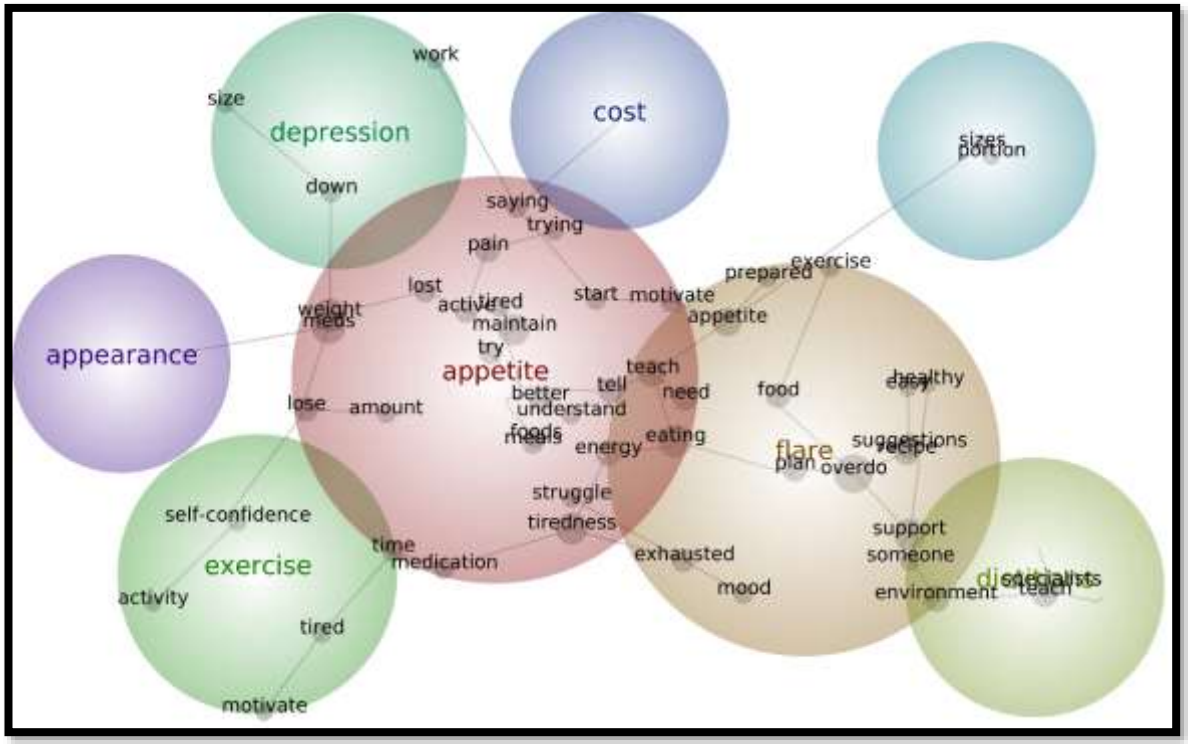

Figure 5.3. Effect of chronic pain on weight management

5.4.1.4 Theme 4: Perceived benefits for including a nutrition intervention into the current service

The main concept which arose was that of overall management (Figure 5.4). This was broken down into a number of aspects: health benefits, knowledge and skills and improved feelings of self-worth. Participants discussed the many health benefits of a nutrition intervention which included a reduction in pain, blood pressure, cholesterol, weight and an increase in general health and muscle strength. One participant stated *"overall better general health"* and another *"greater muscle strength".* Other comments included *"instead of being depressed you're happy", "less pain"* and *"low blood pressure, low cholesterol"*. Another point of discussion was the benefit of gaining knowledge and skills with comments such as *"yes that's right and you end up with better knowledge and skills"*. Participants would like *"help with knowing portion control"*, to know *"what sort of foods you can and can't have"*, *"know what vitamins and nutrients are in what vegetables"* and to know *"how the food affects your pain"*. The other main benefit identified by participants can be described as an increased sense of self-worth. This includes an increase in pride *"you're proud of yourself"*, motivation *"eating the right food motivates you more"*, self-esteem *"just your self-esteem of*

feeling good about yourself" and confidence *"have a bit more confidence and feel happy"*.

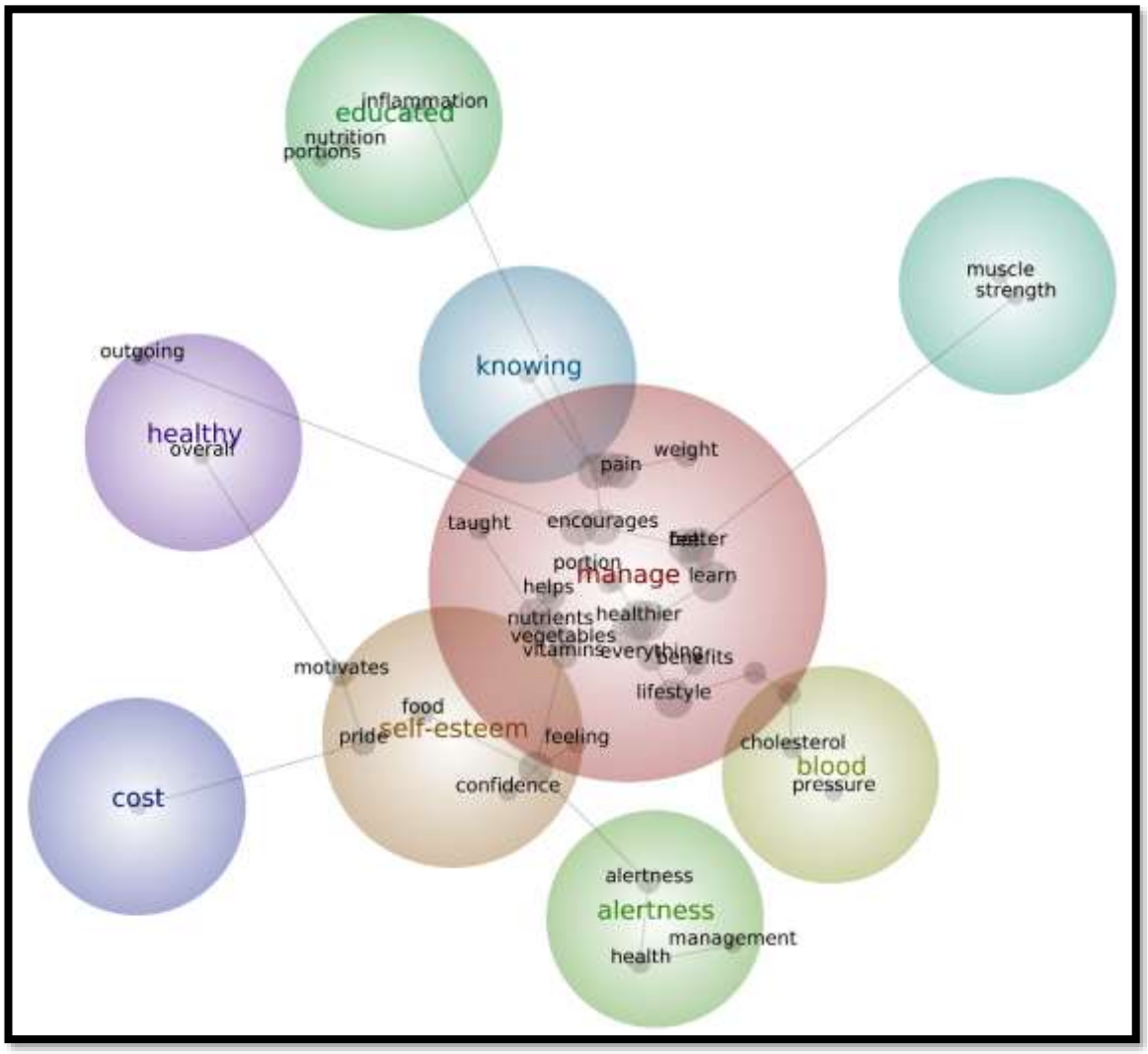

Figure 5.4. Perceived benefits for including a nutrition intervention into the current service

5.4.1.5 Theme 5: Perceived barriers to including a nutrition intervention into the current service

The resounding barrier which was discussed by most participants was cost and can be seen in the concept map (Figure 5.5). One participant stated: *"I've got to work and that's just to pay the accounts and everything, debts and…so yeah, cost is a big factor"*. The context in which cost was a barrier varied from the cost of food to the cost related to travelling and the accumulation of other health care costs. There was debate over the

cost of 'healthy' foods vs 'takeaway' foods with comments such as *"because we all know healthy food is a lot more expensive than junk food and when I couldn't work for five months we noticed it financially. It was hard".* This was followed by another participant *"see I find fresh foods cheaper than takeaway foods, because McDonald's is so expensive".* The cost of travelling and other health care costs was best summarised by this comment *"the cost of trying to fit everything in and do things apart from like going to the appointments and trying to do something to benefit you, you've got to find the cost…because you've got to drive from where you live…you have to come all the way to Newcastle".* The other major theme which arose was lack of motivation *"motivation or lack of"* and breaking current habits and mindsets *"it's difficult to break old habits"* and *"your mindset, that's the hardest thing to break"*. Other concepts were also identified as barriers which included time and distance, mobility, external factors and lack of knowledge. Some participants indicated that they have to travel to attend appointments or have unpredictable routines which affect their ability to participate in an intervention. One participant stated "*how far it is…because where I am there's nothing close"* and another stated: *"my schedule can be from 5 o'clock in the morning anywhere until 11 o'clock at night, so I've got no consistency"*. Limited mobility was also discussed as a barrier, particularly in relation to food shopping: *"not being able to get to the shops, yeah mobility"*. External factors such as the influence of media or social situation also presented a barrier for some people. One participant commented: *"ads on TV"* while another stated: *"you live alone"*. The final barrier was not knowing what is or is not healthy with one participant stating: *"lack of knowledge".*

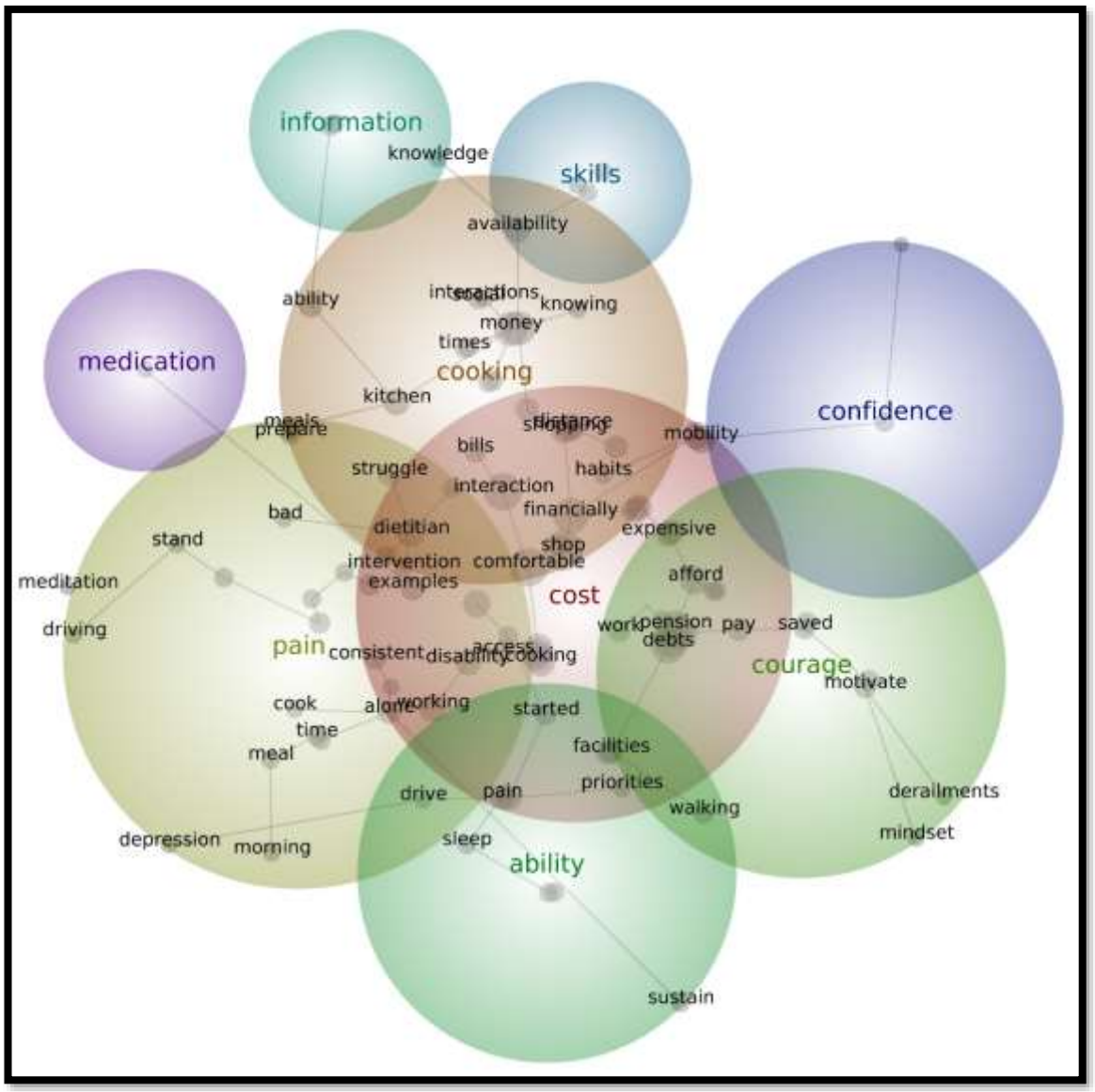

Figure 5.5. Perceived barriers to including a nutrition intervention into the current service

5.4.1.6 Theme 6: Intervention inclusions and preferred delivery

There were a number of suggestions made for what to include (or not include) in a nutrition intervention as seen in concept map (Figure 5.6). Knowledge, aids (visual or practical) and cooking were the main concepts that emerged. In terms of knowledge, patients want information which is more than just generic advice *"want it custom made"* which was easy to understand *"it's got to be easy to understand"*. Practical suggestions included the use of easy recipes *"what I'd want to see is easy recipes because when you're dealing with chronic pain you can't always stand up there*

chopping things for half an hour. It needs to be done and dusted in 10 minutes" and cooking classes or demonstrations *"maybe having a cooking day to actually physically show you what to do because some people can't cook, don't know how to cook"*. Certain topics which participants suggested to include inflammation and other chronic diseases such as heart disease and diabetes: *"I'm sure there's got to be some foods you can't have that would help increase pain levels…learning about inflammation"* and *"I've got a mate…he says he just doesn't know what to have because he can't have this because of the heart and he can't have that because of the diabetes".* The use of interactive aids was preferred over lecture-type approaches: *"I think visual aids, some videos to demonstrate…not just reading and listening to someone speak".* Participants also indicated an interest in cooking classes *"more hands on to go into the cooking day classes"* and *"especially to have a person doing it in front of you, it's more beneficial"*.

There was some overlap when discussing intervention inclusions and preferred delivery mode. The concept map (Figure 5.6) identifies that a group or workshop setting was popular, with some discussion surrounding technology. One participant referred to the groups being run by HIPS as part of their usual care "*Well even like groups like we attend here"* with other participants stating *"in a group you can bounce off each other"* and *"can be really informative and help you"*. Another participant stated: *"I think face to face you absorb it more"*. One participant indicated that travelling to an in-person session would not be a problem for them *"I'm willing to drive so far for it so that must say something"*. There was support for and against technology with some participants agreeing with the use of technology to deliver the intervention *"video calls would be good because you can set a time where you're not busy and everything is okay at the time and if you don't want to come to a group like this because of your pain, someone's still got to check in and make sure you're okay".* Another participant supported the use of technology because *"it beats travelling here".* Whereas another participant stated *"some people haven't got that technology. Some people don't own a computer, they go to the library"*. Ultimately there was a consensus to incorporate both "*maybe a bit of both, maybe both avenues"* and *"we are all individuals we're all different"*.

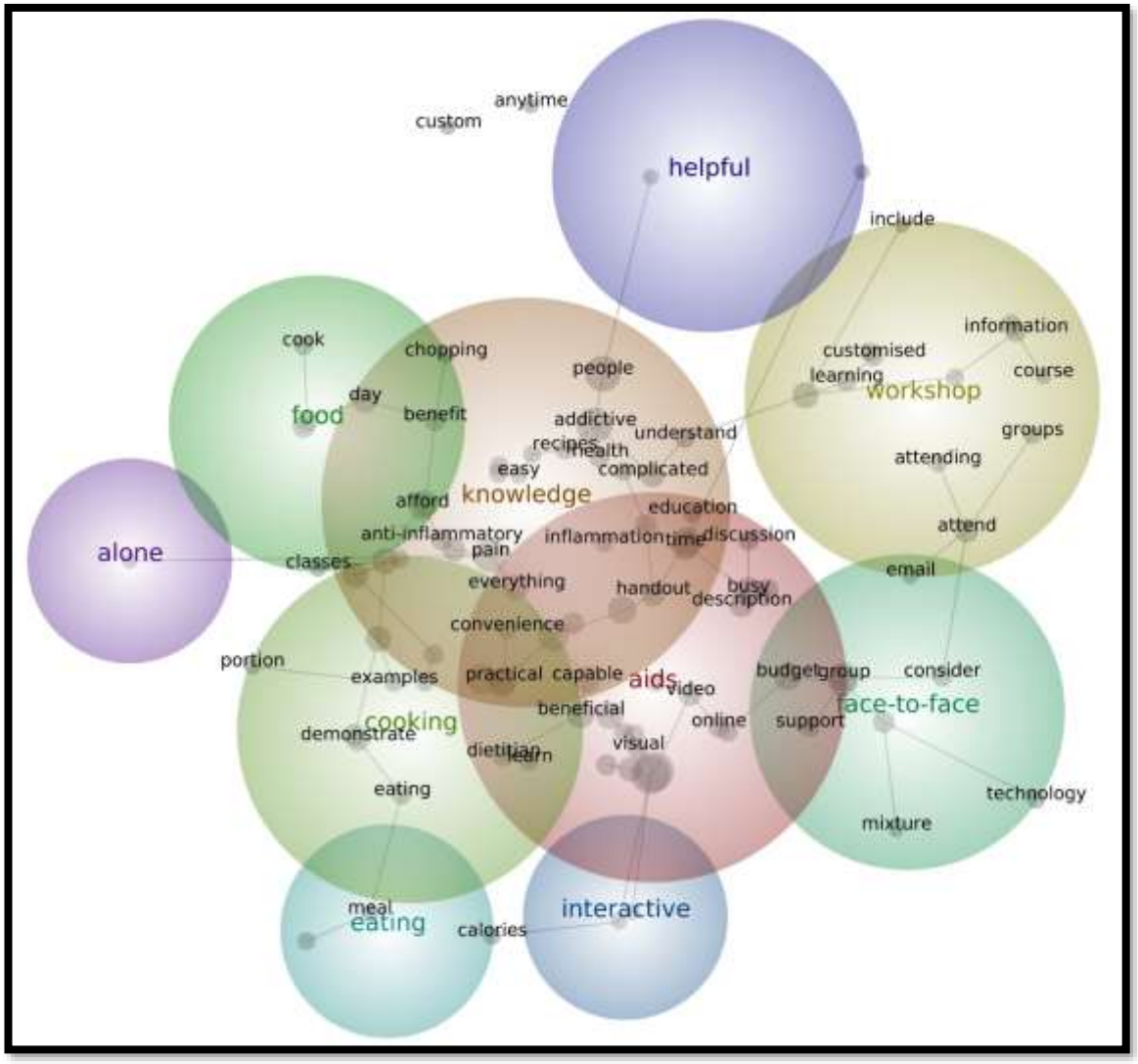

Figure 5.6. Suggested intervention inclusions and preferred delivery

5.4.1.7 Theme 7: Use and confidence using technology

The concept map (Figure 5.7) shows the different types of technologies participants discussed as well as their confidence in using them.

Participants identified a number of different devices and modes of technology including computers, smartphones, apps and websites. Two participants stated they use technology as a distraction from pain *"I like to distract myself from the pain".* Another two specifically stated they regularly used smartphone apps *"I have a diet diary in my smartphone"* and *"I use a meditation app"*.

There was a mix of participants who did have and use various devices compared to those who did not *"I use a computer"* vs *"I don't have a phone and I don't have a computer".* Similarly participants' confidence or enthusiasm for using technology varied with *"for convenience it [the internet] makes it easier…the pain gets to the point where I don't want to be around people"* and another stating *"I'm confident using the internet"*. In contrast another participant stated *"when you go on the internet how you do know that what you're reading is good for you"*.

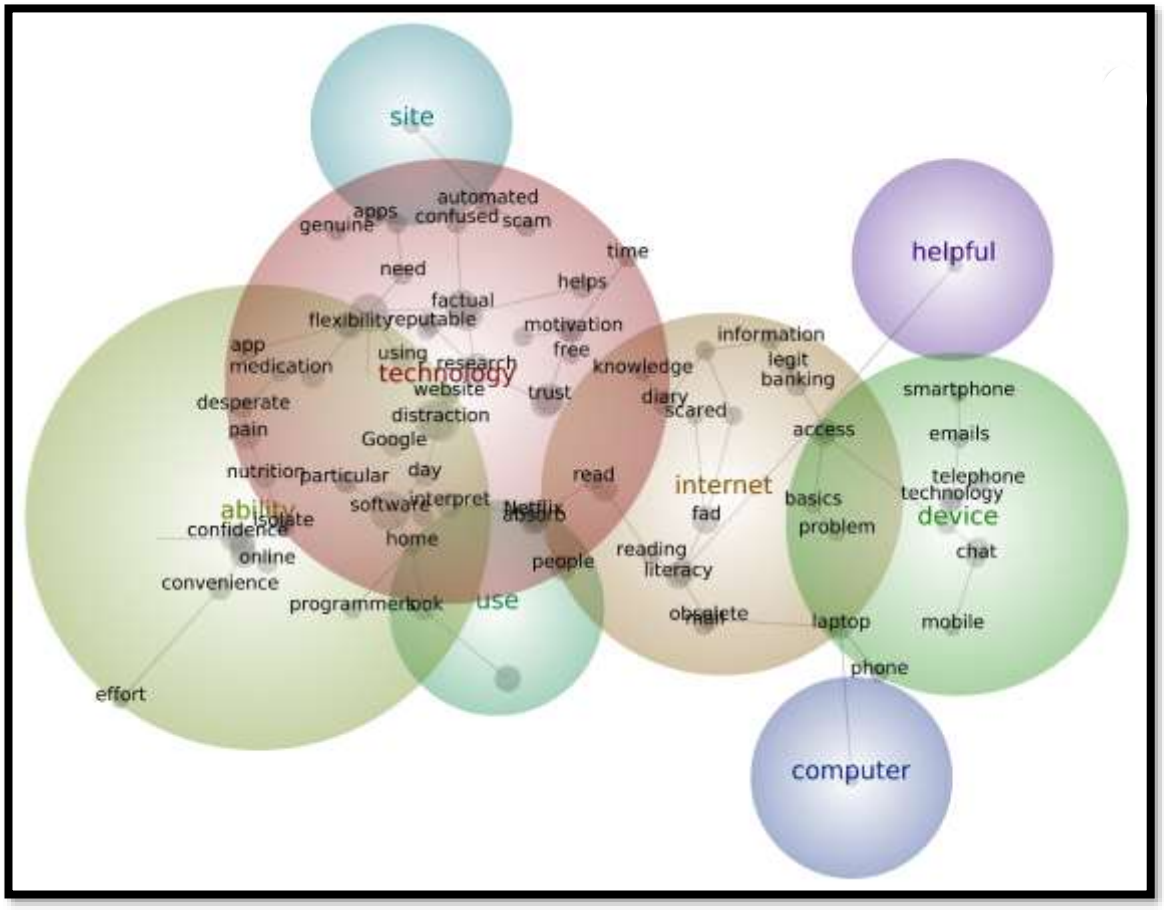

Figure 5.7. Use and confidence of using technology

5.5 Discussion

This current study reports results from focus groups conducted with patients experiencing chronic pain, attending a tertiary pain management clinic in NSW, Australia. Results provide insight into an area which has a limited evidence base and clinical presence, namely the role of nutrition in pain management. The main concepts explored in this qualitative study include: the perceived meaning of "healthy eating"; the influence of chronic pain on dietary intake and behaviours; the influence of chronic pain on weight management; the benefits for and barriers to participating in a nutrition intervention; preferred intervention inclusions and delivery methods; and use and confidence of using technology.

On average, the participants who took part in this study were slightly older (53 years) compared to patients who attended HIPS (n=1023) between July 2017 – June 2018 (52 years) and patients who attended all services in Australia and New Zealand (n=30193) in the same time period (50 years) (43). There were slightly more females who participated (62%) compared to HIPS where 60% of patients are female and all services where 57% are female (43). Just over half of the participants (52%) in this current study had pain for more than five years which is lower than all HIPS patients where 57% report having pain for more than five years (43). However it is higher than all service data showing 39% patients report pain for more than five years (43). The percentage of those who identified having depression/anxiety as a comorbidity was lower than all patients at HIPS and all services with 32% reporting depression/anxiety in this current study compared to 60% of all HIPS patients and 44% of all services patients reporting depression/anxiety (43).

Participants' discussion surrounding the influence pain on dietary intake, behaviours and weight management support the limited literature which has quantified the impact of pain on dietary intake, behaviours and weight management (102, 107-109). However, the qualitative methods used in this current study provides insight into reasons why people experiencing pain have poor quality dietary intakes and higher body mass index compared to those who do not have chronic pain. These insights can be used to tailor interventions to the specific issues faced by people who experience chronic pain as identified in this study. Participants stated that it is too hard to prepare healthy meals and their emotional state influences the types of foods they consume. Future nutrition

interventions in populations with chronic pain need to take this into account by ensuring that the foods suggested are relatively easy to prepare and address the issue of emotional eating adequately.

While no other qualitative studies have focused specially on nutrition and pain management, some of the benefits of participating in a nutrition intervention identified in the current study have also been identified in other qualitative studies which explore biopsychosocial interventions for pain management. The common benefits in this current study and other studies include: increase in pride, self-esteem and confidence. The perceived stigma whether intentional or unintentional associated with chronic pain appears to strongly influence patients ideas towards interventions. Poor self-esteem and confidence is associated with pain experiences with one study finding an inverse association between self-esteem and pain interference ($r = -0.48$, $p<0.001$) (278). The Pain Self Efficacy Questionnaire (78) measures patients' confidence in undertaking tasks and activities despite pain and is included as an outcome in the majority of pain services in Australia and New Zealand (75). By including patients in the development of any pain intervention, nutrition or otherwise, gives patients autonomy and hope that the intervention can benefit them by improving their pride and confidence, as well as catering to their expressed needs and preferences.

There was some misinformation which arose in the focus groups. For example, some participants stated that they thought coconut oil was a product that should be consumed as part of a healthy diet. Other participants agreed with this when it was mentioned. Coconut oil is high in saturated fat (approximately 82%) (279) and the Australian guidelines state that consumption of saturated fat should not exceed 10% of total energy intake (280). Saturated consumption is linked with elevated plasma cholesterol, in particular low density lipoproteins (LDL) and increased risk of heart disease (281). When discussing the benefits of a nutrition intervention participants stated that one of the benefits would be knowing how certain foods and/or nutrients affected pain or other chronic diseases such as heart disease and diabetes. This demonstrates that there is a need and a want for evidence based nutrition education to be available for this population.

The main barrier which was discussed by participants was the cost of food. Some participants perceived the cost of healthy eating to be higher than that of consuming nutrient poor and energy dense takeaway foods while others thought that eating a healthy diet was cheaper than takeaway foods. A systematic review and meta-analysis found that overall, there is no difference between the cost of eating a healthy diet or eating takeaway foods with the cost of healthy eating being $0.04 more than takeaway food but not statistically significantly different (p=0.916) (282). This same study did show that there were differences in the different food groups, for example lean meats are $0.47/200 kcal more expensive than less healthy cut of meat (282). However healthier grains ($0.03 higher) and dairy (-$0.004 lower) products were almost the same as less healthier grain and dairy options (282). The differences between food groups may explain the differences of opinion among participants. Costs associated with the health care system and travelling to and from appointments was also discussed as a barrier. One potential solution to this would be the use of technology to deliver the intervention. This would not only reduce the cost of travel by removing the need to travel but also reduce wait times for patients waiting to access pain management (59, 143). When wait times exceed 6 months there can be consequences for people experiencing chronic pain such as decrease in mood and quality of life and increase in disability (59).

Participants expressed that they wanted an intervention that was easy to understand with practical suggestions, which mirrors the focus group discussion surrounding the impact of chronic pain on dietary intake and weight management. In addition, participants wanted more information and skill development in relation to nutrition for pain management. Any future nutrition interventions should translate scientific nutrition information into easy to understand strategies and take into consideration quick and easy recipes which allows people to make a nutritious meal without affecting their pain.

There were mixed responses regarding delivery methods with some patients wanting face-to-face sessions, while others wanted online approaches, although there seemed to be a consensus that a combination of methods would be acceptable to the participants. Participants preferred an initial in-person group session that could be supported by technology e.g. website or video consultations. This is similar to findings in another series of focus groups conducted with patients experiencing chronic pain which

explored their priorities for pain management (89). Participants in these focus group also preferred to see a health care professional in-person, although in a one-on-one setting with the internet used as a tool to support this and act as a good follow up to reinforce information presented at the one-on-one appointment (89).

The ownership and use of technology was high among participants with only two out of 21 participants not owning a device and not accessing the internet. The majority of participants (19 out of 21, 91%) owned at least one device and used this device to access the internet on a regular basis, most commonly 1-4 times per day, for personal or health related reasons. In contrast, focus groups conducted by Chronic Pain Australia in 2013 found that 24 out of 53 (45%) participants had not used the internet to obtain any pain-related information (89). It was reported that this was primarily due to lack of access, cost associated with accessing the internet and not knowing how to understand the internet (89). In addition, those who did access the internet were unsure how to find reliable information (89). Despite the disparity between this current study and the one conducted by Nielsen et al. in terms of the number of participants who use the internet there are similarities in participants confidence in using the internet to find and interpret health information. Like participants in Nielsen et al's study, participants in the current study also identified difficulties in interpreting health information. This is supported by the quantitative results showing that the majority of participants (ranging from n=10 to n=17 out of 21) answered 'strongly disagreed', 'disagreed' and were 'uncertain' to eight statements related to accessing and understanding health information on the internet. Of all the statements, there were only two where only one participant answered 'strongly agree'.

One of the main strengths of the current study is the use of the COM-B model (150) in designing the focus group protocol. While many qualitative studies have been undertaken with people experiencing pain to find out what they would prefer in a variety of treatment options, very few have used a behaviour theory to inform the design of their study (274, 275). The benefits of using a theory to guide the development of an intervention is that it increases its effectiveness by increasing the likelihood of participants successfully changing their behaviour (283, 284). This current study acknowledges that people need capability, opportunity and motivation (COM-B model)

to change their behaviour (150) and these were used to guide the development of the study protocol to ensure these aspects were addressed.

Another strength of the current study is the inclusion of patients attending a tertiary pain service. Considering the thoughts of the population who will ultimately use a nutrition intervention will lead to a more successful intervention. Despite theme saturation being reached a limitation is that it is a relatively small sample size and only includes patients from one metropolitan tertiary pain service thus limiting the generalisability of the results. There are also some differences in the demographics of participants in this study compared to the general population which also limits the generalisability of the results. It is likely that patients attending other services in other geographical areas will have different feelings and opinions.

The current study identifies important considerations for developing an appropriate nutrition intervention for people experiencing chronic pain. Patients both need and want evidence-based nutrition information relating to pain and other chronic diseases but provided in a simple and practical way via a combination of in-person and technology based delivery. Key barriers such as cost and lack of motivation need to be addressed. The mixed responses regarding the use and confidence of technology also need to be considered to ensure that the intervention is appropriate for everyone experiencing pain. Future research should incorporate these findings and develop and test a nutrition intervention for patients attending a tertiary pain service.

Chapter 6: The effect of a pilot dietary intervention on pain outcomes in patients attending a tertiary pain service (ReJUICE your pain study)

This chapter has been reproduced from: **Brain K**, Burrows TL, Rollo ME, Hayes C, Hodson FJ, Collins CE. The Effect of a Pilot Dietary Intervention on Pain Outcomes in Patients Attending a Tertiary Pain Service. Nutrients. 2019;11(1).

6.1 Abstract

The aim of this study was to examine the effect of a six-week 2x2 design on pain scores, quality of life and dietary intake in patients attending an Australian tertiary pain clinic. The two intervention components were: 1) Personalised dietary consultations or waitlist control and 2) Active or placebo dietary supplement (fruit juice). Sixty participants were randomised into one of four groups at baseline (68% female, mean age 49±15 years) with 42 completing the study (70% retention). All groups had a statistically significant improvements in three of five pain outcomes. The personalised dietary consultation groups had clinically important improvements in three of five pain outcomes compared to the waitlist control groups. All groups had a statistically significant improvement in six of eight quality of life categories post intervention. All groups increased percentage energy from nutrient-dense foods (+5.2±1.4%, $p<0.001$) with a significant group-by-time effect for percentage energy from total fat ($p=0.024$) with the personalised dietary consultations plus placebo fruit juice reporting the largest reduction (-5.7±2.3%). This study indicates that dietitian-delivered dietary intervention can improve pain scores, quality of life and dietary intake of people experiencing chronic pain. Future research should evaluate efficacy in a full-powered randomised control trial.

6.2 Introduction

Chronic non-cancer pain is pain that persists beyond the three months that it normally takes for tissues to heal and is not due to active cancer (15). Chronic non-cancer pain, also termed ‘chronic pain’ has many triggers including injury or disease. However there is no obvious physical cause in about one third of cases (22). Despite numerous catalysts for chronic pain, a common pathophysiological explanation relates to

hypersensitivity of the nervous system and associated dysfunction of the immune and endocrine systems (3, 5). One in five people aged 18 years and over experience chronic pain and this increases to one in three people aged 65 years and over (22). Many people who experience chronic pain have a poor quality of life as chronic pain is associated with depression, social isolation and limited mobility (285). There is also a significant economic burden with total costs due to chronic pain in Australia in 2007 estimated as $34 billion (22). This includes: $11.7 billion in productivity costs, $11.5 billion in burden of disease and $7 billion in health care system costs (22).

With a strong bidirectional link between dietary intake and chronic pain experiences, investigation into the role of nutrition in chronic pain management is of growing interest to researchers and clinicians (254). The individual experience of chronic pain can lead to poor appetite and sub-optimal dietary intake (106, 108) and adversely impact ability to shop for food and cook meals. People who experience chronic pain may rely heavily on convenience and fast foods which are easier to prepare, however these are often energy-dense and nutrient-poor (108). An added complexity is the emotional response to chronic pain which can lead to contrasting responses from complete disinterest in food or the use of food and beverages as a comfort measure with subsequent overconsumption (109). A qualitative study exploring the experiences of adults (87% aged >50 years) who have chronic pain and a Body Mass Index (BMI) $\geq$ 25 kg/m^2 found that emotional or binge eating behaviours as a response to chronic pain were reported commonly and coincided with depression and negative feelings such as guilt (109). Equally important is the impact of dietary intake on the chronic pain experience itself. Diets which are low in fruit and vegetables and high in refined or ultra-processed foods, indicative of the typical 'Western Diet' contribute to a pro-inflammatory state associated with worsening of the chronic pain experience (9, 110). A systematic review of 71 experimental studies investigated the impact of altering dietary patterns, single nutrients, dietary supplements or fasting on chronic pain experiences (264). A meta-analysis identified that altering dietary intake led to a weighted mean reduction in self-reported pain scores [0.9 cm [0.54 cm, 1.27cm)] in studies which used a visual analogue scale to measure pain (264). Existing studies in nutrition and chronic pain were not high quality with half of the studies included in the review rated as of neutral or low quality

using a standardised risk of bias tool, mainly due to interventions not being well described or not detailed enough to allow replication (264).

While the systematic review identified that prescribing a healthy diet assists in pain reduction there are still a number of complexities and barriers (e.g. limited mobility affecting food preparation and/or limited motivation to change behaviour) which need to be considered in population groups experiencing chronic pain, with research examining personalised dietary interventions needed to address these issues and identify appropriate and effective treatment options. The effectiveness of an intervention is also dependent on individuals' behaviours and changing this behaviour is often difficult. The likelihood of an intervention be effective and successful can be improved by using evidence based principles of behaviour change theories. Theories such as the Behaviour Change Wheel conceptualise aspects which influence the behaviour of individuals so that they can be incorporated into interventions (150). The Behaviour Change Wheel incorporates three concepts which influence behaviour change: capability (psychological and physical ability to engage in an activity), motivation (the brains ability to encourage or direct behaviour beyond goals and conscious decision making) and opportunity (factors that lie outside the control of the individual) (150). In identifying any gaps individuals may have in these three concepts, researchers can tailor interventions to increase the capability, motivation an opportunity for those involved and help promote overall behaviour change (150).

Emerging evidence supports a potential role for non-nutritive bioactive compounds in reducing inflammation and modulating the chronic pain experience (124, 125). Polyphenols is an umbrella term for plant based compounds which contain a polyphenolic substructure (286). These can be further categorised into flavonoids and anthocyanins (286). Anthocyanins are water soluble pigments responsible for the red, purple and blue colours in food and the main type of anthocyanin found in plants is called cyanidins (115). Of the edible plants containing anthocyanins, cherries have been identified as containing high concentrations of anthocyanins and have been used in in vitro (116, 117, 120), animal (121-123) and human studies (127, 287) with characteristic metabolic impacts, including cardio and neuroprotective effects, anti-inflammatory action and pain modulating effect. Foods high in polyphenols, including cherries, strawberries, blueberries and plums, have been used in clinical studies (127,

287-289). In addition to potential antioxidant properties, mechanisms through which cherry anthocyanins act on inflammation and pain modulation include inhibition of cyclooxygenase 1 and 2 (COX-1 and COX-2) (116, 119). Studies have shown that anthocyanins are comparable to nonsteroidal anti-inflammatory drugs in terms of ability to inhibit COX-1 and COX-2 enzyme activity (116, 119).

Telehealth, is being used increasingly in clinical services providing greater access to health services for the community. A systematic review identified that using telehealth to provide dietary advice to adults with chronic disease is effective, when compared to usual care, low intensity in person dietary education or non-dietary interventions, in improving diet quality, with a standardised mean difference 0.22 (95% CI: 0.09, 0.34, p = 0.0007) and consumption of fruit and vegetables with a mean difference of 1.04 servings/day (95% CI: 0.46, 1.62 servings/day, p=0.0004) (147). Guidelines for dietetic video consultations (148) for weight management have also been developed that incorporate both telemedicine standards and nutrition care process (131, 290).

The aim of the current pilot study was to investigate the impact of two intervention components 1) Personalised dietary behaviour change delivered using dietetic consultations or a waitlist control and 2) an active or placebo dietary supplement comprising either a high anthocyanins fruit juice (cherry juice) or a placebo fruit juice with low anthocyanins and antioxidants (reconstituted apple juice) on pain scores, quality of life and dietary intake in patients attending a tertiary pain clinic. It was hypothesised that participants who received the dietary behaviour change component and high anthocyanin concentration fruit juice will have a greater reduction in pain score compared to those randomised to the waitlist control plus the placebo juice group.

6.3 Methods

This 2X2 randomized control pilot study has been reported using the CONSORT 2010 guidelines (Supplementary Table S1) (Appendix 38).

6.3.1 Participants

Participants were adults (≥ 18 years old) experiencing chronic pain and being treated by Hunter Integrated Pain Service (HIPS), New South Wales, Australia. HIPS is a multidisciplinary tertiary pain service, available to the public, by referral from a general

practitioner or medical specialist, to people living in the Hunter New England Local Health District and employs 16 clinicians and administrative staff, each with fractional appointments. Each year over 1000 patients are referred to the service. HIPS use a standardised group treatment pathway which includes a series of educative seminars and group workshops to promote a holistic and self-management approach to chronic pain management. Individualised assessment and treatment is offered in selected cases. The standardised pathway includes an orientation seminar, assessment workshop, treatment program and a refresher workshop. These are called: Understanding Pain (UP), Assessment and Planning (A&P), Active Pain Treatment (APT) and Progress Review Group (PRG).

6.3.2 Consent and ethics

All participants were provided with an Information Statement (Appendix 39) and gave their informed consent (Appendix 40) for inclusion before they participated in the study. This study was conducted in accordance with the Declaration of Helsinki and the protocol was approved by Hunter New England Human Research Ethics Committee (17/07/19/4.04) and the University of Newcastle Human Research Ethics Committee (H-2017-0295). This trial was registered retrospectively with the Australian New Zealand Clinical Trials Registry (ACTRN12618001941257).

6.3.3 Recruitment and screening

Participants were recruited to the study if they attended either UP, A&P or PRG between September 2017 and April 2018. Patients were not recruited from APT to prevent the treatment confounding the results of this study. The approximate wait between each session described above, is three months and provided a sufficient window of time to ensure that the standard clinical care did not confound this study. All patients at each of these groups was offered an expression of interest form by the researcher (Figure 6.1). Either the student researcher or a HIPS clinician (when the student researcher was not available) provided a standardised two minute verbal and visual explanation of the study which was presented at the end of each session and Information Statements were made available to patients. Expression of interest forms were collected by the student researcher or clinician and those who indicated interest in the study were then contacted via email and/or phone by the researcher. Patients were screened either via a return email or phone interview. Patients were eligible if they: had

access to reliable broadband internet, able to attend two in person measurement sessions at the University of Newcastle and willing to provide a fasting blood sample. Patients were excluded if they had an intolerance to fruit, were pregnant, had a pacemaker or cochlear implant and/or had a severe medical condition (e.g. insulin controlled diabetes).

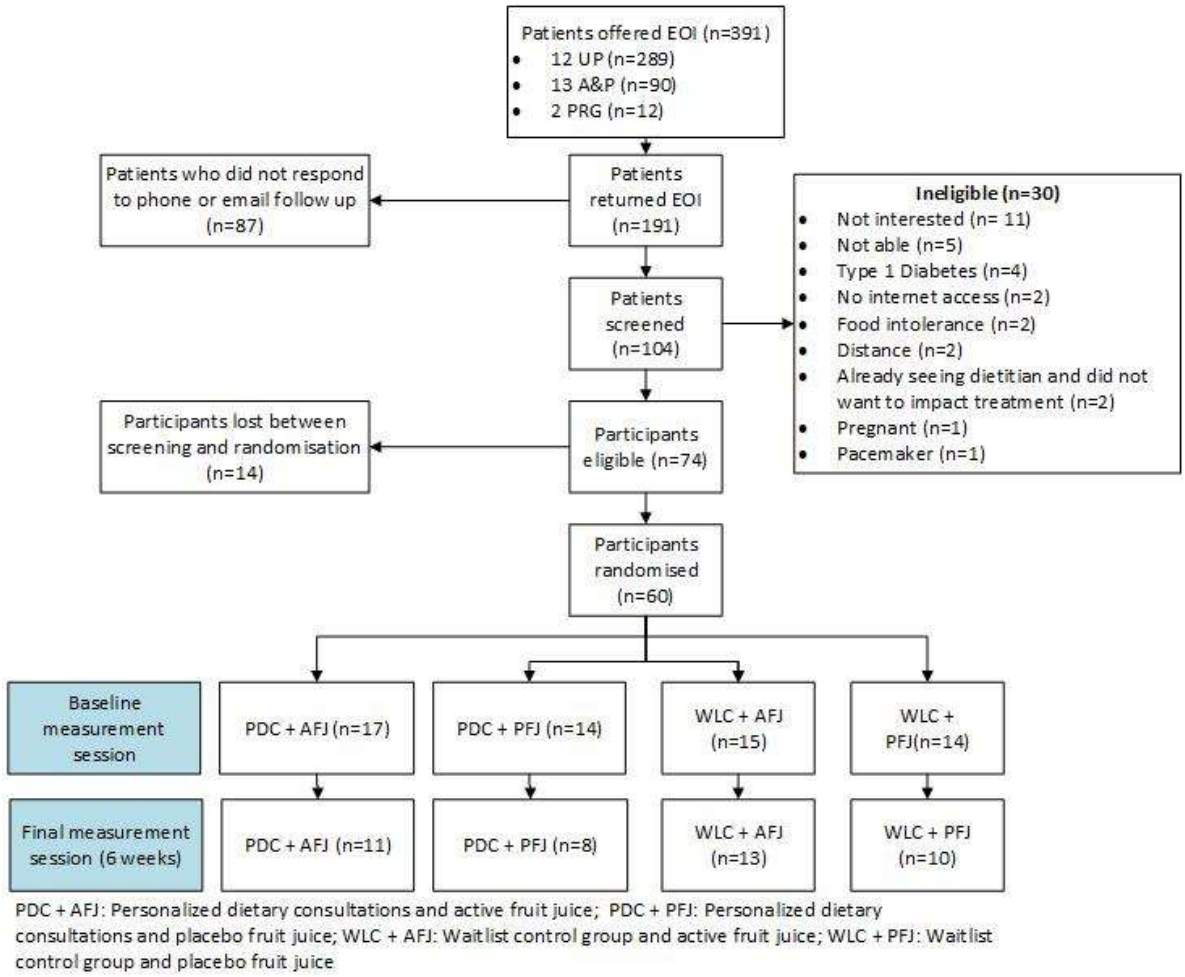

Figure 6.1. Participant flow through study.

6.3.4 Intervention inclusions and delivery

The intervention was comprised of two components: 1) A dietary behaviour change component delivering personalised dietary consultations (PDC) or waitlist control (WLC) and 2) Dietary supplement in the form of a fruit juice. There were two fruit juices included: 1) Active fruit juice (AFJ) (cherry juice) and 2) Placebo fruit juice (PFJ) (apple juice). The intervention ran for six weeks and included four study arms which were provided with different combinations of the intervention components. These

included: 1) PDC and AFJ, 2) PDC and PFJ, 3) WLC and AFJ, and 4) WLC and PFJ. After participants were screened and completed the baseline assessment, they were stratified by gender and randomised, using a computer generated randomisation tool, into one of the four study arms (Figure 6.1).

6.3.4.1 Personalised dietary consultations

Participants received up to three personalised dietary consultations with an Accredited Practicing Dietitian (APD) which were conducted using telehealth (Appendix 41). The initial consultation was booked in the first week of the study and the subsequent consultations were booked about 7-10 days after each other. Participants were encouraged to use the Avaya Scopia® (291) (a video call platform used by Hunter New England Local Health District) to conduct the consultations. Participants were also given the option to conduct the consultation via a phone call.

The participants received a copy of their Australian Eating Survey Report (AES) (292) at least 24 hours prior to the first consultation, allowing them to become familiar with the contents. The AES Report was generated from the AES food frequency questionnaire completed at the measurement session. The AES is a valid and reliable online food frequency questionnaire which assesses participants' usual food and nutrient intake over the past 3-6 months (292). It takes approximately 15 minutes to complete and generates a personalised report which compares the participant's intake to national nutrition guidelines. The report provides a pictorial representation of energy contributions from major food groups, breakdown of energy coming from macronutrients, and core and energy-dense, nutrient-poor food groups, compares micronutrient intake to the Nutrient Reference Values (293) and calculates the Australian Recommended Food Score which indicates overall diet quality (292).

Participants were also asked to complete a Personalised Nutrition Questionnaire (PNQ) to guide discussion on perceived barriers during the call with the dietitian. The PNQ incorporates the Capability, Opportunity, Motivation-Behaviour (COM-B) model and Behaviour Change Wheel Theory (150) in relation to factors which may affect eating behaviours and were tailored for patients experiencing chronic pain. When completing the PNQ, participants were asked to select and prioritise from a list of known factors which most affect their ability to eat healthily. These were presented in three categories:

1) Capability: knowledge, skills and ability; 2) Opportunity: time, access and storage; 3) Motivation: wants, needs and habits. The PNQ provided the dietitian with information on barriers prior to the initial consultation with the participant, allowed streamlining of the session and to facilitate the collection of additional information on the prioritised barriers during the consultation. Accompanying the PNQ is a toolbox where intervention strategies and resources were linked with each of these factors and tailored for individuals with chronic pain. Depending on which factors were selected by participants the corresponding evidence-based resources and strategies were provided to help participants achieve their goals. The strategies which corresponded to these factors were based on the COM-B model and included, but not limited to education; instruction on how to perform a behaviour; empowerment; problem solving; self-monitoring and restructuring the environment. The resources included websites and handouts which were sourced from government departments, the Dietitians Association of Australia, Nutrition Education Materials Online, Australian Healthy Food Guide and Practice-based Evidence in Nutrition.

The first telehealth consultation (30-45 minutes) was structured as follows: introduction; explanation of the AES report with focus on the four main sections: food groups responsible for energy intake, the ARFS, macronutrients and micronutrients; education about the food groups and nutrients important for chronic pain management (e.g. vegetables, fruits, antioxidants, omega-3 and vitamin B); discussion of the chosen PNQ priorities, set goals and discuss strategies and resources to achieve these goals. A summary of the consultation was emailed to each participant immediately after the consultation and a second consultation was scheduled for 7-14 days later. The second consultation (≤30 minutes) included: answering participant questions; identifying and discussing successes and barriers towards achieving goals and troubleshooting solutions to any barriers. If necessary, additional resources were emailed to participants at the end of the consultation. The third consultation was optional and limited to ≤30 minutes. This consultation focused on reinforcing education and strategies provided in the first two consults and additional discussion around goals.

6.3.4.2 Dietary supplement (Active Fruit Juice)

Cherry juice was chosen as the active fruit juice, for its high anthocyanin content (Supplementary Table 2) (Appendix 42). The cherry juice was purchased from an

agricultural research company (Agritechnology) based in Orange, NSW, Australia. Agritechnology produce the cherry juice with the aim to retain the phenolic bioactives. Total red count (TRC) is a measure for total anthocyanins and for the juice used in this pilot study the TRC was 19.3 mg/100 g (Supplementary Table 2). Typically Agritechnology cherry juice is approximately 30 mg/100 g and can reach >100 mg/100 g depending on the season. Data from the Phenol-Explorer database (294) provides the content of anthocyanins and total polyphenols in various foods and shows the high content of these in cherries. The anthocyanins content of cherries range from 54.3-171.42 mg/100 g and the total polyphenol content ranges from 96.81-274.3 mg/100 g depending on the type of cherry (294). Each participant was given 42X 250 ml bottles of cherry juice at their baseline measurement session. Participants were given instructions to consume one bottle a day for six weeks and advised that the juice should be stored in the refrigerator or in a dark and cool location until ready to consume. A written calendar was provided to participants as a reminder to consume the juice each day. Participants were asked to tick off each day once they had consumed the juice and return the calendar at the second measurement session to assess compliance with the intervention. In an attempt to blind the study, participants were told there were two fruit juices, one active and one placebo and that they would be randomly allocated to one or the other.

6.3.4.3 Control group conditions

The control condition for the dietary behaviour change component was a waitlist control group. This group was instructed to continue with their usual diet and not make any dietary changes. At the end of the six week period, participants in this group were given the opportunity to participate in the dietary behaviour change intervention and given full access to all components outlined above.

The placebo fruit juice was a reconstituted apple juice and processed in such a way which would have degraded any antioxidant content. In addition, the Phenol-Explorer database shows that apples only have 0.93 mg anthocyanins per 100 g and 56.32 mg total polyphenols per 100 g (294). Participants who received the apple juice were given the same quantity, instructions and calendar to record their consumption. The apple juice was the Orchy brand and purchased from Bevco, based in Thornlands, Queensland, Australia.

6.3.5 Measurements

Participants were scheduled to attend a baseline measurement session (60-90 minutes) at the University of Newcastle at a time mutually agreeable to them and the researcher. Height and weight were measured, using a standardised protocol, and a fasting blood sample taken by the researcher and/or a research assistant. These measures, with exception of height, were repeated at the final measurement session held six weeks after the baseline session. Participants also completed an online questionnaire, either at the session or it was emailed to them to complete later that day. The online questionnaire collected demographic data including: age, gender, country of birth, Indigenous descent, employment status and comorbidities. There were also questions to obtain an overall description of pain from participants: cause of pain, main pain site, time experiencing pain and health care use.

The main outcome measures were included in this questionnaire and participants completed these questions at the baseline (Appendix 43) and six week measurement session (Appendix 44). These included pain, quality of life and dietary intake.

6.3.5.1 Pain

Current pain was measured by participants selecting a point on a 100 mm visual analogue scale with a higher score indicating more pain (151). Overall pain severity (rated on a score of 1-10) and interference (average of seven items is calculated as a score out of 10) were measured using the Brief Pain Inventory which is a validated pain assessment tool (76, 239). Pain severity is also categorised with a score of 0-4 indicating mild pain, 5-6 moderate pain and 7-10 severe pain (75). Pain interference is not categorised but the higher the score, the higher the interference (75). Pain self-efficacy is measured using the validated Pain Self Efficacy Questionnaire (PSEQ) which is a sum from 10 questions rated as 0 = not confident at all to 6 = completely confident (78). Results are categorised as severe < 20, moderate 20-30, mild 31-40 and minimal impairment >40 (78). The Pain Catastrophising Scale (PCS) was used to measure pain catastrophising with three sub-categories incorporated into the scale: rumination, magnification and helplessness (240). A score of <20 indicates mild catastrophising, 20-30 is high and >30 is severe.

6.3.5.2 Quality of life

Quality of life was measured using the Short-Form 36 (295) with eight categories containing a number of items including: physical function (10 items), role limitations (physical limits)(4 items), role limitations (emotional issues) (3 items), energy and fatigue (4 items), emotional wellbeing (5 items), social functioning (2 items), pain (2 items) and general health (5 items) (295). Participants give their responses on a scale from one to three up to one to six depending on the question. This is then scored in ascending or descending order using predetermined values. These are then averaged depending on the number of items, with all questions scored out of 100.

6.3.5.3 Dietary intake

This was measured using the Australian Eating Survey Food Frequency Questionnaire (AES FFQ) which is aimed at capturing typical intake over a long period of time. The AES FFQ also asks how often participants eat 120 commonly consumed foods in Australia and has been validated for use in Australian adults (292). Upon completion of the AES FFQ a report is generated which compares the participants energy intake, macro- and micro-nutrient breakdown to national dietary guidelines. Diet quality is calculated using the Australian Recommended Food Score (ARFS) (292). The total score which is out of 73 is made up of scores from each of the core food groups such as vegetables, fruit, meat and alternatives, grains, dairy, water and condiments.

6.3.5.4 Process evaluation

Participant's satisfaction with the program and its components as well as changes to nutrition related behaviours were assessed using the final questionnaire. Participants were asked to rank their satisfaction on a 5-point Likert scale for: overall satisfaction, AES FFQ satisfaction, juice satisfaction and for those who received the personalised dietary consultations the AES report and telehealth consultations. The response options varied from: very satisfied, to very unsatisfied. Those participants who received the PDC were asked to rate their agreement that the program encouraged them to change eight nutrition-related behaviours. These nutrition related behaviours included: eat more fruit and vegetables; eat fewer discretionary choices; change food products they purchased, read nutrition information on food products; keep a record of food and drink

consumption; set nutrition goals; download healthy eating apps and be mindful in using food to cope with pain.

6.3.6 Data analysis

Data was analysed using SPSS version 25 (IBM® SPSS® Statistics, IBM Corp. Armonk, NY, USA). Normality testing was undertaken by generating histograms and running the Shapiro-Wilk test to determine if data was normally distributed. Demographic and participants description of pain were analysed using descriptive statistics. Generalised linear mixed models were undertaken for each outcome variable to determine if any effects were due to differences between time (baseline and 6 weeks), groups (PDC and AFJ; PDC and PFJ; WLC and AFJ; WLC and PFJ) and also group by time interaction. Intention to treat was used where there was missing data. Statistical significance was set at $p<0.05$.

6.4 Results

6.4.1 Number of study participants

A total of 391 patients from over 27 HIPS clinical sessions were invited to participate in the study. Of these, 191 returned an expression of interest form. After screening (n=30 ineligible), 74 participants were eligible and of these 60 attended the baseline measurement session and were randomised into the four study arms (Figure 6.1). The majority of those who did not return an EOI did not participate in follow-up correspondence (phone and/or email) following the HIPS session. At the 6 week measurement 18 participants were lost to follow up, leaving 42 in the sample (70% retention).

6.4.2 Participant demographics

Participants were predominantly female (68.3%) and with a mean age of 49±15 years and BMI 32.6±7.7 kg/m^2 (Table 6.1). Ninety percent of participants were born in Australia and seven percent identified as being of Aboriginal and/or Torres Strait Island descent. The most commonly selected employment status was *unemployed (due to pain)* (n=16), followed by *retired* (n=12) and *part time paid work* (n=10). In terms of self-reported comorbidities, participants reported from zero to five comorbidities with the three most common being depression or anxiety (n=35), osteoarthritis (n=24) and high

blood pressure (n=15). There were no significant differences in participant demographics between groups at baseline.

Table 6.1. Demographic characteristics of participants at baseline.

	PDC + AFJ (n=17)	**PDC + PFJ (n=14)**	**WLC + AFJ (n=15)**	**WLC + PFJ (n=14)**	**Total (n=60)**	**P-value**
Female # (%)	12 (70.6)	10 (71.4)	9 (60)	10 (71.4)	41 (68.3)	0.896
Male # (%)	5 (29.4)	4 (28.6)	6 (40)	4 (28.6)	19 (31.7)	
Age	48.24±14.60	47.00±15.66	49.27±16.72	50.93±13.85	48.83±14.92	0.930
BMI	33.14±8.31	32.83±8.15	33.43±5.82	30.78±8.74	32.59±7.70	0.561
Employment # (%)						
- Unemployed (due to pain)	7 (41.2)	4 (28.6)	5 (33.3)	0 (0)	16 (26.7)	0.088
- Retired	3 (17.6)	2 (14.3)	4 (26.7)	3 (21.4)	12 (20)	
- Part time paid work	0 (0)	3 (21.4)	3 (20.0)	4 (28.6)	10 (16.7)	
- Unemployed (not due to pain)	0 (0)	2 (14.3)	0 (0)	3 (21.4)	5 (8.3)	
- Home duties	1 (5.9)	2 (14.3)	0 (0)	1 (7.1)	4 (6.7)	
- Full time paid work	2 (11.8)	1 (7.1)	0 (0)	1 (7.1)	4 (6.7)	
- Studying	2 (11.8)	0 (0)	2 (13.3)	0 (0)	4 (6.7)	
- At work (limited hours/duties)	1 (5.9)	0 (0)	1 (6.7)	1 (7.1)	3 (5.0)	
- On leave from work due to pain	1 (5.9)	0 (0)	0 (0)	1 (7.1)	2 (3.3)	

PDC + AFJ: Personalised dietary consultations and active fruit juice; PDC + PFJ: Personalised dietary consultations and placebo fruit juice; WLC + AFJ: Waitlist control group and active fruit juice; WLC + PFJ: Waitlist control group and placebo fruit juice. P-values were calculated using ANOVA and exact Chi-squared tests.

6.4.3 Participants description of their pain

The majority of participants (77%) described their pain as *always there, but the intensity changes* with the three most commonly reported pain sites being back (n=19), shoulder (n=5) and leg (n=5). Over half the participants (53%) reported they had been experiencing their pain for more than 5 years, 40% for 1-5 years and 7% reported having had pain for less than 1 year. The three most common answers for 'how did the main pain begin' included: no obvious cause (n=18), related to another illness (n=12)

and injury at work or school (n=11). Participants also reported healthcare use in the last three months, on average the participants accessed GPs about three times and allied health professionals and tests and scans approximately twice in the last three months. Visits to a medical specialist or emergency department for pain were, on average, less than once in the last three months.

6.4.4 Intervention compliance

Overall, participants reported they were highly compliant with the intervention protocol, with the majority reporting to have consumed all 42 bottles of juice over the six week period (Table 6.2). Only nine participants reported consuming less than 42 bottles (ranged 21-41 bottles), with the main reasons for non-compliance being: they forgot or they went on holidays during the six weeks and forgot or were unable to take the juice with them. One participant had to undergo surgery during the study and was only able to consume the juice for 21 days, the data from this participant and all participants, was included in the intention-to-treat analysis.

A total of 19 out of 31 participants randomised to the PDC groups took part in the telehealth sessions, completing at least one session. Twelve out of 17 were from the group which also received the AFJ and seven out of 14 received the PFJ (Table 6.2). Nine of the participants who did not attend, were lost to follow up and also did not attend the second measurement session. The other three participants did attend the final measurement session, however throughout the duration of the study they forgot or had other commitments and continually rescheduled their consultations. Participants were required to attend the first two consultations with the third consultation being optional. Of the 19 participants who completed the telehealth sessions 89% (n=17) attended two or more consultations. The remaining two participants only completed one session.

In the group which received the AFJ, two participants attended one consultation, three participants attend two consultations and seven participants attended three consultations. In the PFJ group three participants attended two sessions and four attended three sessions.

6.4.5 Pain outcomes

When all four groups were compared over time, there was no group-by-time effect for any pain variables. This was also true when the groups were collapsed and all participants receiving PDC were compared to all participants receiving the WLC and the participants receiving AFJ were compared to those receiving PFJ.

All groups had a statistically significant improvement in three of the five pain variables over the duration of the study (Table 6.2, Figure 6.2). These included pain interference (average Δ -0.9±0.3, p=0.003), pain self-efficacy (average Δ +6.2±2.2, p=0.004) and pain catastrophising (average Δ -3.8±1.8, p=0.046).

The changes between baseline and six weeks for current pain, pain interference and pain self-efficacy were clinically important, although not statistically significant. Clinical importance is considered as 2.5-3 cm reduction for the visual analogue scale, measuring current pain (125, 296). Clinically important pain interference is a reduction of >1 point on the BPI inference score and for self-efficacy an increase of ≥7 cm and a change to another severity category on the PSEQ [40]. For current pain, both PDC groups and all groups combined reached clinical importance. Both PDC groups reached clinical importance for pain interference and self-efficacy. Changes in pain severity and pain catastrophising were not clinically important or statistically significant.

On average, at baseline all participants rated their pain severity as moderate (BPI) and this did not change over time. Pain self-efficacy was also reported as moderate for all groups at baseline. However, at six weeks, all but the WLC and PFJ reported a lower level of pain and the mean scores were categorised as ‘mild’. At baseline all groups and the total were categorised as high for pain catastrophising, however at six weeks, all groups, except the PDC and PFJ (which remained in the high category) were categorised as mild.

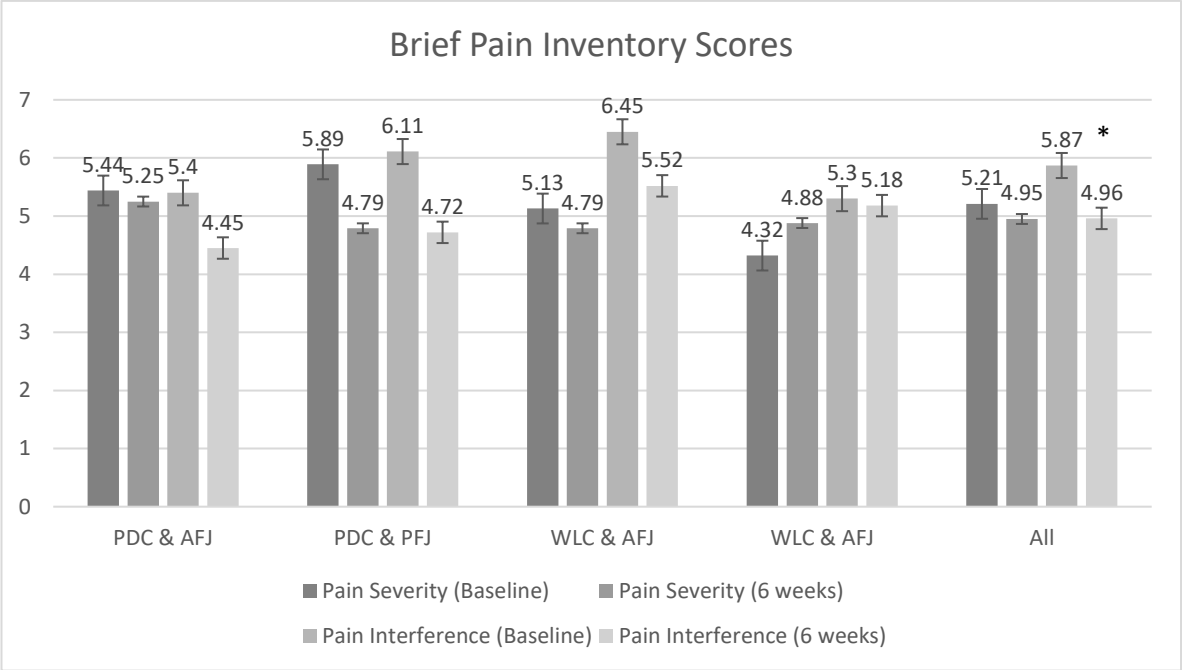

Figure 6.2. Pain severity and interference (mean±SE).

* All groups had a statistically significant reduction in pain interference (p=0.003)

6.4.6 Quality of life outcomes

The quality of life score is comprised of eight categories. Table 6.2 indicates that there are no statistically significant differences between groups at baseline. When groups were compared over time, there was no group by time effect for any pain variables. This was also true when the results were compared between the PDC group and WLC group and the two supplement groups.

All groups had a statistically significant improvement in six of the eight quality of life categories over the duration of the study. These include physical function (average Δ +8.1±3.4, p=0.016), physical role limitations (average Δ +20.6±5.6, p<0.001), emotional role limitations (average Δ +27.1±7.0, p<0.001), emotional wellbeing (average Δ +8.7±2.8, p=0.003), social functioning (average Δ +7.4±2.4, p=0.001) and general health (average Δ +8.3±2.2, p<0.001).

6.4.7 Dietary outcomes

When groups were compared over time a significant group by time effect for reduction in the total percentage energy derived from total fat, with the PDC and AFJ groups achieving a significant reduction in intake (-5.7±2.3%, p=0.024) over time, compared to

other groups. This group by time effect was also present when the PDC participants (-3.83±1.71%) were compared to the WLC participants (2.06±1.56%), p= 0.013. These results were not significant when the AFJ participants (-0.24±1.65%) were compared to the PFJ participants (0.83±1.79%) (p=0.807).

A comprehensive set of food and nutrient intake and diet quality variables were evaluated (Table 6.3). All groups had a statistically significant improvement in three variables over time. These were energy intake (average Δ -788±364 kJ, p=0.043), percentage energy from core foods (average Δ +5.2±1.4%, p<0.001) and percentage energy from energy-dense, nutrient-poor foods (average Δ -5.2±1.4%, p=0.000). Mean energy intake reduced in both PDC groups and the WLC with AFJ (-1540±786 kJ, -652±836 and -1309±689 kJ, respectively) and increased in the WLC and PFJ group (+349±754 kJ).

A description of the participants' dietary status at baseline shows that the proportion of energy coming from carbohydrates, protein, total fat, saturated fat and alcohol was 44.4±1.2%, 19.0±0.6%, 34.5±0.9%, 14.8±0.4% and 2.8±0.7% respectively. Diet quality, measured using the total ARFS and subcategories was low at baseline with the total overall score 29.1±1.4 at baseline.

Table 6.2. Pain and quality of life outcomes

Outcome variable (mean ± SE*)	Time point	PDC + AFJ	PDC + PFJ	WLC + AFJ	WLC + PFJ	Total	Time F stat (p-value)	Group F stat (p-value)	Group x Time F stat (p-value)
Number of participants	Baseline	17	14	15	14	60			
	6 weeks	11	8	13	10	42			
Number of juice bottles consumed (Maximum 42)	6 weeks	39.64±1.89	41.00±0.76	41.46±0.31	41.90±0.10	41.00±3.39			
Telehealth attendance	N/A	12	7	N/A	N/A	N/A			
Pain									
VAS†	Baseline	48.24±5.31	52.00±5.85	45.40±5.65	47.64±5.85	48.27±2.75	1.16 (0.254)	0.102 (0.959)	0.113 (0.952)
	6 weeks	43.87±6.39	44.99±7.43	43.61±6.00	45.68±6.74	44.57±3.20			
	Δ6wk-baseline	-4.37±6.71	-7.02±7.77	-1.78±6.39	-1.96±7.11	-3.69±3.37			
PSEQ^	Baseline	26.82±3.07	21.29±3.38	26.87±3.27	25.21±3.38	25.17±1.62	8.835 **(0.004)**	0.606 (0.613)	1.181 (0.321)
	6 weeks	35.21±3.74	33.61±4.37	30.75±3.48	26.41±3.94	31.37±1.91			
	Δ6wk-baseline	8.38±4.15	12.32±4.79	3.89±3.67	1.19±4.40	6.21±2.16			
PCS#	Baseline	21.24±3.27	27.43±3.60	21.60±3.48	24.93±3.60	23.63±1.72	4.074 **(0.046)**	0.831 (0.480)	0.073 (0.974)
	6 weeks	18.23±3.80	24.70±4.37	17.63±3.64	19.96±4.03	19.86±1.93			
	Δ6wk-baseline	-3.02±3.49	-2.73±4.05	-3.97±3.28	-4.97±3.68	-3.78±1.75			
Quality of life									
Physical function	Baseline	45.59±6.91	42.86±7.62	36.67±7.36	38.57±7.62	41.08±3.63	6.040 **(0.016)**	0.689 (0.561)	0.293 (0.830)
	6 weeks	55.86±7.87	56.22±9.04	42.25±7.66	43.79±8.41	49.13±4.02			
	Δ6wk-baseline	10.28±6.72	13.37±7.83	5.58±6.30	5.22±7.09	8.05±3.38			
Role limitation (physical limits)	Baseline	23.53±7.97	12.50±8.78	1.67±8.48	10.71±8.78	12.50±4.28	14.133 **(<0.001)**	2.053 (0.112)	0.238 (0.870)
	6 weeks	43.78±9.76	34.78±11.40	17.23±9.06	39.48±10.26	33.13±5.03			
	Δ6wk-baseline	20.25±11.04	22.28±12.74	15.57±10.59	28.77±11.73	20.63±5.62			
Role limitation (emotional issues)	Baseline	50.98±9.78	23.81±10.77	26.67±10.41	19.05±10.77	31.11±5.23	16.526 **(<0.001)**	0.369 (0.776)	1.838 (0.146)
	6 weeks	53.41±11.93	60.98±13.94	55.10±11.10	64.24±12.56	58.25±6.17			
	Δ6wk-baseline	2.43±13.31	37.17±15.37	28.44±12.75	45.19±14.14	27.14±7.02			
Energy & fatigue	Baseline	35.294.84	33.21±5.34	22.67±5.16	30.71±5.34	30.58±2.62	4.650 (0.34)	2.409 (0.072)	0.639 (0.592)
	6 weeks	48.56±5.75	35.67±6.67	26.95±5.45	26.63±6.09	39.92±3.00			

	Δ6wk-baseline	13.26±5.75	2.46±6.68	4.28±5.45	5.92±6.09	6.33±2.97			
Emotional wellbeing	Baseline	60.71±4.79	49.43±5.28	54.40±5.10	50.29±5.28	54.07±2.53	9.348 **(0.003)**	0.488 (0.692)	0.485 (0.693)
	6 weeks	63.81±5.67	61.86±6.57	64.25±5.38	60.76±6.00	62.80±2.89			
	Δ6wk-baseline	3.12±5.62	12.43±6.52	9.85±5.32	10.48±5.94	8.73±2.83			
Social functioning	Baseline	27.94±3.24	25.89±3.58	16.67±3.45	15.18±3.58	21.67±1.84	11.342 **(0.001)**	5.285 (0.002)	0.401 (0.753)
	6 weeks	37.15±3.98	33.36±4.66	20.98±3.69	26.30±4.19	29.07±2.16			
	Δ6wk-baseline	9.21±4.55	7.46±5.25	4.32±4.38	11.12±4.84	7.40±2.36			
Pain	Baseline	37.21±4.83	48.39±5.33	36.00±5.15	36.96±5.33	39.46±2.57	0.345 (0.559)	1.107 (0.350)	0.768 (0.515)
	6 weeks	44.91±5.95	44.02±6.96	33.65±5.51	44.49±6.25	41.27±3.05			
	Δ6wk-baseline	7.71±6.92	-4.38±7.97	-2.35±6.66	7.52±7.36	1.82±3.59			
General health	Baseline	43.82±4.82	38.93±5.31	39.67±5.13	27.86±5.31	37.92±2.65	15.839 **(<0.001)**	2.567 (0.059)	0.958 (0.416)
	6 weeks	54.10±5.40	53.59±6.17	44.30±5.31	33.98±5.78	46.17±2.89			
	Δ6wk-baseline	10.27±4.30	14.66±5.02	4.63±4.02	6.12±4.54	8.25±2.19			

PDC + AFJ: Personalised dietary consultations and active fruit juice; PDC + PFJ Personalised dietary consultations and placebo fruit juice; WLC + AFJ: Waitlist control group and active fruit juice; WLC + PFJ: Waitlist control group and placebo fruit juice. * Standard error; † Visual analogue scale; ^ Pain Self Efficacy Questionnaire; # Pain Catastrophising Scale.

Table 6.3. Dietary outcomes.

Outcome variable (mean ± SE*)	Time point	PDC + AFJ	PDC + PFJ	WLC + AFJ	WLC + PFJ	Total	Time F stat (p-value)	Group F stat (p-value)	Group x Time F stat (p-value)
Energy (kJ) (recommended intake)	Baseline	9247.00±932.65	9051.39±1034.68	9046.07±963.23	8138.00±1034.98	8870.61±496.16	4.210 (0.043)	0.032 (0.992)	1.263 (0.292)
	6 weeks	7708.05±1059.79	8399.67±1149.39	7736.72±1007.31	8487.45±1094.25	8082.97±239.08			
	Δ6wk-baseline	-1539.92±785.52	-651.72±835.58	-1309.35±689.08	349.45±753.60	-787.64±363.89			
Carbohydrates (% of total energy (E)) 45-65% (280)	Baseline	43.06±2.32	46.31±2.58	42.87±2.40	45.31±2.58	44.39±1.24	1.703 (0.195)	1.530 (0.212)	0.440 (0.725)
	6 weeks	40.33±3.01	46.06±3.21	38.04±2.65	44.61±2.90	42.26±1.47			
	Δ6wk-baseline	-2.74±2.29	-0.25±3.52	-4.82±2.97	-0.70±3.24	-2.13±1.63			
Protein (% total E) 15-25% (280)	Baseline	19.81±1.08	18.23±1.20	21.00±1.12	17.08±1.20	19.03±0.58	0.128 (0.721)	2.920 (0.038)	0.769 (0.515)
	6 weeks	18.50±1.35	18.38±1.44	22.22±1.21	17.95±1.32	19.26±0.67			
	Δ6wk-baseline	-1.31±1.32	0.15±1.41	1.21±1.18	0.88±1.28	0.23±0.65			
Fat (% total E) 20-35% (280)	Baseline	35.81±1.61	33.69±1.79	35.20±1.66	33.08±1.79	34.45±0.86	0.633 (0.428)	2.156 (0.099)	3.290 (0.024)
	6 weeks	30.09±2.10	32.07±2.23	39.13±1.84	32.87±2.01	33.54±1.02			
	Δ6wk-baseline	-5.73±2.30**	-1.62±2.47	3.93±2.09	-0.21±2.27	-0.91±1.14			
Saturated fat (% total E) < 10% (297)	Baseline	14.63±0.83	14.46±0.92	15.33±0.86	14.85±0.92	14.82±0.44	1.624 (0.206)	2.259 (0.087)	2.029 (0.116)
	6 weeks	11.88±1.08	13.70±1.15	16.50±0.95	14.21±1.03	14.07±0.53			
	Δ6wk-baseline	-2.75±1.18	-0.77±1.26	1.17±10.7	-0.63±1.16	-0.75±0.59			
	Baseline	2.00±1.26	2.39±1.39	1.47±1.30	5.23±1.39	2.77±0.67			

Alcohol (% total E) < 5% (297)	6 weeks	0.04±1.46	4.03±1.58	1.06±1.37	5.52±1.49	2.66±0.74	0.034 (0.854)	2.485 (0.066)	1.541 (0.209)
	Δ6wk-baseline	-1.96±1.18	1.65±1.26	-0.40±1.04	0.29±1.14	-0.12±0.18			
	Baseline	44.81±1.60	47.31±1.77	47.40±1.65	48.54±1.77	47.02±0.85			
Saturated fat (% total fat)	6 weeks	38.85±2.12	46.98±2.25	46.20±1.84	47.34±2.01	44.84±1.03	3.085 (0.083)	3.840 (0.012)	1.054 (0.373)
	Δ6wk-baseline	-5.97±2.48	-0.32±2.66	-1.20±2.27	-1.20±2.47	-2.17±1.24			
	Baseline	41.56±1.28	40.31±1.42	40.13±1.32	39.54±1.42	40.39±0.68			
MUFA (% total fat)	6 weeks	37.80±1.69	40.41±1.80	41.55±1.47	40.47±1.61	40.06±0.82	0.109 (0.742)	0.208 (0.891)	1.444 (0.236)
	Δ6wk-baseline	-3.76±1.99	0.10±2.14	1.42±1.83	0.94±1.99	-0.33±0.99			
	Baseline	41.56±1.28	40.31±1.42	40.13±1.32	39.54±1.42	40.39±0.68			
PUFA (% total fat)	6 weeks	37.80±1.69	40.41±1.80	41.55±1.47	40.47±1.61	40.06±0.82	0.109 (0.742)	0.208 (0.891)	1.444 (0.236)
	Δ6wk-baseline	-3.76±1.99	0.10±2.14	1.42±1.83	0.94±1.99	-0.33±0.99			
Fiber (g) 25-30 g/day (280)	Baseline	25.79±2.41	25.17±2.67	22.79±2.49	19.71±2.67	23.39±1.28	2.365 (0.128)	0.901 (0.444)	0.593 (0.621)
	6 weeks	23.54±2.86	23.19±3.08	19.15±2.65	20.24±2.88	21.53±1.44			
	Δ6wk-baseline	-2.25±2.47	-1.98±2.67	-3.74±2.18	0.54±2.38	-1.86±1.21			
Thiamin (mg)	Baseline	1.53±0.18	1.60±0.20	1.47±0.19	1.36±0.20	1.49±0.10	1.288 (0.260)	0.398 (0.755)	0.432 (0.730)
	6 weeks	1.43±0.21	1.57±0.23	1.21±0.20	1.34±0.22	1.39±0.12			
	Δ6wk-baseline	-0.10±0.18	-0.03±0.20	-0.26±0.16	-0.02±0.18	-0.10±0.09			
Riboflavin (mg)	Baseline	2.19±0.35	2.40±0.38	2.56±0.36	1.80±0.38	2.24±0.18	0.247 (0.620)	0.602 (0.615)	0.341 (0.796)
	6 weeks	2.18±0.37	2.38±0.41	2.34±0.37	1.84±0.40	2.18±0.19			
	Δ6wk-baseline	-0.02±0.23	-0.01±0.24	-0.23±0.20	0.04±0.22	-0.06±0.11			

Niacin (mg)	Baseline	26.99±2.60	23.693±2.88	24.16±2.68	20.70±2.88	23.87±1.38	0.703 (0.404)	0.358 (0.783)	0.948 (0.421)
	6 weeks	23.62±3.05	23.73±3.29	21.53±2.84	22.44±3.09	22.83±1.54			
	Δ6wk-baseline	-3.37±2.53	0.10±2.69	-2.63±2.23	1.75±2.44	-1.04±1.24			
Calcium (mg)	Baseline	971.25±226.83	1160.92±251.65	1483.19±234.27	827.11±251.65	1110.62±120.63	0.340 (0.562)	1.307 (0.277)	0.256 (0.857)
	6 weeks	972.89±238.22	1051.28±261.85	1445.13±238.12	847.12±256.59	1079.10±124.46			
	Δ6wk-baseline	1.63±111.10	-109.64±117.95	-38.06±96.61	20.01±105.78	-31.51±54.07			
Iron (mg)	Baseline	13.47±1.46	13.06±1.62	12.75±1.51	11.22±1.62	12.63±0.78	1.545 (0.217)	0.156 (0.925)	1.978 (0.123)
	6 weeks	11.40±1.62	13.16±1.77	11.04±1.56	12.26±1.69	11.96±0.83			
	Δ6wk-baseline	-2.08±1.09	0.10±1.16	-1.71±0.96	1.04±1.04	-0.66±0.53			
Zinc (mg)	Baseline	13.69±1.56	12.65±1.73	14.48±1.61	11.02±1.73	12.96±0.83	1.410 (0.238)	0.344 (0.793)	1.506 (0.219)
	6 weeks	11.68±1.74	11.72±1.89	13.27±1.67	12.36±1.81	12.26±0.89			
	Δ6wk-baseline	-2.01±1.21	-0.93±1.29	-1.20±1.06	1.34±1.16	0.70±0.59			
Core (%E)	Baseline	57.77±3.31	57.77±3.78	67.20±3.52	47.92±3.78	57.66±1.80	13.286 (0.000)	6.186 (0.001)	0.633 (0.596)
	6 weeks	61.88±3.94	61.67±4.20	75.52±3.68	52.34±3.99	52.85±1.98			
	Δ6wk-baseline	4.11±3.03	3.90±3.05	8.32±2.52	4.42±2.75	5.19±1.42			
Energy-dense, nutrient-poor (%E)	Baseline	42.24±3.21	42.23±3.78	32.80±3.52	52.08±3.78	42.34±1.80	13.286 (0.000)	6.186 (0.001)	0.633 (0.596)
	6 weeks	38.12±3.94	38.33±4.20	24.48±3.68	47.66±3.99	37.15±1.98			
	Δ6wk-baseline	-4.11±3.03	-3.90±3.05	-8.23±2.52	-4.42±2.75	-5.19±1.42			
ARFS†: Total (73 points)	Baseline	30.69±2.65	32.54±2.94	27.60±2.74	25.69±2.94	29.13±1.41	0.028 (0.868)	1.080 (0.362)	0.211 (0.888)
	6 weeks	31.49±3.06	31.95±3.23	26.64±2.85	26.82±3.08	29.30±1.53			

	Δ6wk-baseline	0.81±2.21	-0.59±2.22	-0.66±1.83	1.13±2.00	0.17±1.04			
ARFS: Vegetables (21 points)	Baseline	13.31±1.33	11.77±1.48	10.20±1.37	10.92±1.48	11.55±0.71	0.400 (0.529)	0.819 (0.487)	0.259 (0.855)
	6 weeks	12.77±1.67	13.10±1.72	10.64±1.47	11.49±1.60	12.00±0.81			
	Δ6wk-baseline	-0.54±1.50	1.33±1.52	0.44±1.26	0.56±1.38	0.45±0.71			
ARFS: Fruit (12 points)	Baseline	3.44±0.77	6.08±0.85	4.73±0.79	2.77±0.85	4.25±0.41	0.569 (0.453)	2.153 (0.099)	0.863 (0.464)
	6 weeks	3.70±0.90	4.92±0.94	4.62±0.83	2.82±0.90	4.01±0.45			
	Δ6wk-baseline	0.26±0.68	-1.15±0.68	-0.11±0.56	0.05±0.62	-0.24±0.32			
ARFS: Meat, chicken & fish (7 points)	Baseline	2.81±0.35	3.15±0.39	2.40±0.36	2.31±0.39	2.67±0.19	0.064 (0.801)	1.090 (0.358)	0.107 (0.956)
	6 weeks	3.03±0.46	3.01±0.47	2.45±0.39	2.40±0.43	2.72±0.22			
	Δ6wk-baseline	0.22±0.45	-0.14±0.46	0.05±0.39	0.10±0.42	0.06±0.22			
ARFS: Vegetarian choices (6 or 12 points)	Baseline	2.13±0.31	1.85±0.34	1.47±0.32	1.54±0.34	1.74±0.17	1.663 (0.201)	0.940 (0.425)	0.160 (0.923)
	6 weeks	1.72±0.42	1.74±0.42	1.33±0.35	1.13±0.38	1.48±0.20			
	Δ6wk-baseline	-0.41±0.43	-0.11±0.44	-0.14±0.37	-0.41±0.40	-0.27±0.21			
ARFS: Grains (13 points)	Baseline	3.94±0.47	3.92±0.52	4.07±0.48	3.54±0.52	3.87±0.25	1.189 (0.279)	0.182 (0.908)	1.350 (0.264)
	6 weeks	4.41±0.61	4.44±0.62	3.50±0.52	4.32±0.57	4.17±0.29			
	Δ6wk-baseline	0.47±0.58	0.52±0.59	-0.57±0.49	0.78±0.54	0.30±0.28			
ARFS: Dairy (11 points)	Baseline	3.38±0.46	4.62±0.51	3.27±0.47	3.54±0.51	3.70±0.24	0.363 (0.548)	0.782 (0.507)	0.959 (0.416)
	6 weeks	3.67±0.57	3.79±0.59	3.15±0.50	3.63±0.55	3.56±0.28			
	Δ6wk-baseline	0.29±0.50	-0.83±0.50	-0.12±0.42	0.09±0.46	-0.14±0.23			
	Baseline	1.19±0.18	0.62±0.20	0.73±0.19	0.62±0.20	0.79±0.10			

ARFS: Condiments (2 points)	6 weeks	1.46±0.24	0.86±0.24	0.53±0.20	0.86±0.22	0.93±0.11	1.460 (0.230)	3.374 (0.022)	1.115 (0.347)
	Δ6wk-baseline	0.27±0.24	0.25±0.25	0.20±0.21	0.25±0.23	0.14±0.12			
	Baseline	0.50±0.12	0.54±0.14	0.73±0.13	0.46±0.14	0.56±0.07			
ARFS: Water (1 point)	6 weeks	0.75±0.15	0.61±0.16	0.85±0.13	0.30±0.15	0.63±0.07	1.138 (0.254)	1.867 (0.141)	1.911 (0.134)
	Δ6wk-baseline	0.25±0.13	0.08±0.13	0.11±0.11	-0.16±0.12	0.07±0.06			

PDC + AFJ: Personalised dietary consultations and active fruit juice; PDC + PFJ Personalised dietary consultations and placebo fruit juice; WLC + AFJ: Waitlist control group and active fruit juice; WLC + PFJ: Waitlist control group and placebo fruit juice. * Standard error; † Australian Recommended Food Score; ** statistically significant.

6.4.8 Process evaluation

Overall there were no significant differences between groups in satisfaction and measures obtained within the study process evaluation from participants who completed the study (n=42). The majority of these participants were either satisfied (n=16) or very satisfied (n=19) with the study overall. The remaining participants (n=7) responded as 'neutral' when reporting their satisfaction with the study. Overall participants were satisfied or very satisfied with the AES FFQ (n=32), with nine stating they felt neutral and one unsatisfied. Thirty-six participants were satisfied or very satisfied with the fruit juice, with five participants responding as 'neutral' and one participant stating they were unsatisfied.

For those participants who participated in the PDC and who completed the study (n=16 of 42), 100% of participants agreed or strongly agreed that the AES personal nutrition report was useful, helped them to identify areas of their diet that could be improved or areas they were already doing well and that it provided enough information to guide changes to their dietary intake. Overall, 15 participants were satisfied or very satisfied with the AES report and one remained neutral. In terms of the dietary consultations, 12 participants were satisfied or very satisfied with four participants remaining neutral. Participants agreed or strongly agreed that being involved in the behavioural intervention had encouraged them to consume more fruit and vegetables (100%), less energy-dense, nutrient-poor foods (88%), read nutrition labels (88%), change the food products they commonly purchase (94%), and set nutrition goals (94%).

6.5 Discussion

The aim of the current pilot study was to evaluate whether provision of personalised telehealth dietary consultations with or without supplemental fruit juice high in anthocyanins could lead to a reduction in pain scores within a clinical population experiencing chronic pain. Of all the pain, quality of life and dietary outcomes the only significant group by time effect was for the reduction in total percentage energy from total fat favouring the PDC and AFJ group (-5.7±2.3%, p=0.024). Other significant results involved all groups which demonstrated statistically significant improvements in three pain variables, six quality of life categories and three aspects of dietary intake. This pilot study provides a comprehensive description of the change in dietary intake and diet quality compared to the studies identified in the systematic review (264) where

few provided a clear description of the intervention and/or a change in these outcomes. The current pilot study provides valuable data and insights on the feasibility of conducting an evidence based dietary intervention in a clinical population experiencing chronic pain and will be used to inform the design in future trials.

When comparing the current participants' demographic and pain information to the Australian and New Zealand dataset consisting of 16790 individuals with chronic pain from 2016 the electronic Persistent Pain Outcomes Collaboration (ePPOC), the current pilot study sample included more women, participants of Aboriginal or Torres Strait Islander descent and individuals of higher weight status as measured using BMI (23). Participants in the current pilot study were younger, had a higher BMI and reported slightly less pain compared to Australian and New Zealand population data, however all other characteristics were similar between sample populations (23). These similarities indicate that the participants in this current study are similar to patients attending pain services in Australia and New Zealand and suggest the results from the current pilot study may be generalisable to the Australian and New Zealand populations experiencing chronic pain.

Diet quality in the current pilot study was measured by the Australian Recommended Food Score (ARFS), which is a validated brief diet quality index that provides an indication of the relationship between consuming a variety of whole foods and chronic disease risk with a higher score indicating higher intake and lower risk of disease (298, 299). Low diet quality is linked to an increased risk of cardiovascular disease, some cancers and higher all-cause mortality (299). Given that comorbidities are highly prevalent in individuals experiencing chronic pain, more so at HIPS compared to other services (154), it is not surprising that participants reported low diet quality at baseline and 6 weeks, reflective of limited diet variety overall and also within food group categories. Williams et al. found that the total ARFS among a group of Australian adults (n=93,252) was 34.1±9.7; vegetable subcategory 11.5±4.3; fruit 5.5±2.9; meat 3.0±1.6; meat alternatives 2.6±1.3; grains 5.7±2.3 and dairy 4.0±2.1 (298). With the exception of the vegetable subcategory, diet quality of participants in the current pilot study is lower than those in the general population and remained low post-intervention which is of concern. The vegetable category was comparable between studies with the current pilot study identifying that at baseline, the vegetable score was 11.6±0.7 (out of a possible

21) which indicates that overall, the variety of vegetables usually being consumed over a week in both populations is low. The current pilot study is one of very few to have reported on diet quality of patients attending a chronic pain service, rather than reporting only selected nutrients (264). These results suggest that a bigger emphasis should be placed on how to improve overall diet quality and diversity by improving intakes of a range of nutrient-rich foods and future studies should investigate potential barriers contributing to these poor diet quality results.

There were significant reductions in total energy intake, percentage energy from energy-dense, nutrient-poor foods and a significant increase in percentage energy from nutrient-rich core foods in all intervention groups over the duration of the pilot study. The 2011-2012 National Nutrition and Physical Activity Survey (NNPAS) (300) estimated the percentage energy from energy-dense, nutrient-poor foods and macronutrients using a single 24 hour recall collected on 12,000 Australian adults (154). While different dietary assessment tools were used in the NNPAS compared to the current pilot study, it is interesting to compare dietary intakes of the Australian population with the participants in the current pilot study. The NNPAS reported that in Australia, energy-dense, nutrient-poor foods were contributing 35% of total energy intake (300). At baseline, the participants in this study had 42% of their energy coming from energy-dense, nutrient-poor foods and after the intervention this reduced to 37% which is closer to national data. The distribution of the percentage of energy intake from carbohydrate (NNPAS: 45%, this study: 44%) and protein (18%, 19%) is similar between the two studies (300). There were differences in total fat, saturated fat and alcohol with total fat (34%) and saturated fat (15%) higher in this study compared to the NNPAS (31% and 12% respectively) (300). The contribution of alcohol to energy intake was lower in this study (2.8%) compared to the national data (3.4%) (300). From a global perspective, the dietary intake of the participants in this current study can be compared to studies conducted in the United States of America (USA) and Europe. The 2003-2006 National Health and Nutrition Examination Study (NHANES) conducted in the USA collected dietary intake data for 9490 adults using 24 hour recall (301). There were 20 food groups identified as contributing to energy intake (301). Of these food groups half can be classified as energy-dense nutrient-poor foods and approximately 37% of the total energy intake came from these foods (301). Compared to this current study, the percentage energy coming from energy-dense nutrient-poor foods is equal after the

intervention where it was calculated that 37% of the energy intake of participants in this current study was coming from energy-dense nutrient-poor foods. Total energy intake was higher in the NHANES study (9247 kJ) (301) compared to this current study where at baseline participants were consuming 8870 kJ on average. The distribution of percentage energy from carbohydrates was higher in the USA (52%) compared to 44% in this current study while the percentage energy from protein was lower (NHANES: 15%, this study: 19%) (301). Percentage energy from fat intake was the same with both studies reporting 34% whereas saturated fat contributed less in the USA (12%) compared to this study (15%) (301). Total fiber intake was higher in the USA (28 g) compared to this study (22 g) (301). The European Prospective Investigation into Cancer and Nutrition (EPIC) have also collected dietary intake data using a 24 hour recall in 37,000 residents across 10 European countries (302). On average the energy intake for males in Europe was higher than this current study with a range of 9223-12083 kJ (compared to 8870 kJ) and lower for females with a range from 6968-8694 kJ (compared to 8870 kJ) (302). There are vast dietary patterns across Europe which are reflected in the ranges of percentage energy coming from carbohydrates (35-50%), protein (13-21%) and fat (30-42%) (302). The percentage energy coming from carbohydrates (44%), protein (19%) and fat (34%) at baseline in this current study all fall within these ranges (302).

There were two components to the current dietary intervention, the personalised dietary consultations and the dietary supplement. While there was no change to diet quality from the reported intake between groups the process evaluation shows that it was well accepted. This mirrors results from a recent study which found that nutrition-related goals were reported as being popular among people with chronic pain [50]. While some chronic pain services utilise telehealth to reach patients, it is not used to deliver targeted nutrition advice in a chronic pain population which makes this a unique pilot study. While only 61% of those randomised to the PDC groups attended any of the consultations, of the 61% who did attend, 89% (n=17) attended the two recommended dietary consultations and/or the third optional consultation. Participants were also highly satisfied with the pilot study and its components. These results suggest that the use of telehealth was acceptable and satisfactory for the delivery of nutrition care to most patients with chronic pain. However, 39% of participants randomised to the PDC groups did not take part in the telehealth intervention component and further exploration

of the reasons behind lack of engagement in this mode of healthcare delivery is warranted.

The limited between group differences in the current pilot study may be attributed to the small sample size and potentially a placebo effect such that people enrolling in a dietary intervention, regardless of what intervention they received, had an improvement in pain, quality of life and dietary intake. Current literature suggests that participants in experimental trials are likely to have a larger placebo effect compared to a clinical trial and this is particularly so for placebo analgesia research such as this pilot study, potentially due to the neurotransmitters associated with the placebo response which are shared with the pain experience (303). In addition, both chronic pain and the placebo effect have a biopsychosocial component. The biomedical aspect involves the neurotransmitters and both chronic pain and the placebo effect share the same neurotransmitters which include opioids and dopamine (304). These are mediated by expectancy, conditioning, motivation and reward. For example, the expectancy of a reduction in pain can activate the opioid mediated analgesics pathways and can lead to an increase in endogenous opioids in those people who experience this. In terms of dopamine, reduced pain can be seen as a reward and the prospect of pain relief (real or placebo) can stimulate the dopaminergic pathway leading to a reduction in the chronic pain experience. These responses are also modulated by the context or the psychosocial aspects of receiving a placebo treatment. The relationship between the participant and the researcher influences the placebo response. Attending a medical specialist appointment or participating in a research study triggers a response before any treatment is given. Studies have shown that a placebo treatment is effective in people with chronic pain (304-306). It is possible in this pilot study, that the participants had high expectations, especially given the novel nature of the treatment. Anecdotally many participants expressed that they were willing to 'try anything' to help relieve their pain. The current pilot study was also delivered by a qualified expert in nutrition and dietetics and supported by clinicians from a tertiary pain service, hence the experience and credibility of the research team which may have influenced the participants' expectations coming into the study and therefore contributing to a placebo response (303, 304).

This current pilot study found clinically important results favouring the PDC relative to the WLC groups. Clinically important changes for the BPI, PSEQ and PCS have been established through the establishment of ePPOC (75). For pain severity (BPI) minimal, moderate and substantial improvement is classified as an increase by 10%, 30% or 50%, respectively, with emphasis on moderate and substantial change (75). In the current pilot study, only the PDC and PFJ group reached minimal clinically important improvements. Clinically important change for pain interference (BPI) and self-efficacy (PSEQ) was achieved in both PDC groups, as demonstrated by at least a one point reduction in the BPI score and seven or more point increase, with movement to a lower pain severity category in the PSEQ (75). There were no clinically important results for the PCS. In terms of the VAS there are mixed reports in regard to what is considered clinically important, with some studies reporting a 2.5 cm change and others reporting a 3 cm change is considered clinically important (125, 296). In the current pilot study, there was a clinically important group effect when all groups were combined, with >3 cm decrease in pain as measured by PDC groups having the highest change compared to the WLC groups with a maximum 2 cm reduction. These results indicate that the treatment effect for people experiencing chronic pain is of a sufficient magnitude to warrant clinical pain services to consider including a personalised dietary intervention into their treatment program to further improve the pain experience of their patients. In the current pilot study, 52% of participants had clinically important changes in pain interference and pain self-efficacy. This change can be compared to data reported by ePPOC that 68% of patients had clinical important improvements in pain interference and 48% in pain self-efficacy (23). Two studies have examined the effect of the use of amitriptyline in managing pain triggered by spinal cord injury (307) or amputation (308). These studies did not find any statistically significant results post intervention (307, 308). However when the data was pooled and examined for clinical importance, approximately one third (33%) of participants reported a clinically meaningful reduction in pain, as measured using a self-reported pain rating scale (309). Similarly, a study exploring a self-help intervention based on acceptance and commitment therapy found that 28% of those in the intervention group had a clinically important benefit for pain interference (310). The proportion of participants who had a clinically meaningful reduction in pain is lower in both of these studies, compared to this current pilot study and multidisciplinary care (as shown in ePPOC data). The differences between these

studies and the current pilot study is that the use of medication is a passive treatment, while self-help provides personalisation or guidance to assist participants.

One of the limitations of this study is the high loss to follow up with 30% of participants dropping out of the study with a higher proportion coming from the treatment groups than the control groups. In addition, of those who were randomised to receive the personalised dietary consultations only 61% completed at least one session. It is possible that only those who perceived a benefit from the study decided to complete the study. The small sample size and lower power to determine statistically significant outcomes are other limitations of the current study. However, it is a pilot study to determine whether the inclusion of a telehealth component for delivery of personalised dietary counselling by a dietitian is acceptable and the preliminary impact over a relatively short duration. The current study demonstrates the feasibility of this technology in delivering nutrition care to this group. Many individuals with chronic pain have additional barriers to attending physical in-person sessions with a dietitian. As such, this further supports the need for a larger, appropriately powered trial to determine effectiveness.

To the authors' knowledge, this is the first pilot study to implement a comprehensive dietary intervention of high methodological quality within a chronic pain clinical population. The other strengths of the current trial should be acknowledged and include the stratification of males and females as part of the randomisation process. The current pilot study also addressed some of the limitations of current literature exploring nutrition's role in pain management (264), such as providing a clear description of the dietary intervention used compared to previous studies of the effect of nutrition in pain management which have had poor descriptions. Furthermore, validated measures to assess pain, quality of life and dietary intake were used. Previous studies have often relied on a single item measure, such as a VAS, which is easy to implement but does not capture the complexity of pain. Other tools such as the BPI, PSEQ and PCS incorporate the biopsychosocial factors involved in the pain experience and provide a multidimensional measurement of pain. The current pilot study included all these measures so that results could be more easily compared to other studies which used a VAS, but also to provide a robust assessment of pain using multidimensional tools. The current pilot study also includes a validated FFQ to accurately evaluate participants'

dietary intake and diet quality. Providing detailed description of methods and intervention allows replication and future refinements.

6.6 Conclusions

While group-by-time differences were not statistically significant, all groups demonstrated improvements in perceived pain, quality of life and dietary intake. Improvements in pain interference and pain self-efficacy were clinically meaningful in the two groups receiving personalised dietary consultations compared to the waitlist control groups. The current pilot study demonstrates potential benefits from providing people who experience chronic pain with a personalised dietary intervention using telehealth. The current pilot study provides data to inform sample size calculations for a future multicentre trial to determine the efficacy of a personalised dietary intervention as part of chronic pain management. Future studies should also consider potential motivators and barriers which may have contributed to the results of the current pilot study to improve the trial design and success of future studies.

Chapter 7: Thesis Discussion

This thesis comprises five studies which are presented in Chapters' 2 to 6. These collectively aim to answer the overall research question: *How can people experiencing chronic pain use nutrition as part of their pain management approach?* These chapters also address the Primary Aims which are:

1. Generate new evidence to address gaps in the literature exploring the role of dietary intake and nutrition in the management of chronic pain.

2. Develop, implement and assess the effectiveness of a personalised dietary intervention for people experiencing chronic pain.

These chapters also address the Secondary Aims outlined in Figure 7.1.

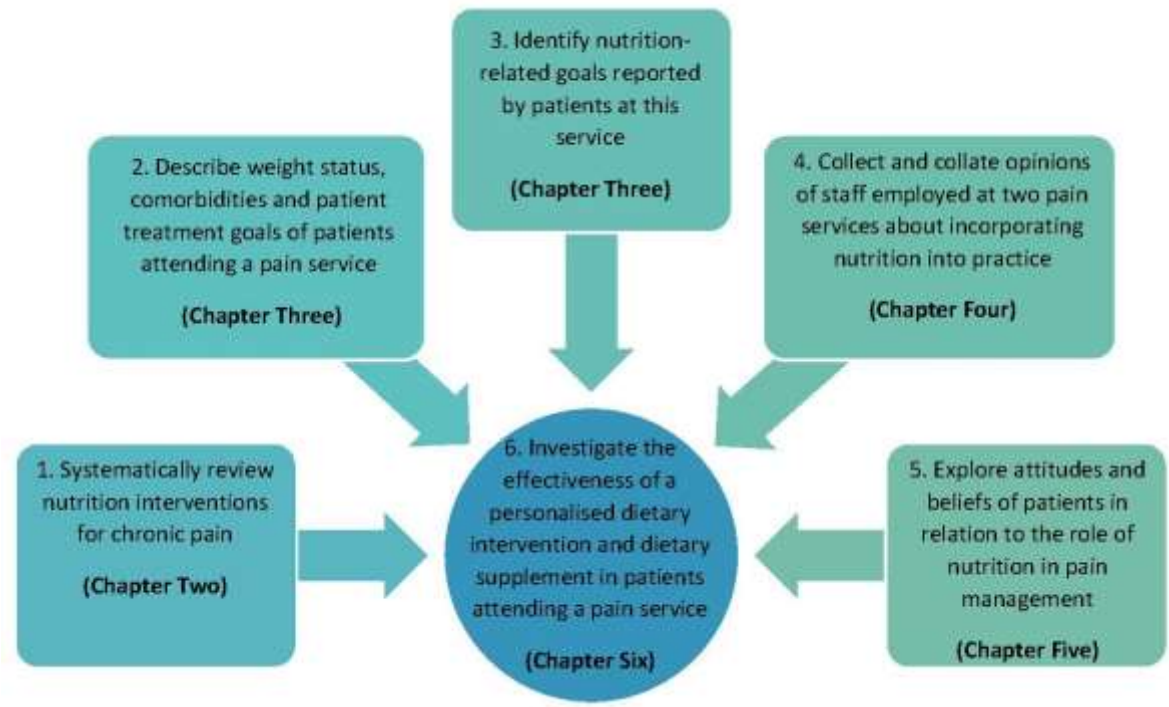

Figure 7.1: Relationship between the Secondary Aims and chapters in this thesis

The purpose of this final chapter is to synthesise the findings across studies and to discuss the overall findings. The strengths and limitations will also be acknowledged and a series of recommendations for future research and implications practice will be presented.

7.1 Summary of findings

7.1.1 Chapter 2: A systematic review and meta-analysis of nutrition interventions for chronic non cancer pain

This chapter has generated new evidence by being the first to collectively synthesise existing nutrition interventions that had aimed to help people experiencing chronic pain or related conditions (Primary Aim 1). This provided a rationale and ground work for the development of the intervention study presented in the 6th Chapter (Primary Aim 2) of this thesis.

Seventy-one studies were included in the review with the majority (n=46) of existing studies prescribing participants a nutrition supplement such as omega-3, vitamin or mineral supplement. Following this only 16 studies altered overall diet, examples of this were prescribing participants a vegetarian or vegan diet; five studies altered a single nutrient such as fibre or fat and finally four studies tested the effectiveness of fasting by restricting energy intake to 300-350 kJ/day. Of all the studies included, those which sought to alter overall dietary intake had the highest proportion of studies (12 out of 16) which reported statistically significant results. The meta-analysis of a sub-set of studies that used a VAS for self-reported pain found that overall a change in any aspect of diet has a statistically significant reduction in self-reported pain severity with studies changing overall diet or a single nutrient having the greatest effect.

This review demonstrated that there is a large variation in the types of nutrition interventions which have been investigated to date. Even within each category there is diversity, for example those which prescribed a nutrition supplement used different types and doses of supplements. In addition, many of these studies concentrated on the triggers to chronic pain, rather than chronic pain itself. Only two studies recruited people experiencing chronic pain, while the remainder recruited those with a pain related condition such as rheumatoid or degenerative arthritis, which are considered a trigger for chronic pain. Both the variety of nutrition interventions and the complexity of chronic pain has led to large heterogeneity amongst the included studies.

This review identified many limitations including poor methodological quality and poor reporting of dietary interventions. This has left gaps in the current evidence exploring the effect of nutrition intervention on the pain experience. There is need for further

research to address these limitations and for high quality studies to be conducted which clearly report the intervention components, so that researchers can identify the most effective interventions for pain management.

7.1.2 Chapter 3: Population characteristics in a tertiary pain service cohort experiencing chronic non-cancer pain: Weight status, comorbidities and patient goals

Limited information exists on the weight status, comorbidities and treatment goals set by patients in a clinical setting. This chapter addresses this gap by collating and analysing this information from patients attending Hunter Integrated Pain Service (Primary Aim 1). This chapter also identifies the number and type of nutrition related goals set by patients in order to examine the need and want for nutrition education by patients attending this service. This will assist in formulating the intervention presented in Chapter 6 (Primary Aim 2).

Data was collected from two key tools which were completed by patients attending Hunter Integrated Pain Service between June-December 2014. These tools included: 1) The ePPOC referral questionnaire (n=166) which collects information on demographic, pain description and weight and 2) The Pain Assessment and Recovery Plan (PARP) (n=153) which is used for patients to identify problems and corresponding solutions associated with their pain experiences. The PARP incorporates the five key areas which make up the whole-person approach to pain management: biomedical, mindbody, connection, physical activity and nutrition.

The average BMI was 31±7 kg/m^2 (range 18.52-54.46 kg/m^2) with 21% patients in the normal BMI category (18.5-24.99 kg/m^2), 33% in the overweight category (25-29.99 kg/m^2) and 45% in the obese category (≥30 kg/m^2). The majority of these patients (87% females and 77% males) had a waist circumference that put them at risk of developing a chronic disease (≥80 cm females and ≥94 cm for males). Twenty-three percent of patients set a nutrition related goal, this was second to physical activity (39% of patients chose a physical activity related goal). Of those who chose a nutrition related goal, 27% wanted to improve their overall diet; 47% specifically indicated one of the following: reduce soft drink or sugar consumption, reduce portion size, and increase vegetable intake or water intake, with the last 27% wanting to reduce their weight or waist circumference.

This study allowed for the opportunity to evaluate weight status, comorbidities and patient treatment goals of patients at a tertiary pain service in a metropolitan area of New South Wales, Australia. Time is often limited in a clinical setting and while processes are in place to analyse and compare data on patient demographics and pain outcomes via ePPOC, a national outcome database, the exploration of other important aspects such as diet does not occur which is an important contributor (9, 107) to an individual's pain experience and their outcomes. Understanding the weight status and comorbidities of people experiencing pain provides a benchmark for possible nutrition intervention studies within pain services in the future. Furthermore, analysis of the treatment goals set by patients themselves highlighted that diet and nutrition is of interest and importance to patients and there is a need to explore this further in order to provide high quality care that is patient centred.

7.1.3 Chapter 4: Perceptions of tertiary pain service staff on including nutrition support within current treatment: A qualitative study

Qualitative data provides a wealth of information which goes beyond quantitative data sets. Gathering the experiences of staff who work with people experiencing pain provides valuable insight into the facilitators and barriers which may encourage or deter patients to change their behaviour. This is a novel study which provides information which has not been previously explored (Primary Aim 1). The insight obtained in this study was used to inform the development of the intervention study (Primary Aim 2). Additional insight was also obtained to see how a nutrition intervention would fit into an existing service and identify areas for future capacity building. This is particularly important in chronic pain management due to the complexity of the condition and the multiple factors that influence both the patient and clinician experience. The data presented in this chapter also complements data collected from patients which is presented in Chapter 5. The viewpoints of both staff and patients provide a more holistic understanding of the person experiencing pain and those staff managing pain within a tertiary pain service.

Two focus groups were held with staff from Hunter Integrated Pain Service (HIPS), a metropolitan service and one with Tamworth Integrated Pain Service (TIPS), a rural service, with the aim to collect the thoughts and opinions of staff regarding the integration of nutrition support into existing clinical practice. The disciplines

represented at these focus groups included nursing (n=5), administration (n=3), psychology (n=2), physiotherapy (n=2) and medical (n=1). There was a wealth of experience among staff with the average time worked in their respective disciplines 18.4±12.8 years (range 2-36 years) and more specifically the average time worked in the speciality of pain management 6.5±6.6 years (range 1-20 years).

In relation to perceived benefits to patients for providing a nutrition intervention, the main concepts which emerged included whole-person wellness (e.g. good nutrition goes beyond pain management) and providing skills and self-confidence to the patient. The key barriers staff perceived for patients included psychological relationship with food (e.g. pleasure of food and reward processes), lack of motivation, low health literacy, food environment (e.g. marketing and availability of processed foods) and access (both distance and availability of Accredited Practicing Dietitians (APD's)). Benefits for the pain service identified were the provision of a whole-person treatment approach and improved patient outcomes. Barriers for the service identified were: time (e.g. extending programs to include more nutrition may strain current resources and may lead to participant fatigue), lack of dietetic expertise within the service, and lack of confidence in current staff to provide nutrition advice. Preferences for intervention content were: evidence-based, simple education and skill development with practical strategies and visual incentives, with a focus on nutritional benefits for pain experiences, not weight management. The overall preferred intervention delivery method was a flexible combination of face-to-face and online/technology-based resources with the intervention ideally developed and/or delivered by an APD.

Technology is not routinely used to provide care at these services so the use and confidence of using technology was also explored with participants stating that it does allow for a wider reach and assists with monitoring success (e.g. using a Fitbit). Staff felt confident using it but concerned about the added time it might take to set up and learn how to use and teach the software.

Staff acknowledged the importance and need to include dietitians into current pain services. Another important finding which should be considered when informing future studies is that the focus of a nutrition intervention should be on pain management rather than weight management. Despite mixed feelings about patients using technology to deliver services, the use of technology helps to overcome barriers such as access and

travelling long distances to access speciality services. While the majority of Australians have access to the internet (86%) and/or a smartphone (88%) (138, 140) there are still some barriers to providing nutrition advice in public and private healthcare settings. Currently, the Medicare Benefits Scheme does not cover telehealth appointments with allied health professionals, including dietitians. This means patients cannot get financial assistance for attending such appointments (266). Telehealth appointments are an excellent solution to access issues and as such allied health professionals, especially dietitians and the Dietitians Association of Australia need to continue to advocate for the inclusion of allied health professionals on the Medicare Benefits Scheme. It would also be important to conduct these focus groups with staff from other diverse speciality pain services to ensure that all viewpoints are taken into consideration as there would be different needs at different services.

7.1.4 Chapter 5: Exploring the attitudes and beliefs of nutrition's role in pain management through semi-structured focus groups with patients experiencing chronic pain

As stated in section 1.3 this study complements Chapter 4 by examining the thoughts of patients attending Hunter Integrated Pain Service (HIPS). There are no previous studies which have utilised qualitative methods to collect the views and experiences of people experiencing chronic pain in relation to nutrition's role in pain management (Primary Aim 1). The findings from this study also informed the development of the intervention study presented in Chapter 6 (Primary Aim 2).

Focus groups (n=5) were also conducted with patients (n=21) from HIPS. Approximately half of the participants reported that they completed the household food shopping and cooking for themselves; 24% and 33% reported their partner did the food shopping and cooking; while 24% share the food shopping and 14% share the cooking with another family member. All participants owned at least one device with a smartphone being the most popular followed by laptop, tablet and desktop. Participants expressed mixed responses with some stating they felt confident using technology and supported the idea of using it to deliver the intervention whereas others stated opposite views and lacked confidence in knowing what information they should look for online. Patients felt they would gain overall health benefits and an increase in knowledge, skills and feelings of self-worth. The key barriers patients identified were cost, lack of

motivation and knowledge, limited mobility, living alone and solicitous family members.

Patients expressed that they would like personalised or custom made education about nutrition and pain as well as nutrition's role in managing other chronic diseases. Practical suggestions and cooking demonstrations were also popular. Overall, patients wanted the intervention to be delivered using a group or workshop setting with some supporting the use of technology and others preferring in-person sessions. Ultimately patients expressed that the best way to deliver the intervention would be to incorporate the two delivery methods to increase flexibility

This chapter highlights the need for nutrition education due to misinformation and misconceptions, as exampled by participants believing coconut oil is a healthy choice. It also demonstrates a want for nutrition education for individuals experiencing chronic pain. Participants expressed a desire to learn more about nutrition for pain management and other health benefits such as reducing blood pressure and cholesterol levels. Participants also wanted simple and practical resources with flexible delivery methods. As previously discussed, telehealth is a perfect solution to barriers such as access, however as identified in the focus groups held with patients, cost is a major issue to accessing allied health or dietetic services. This highlights the need to generate evidence on the feasibility, acceptability and effectiveness of nutrition care via telehealth for patients with chronic pain. It also provides important evidence supporting the need to advocate for policy change and for dietitians and other allied health professionals to be included on the Medicare Benefits Scheme for telehealth.

7.1.5 Comparing and contrasting responses from staff focus groups (Chapter 4) and patient focus groups (Chapter 5)

There were many similarities between the responses discussed in the staff focus groups and the patient focus groups.

7.1.5.1 Perceived benefits for patients for participating in a nutrition intervention

Staff were asked what they perceived the benefits would be for patients participating in a nutrition intervention. The discussion closely mirrored that of the patients when asked what they perceived the benefits would be for themselves in participating in a nutrition

intervention. There were no concepts which were unique to either the patient focus groups or staff focus groups.

Both staff and patients identified that patients would receive overall health benefits, beyond that of pain management. Staff and patients spoke about broad health benefits such as feeling more energetic, overall wellness and happiness. The patients were more specific as they also identified improvements to their blood pressure or cholesterol levels.

Improving knowledge and self-confidence were also common in both groups. Staff particularly noted the mistaken nutrition-related beliefs that patients have for example in thinking that potato chips are a vegetable. This was also identified in the patient focus groups where some patients thought that coconut oil was a healthy food which can be consumed regularly. These examples demonstrate the need for evidence-based nutrition education to ensure that patients are able to learn what is genuinely a healthy option. Patients also identified gaps in their own knowledge as they expressed a benefit would be knowing what healthy foods are, especially those that help with pain and gaining knowledge on what is a healthy portion size to help control food intake.

Self-confidence was also a major concept which was discussed by staff and patients. Staff felt that patients perceive themselves as incapable of making healthy lifestyle changes. Patients felt that by participating in a nutrition intervention they would gain pride, motivation and self-confidence in making nutrition-related and overall lifestyle changes. Extrapolating these concepts identified by patients, puts into context another point which was raised by staff in that they felt changing diet was easier than some of the other changes required of patients attending HIPS e.g. weaning opioids. Patients seemed to support this by implying that the self-confidence they would gain from a nutrition intervention would help them in making other lifestyle changes.

7.1.5.2 Perceived barriers to patients participating in a nutrition intervention

A distinctive difference between staff and patients responses were seen when asked of the barriers to participating in a nutrition intervention. Patients spent most of their time discussing the costs involved and how that would impede their participation or success in being involved in a nutrition intervention. Everyday costs were discussed at first, and

then drilled down to debating the difference in cost between healthy and unhealthy foods with some feeling it was more expensive to eat a healthy diet and others felt the opposite. Other costs such as travelling to access the intervention or other health care costs such as those associated with health care professional appointments were also discussed. Of all the staff who participated in the focus groups, only one mentioned the cost of seeing an Accredited Practicing Dietitian (APD) as a barrier. Other staff felt that the difficulty accessing APD's would be a greater barrier.

While cost of healthy food options dominated the patient focus groups, there were some similarities between the groups. Some patients identified that food marketing, especially in the media made it difficult to make healthy food choices. This was also identified by staff as a perceived barrier for patients and discussed in the staff focus groups in more detail.

Patients also discussed their ability to shop and prepare food as a barrier to healthy eating which was not identified by staff. However, in contrast, staff identified that comfort eating may be a potential barrier which was not identified by patients.

7.1.5.3 Intervention inclusions and delivery

Interestingly, when asked about what should be included in a nutrition intervention, staff initially focused on the education topics whereas patients' first response was that the intervention had to be easy. Staff also identified that interventions had to be easy and simple and patients did give some suggestion as to what they wanted to learn, however the priorities between the two groups seemed to differ.

A major concept which was identified by staff was that the nutrition intervention should focus on pain management and not weight management. Patients wanted to know about foods to help with pain as well as other chronic diseases such as heart disease and diabetes. Patients did not discuss weight as a focus of the intervention. Patients may not have brought this up for the same reasons that staff did discuss this. Staff felt that weight is a sensitive issue and surrounded by stigma which makes it a topic which both patients and some clinicians want to avoid. It is possible that patients did not discuss weight management for these reasons. Alternatively patients may not prioritise weight as being an issue when compared to pain management, heart disease or diabetes.

Patients were more concerned with ensuring that any intervention would be easy to understand and implement given their pain experiences. Patients also wanted practical and hands on type help with cooking demonstrations being a popular suggestion.

There were also similarities with both staff and patients suggesting visual aids and interactive activities rather than being dictated too. Staff and patients also suggested to include healthy recipe options.

There was consensus among both staff and patients about the preferred delivery method of the intervention. This was to use a combination of both in-person and technology in order to make it flexible and readily available to all patients, regardless of their location and ability to use technology. The preferred delivery for the in-person component is by a group workshop which could be easily integrated into the current group program provided by HIPS (74). Patients identified one of the main benefits of a group setting, from their perspective was the ability to bounce ideas off and support each other.

7.1.5.4 Use and confidence of using technology

There were mixed responses among staff and patients about their ability to use technology. Staff felt reasonably comfortable using technology but emphasised that it would need to be easy to use and timely. Staff felt that patients would benefit from using technology to monitor their food intake and activity by using apps and wearable devices. In contrast, patients focused more on whether they felt confident using technology or not with some happy and confident using devices such as computers, or smartphones and others who were not interested in using these devices or unsure how to identify evidence-based and high quality information on the internet.

7.1.6 Chapter 6: The effect of a pilot dietary intervention on pain outcomes in patients attending a tertiary chronic pain service (ReJUICE your pain study)

The final chapter of this thesis brings together the findings from all the preceding chapters. The systematic review reaffirming that changing dietary intake can reduce pain experiences as well as identifying limitations within existing intervention studies which were addressed in this current study. A need and want or desire for a nutrition intervention was confirmed by analysing patients' treatment goals in Chapter 5. Finally, the two qualitative studies with staff and patients provided insight into the facilitators

and barriers to behaviour change as well as the preferred intervention inclusions and delivery method. For example, the participants in both focus groups indicated that they would like the delivery of a nutrition intervention to be flexible and as such they were encouraged to utilise video coaching for their personalised dietary consultations, however phone calls were also made available. These were taken into account in the development of this study where the feasibility and effect were examined (Primary Aim 2).

A six week randomised control trial was conducted to test the effectiveness of two dietary interventions on pain scores, quality of life and dietary intake of patients attending Hunter Integrated Pain Service. The personalised dietary advice was chosen because it was identified in the systematic review that overall dietary change reduces pain, however the focus groups also identified a number of barriers (e.g. limited mobility or motivation) which are better addressed using a personalised approach (137). The cherry juice was chosen as it was identified in the systematic review and other studies (127, 264) as a novel and potentially effective bioactive dietary supplement for pain. Sixty participants were randomised to one of four groups:

1. Personalised dietary advice and active fruit juice (cherry)
2. Personalised dietary advice and placebo fruit juice (apple)
3. Waitlist control group and active fruit juice (cherry)
4. Waitlist control group and placebo fruit juice (apple)

Those who received the personalised dietary advice were offered up to three telehealth sessions delivered by an Accredited Practicing Dietitian who used results from the AES FFQ and PND to personalise the education and resources provided and enable appropriate goal setting. The waitlist control group were asked to maintain their usual diet during the study and received access to the personalised dietary advice at the end of the study.

Participants were also given 42 x 250 ml bottles of either cherry or apple juice with instructions to consume one each day for the duration of the study.

Forty-two participants completed the study with all groups reporting a statistically significant improvement in pain interference (-0.9±0.3 points, p=0.003), pain self-efficacy (+6.2±2.2 points, p=0.004) and pain catastrophising (-3.8±1.8 points, p=0.046).

The changes in pain at 6 week follow up self-reported using a visual analogue scale, pain interference and pain self-efficacy were all clinically important in the groups which received the personalised dietary consultation compared to the waitlist control groups, with a statistically significant change ≥2.5-3 cm, ≥1 point and ≥ 7 points; respectively ($p<0.05$). All groups had a statistically significant improvement in six of eight quality of life categories at the end of the study. All groups increased percentage energy from nutrient-dense foods (+5.2±1.4%, $p<0.001$) with percentage energy intake from total fat having a significant group-by-time effect ($p=0.024$) with personalised dietary consultations plus placebo fruit juice having the largest reduction (-5.7±2.3%) compared to the other groups. The majority of participants (83%) reported as being satisfied/very satisfied with the intervention.

This intervention was found to be acceptable by participants who found the overall study and its components satisfactory. While there was only one group-by-time effect among all the outcomes, the majority of outcomes improved over time in all study groups indicating, like the systematic review that altering dietary intake whether by supplement or overall dietary change may help to reduce pain experiences. The intervention also found that there were clinically important results for three of the pain outcomes which favoured the personalised dietary consultations over the waitlist control groups. This warrants further investigation by way of a larger, fully powered trial.

This intervention study also addresses some of the limitations identified in the systematic review. Many studies did not provide a comprehensive description of the content of their interventions. This was addressed in this study as particular attention was paid to ensure a detailed description of the intervention and the methodologies were provided. Due to resource constraints this intervention did not include a longer follow up period and this remains a limitation as identified in the systematic review and this current study.

7.2 Strengths and limitations

The resounding strength of this thesis is that it was undertaken in collaboration with multidisciplinary pain clinicians at Hunter Integrated Pain Service and nutrition and dietetic researchers from the University of Newcastle with the goal of translating current evidence on nutritional management of chronic pain into clinical practice. As outlined,

pain clinicians and those people experiencing chronic pain have expressed a need for a comprehensive and evidence-based nutrition intervention to be available to patients attending specialist pain services. However, the relationship between nutrition and chronic pain has not been researched in detail and from a clinical perspective resources are limited. This has prevented the development and implementation of a nutrition intervention and also the access to individual patient consultations with Accredited Practicing Dietitians. This thesis has been able to overcome these barriers through the productive collaboration formed between dietetic researchers and clinicians. For example patients and staff were consulted prior to the development of the intervention study using focus groups. In addition, the intervention study included in this thesis was informed by a systematic review, with views of patients and staff and importantly utilised existing Hunter New England Local Health District telehealth infrastructure so that it can be readily implemented into current practice with the model of care transferrable across other Local Health Districts.

This is the first body of work to scientifically and clinically address the need and desire for a nutrition intervention for those experiencing chronic pain. The heterogeneity of the studies included in the systematic review highlights that this is a unique area for clinical research due to the lack of consensus in this area. While this is a novel body of work, extensive planning went into the structure and development of this thesis to ensure that it would have practical applications and the potential to reach and achieve population-wide health improvements. The work presented in this thesis addresses a substantial gap in the literature. It also forms the first step of the scaling up process outlined by NSW Health in their guide translational research and population health interventions (311). The aim of this is to create effective interventions and then make considered efforts to increase the impact and sustainability of the intervention for the population as a whole (311). Assessing the feasibility and effectiveness of an intervention are two steps in this process which have been addressed in this thesis by undertaking the intervention study outlined in Chapter 6.

This body of work also aligns with national strategies such as the Medical Research Futures Fund (MRFF) which builds on the Strategic Review of Health and Medical Research conducted in 2012 (312). The objectives of the MRFF also align with this body of work. One of these shared objectives is to improve the health of people

experiencing chronic pain and thereby reducing costs to the health service (313). Another objective is to create collaborations between researchers and the health service as such this has been achieved in conducting this body of work (313). This collaboration assists in incorporation of research findings into health care services and health care policies which is another objective of the MRFF (313). The findings from this thesis can be scaled up and translated to other services and appropriate measurement of impact. I have developed a logic model (Figure 7.2) to demonstrate this.

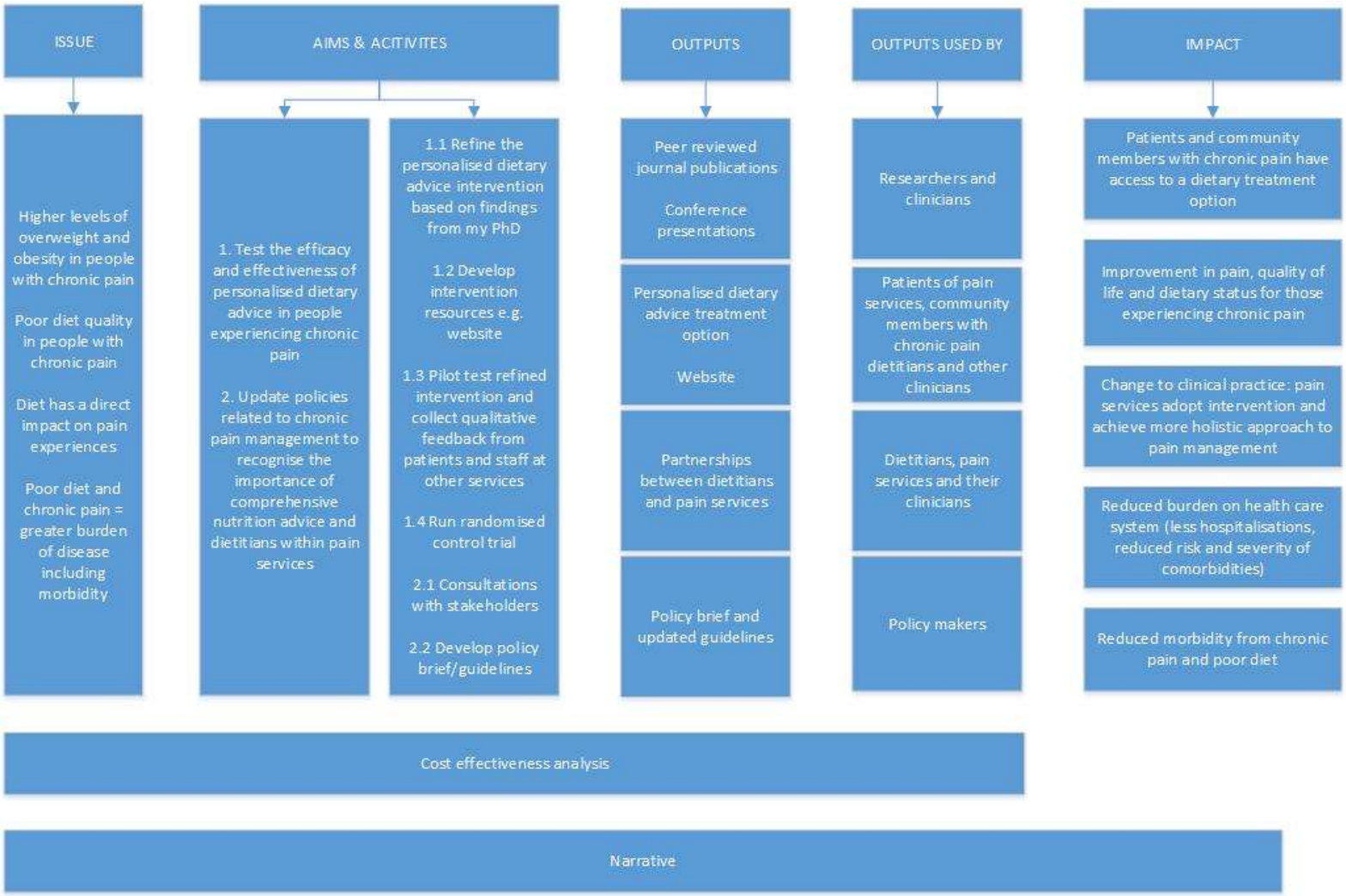

Figure 7.2. Logic model to assess impact of future translation studies

There are numerous measurement tools which can be used to measure pain severity, with each one having a number of pros and cons (151, 314). This thesis uses a number of tools in order to compare results with previous research and clinical outcomes. It was identified in the systematic review (264) that the majority of studies use the single-item visual analogue scale. This is relatively easy for participants to use and researchers to score and interpret (151, 314). However, given that chronic pain is influenced by multiple biopsychosocial and lifestyle factors, more robust and multidimensional tools are better able to capture the complexity of chronic pain (151, 314). In undertaking the data collection for Chapter 3 it was identified that clinical services commonly use the Brief Pain Inventory, Pain Self Efficacy Questionnaire and Pain Catastrophising Scale (154). This is further supported by the number of Australian and New Zealand pain services (n=64 in 2017-2018) who submit data to the electronic Persistent Pain Outcomes Collaboration (43), all of which use these tools. In the intervention study, all of these tools were used, so that the results could be compared to the literature and to clinical outcomes.

The combination of quantitative and qualitative data was used to inform the intervention study. By including the thoughts of people who experience pain and the health care professionals who treat them the development of an acceptable and effective intervention is strengthened. From a patient perspective, it is important to include their opinions on what they would like in a nutrition intervention as well as gather evidence on what might facilitate or impede their participation or success to ensure that these issues are addressed as part of the development stage. Again, this addresses another of the MRFF objectives which is to maximise opportunities for research translation by engaging with consumers (313). It also addresses the standards and goals from 1) Australian commission on safety and quality in health care where standard two relates to partnering with consumers to optimise care (315) and 2) National Pain Strategy 2010 where goal two is to ensure consumers are knowledgeable, empowered and supported (53). It is also important to gather the thoughts of staff who currently assess and treat people experiencing chronic pain. Given their experience they are well placed to provide insight on what currently works or does not work when it comes to providing advice to people experiencing pain. The administrative staff at HIPS and TIPS have substantial contact with patients, in particular over the phone. Patients attend multiple seminars and workshops with HIPS over a long period of time which can last up to 12

months. Over this time, patients interact with administration staff on several occasions to confirm attendance or to contact a clinician for a phone consultation or in a crisis. The administrative staff also prepare the materials used in the assessment and treatment workshops and enter patient questionnaire and feedback data into the system. As such it was pertinent to include their opinions given their involvement at the service. There was consistency between the responses given by all staff, regardless of their discipline. From a moderator perspective, the only difference was that administrative staff were more focused on the patient experience whereas the clinicians provided perspectives from both the patient perspective and their own perspective.

Incorporating their clinical experience via the qualitative study outlined in Chapter 5 is likely to improve the participation and success of an intervention. Furthermore, with the intention to incorporate this intervention into current clinical service provision, it is crucial to identify any facilitators or barriers from this perspective. This has been done by utilising qualitative methods to gather this information.

The intervention study was found to be acceptable for patients with the majority finding that participating in the study was a satisfactory experience. There was high interest among patients, of both genders, at HIPS to participate in the study. For those who did participate the retention was very good with 70% of participants remaining in the study at follow up.

A limitation of this thesis is that the majority of the work was undertaken at a single site. Hunter Integrated Pain Service is a tertiary specialist pain centre based at a public hospital service in a metropolitan area. The findings from this thesis may not be generalisable to other services especially private and/or rural and remote services. However, there was an opportunity to include staff from Tamworth Integrated Pain Service, a regional clinic in rural NSW, in the qualitative research which was conducted. This provides insight into the different needs of other services, especially one that is in a rural setting with different levels of infrastructure and resources.

Despite the progress in defining chronic pain and understanding the pathophysiology behind the condition, this body of work faced challenges when synthesising previous studies which had tested nutrition interventions aimed at reducing pain experiences. The systematic review presented in Chapter 2 is limited to pain-related conditions with only

two of the 71 studies testing their intervention in a true clinical population experiencing chronic pain.

Another limitation is that the intervention study was unable to address all the deficiencies identified in the systematic review. In particular, the intervention study did not have an extended follow up period. As such, the sustainability and long term effects of the intervention could not be assessed.

Finally, the intervention study did not did not provide a comprehensive explanation for the anthocyanin content of the cherry crush.

7.3 Recommendations for research

1. The limited quality of the studies included in the systematic review highlights the need for future studies that provide more detailed information about the intervention and methodology used in experimental studies. A thorough explanation of the intervention should be included so readers can clearly identify the intervention content, mode and frequency of delivery and qualifications of the person who delivered the intervention. This could be done using the template for intervention description and replication (TIDieR) checklist and guide which has been developed to ensure intervention studies are reported in enough detail that they can be implemented by clinicians or other researchers (316). Consideration of which outcome measures should be undertaken to ensure the most appropriate validated measure of pain is used. This consideration should also be extended to studies which measure and report dietary intake and/or diet quality. If future studies better report methodologies and results this would lead to easier and more consistent synthesis of results. It would also allow for a more meaningful meta-analysis where the impact of the intervention can be interpreted clearly. In addition, these results would be more powerful and assist in filling the evidence gap in relation to nutrition's role in chronic pain management.

2. It has been demonstrated by the results from the pilot dietary intervention that the intervention component is considered acceptable and clinically meaningful to those experiencing chronic pain. Therefore a larger, higher powered experimental study is warranted. As identified in the systematic review this study should also have a longer follow up period. The information presented in this body of work provides enough information to calculate the sample size needed to be powered to show the effect of a larger study. The sample size calculation for a larger intervention study was calculated using PS Power and Sample Size Calculations, version 3.0, January 2009 (317) and is as follows:

   Independent t-test with power of 80% and Type I error probability associated with the null hypothesis set at 0.05. The value for the difference in population means was 0.25 which is the difference in population means for pain severity in Chapter 6 (pilot dietary intervention). The standard deviation (SD) was calculated from the standard error (SE) for pain severity from Chapter 6 (SE X $\sqrt{N}$ = SD) where N was the

number of people in the study. Using the values from Chapter 6 this equalled: 0.25 X √60 1.94. The ratio of control(s) per experimental participants was 1:1.

These values led to the following result for sample size: If the true difference in the experimental and control means is 0.25, the study will need 946 experimental subjects and 946 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with power of 0.8 and type 1 error probability 0.05.

This sample size calculation would also be powered to find a statistically significant change in pain interference as 103 participants would be needed in the experimental group and 103 participants would be needed in the control group.

The results of this sample size calculation indicate that a randomised control trial would be most appropriate and the exact study design would be dependent on the resources available. Importantly, the study should also include an economic analysis to determine the cost effectiveness of the study for the health care system and the individual. The RE-AIM framework (Reach, Effectiveness, Adoption, Implementation and Maintenance) should be utilised to ensure the success and maximise the effect of translating this research into practice (318). To assess the effectiveness of this translation the Framework to Assess the Impact of Translational health research (FAIT) should also be incorporated to quantify the impact of the research translation (319).

3. A larger study should also use a factorial design and analysis to examine the interrelationships among the groups. This would be beneficial as the interventions could be collapsed and compared, this would allow for the comparison of the personalised dietary advice with the waitlist control group and the active fruit juice (cherry juice) and placebo fruit juice (apple juice). This will add statistical power and allow for a more in-depth comparison between the two interventions.

4. Future studies which test the effectiveness of a nutrition intervention on pain severity, pain self-efficacy, physical function and quality of life should also consider the effectiveness of nutrition interventions on other outcomes related to the highly

prevalent comorbidities experienced by those with chronic pain. For example changes to weight status, blood pressure and blood lipids, glucose and subsequently the risk or severity of obesity and heart disease should be analysed. Given the high prevalence of depression and low pain self-efficacy in people experiencing pain and the impact this has on dietary behaviours it would also be appropriate to explore this in more detail.

5. The use of dietary assessment methods should also be considered in future studies. The intervention study in this body of work used a retrospective dietary assessment tool, a food frequency questionnaire (FFQ) which measures usual food and nutrient intake over the past 3-6 months. Typically used to measure dietary intake and/or dietary change over a long period of time (ie. ≥ 3 months), it was used to measure dietary changes over a 6 week period which may limit the findings. However, a previous study has used this same tool in a short intervention where the dietary change was measured with a minimum follow up of 6 weeks with the average follow-up being 9.5±2.5 weeks (320) Incorporating another dietary assessment tool, such as a prospective one (e.g. image based food record) would enhance the reliability of the dietary intake of participants. A hand written food record can be time consuming and burdensome, more so for those experiencing chronic pain who may find the task difficult due their pain. Participant burden can be reduced by taking advantage of advancements in technology and using image based food records. Using image based food records removes the need to weigh and record each food item consumed by a participant and therefore be more appealing, especially if they are asked to complete a retrospective dietary assessment tool as well. Future studies could also use a combination of 24 hour recalls (short term dietary intake) and FFQ (long term dietary intake) to increase the reliability of participant's intake.

6. Future studies should also include a measure of anthocyanin consumption /metabolism by including either a plasma or urinary biomarker to better evaluate the participants' levels of anthocyanins. This would allow researchers to determine the amount of anthocyanins coming from the supplement and compare the dosage with pain outcomes.

7. Future study designs should include a more comprehensive analysis of polyphenols and anthoycanins. An analysis of the anthocyanin content of any anthocyanin-rich

supplements used in future research should be undertaken and reported. This can be done using high performance liquid chromatology which would determine the oxygen radical absorbance capacity and milligrams of red pigment. In addition, measurement and analysis of plasma and/or polyphenols should also be incorporated into future research to better evaluate the participant's consumption and metabolism of polyphenols and anthocyanins. Comparing this with the polyphenol/anthocyanin content of the supplement and the participant's background diet would allow researchers to determine the impact of the anthocyanin content of the supplement and how it may be affected by metabolism. The metabolism of anthoycanins varies for each individuals. The gut microbiota plays a significant role in this metabolism. Anthoycanins also modulate gut bacteria with a recent systematic review finding that anthoycanins had a significant effect on the proliferation of Bifidobacterium spp. which treats irritable bowel syndrome and inhibits Clostridium histolyticum which is pathogenic in humans (321). Given this relationship, future studies which include anthoycanins should collect data on the microbiota to ascertain whether this influences outcomes such as inflammation and pain.

8. For studies that use telehealth to deliver the intervention it should be noted that in the current study in this thesis phone calls were preferred over video consultations. The reasons for this should be investigated and future studies should offer more than one mode of delivering the intervention to ensure is it feasible in a clinical setting.

9. The patient's nutrition-related goals presented in Chapter 3 only capture patients from Hunter Integrated Pain Service. It would be important to find out the number and type of nutrition-related treatment goals set by patients at other specialist pain services as there may be differences based on the service type and location. These could be compared to the goals set by patients at Hunter Integrated Pain Service which would add depth to the data presented in Chapter 3. By examining the types of nutrition-related goals it would also help to refine the wants and desires of patients and subsequently inform any future intervention studies.

10. All future studies should consider examining both statistically significant results and clinically important results. Clinically important change is one of the main focuses in the reports generated by ePPOC with the purpose to ensure that patients have the best possible outcomes and services are providing best practice interventions (43,

75). The pain assessment tools which are used in ePPOC and also used in the intervention study presented in Chapter 6 include: the Brief Pain Inventory, Pain Self-Efficacy Questionnaire and the Pain Catastrophising Scale (76, 78, 240). The clinical important recommendations for these tools are presented in Table 7.1.

Table 7.1: Clinical importance for three pain assessment tools

Assessment tool	Scoring	Clinical importance
Brief Pain Inventory (severity score)	Numeric scale 0-10 0-4 = mild 5-6 = moderate 7-10 = severe	≥ 10% = minimally important change ≥ 30% moderate important change ≥ 50% substantial important change
Brief Pain Inventory (interference score)	Numeric scale 0-10, higher the score = higher the interference	Change of 1 point over the average of 7 items
Pain Self-Efficacy Questionnaire	Sum of scores from 10 questions with numeric scale 0-10 < 20 = severe 20-30 = moderate 31-40 = mild >40 minimal impact	Change in score of ≥ 7 points combined with a movement to a different severity category
Pain Catastrophising Scale	Sum of scores from 13 questions with numeric scale 0-6 < 20 = mild 20-30 = high > 30 = severe	Change in score of ≥ 6 points combined with movement to a different severity category

ePPOC uses the IMMPACT group's recommendations (79) to calculate the clinical significance for these assessment tools and future studies should also use these recommendations to calculate clinical meaningful changes in pain outcomes to ensure consistency and allow for comparison in results with other studies and service data. Statistically significant results may not also mean clinically important results and vice versa (322, 323). Given pain is a subjective experience, it is important to measure clinically important changes to ensure patients are able to get a meaningful change in their pain, quality of life, function and overall health (323).

11. The results of the intervention indicate a possible placebo effect which occurred in the intervention study and a future study should be designed to test this. All groups had improvements in pain, quality of life and dietary outcomes, despite two groups only receiving the placebo fruit juice. There is growing evidence and interest in the placebo effect in pain management. Research shows that the neurotransmitters involved in pain are also involved when a placebo intervention is tested (304). Furthermore, both are modulated by expectancy, conditioning, motivation and reward (304). Many studies have been designed to test the placebo effect in pain management e.g. placebo surgeries and placebo drugs. None have explored the effect of a nutrition placebo. Since the intervention study has been conducted, which used cherry juice to test the effect of anthocyanins on pain severity, there has been innovative advancements and cherries can now be freeze-dried to produce a powder while still maintaining a high level of high quality anthocyanins (total red colour 150 mg/100 g) (324). This is much higher, and more likely to have a significant effect, than the total red colour in the cherry juice used in the intervention study (19 mg/100 g). This may be a more efficient way of testing the role of anthocyanins in pain management as it would be easier to create a true placebo of cherry powder than it is to create a true placebo of cherry juice.

7.4 Implications for practice

1. The current body of work provides evidence indicating that a nutrition intervention which has been well-informed by patients and staff at Hunter Integrated Pain Service and which is developed and delivered by a qualified dietitian is effective in achieving a significant group-by-time effect for percentage energy coming from total fat for the group receiving the personalised dietary advice and active fruit juice. Statistically significant results were also found for all groups over time for three *pain outcomes*: pain interference, pain self-efficacy, pain catastrophising; six *quality of life outcomes*: physical function, physical and emotional role limitation, emotional wellbeing, social function and general health; and three *dietary outcomes*: energy intake, percentage energy from core foods and percentage energy from energy dense, nutrient poor foods. Clinically meaningful results were also found for current pain, pain interference and pain self-efficacy which favoured the groups which received the personalised dietary advice. This warrants the investigation of

changes to patient outcomes when an Accredited Practicing Dietitian is included in the assessment and treatment of patients attending pain services.

2. Given there is still limited information on adequacy of patient's dietary intakes, pain services should consider using a standardised and evidence-based dietary assessment tool such as a food frequency questionnaire. The Australian Eating Survey Food Frequency Questionnaire (292) would be ideal to capture the dietary status of patients. While there is a cost associated with using this, it can be completed online and only takes 15 minutes to complete. Alternatively an Accredited Practicing Dietitian is trained to conduct thorough dietary assessments and could do so as part of their consultations with patients. However, understanding there are resource and funding limitations in the public system there is a free and readily available, albeit brief dietary quality assessment tool which could be used such as the Healthy Eating Quiz™ (298). For services such as Hunter Integrated Pain Service who already include a nutrition component to their assessment and treatment of pain, the Australian Eating Survey Food Frequency Questionnaire could be incorporated into current practice. For other services who do not, the Australian Eating Survey Food Frequency Questionnaire or Healthy Eating Quiz could be made available in waiting rooms or during breaks in group treatment sessions so as not to take away from clinicians' time.

3. The use and acceptability of telehealth, in particular phone calls, in the intervention study show that this is viable alternative to in-person appointments. It also reduces burden to patients who, in the focus groups, indicated that cost and travel were barriers to accessing care. Pain services should consider expanding their use of telehealth in a multidisciplinary setting. In a private setting, there are still restrictions on claiming funding for allied health appointments conducted using telehealth, especially with dietitians. At this time, patients cannot be reimbursed for attending dietitian appointments delivered via telehealth and as such cost will remain a barrier to accessing care and patients experiences will continue to worsen with long wait times in the public system having a detrimental effect on their quality of life. Professional bodies such as the Dietitians Association of Australia need to continue to advocate to the Commonwealth Government for Medicare patients and better reimbursement for private health insurance.

4. At a policy level, advocacy for nutrition needs to continue. The Australian Pain Society is already making changes to ensure that dietitians are given the opportunity to contribute to policies and frameworks which are being developed at a national level. For example The Australian Pain Society Relationships Committee, which has multidisciplinary representation of professional societies with a pain interest in Australia, has recently invited a representative of the Dietitians Association of Australia onto the committee. In addition, nutrition themed topical sessions have been accepted in 2018 and 2019 at the Australian Pain Society Conference with one of the national speakers at the 2019 conference to be an Advanced Accredited Practicing Dietitian. This begins to give dietitians a national voice and allows for the dietetic discipline to provide feedback on many national initiatives such as the National Action Plan for Pain 2018. Networking needs to continue between pain clinicians and dietitians to bridge the gap between these professions.

7.5 Concluding remarks

Chronic pain is a debilitating condition which is highly prevalent worldwide, and it is expected that prevalence will continue to increase over time. Chronic pain severely impacts individuals on a daily basis affecting mood, ability to work and socialise. Best practice for pain management includes active treatment incorporating a multidisciplinary biopsychosocial and lifestyle approach which addresses each of the following aspects equally: biomedical (underlying conditions and medications); mindbody (depression & anxiety); connection (to people, place and purpose); physical activity and good nutrition. With the exception of nutrition, each of these is well represented in pain services with pain specialists, nurses, psychologists and physiotherapists. Nutrition is currently an area that is lacking and not receiving equal attention compared to the other aspects listed above.

This body of work addresses this gap by generating evidence to support the need and want for comprehensive nutrition interventions. Given this is a unique area of work, the development of a nutrition intervention was informed using both quantitative and qualitative data. This thesis and the intervention study was led by an Accredited Practicing Dietitian to ensure that this research was undertaken by an expert qualified in nutrition and dietetics.

The findings from this thesis indicate that there is a need for, and importantly that patients at Hunter Integrated Pain Service want a comprehensive nutrition intervention to be included within pain management services. Ultimately, future research and publications needs to explore the impact of a personalise nutrition intervention by conducting a fully powered trial with a longer follow up period to confirm the effectiveness and potential scale up of nutrition interventions delivered to people experiencing chronic pain.

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Appendices

Appendix 1. Permission to reproduce PROSPERO registration: *The association between nutrition and chronic pain: A systematic review*

As an author of the PROSPERO protocol titled "The association between nutrition and chronic pain: a systematic review", I give permission for this to be published as an appendix in Katherine Brain's thesis. I also give permission for this to be published via the University of Newcastle's online institutional repository, NOVA.

Ms Katherine Brain	Date: 10/1/2019
Associated Professor Tracy L Burrows	Date: 10/1/2019
Dr Megan E Rollo	Date: 10/1/2019
Ms Li Kheng Chai	Date: 10/1/2019
Ms Erin Clarke	Date: 10/1/2019
Dr Chris Hayes	Date: 10/1/2019
Ms Fiona J Hodson	Date: 10/1/2019
Professor Clare E Collins	Date: 10/1/2019

Katherine Brain

Subject: Copyright permission request

From: CRD Register <crd-register@york.ac.uk>
Sent: Tuesday, 8 January 2019 9:52 PM
To: Katherine Brain <Katherine.Brain@uon.edu.au>
Subject: Re: Copyright permission request

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Regards, PROSPERO administrator

On Tue, 8 Jan 2019 at 00:02, Katherine Brain <Katherine.Brain@uon.edu.au> wrote:

> To whom it may concern,
>
> I would like to include the systematic review protocol titled "The association between nutrition and chronic pain: A systematic review" (http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017055420) as an appendix in my PhD thesis. I have referred to this protocol throughout my thesis which is titled "Nutrition's role in the management of chronic pain".
>
> Once my thesis is approved, it will be published on the University of Newcastle's online institutional repository (NOVA).
>
> I would like to ask for a non-exclusive licence to copy and communicate this protocol via the University of Newcastle's online institutional repository NOVA.
>
> Many thanks,
> Katherine
>
> **KATHERINE BRAIN (APD)**
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> **PhD Candidate, Research Assistant**
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>
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> 
>

Appendix 2. PROSPERO registration: *The association between nutrition and chronic pain: A systematic review*

PROSPERO
International prospective register of systematic reviews

NHS
National Institute for Health Research

The association between nutrition and chronic pain: a systematic review

Katherine Brain, Tracy Burrows, Megan Rollo, Li Kheng Chai, Erin Clarke, Chris Hayes, Fiona Hodson, Clare Collins

Citation

Katherine Brain, Tracy Burrows, Megan Rollo, Li Kheng Chai, Erin Clarke, Chris Hayes, Fiona Hodson, Clare Collins. The association between nutrition and chronic pain: a systematic review. PROSPERO 2017 CRD42017055420 Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017055420

Review question

To determine the effectiveness of diet-based interventions that have been conducted with people who experience chronic pain
To identify any existing relationships between dietary intake/behaviours and experiences (frequency, intensity and severity) of chronic pain in observational studies

Searches

Sources: MEDLINE, The Cochrane Library, EMBASE, CINAHL, Scopus, PsycINFO, Informit, AMED
Dates: 1980 to current
Restrictions: English language, humans (adults>18yo), exclude cancer related pain

Types of study to be included

Review Question 1: All experimental study types (e.g RCT, pre-post)Review Question 2: All observational (e.g. case control, cohort, cross sectional)For both review questions the following study types will be excluded: case studies, literature, narrative and systematic reviews, commentaries, editorials and abstracts

Condition or domain being studied

Chronic or persistent pain; is defined as pain that exists beyond typical tissue healing time of over 12 weeks (1). It can include conditions such as back pain (especially lower back), arthritis (all types), neuropathic pain, fibromyalgia, phantom pain, sciatica/radicular pain, complex regional pain syndrome, shingles/post herpetic neuralgia, trigeminal neuralgia (facial pain), visceral pain, headache/migraine and pelvic pain/endometriosis (2). Chronic pain can also exist without any identifiable cause, in Australia up to 33% of people who experience chronic pain are unable to identify a cause (3). For this particular research we will be excluding cancer related chronic pain.
References:
1. Australian Pain Management Association. What is chronic pain? 2015 [cited 2015 13 May]; Available from: http://www.painmanagement.org.au/resources/about-pain/what-is-chronic-pain.html.
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3. MBF Foundation and University of Sydney Pain Management Research Institute. 2007, The high price of pain: The economic impact of persistent pain in Australia

Participants/population

Human: adults (>18years) who experience chronic pain, as described in 'condition being studied'.

Intervention(s), exposure(s)

1. Dietary intake/diet quality (e.g. government dietary guidelines or specific foods)
2. Specific nutrients (e.g. omega 3, amino acids, antioxidants, macro- and micro-nutrients)
3. Dietary supplements (e.g. vitamins, minerals, protein; exclude non-nutritive supplements)
4. Weight management interventions (e.g. energy restriction)

Interventions or exposures where nutrition therapy or supplements are intravenously administered will be excluded.

Comparator(s)/control

For experimental studies any comparator will be included. For example no intervention control groups and

standard practice control groups would be included.

Context

There is a high prevalence of chronic pain in Australia, with 1 in 5 adults aged 25-64 and up to 1 in 3 adults aged = 65 years experiencing this condition (1). Prevalence rates are expected to increase; in 2007 approximately 3.2 million Australians suffered from chronic pain and this is set to increase to 5 million by 2050 (2).
There is a large personal burden associated with chronic pain. People who experience chronic pain often have a decreased quality of life, limited social contact and poor mental health. One aspect that has not been widely studied is the nutrition status of people who experience pain. People with chronic pain are more likely to have a poor nutrition status as pain can impact on appetite, eating patterns and the ability to prepare and consume food (3).
There is also a substantial economic cost associated with chronic pain. People who experience chronic pain are more likely to be high users of the health care system (4). The economic cost of chronic pain is estimated to be $34 billion, this includes $11 billion in productivity losses and $7 billion in direct medical costs (2).
At present, the Hunter Integrated Pain Service (HIPS) is one of many providers who use a multidisciplinary treatment approach to help people manage pain. Evidence suggests that diet can improve pain experiences and furthermore, existing HIPS clients have identified the need for a nutrition component to be included in the treatment pathway. Despite this; a comprehensive nutrition treatment option does not exist.
A successful dietary intervention would be a cost effective way to improve quality of life, nutritional status and reduce the risk of other chronic disease in this population.
This systematic review is one of the first steps in identifying associations and links between nutrition and chronic pain. The results will help inform future studies and the development of a dietary intervention.
References:
1. Henderson, J.V., et al., Prevalence, Causes, Severity, Impact, and Management of Chronic Pain in Australian General Practice Patients. Pain Medicine, 2013. 14(9): p. 1346-1361.
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Main outcome(s)

A change in chronic pain (frequency/intensity/severity) as measured by tools such as the Brief Pain Inventory or Visual Analogue Scale.

Additional outcome(s)

1. Report of change dietary intake/behaviour (e.g. weighed/estimated food record, food frequency questionnaire, 24 hour recall, food intake checklists, diet history)
2. Weight status (body mass index, waist circumference or waist to hip ratio)
3. Quality of life
4. Risk of chronic disease (e.g blood pressure, blood lipids)
5. Mental health status (e.g. DASS-21)

Data extraction (selection and coding)

Two independent reviewers will screen the titles and abstracts of the studies that are compiled from the database search. If a study is considered relevant or if there is not enough information, the full text will be retrieved for further evaluation. Two independent reviewers will assess the full text against the inclusion and exclusion criteria to determine if they are suitable and included in the review. Any disagreements will be resolved using a third reviewer.
Data that will be extracted will include study details (author, year, country), study design, participant characteristics (age, gender, pain type/diagnosis), intervention (method, content and materials, mode of delivery, duration, follow up), measurement tools, outcomes (primary and secondary), key findings and study limitations.

Risk of bias (quality) assessment

Retrieved articles will be critically appraised using the American Dietetic Association's Quality Criteria Checklist for Primary Research. This is a standardised tool that assesses participant selection, intervention

description, statistical analysis, sources of bias and funding.

Strategy for data synthesis
Studies will be categorised based on the pain types and intervention methodology. A descriptive analysis will take place where similarities and differences between intervention methods and outcomes will be identified and the effectiveness of intervention studies will be reported.
If possible, similar studies will be pooled together in a meta-analysis.

Analysis of subgroups or subsets
If possible, a sub-analysis will take place, based on pain type and/or interventions.

Contact details for further information
Professor Collins
Clare.Collins@newcastle.edu.au

Organisational affiliation of the review
University of Newcastle
www.newcastle.edu.au

Review team members and their organisational affiliations
Ms Katherine Brain. PhD Candidate, School of Health Sciences, University of Newcastle, Australia
Dr Tracy Burrows. Associate Professor, School Health Sciences, University of Newcastle, Australia
Dr Megan Rollo. Post-doctoral research fellow, Priority Research Centre in Physical Activity and Nutrition, University of Newcastle, Australia
Ms Li Kheng Chai. PhD Candidate, School of Health Sciences, University of Newcastle, Australia
Ms Erin Clarke. PhD Candidate, School of Health Sciences, University of Newcastle, Australia
Dr Chris Hayes. Director, Hunter Integrated Pain Service, Division of Anaesthesia, Intensive Care and Pain Management, John Hunter Hospital
Ms Fiona Hodson. Clinical Nurse Consultant, Pain Management, Hunter Integrated Pain Service, Division of Anaesthesia, Intensive Care and Pain Management, John Hunter Hospital
Professor Clare Collins. Senior research fellow, School of Health Sciences and Priority Research Centre in Physical Activity and Nutrition, University of Newcastle

Type and method of review
Systematic review

Anticipated or actual start date
02 November 2015

Anticipated completion date
28 April 2017

Funding sources/sponsors
Nil

Conflicts of interest
None known

Language
English

Country
Australia

Stage of review
Review Completed not published

Details of final report/publication(s)
Brain K, Burrows TL, Rollo ME, Chai LK, Clarke ED, Hayes C, Hodson FJ, Collins CE. A systematic review

and meta-analysis of nutrition interventions for chronic noncancer pain. Journal Human Nutrition & Dietetics. 2018. doi: 10.1111/jhn.12601.

https://doi.org/10.1111/jhn.12601

https://onlinelibrary.wiley.com/doi/full/10.1111/jhn.12601

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Chronic Disease; Chronic Pain; Humans; Nutritional Status

Date of registration in PROSPERO
22 January 2017

Date of publication of this version
22 January 2019

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	Yes
Risk of bias (quality) assessment	Yes	Yes
Data analysis	Yes	Yes

Versions
22 January 2017
22 January 2019

Appendix 3. Permission to reproduce the Australian Pain Society Media Release

From: Australian Pain Society
To: Katherine Brain
Cc: Fiona Hodson
Subject: Re: Permission to reprint media release in PhD thesis-granted
Date: Thursday, 13 December 2018 11:19:54 AM
Attachments: 20180326 APS Media Release_Diet and Chronic Pain.pdf
Christmas_Closure-only_Image_Notice_2018_sig.jpg
2019 Australian Pain Society (2).png

Hi Katherine,

Thank you for your email.

I have discussed your request with the Australian Pain Society (APS) President, Ms Fiona Hodson, and the APS confirms that:

1. You may include the attached media release (clean copy), dated 26MAR18, as an appendix to your PhD thesis
2. The APS grants non-exclusive licence to copy and communicate this media release via the University of Newcastle's online institutional repository NOVA

We wish you well with the submission of you PhD thesis and would be pleased to be advised when your doctorate is awarded.

Kind regards,

Tracy

Tracy Hallen
APS Secretariat
(Mon-Thurs)

PO Box 637
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W: https://www.apsoc.org.au
E: aps@apsoc.org.au

On 13 Dec 2018, at 9:01 AM, Katherine Brain <Katherine.Brain@uon.edu.au> wrote:

Hi Tracy,

I would like to include the attached media release as an appendix in my PhD thesis as an example of how I have communicated the work I have done as part of my PhD. I am emailing to request permission to include this in my PhD thesis.

Once my thesis is approved, it will be published on the University of Newcastle's online institutional repository which is called NOVA and I would like to ask for for non-exclusive licence to copy and communicate the media release via the University of Newcastle's online institutional repository NOVA.

Thanks,
Katherine

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Australia

<20180326 APS Media Release_Diet and Chronic Pain.pdf>

Appendix 4. Media release: Foods to eat if you have chronic pain

THE AUSTRALIAN PAIN SOCIETY
www.apsoc.org.au

APS Secretariat
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North Sydney NSW 2059
T: 02 9016 4343
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W: www.apsoc.org.au
Twitter: @AusPainSoc

MEDIA RELEASE

FOODS TO EAT IF YOU HAVE CHRONIC PAIN

EMBARGO MONDAY MARCH 26, 12.01AM

With growing emphasis on lifestyle-based treatments for chronic pain, there's promising new research about the potential benefits from a specially designed, anti-inflammatory diet.

Dietitian and University of Newcastle PhD student Katherine Brain is examining the growing body of evidence indicating that foods containing nutrients such as antioxidants, Omega 3, Vitamin B, and fibre may have a role in reducing pain intensity and frequency.

Ms Brain will present her preliminary results at the Australian Pain Society annual scientific meeting in Sydney in April.

Ms Brain is completing a trial involving a group of 80 chronic pain patients to investigate whether their symptoms improve after taking a fruit juice containing high levels of anti-oxidants.

The patients, who attend Hunter Integrated Pain Service based at the John Hunter Hospital in Newcastle, are divided into different groups. Some are given the specially prepared fruit juice while others receive a regular fruit juice.

Patients also receive one-on-one consultations with personalised dietary advice specifically for pain management and setting individual nutrition and healthy lifestyle goals.

Ms Brain is examining whether patients within the group that have co-morbidities such as type 2 diabetes, heart disease, obesity, anxiety and depression, can benefit when following a healthy dietary pattern that emphasises specific nutrients.

Participants are finding the approach manageable and some have seen positive changes. Further results will be available at the conference.

Ms Brain said: "The relationship between diet and chronic pain is thought to be related to the role diet plays in limiting inflammation levels in the body and how healthy eating leads to a healthy and efficient nervous system. This in turn helps to reduce the sensation of pain and helps to improve mood and functionality."

Ms Brain is also interested in whether improving general gut health can reduce pain and inflammation. "While the link between diet and pain relief is far from proven, it's an area that warrants further research. Ultimately, by strengthening the link between pain and nutrition, then pain clinics offering physical and psychological therapies might need to include a dietitian in their program."

The research is particularly important as the focus moves away from pain-related medications and towards a holistic approach to pain management where equal attention is paid to mood, physical activity, connection and nutrition.

It's estimated that one in five Australians are living with chronic pain, which lasts more than three months after injury, surgery or illness. One in five GP consultations involves chronic pain.

Media contact: Belinda Tromp 0418 395 898
Australian Pain Society | 38th Annual Scientific Meeting | 8-11 April 2018 | International Convention Centre Sydney

The Australian Pain Society (APS) is Australia's leading forum of university-trained health professionals (including GP and specialist doctors, nurses, occupational therapists, pharmacists, physiotherapists, psychologists and other allied health professionals and researchers) trained in the recognition, research, management and advocacy around all aspects of pain in Australia.

Appendix 5. 9 things to know about nutrition and pain

https://www.ausdoc.com.au/news/9-things-know-about-nutrition-and-pain

Appendix 6. Permission to reproduce Figure 1.1: Nociceptive pathway between the periphery and central nervous system

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11th December 2018

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Appendix 8. Permission to reproduce Figure 1.3: The whole-person approach to pain management

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Appendix 9. Statement of contribution and collaboration for Chapter 2: A systematic review and meta-analysis of nutrition interventions for chronic non-cancer pain

I attest that Research Higher Degree candidate Katherine Brain contributed to the following paper:

Brain K, Burrows TL, Rollo ME, Chai LK, Clarke ED, Hayes C, Hodson FJ and Collins CE. A systematic review and meta-analysis of nutrition interventions for chronic noncancer pain. Journal of Human Nutrition and Dietetics: The official journal of the British Dietetic Association. 2018.

Katherine Brain contributed to the methodological design of the study including drafting the systematic review protocol, developing and running the search strategy, the screening process, data extraction and risk of bias assessment and drafting the manuscript. Associate Professor Tracy L Burrows, Dr Megan E Rollo, Dr Chris Hayes, Ms Fiona J Hodson and Professor Clare E Collins assisted with the development of the study design, participated in the screening process and contributed to the development of the systematic review protocol and manuscript within their capacity as PhD supervisors. Ms Li Kheng Chai and Ms Erin D Clarke were involved in the screening process, data extraction and risk of bias assessment. All authors approved the final manuscript.

Ms Katherine Brain Date: 12/12/2018

Associated Professor Tracy Burrows Date: 12/12/2018

Dr Megan E Rollo Date: 12/12/2018

Ms Li Kheng Chai Date: 12/2/2018

Ms Erin D Clarke Date: 16/12/2018

Dr Chris Hayes Date: 12/12/2018

Ms Fiona J Hodson Date: 12/12/2018

Professor Clare E Collins Date: 12/12/2018

Professor Robert Callister Date: 18/12/2018

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Appendix 11. Supplementary Table S1: PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	6
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5-6

Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	51
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6-7
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	7
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	28-36 & 43-48
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	36-43

Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	8-16
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	13-16
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	8-9
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	16-20
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	19
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	20
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	20-21

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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Appendix 12. Supplementary Table S2: Medline search strategy

#	Searches	Results
1	Chronic Pain/	5520
2	persistent pain.mp.	3283
3	exp Back Pain/	31198
4	exp Neuralgia/	15039
5	Trigeminal Neuralgia/	5885
6	Hyperalgesia/	8702
7	Fibromyalgia/	6810
8	Phantom Limb/	1613
9	exp Complex Regional Pain Syndromes/	4619
10	exp Nociceptive Pain/	598
11	Headache/	23697
12	Endometriosis/	18059
13	migraine with aura/ or migraine without aura/ or tension-type headache/	3365
14	exp arthritis, infectious/ or arthritis, psoriatic/ or exp arthritis, rheumatoid/ or chondrocalcinosis/ or exp gout/ or exp osteoarthritis/ or periarthritis/ or sacroiliitis/ or exp spondylarthritis/	174550
15	Pain/	115116
16	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15	392301
17	Food/	24745
18	exp Diet/	212507
19	Eating/	44174
20	exp Appetite/	8584
21	exp food habits/ or food preferences/	34122
22	nutrition*.mp.	272288
23	nutrient*.mp.	85310
24	Diet Therapy/	9796
25	17 or 18 or 19 or 20 or 21 or 22 or 23 or 24	562069
26	16 and 25	3192
27	limit 26 to (english language and humans and yr="1980 -Current" and "all adult (19 plus years)")	1190

Appendix 13. Statement of contribution and collaboration for Chapter 3: Population characteristics in a Tertiary Pain Service Cohort Experiencing Chronic Non-Cancer Pain: Weight Status, Comorbidities and Patient Goals

I attest that Research Higher Degree candidate Katherine Brain contributed to the following paper:

Brain K, Burrows T, Rollo ME, Hayes C, Hodson FJ, Collins CE. Population Characteristics in a Tertiary Pain Service Cohort Experiencing Chronic Non-Cancer Pain: Weight Status, Comorbidities, and Patient Goals. Healthcare (Basel). 2017;5(2).

Katherine Brain contributed to the methodological design of the study including drafting the ethics application, extracting and analysing the data and drafting the manuscript. Associate Professor Tracy L Burrows, Dr Megan E Rollo, Dr Chris Hayes, Ms Fiona J Hodson and Professor Clare E Collins assisted with the development of the study design and contributed to the development of the ethics application and manuscript within their capacity as PhD supervisors. All authors approved the final manuscript.

Ms Katherine Brain Date: 12/12/2018

Associated Professor Tracy L Burrows Date: 12/12/2018

Dr Megan E Rollo Date: 12/12/2018

Dr Chris Hayes Date: 12/12/2018

Ms Fiona J Hodson Date: 12/12/2018

Professor Clare E Collins Date: 12/12/2018

Professor Robert Callister Date: 13/12/2018

Deputy Head of Faculty of Health and Medicine (Research and Research Training)

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Katherine Brain

Subject: permission to use ePPOC questionnaire

From: Hilarie Tardif <hilarie@uow.edu.au>
Sent: Tuesday, 10 September 2019 10:23 AM
To: Katherine Brain <katherine.brain@newcastle.edu.au>
Cc: Chris Hayes (Hunter New England LHD) <Chris.Hayes@health.nsw.gov.au>
Subject: RE: permission to use ePPOC questionnaire

Hi Katherine

Thanks for your email and sorry for the delay getting back to you. And congratulations on finishing your PhD – you must be feeling great!
Our ePPOC questionnaire is on our website (so is in the public domain).

Many thanks, Hilarie

From: Katherine Brain <katherine.brain@newcastle.edu.au>
Sent: Thursday, 5 September 2019 9:30 AM
To: Hilarie Tardif <hilarie@uow.edu.au>
Cc: Chris Hayes (Hunter New England LHD) <Chris.Hayes@health.nsw.gov.au>
Subject: Re: permission to use ePPOC questionnaire

Dear Hilarie,

I would like to include the attached version of Hunter Integrated Pain ePPOC referral questionnaire as an appendix in my PhD thesis. I have referred to this throughout my thesis titled: The role of nutrition in chronic pain management.

I understand that the following questionnaires are not owned by ePPOC, and as such I have sought and received permission from the original owners to include the following:

- BPI
- DASS-21
- PCS
- PSEQ

My thesis has been approved and it will now be published on the University of Newcastle's online institutional repository (NOVA).

I would like to ask for a non-exclusive licence to copy and communicate the ePPOC referral questionnaire via the University of Newcastle's online institutional repository, NOVA.

Thanks
Katherine

Katherine Brain (APD, BNutr&Diet Hon I) | Research Academic PhD Candidate
School of Health Sciences | Faculty of Health & Medicine
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1

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Title or numeric reference of the portion(s)	Figure 1. Suggested pain chart for studies of recurrent and chronic pain adopted as part of the SUPER-KIDZ pain assessment project
Title of the article or chapter the portion is from	Pain charts (body maps or manikins) in assessment of the location of pediatric pain
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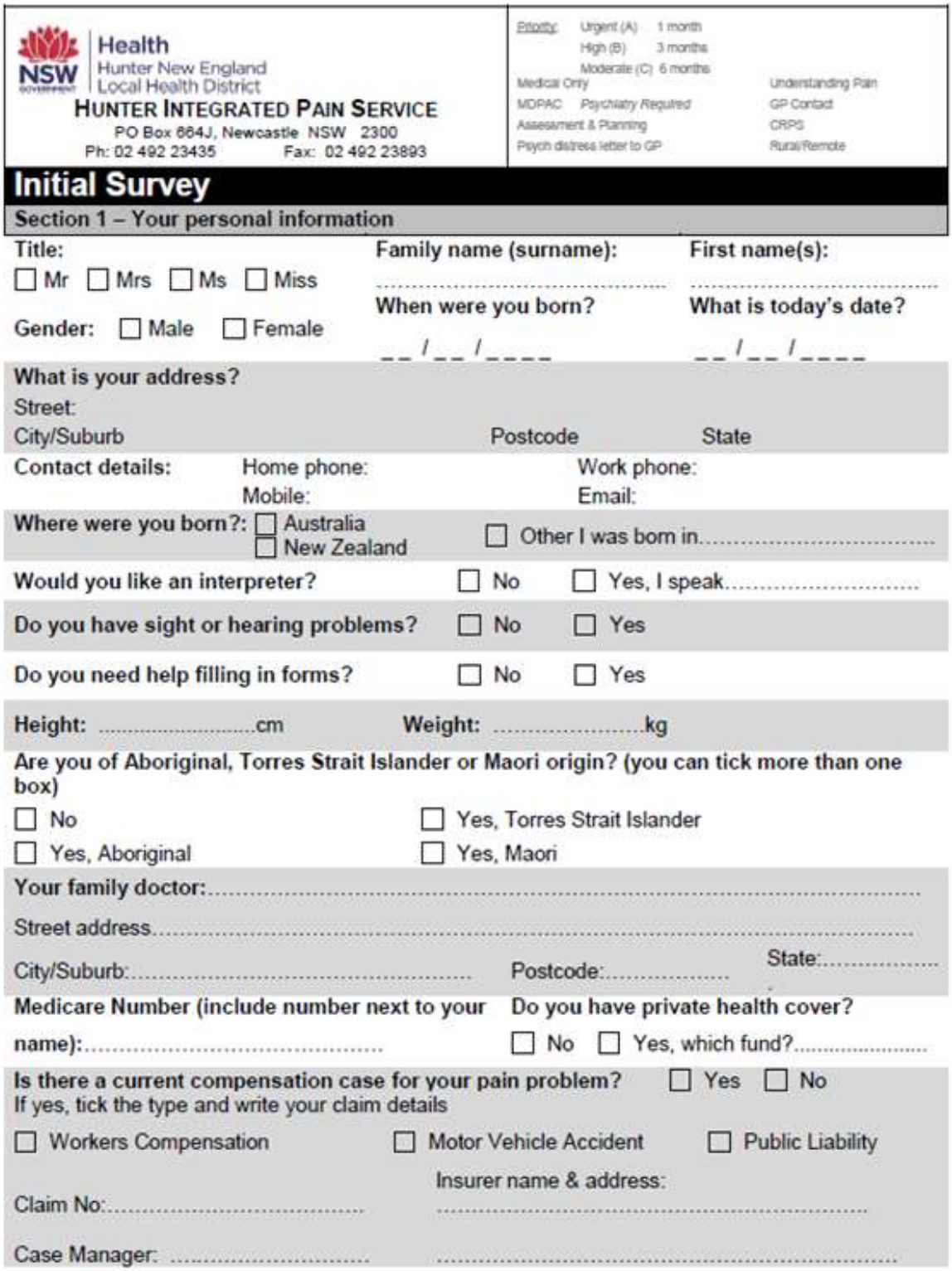
Appendix 20. ePPOC referral questionnaire



Health
Hunter New England
Local Health District

HUNTER INTEGRATED PAIN SERVICE

PO Box 664J, Newcastle NSW 2300
Ph: 02 492 23435 Fax: 02 492 23893

Priority: Urgent (A) 1 month
High (B) 3 months
Moderate (C) 6 months

Medical Only | Understanding Pain
MDPAC Psychiatry Required | GP Contact
Assessment & Planning | CRPS
Psych distress letter to GP | Rural/Remote

Initial Survey

Section 1 – Your personal information

Title:
☐ Mr ☐ Mrs ☐ Ms ☐ Miss

Family name (surname): .....

First name(s): .....

Gender: ☐ Male ☐ Female

When were you born? __ / __ / ____

What is today's date? __ / __ / ____

What is your address?
Street:
City/Suburb Postcode State

Contact details: Home phone: Work phone:
Mobile: Email:

Where were you born?: ☐ Australia ☐ New Zealand ☐ Other I was born in.....

Would you like an interpreter? ☐ No ☐ Yes, I speak.....

Do you have sight or hearing problems? ☐ No ☐ Yes

Do you need help filling in forms? ☐ No ☐ Yes

Height: .....cm Weight: .....kg

Are you of Aboriginal, Torres Strait Islander or Maori origin? (you can tick more than one box)

☐ No ☐ Yes, Torres Strait Islander
☐ Yes, Aboriginal ☐ Yes, Maori

Your family doctor:.....
Street address.....
City/Suburb:..... Postcode:..... State:.....

Medicare Number (include number next to your name):.....

Do you have private health cover?
☐ No ☐ Yes, which fund?.....

Is there a current compensation case for your pain problem? ☐ Yes ☐ No
If yes, tick the type and write your claim details

☐ Workers Compensation ☐ Motor Vehicle Accident ☐ Public Liability

Claim No:.....

Insurer name & address:
.....

Case Manager: .....
.....

Version 8, July 2014 1

Marital Status: **If we need to call you can we leave a message?** ☐ Yes ☐ No

What is your current work status? (you can tick more than one box)

☐ Full time paid work	☐ Unemployed due to pain	☐ Retired
☐ Part time paid work (_____hrs)	☐ Unemployed (not due to pain)	☐ Home duties
☐ At work – limited hours / duties	☐ Studying (e.g. school, uni)	☐ Voluntary work
☐ On leave from work due to pain	☐ Retraining	

Does pain affect the number of hours you work or study? ☐ Yes ☐ No

Does pain affect the type of work you are able to do? ☐ Yes ☐ No

How did the main pain begin?

☐ Injury at home	☐ After surgery	☐ Related to another illness
☐ Injury at work/school	☐ Motor vehicle crash	☐ No obvious cause
☐ Injury in another setting	☐ Related to cancer	☐ Other .....

How long have you had the main pain? (tick one box only)

☐ Less than 3 months	☐ 12 months to 2 years	☐ More than 5 years
☐ 3 to 12 months	☐ 2 to 5 years	

Which statement best describes the pain? (tick one box only)

☐ The pain is always there and always has the same intensity

☐ The pain is always there but the intensity changes

☐ The pain comes and goes. I am pain-free for less than 6 hours at a time

☐ The pain comes and goes and lasts up to an hour at a time.

☐ The pain comes every few days or weeks

Do you have any of these medical problems?

☐ Heart disease	☐ Rheumatoid arthritis	☐ Anaemia or other blood disease
☐ High blood pressure	☐ Kidney disease	☐ Osteoarthritis, degenerative arthritis
☐ Lung disease	☐ Depression/Anxiety	☐ Ulcer or stomach disease
☐ Diabetes	☐ Cancer	☐ Stroke or other neurological condition

☐ Other medical problems (please specify) .....

Section 2 – Your health service use

How many times in the past 3 months have you:

1. Seen a general practitioner (GP) about pain?	.....times
2. Seen a medical specialist (e.g. orthopaedic surgeon) about pain?	.....times
3. Seen health professionals other than doctors (e.g. physiotherapist, chiropractor, psychologist) about pain?	.....times
4. Visited a hospital emergency department about pain? Include all visits, even if you were not admitted to the hospital.	.....times
5. Been admitted to hospital as an inpatient because of pain?	.....times
6. Had tests (e.g. X-rays, scans) relating to pain?	.....times

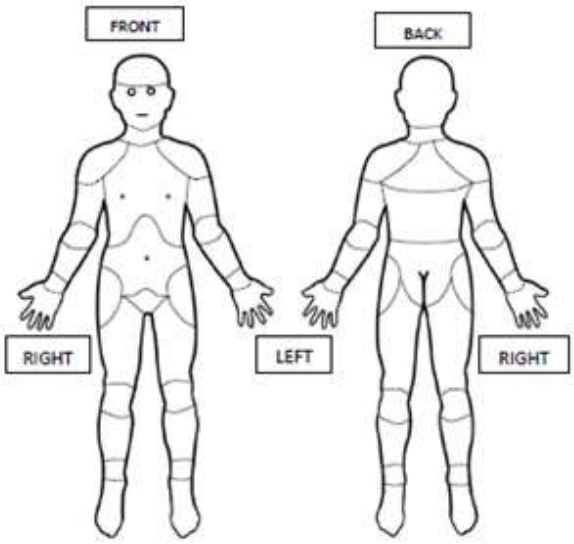
Section 3 – Your medications

What medications do you take? (include all prescription and over-the-counter medicines)

Medicine name (on the label)	Medicine strength (on the label)	How many do you take per day?	How many days per week do you take this medication?

Section 4 – BPI †

1. On the diagram below, shade in where you feel pain. Put an X where it hurts most.



2. Rate your pain by circling the number that best describes the following: (circle one number for each item, 0 = *No pain*, and 10 = *Pain as bad as you can imagine*)

a) Your *worst* pain in the last week?	0 No pain	1	2	3	4	5	6	7	8	9	10 Pain as bad as you can imagine
b) Your *least* pain in the last week?	0 No pain	1	2	3	4	5	6	7	8	9	10 Pain as bad as you can imagine
c) Your pain on *average*?	0 No pain	1	2	3	4	5	6	7	8	9	10 Pain as bad as you can imagine
d) Your pain right *now*?	0 No pain	1	2	3	4	5	6	7	8	9	10 Pain as bad as you can imagine

3. During the past week, how much has pain interfered with the following: (circle one number for each item, where 0 = *Does not interfere*, and 10 = *Completely interferes)*

a) Your general activity?	0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Completely interferes
b) Your mood?	0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Completely interferes
c) Your walking ability?	0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Completely interferes
d) Your normal work (both outside and inside the home)	0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Completely interferes

e) Your relationship with other people?	0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Completely interferes
f) Your sleep?	0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Completely interferes
g) Your enjoyment of life?	0 Does not interfere	1	2	3	4	5	6	7	8	9	10 Completely interferes

Section 5 – DASS21#

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you *over the past week*. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or a good part of time
3 Applied to me very much, or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (e.g. in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3

18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

Section 6 – PSEQ*

Rate how confident you are that you can do the following things **at present** despite the pain. Circle one of the numbers on the scale under each item where 0 = *Not at all confident* and 6 = *Completely confident*. Remember this questionnaire is not asking whether or not you have been doing these things, but rather how confident you are that you can do them at present, **despite the pain.**

1) I can enjoy things, despite the pain	0 Not at all confident	1	2	3	4	5	6 Completely confident
2) I can do most of the household chores (e.g. tidying-up, washing dishes etc.) despite the pain	0 Not at all confident	1	2	3	4	5	6 Completely confident
3) I can socialise with my friends or family members as often as I used to do, despite the pain	0 Not at all confident	1	2	3	4	5	6 Completely confident
4) I can cope with my pain in most situations	0 Not at all confident	1	2	3	4	5	6 Completely confident
5) I can do some form of work, despite the pain ("work" includes housework, paid and unpaid work)	0 Not at all confident	1	2	3	4	5	6 Completely confident
6) I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain	0 Not at all confident	1	2	3	4	5	6 Completely confident
7) I can cope with my pain without medication	0 Not at all confident	1	2	3	4	5	6 Completely confident
8) I can still accomplish most of my goals in life, despite the pain	0 Not at all confident	1	2	3	4	5	6 Completely confident
9) I can live a normal lifestyle, despite the pain	0 Not at all confident	1	2	3	4	5	6 Completely confident
10) I can gradually become more active, despite the pain	0 Not at all confident	1	2	3	4	5	6 Completely confident

Section 7 – PCS^

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feeling that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

		Not at all	To a slight degree	To a moderate degree	To a great degree	All the time
1	I worry all the time about whether the pain will end	0	1	2	3	4
2	I feel I can't go on	0	1	2	3	4
3	It's terrible and I think it's never going to get any better	0	1	2	3	4
4	It's awful and I feel it overwhelms me	0	1	2	3	4
5	I feel I can't stand it anymore	0	1	2	3	4
6	I become afraid that the pain will get worse	0	1	2	3	4
7	I keep thinking of other painful events	0	1	2	3	4
8	I anxiously want the pain to go away	0	1	2	3	4
9	I can't seem to keep it out of my mind	0	1	2	3	4
10	I keep thinking about how much it hurts	0	1	2	3	4
11	I keep thinking about how badly I want the pain to stop	0	1	2	3	4
12	There's nothing I can do to reduce the intensity of the pain	0	1	2	3	4
13	I wonder whether something serious may happen	0	1	2	3	4

Section 8 – More information

Have you come to a pain clinic before? ☐ Yes ☐ No

If yes, which clinic?.....

If yes, when was your last appointment?.....

What health professionals you are seeing? (eg. physiotherapist, chiropractor, psychologist, naturopath)?

Name	Type of treatment	Suburb/Town	Can we contact them? Y / N
eg. John Brown	*Exercise physiologist*	*Waratah*	Y

What operations have you had for your pain problem?

Type of operation	Date	Surgeon

Do you think you need more medication, or stronger medication?

☐ agree strongly ☐ agree ☐ unsure
☐ disagree ☐ disagree strongly

Pain medications and treatments have side effects. How severe have the side effects been in the last week? Please circle a number.

0 1 2 3 4 5 6 7 8 9 10

No side effects **Severe side effects**

What other medications have you taken for pain in the past? Do not write the ones from Section 3. Were they helpful?

Medication Name	Dose	How often	Was it helpful? Very	Some what	Slightly	No	Side effects

Do you smoke?

☐ Yes ☐ No, I am an ex-smoker ☐ No, I have never smoked

If you smoke, how many cigarettes do you smoke in a normal day:

☐ Less than 5 ☐ 5-14 ☐ more than 15

How many days per week do you drink alcohol?

☐ less than 1 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

If you drink alcohol, how many *standard* drinks do you usually have on these days:

☐ 1-2 ☐ 3-4 ☐ 5-6 ☐ 7-8 ☐ 8-15 ☐ more than 15

Do you ever drink alcohol to relieve pain? ☐ No ☐ Yes

How many cups of caffeinated drinks (ie. tea/coffee/caffeinated or energy drinks) do you have per day?

☐ 0 ☐ 1-3 ☐ 4-5 ☐ 6-7 ☐ more than 8

Your Story
This is a place where you can tell *your* story. This may be how the pain affects you and your life. You may want to write how you manage the pain and its effect on your life now.

.....

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Teaching and Research

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If you do not want us to use your answers for research it will not affect your care at HIPS.

Please tick one box

☐ Use my information for research at HIPS

OR

☐ I do not want HIPS to use my information for research

Signature _____ Date _____

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Triage	☐ Group pain management program ☐ Combined Group and Individual		☐ Individual appointments ☐ One-off intervention	
Medication	Opioid addiction maintenance program? ☐ Yes ☐ No			
	If yes: Number of analgesic drug groups: ..... (exclude opioids)		**If no:** Number of analgesic drug groups: ..... (whether or not prescribed for pain) Daily oral morphine equivalent: ..... mg Opioid medication > 2 days/week ☐ Yes ☐ No	
	Note: Major drug groups are: Opioids, Paracetamol, NSAIDs, Antidepressants, Anticonvulsants Benzodiazepines			
BPI main pain site	☐ Head (exc face) ☐ Face'jaw/temple ☐ Throat/neck ☐ Shoulder ☐ Chest ☐ Upper arm	☐ Elbow ☐ Forearm ☐ Wrist ☐ Hand ☐ Abdomen ☐ Hip	☐ Groin/pubic area ☐ Thigh ☐ Knee ☐ Calf ☐ Ankle ☐ Foot	☐ Upper back ☐ Mid back ☐ Low Back
BPI other pain site	☐ Head (exc face) ☐ Face'jaw/temple ☐ Throat/neck ☐ Shoulder ☐ Chest ☐ Upper arm	☐ Elbow ☐ Forearm ☐ Wrist ☐ Hand ☐ Abdomen ☐ Hip	☐ Groin/pubic area ☐ Thigh ☐ Knee ☐ Calf ☐ Ankle ☐ Foot	☐ Upper back ☐ Mid back ☐ Low Back

[†] Pain Chart Source: Childhood Arthritis and Rheumatology Research Alliance, www.carragroup.org, von Baeyer CL et al, *Pain Management*, 2011;1(1):61-68.

[‡] Brief Pain Inventory severity questions, reproduced with acknowledgment of the Pain Research Group, the University of Texas MD Anderson Cancer Centre

[#] Lovibond SH & Lovibond PF (1995)

[*] Nicholas MK (1989)

[^] Sullivan MJL (1995)

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From: Chris Hayes (Hunter New England LHD) <Chris.Hayes@health.nsw.gov.au>
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Subject: Copyright permission request - PARP

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My thesis has been approved and it will now be published on the University of Newcastle's online institutional repository (NOVA).

I would like to ask for

Thanks
Katherine

Katherine Brain (APD, BNutr&Diet Hon I) | Research Academic PhD Candidate
School of Health Sciences | Faculty of Health & Medicine
Priority Research Centre for Physical Activity and Nutrition

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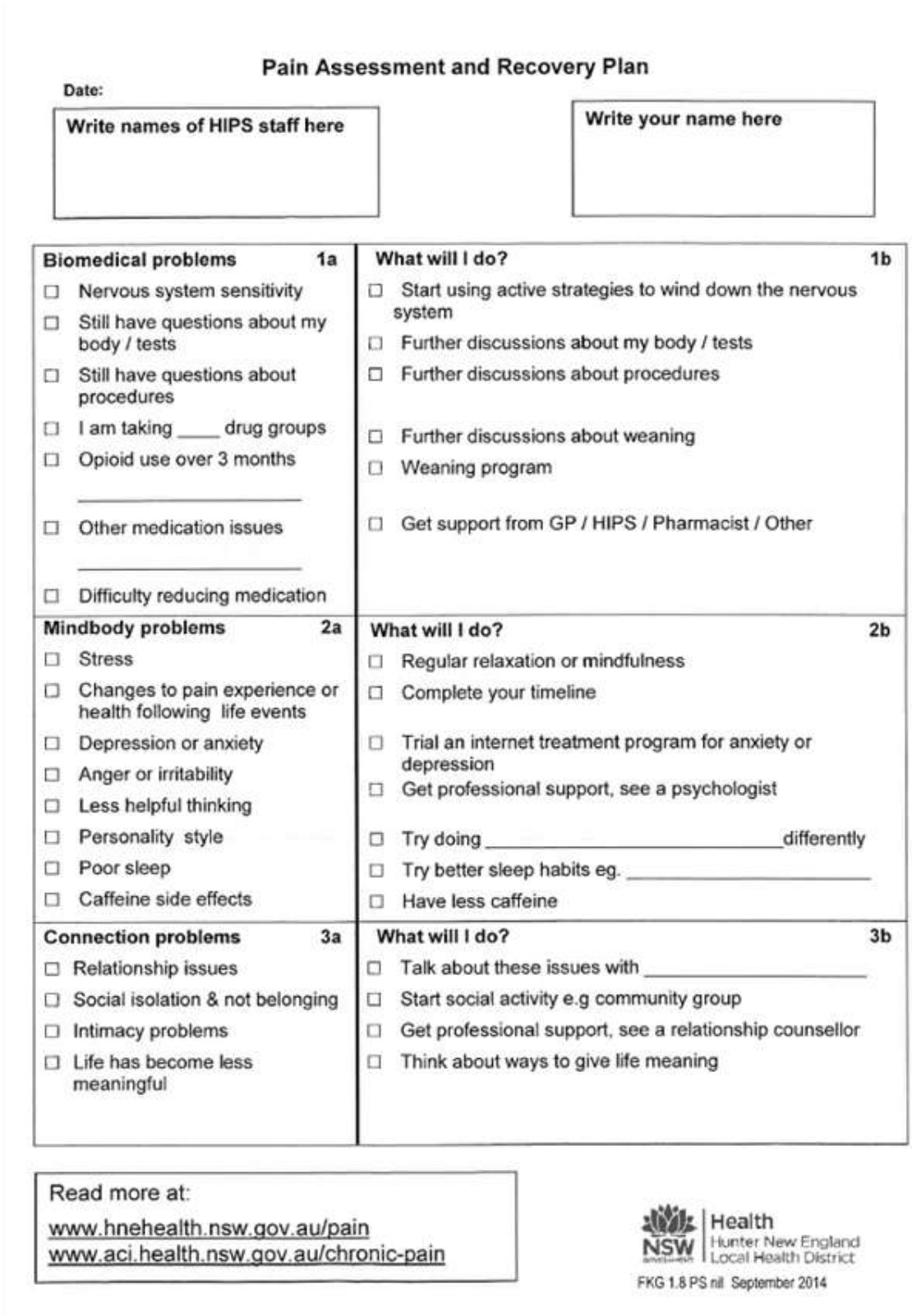
Appendix 22. Pain Assessment and Recovery Plan



Pain Assessment and Recovery Plan

Date:

Write names of HIPS staff here	Write your name here

Biomedical problems 1a	What will I do? 1b
☐ Nervous system sensitivity	☐ Start using active strategies to wind down the nervous system
☐ Still have questions about my body / tests	☐ Further discussions about my body / tests
☐ Still have questions about procedures	☐ Further discussions about procedures
☐ I am taking ____ drug groups	☐ Further discussions about weaning
☐ Opioid use over 3 months _____	☐ Weaning program
☐ Other medication issues _____	☐ Get support from GP / HIPS / Pharmacist / Other
☐ Difficulty reducing medication	

Mindbody problems 2a	What will I do? 2b
☐ Stress	☐ Regular relaxation or mindfulness
☐ Changes to pain experience or health following life events	☐ Complete your timeline
☐ Depression or anxiety	☐ Trial an internet treatment program for anxiety or depression
☐ Anger or irritability	☐ Get professional support, see a psychologist
☐ Less helpful thinking	☐ Try doing _____differently
☐ Personality style	☐ Try better sleep habits eg. _____
☐ Poor sleep	☐ Have less caffeine
☐ Caffeine side effects	

Connection problems 3a	What will I do? 3b
☐ Relationship issues	☐ Talk about these issues with _____
☐ Social isolation & not belonging	☐ Start social activity e.g community group
☐ Intimacy problems	☐ Get professional support, see a relationship counsellor
☐ Life has become less meaningful	☐ Think about ways to give life meaning

Read more at:
www.hnehealth.nsw.gov.au/pain
www.aci.health.nsw.gov.au/chronic-pain

NSW Health
Hunter New England
Local Health District

FKG 1.8 PS nil September 2014

Activity problems 4a	**What will I do?** 4b
☐ Braces, heat packs, wraps, TENS, cushions / other ☐ Lying down for ____ hrs a day ☐ Sitting down for ____ hrs a day ☐ Not doing 30-60 min of physical activity every day ☐ Avoiding activity ☐ 5 sit to stands in _____ sec ☐ Comfortably lifts _____ kg to head height	☐ Start weaning off _____ ☐ Wean off lying down ☐ Break up sitting time / sit less ☐ Start a planned daily walk ☐ Gradually restart_____ ☐ Start a strength program for _____ Get support from: ☐ A community program e.g. hydrotherapy, Heartmoves ☐ My GP for a referral to a physio / exercise physiologist
Nutrition problems 5a	**What will I do?** 5b
☐ Waist _____ cm ☐ Unbalanced diet ☐ Too much sugar ☐ Not drinking enough water ☐ Not eating enough fruit / vegies ☐ Smoking ☐ Too much alcohol ☐ Other drug use	☐ Start having less sugary food, drinks and juices ☐ Start drinking more water ☐ Eat 5 serves of vegies and 2 serves of fruit a day ☐ Trial fish oil (2000mg twice a day) ☐ Quit smoking ☐ Limit alcohol to 2 standard drinks per day or less ☐ Quit drugs Get support from: ☐ Get Healthy information line 1300 806258 ☐ My GP for a referral to a dietitian ☐ Quitline on 131 848 or my GP ☐ Drug & Alcohol line on 1800 052222

I will START

What? _____

When? _____

How? _____

Who? _____

Next steps	***Discuss this plan with my GP***	☑
	Follow up phone call from HIPS	***Yes / No***
	Attend Supported Self-Management group at HIPS	***Yes / No***

Hunter Integrated Pain Service, John Hunter Hospital **Ph: 02 4922 3435**

Appendix 23. Statement of contribution and collaboration for Chapter 4: Perceptions of tertiary pain service staff on including nutrition support within current treatment: A qualitative study

I attest that Research Higher Degree candidate Katherine Brain contributed to the following paper:

Brain K, Burrows TL, Rollo ME, Thompson DI, Hayes C, Hodson FJ and Collins CE. Perceptions of tertiary pain staff on including nutrition support within current treatment: A qualitative study. SAGE Pathway [Under Review]

Katherine Brain contributed to the methodological design of the study including drafting the ethics application, the focus group protocol, recruitment materials and participant questionnaires. Katherine Brain also conducted the focus groups, analysed quantitative and qualitative data and drafted the manuscript. Associate Professor Tracy L Burrows, Dr Megan E Rollo, Dr Chris Hayes, Ms Fiona J Hodson and Professor Clare E Collins assisted with the development of the study design and contributed to the development of the ethics application and manuscript within their capacity as PhD supervisors. Professor Debbe I Thompson provided assistance in qualitative research methodologies and reviewed the focus group protocol. All authors approved the final manuscript.

Ms Katherine Brain Date: 12/12/2018

Associated Professor Tracy L Burrows Date: 12/12/2018

Dr Megan E Rollo Date: 12/12/2018

Professor Debbe I Thompson Date: 16/12/2018

Dr Chris Hayes Date: 12/12/2018

Ms Fiona J Hodson Date: 12/12/2018

Professor Clare E Collins Date: 12/12/2018

Professor Robert Callister Date: 18/12/2018

Deputy Head of Faculty of Health and Medicine (Research and Research Training)

Appendix 24. Staff Focus Group Protocol

As participants arrive

1. Ask them to read the information statement, ask any questions and sign the consent form (if they have not already done so)
2. Ask them to write a different name on their name tags (ensure it is not their own). Can be funny
3. Ask them to take a bathroom break now if they need to so as not to interrupt the session
4. Ask them to fill out the pre-focus group questionnaire (asking profession, how long they have been practicing, use of technology)

Before starting focus group

1. Thank everyone for coming
2. Introduce myself and my role (guide discussion and ensure everyone has the opportunity to contribute)
3. Introduce moderator and their role (keep everything on track and make some notes in case there is a problem with the recording)
4. Reason for the interview/how the information will be used: As health care professionals who treat or interact with people experiencing chronic pain, I would like to discuss your opinions, regarding the reasons why people experiencing chronic pain do or do not eat healthy. We are also aiming to create a nutrition related treatment option for people experience chronic pain and would like to know how you think this might fit into the current service at HIPS. It is really important to hear all your thoughts and opinions relating to nutrition and how it impacts on chronic pain (and vice versa). There are no right or wrong answers so please speak up, we really want to hear from everyone!
5. Interview procedure: we will be recording today's conversation and making some notes. This will remain confidential and secured in locked filing cabinet and will only be accessed by the research team. You will notice we have asked everyone to choose a different name so that you will not be identified and all comments will remain anonymous. I would like to ask that everyone speaks one at a time, avoid personal conversations as this will make it difficult to record the session.
6. Is everyone ready to get started? *Remind participants the tape recorder is starting*

1. Let's start by quickly talking about everyone's favourite food
2. As I mentioned earlier, we are interested in finding out what you think about nutrition and its relationship to chronic pain. So let's continue to talk about food. When you hear the words "healthy eating", what is the first thing that comes to mind? (Ask for examples of healthy foods)
The next few questions relate to your experience in treating people who experience chronic pain. Can you please try to reflect on this when answering these questions
3. In your experience, how might chronic pain influence nutrition? *Prompts: 1. Healthy food selection, 2. Unhealthy food selection, 3. Alcohol consumptions, 4. Meal patterns.* ***Probe to identify how***
4. In what ways, if at all, might chronic pain affect behaviours related to nutrition? *Prompts: 1. Food shopping, 2. Cooking, 3. Eating out, 4. Skipping meals, 5. Overeating.* ***Probe to identify how***
5. In your experience, in what ways might chronic pain affect body weight *Probe to identify what might make it difficult for people with chronic pain to: 1. Gain weight, 2. Lose weight, 3. Achieve a healthy body weight and 4. Maintain a healthy body weight.*
6. What might help people with chronic pain achieve and maintain a healthy body weight?
I would now like to move onto discuss the implementation of a nutrition intervention at HIPS
7. What benefits, if any, would you expect people to get from participating in a nutrition intervention? *Prompts: 1. Reduction in pain, 2. Lose weight, 3. Feel better, 4. Increase nutrition knowledge/skills, 5. Build confidence.* ***Probe to identify more information***
8. What barriers, if any, do you think patients might face if they participated in a nutrition intervention?

Prompts: 1. Motivation, 2. Accessibility, 3. Appropriateness of material, 4. Lack of knowledge/skills/confidence, 5. Fear. ***Probe to identify more information***
9. On a scale of 1 (not very useful) to 10 (extremely useful) how useful would a nutrition intervention be to people experiencing chronic pain? *Probe to identify reasons for choosing this rating*
10. If we offered a nutrition program to people experiencing chronic pain, what would you expect the program to include? What would you expect the program NOT to include?
11. How would the program be delivered? *Prompts: 1. Group sessions, 2. Individual sessions, 3. In person, 4. Over the internet, 5. Mobile technology (text messaging and apps), 6. Combination (which ones?). Probe to identify which they would find most appealing*
15. Tell me your thoughts about patient's ability to use technology? *Prompts: 1. Knowledge, 2. Skills, 3. Confidence, 4. Access, 5. Fear*
12. Tell me your thoughts about your ability to use technology? *Prompts: 1. Knowledge, 2. Skills, 3. Confidence, 4. Access, 5. Fear*
13. Considering the current service provided at HIPS, how would a nutrition intervention fit into the day to day running of HIPS?
14. What benefits, if any, would you expect the service to get from incorporating a nutrition intervention? *Prompts: 1. Improve knowledge/skills, 2. Better patient outcomes, 3. Use of an additional treatment option*
15. What barriers, if any, do you think the service might face from including a nutrition intervention in the current service? *Prompts: 1. Knowledge/skills, 2. Infrastructure, 3. Staff confidence, 4. Changes to professional identity*
16. All things considered ***[moderator to provide overall summary]*** *is this an adequate summary? Did I correctly describe what was said? Finally have we missed anything? And is there anything that you came wanting to say and you didn't get the chance to say?*

Upon finishing the focus group

Internal envelops are available if you would like to submit any confidential and anonymous comments. Please take one if you would like to add additional comments.

Appendix 25. Information Statement for staff focus groups (Hunter Integrated Pain Service)

Professor Clare Collins
Professor in Nutrition and Dietetics
NHMRC Senior Research Fellow
Co-director, Priority Research Centre in Physical Activity and Nutrition
Rm 310, Level 3 ATC Building
School of Health Sciences
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Callaghan, NSW, 2308
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THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Information Statement for the Research Project:
Document Version 2; dated 30/6/2016

Using focus groups to explore nutrition's role in chronic pain management

Staff at Hunter Integrated Pain Service are invited to participate in the research project identified above which is being conducted by the research team from the University of Newcastle and Hunter Integrated Pain Service.

The research is part of Katherine Brain's PhD study at the University of Newcastle, supervised by Professor Clare Collins from the School Health Sciences at the University of Newcastle

Why is the research being done?
The aim of this research is to understand how nutrition contributes to and/or affects pain experiences. We also plan to find out what you think patients would like included (or not included) in a nutrition program, as well as the factors that help and support patients (motivators) and make it harder (barriers) to eating healthily. The information obtained from this research will inform the development of a nutrition program targeted to the needs of people experiencing pain.

Who can participate in the research?
We are seeking clinical and administrative staff who work at Hunter Integrated Pain Service.

What would you be asked to do?
If you agree to participate, you will be asked to attend a focus group where you will be asked to participate in discussions relating to nutrition and pain. The focus group questions will give participants the opportunity to discuss ideas on nutrition and how food relates to patients' pain experiences. All responses will be kept anonymous and confidential. The focus group will be audio-recorded and transcribed using an outside transcription service. This service has been used in other researcher projects conducted at the University of Newcastle and has been deemed valid and reliable. The transcription services referred will be bound by a confidentiality agreement. You will be given an opportunity to review and/or edit the transcribed interview contents. De-identified copies of the transcripts will be sent to you via email. Participants will also be asked to complete a short questionnaire where they will be asked to specify their profession and years working in the profession.

What choice do you have?
Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you. If you do decide to participate, you may withdraw from the project at any time.

How much time will it take?
The focus group will take approximately 1 hour to complete and will be held at the John Hunter Hospital.

What are the risks and benefits of participating?
There is the possibility that some discussion may be considered sensitive and if you ever feel uncomfortable you can stop participating at any time. You can also contact NSW Mental Health Line 1800 011 511 should you wish to seek further support regarding any of the issues raised within the focus groups. Those who complete the focus groups will provide valuable information to inform the design of a program that could benefit the health and wellbeing of people experiencing chronic pain. Refreshments will be available.

How will your privacy be protected?
All of the information provided will remain confidential and only the research team will be access the information. All the information will be stored on a password protected computer of the student researcher (Katherine Brain) and in a locked filing cabinet, both are securely located at the University of Newcastle. Data will be retained for a minimum of 5 years as per University of Newcastle requirements.

How will the information collected be used?
The information collected will be used to help develop a nutrition program for people who experience chronic pain. The results will be published in a journal article and in the PhD thesis of Katherine Brain. You will not be identified in any reports arising from the study. You can access a summary of the results of the research by emailing the student researcher, Katherine Brain (Katherine.Brain@uon.edu.au).

What do you need to do to participate?
Please read this Information Statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, please contact Katherine Brain (Email: Katherine.Brain@uon.edu.au, Phone: (02) 49218673) or the chief investigator Professor Clare Collins (Email: Clare.Collins@newcastle.edu.au, Phone (02) 49215646).

If you would like to participate or would like more information, please contact Katherine Brain (Email: Katherine.Brain@uon.edu.au or Phone: 49218673)

Thank you for considering this invitation.

Professor Clare Collins (Chief Investigator) Katherine Brain (Student Researcher)

Complaints about this research
This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 16/07/20/5.04

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email HNELHED-HREC@hnehealth.nsw.gov.au

Appendix 26. Information Statement for staff focus groups (Tamworth Integrated Pain Service)

Professor Clare Collins
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Faculty of Health
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Callaghan, NSW, 2308
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Email: Clare.Collins@newcastle.edu.au

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Information Statement for the Research Project:
Document Version 1; dated 17/8/2016

Using focus groups to explore nutrition's role in chronic pain management

Staff at Tamworth Integrated Pain Service are invited to participate in the research project identified above which is being conducted by the research team from the University of Newcastle and Hunter Integrated Pain Service.

The research is part of Katherine Brain's PhD study at the University of Newcastle, supervised by Professor Clare Collins from the School Health Sciences at the University of Newcastle

Why is the research being done?
The aim of this research is to understand how nutrition contributes to and/or affects pain experiences. We also plan to find out what you think patients would like included (or not included) in a nutrition program, as well as the factors that help and support patients (motivators) and make it harder (barriers) to eating healthily. The information obtained from this research will inform the development of a nutrition program, one that is translatable across services, targeted to the needs of people experiencing pain.

Who can participate in the research?
We are seeking clinical and administrative staff who work at Tamworth Integrated Pain Service.

What would you be asked to do?
If you agree to participate, you will be asked to attend a focus group where you will be asked to participate in discussions relating to nutrition and pain. The focus group questions will give participants the opportunity to discuss ideas on nutrition and how food relates to patients' pain experiences. All responses will be kept anonymous and confidential. The focus group will be audio-recorded and transcribed using an outside transcription service. This service has been used in other researcher projects conducted at the University of Newcastle and has been deemed valid and reliable. The transcription services referred will be bound by a confidentiality agreement. You will be given an opportunity to review and/or edit the transcribed interview contents. De-identified copies of the transcripts will be sent to you via email. Participants will also be asked to complete a short questionnaire where they will be asked to specify their profession and years working in the profession.

What choice do you have?
Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you. If you do decide to participate, you may withdraw from the project at any time.

How much time will it take?
The focus group will take approximately 1 hour to complete and will be held at the John Hunter Hospital.

What are the risks and benefits of participating?
There is the possibility that some discussion may be considered sensitive and if you ever feel uncomfortable you can stop participating at any time. You can also contact NSW Mental Health Line 1800 011 511 should you wish to seek further support regarding any of the issues raised within the focus groups. Those who complete the focus groups will provide valuable information to inform the design of a program that could benefit the health and wellbeing of people experiencing chronic pain. Refreshments will be available.

How will your privacy be protected?
All of the information provided will remain confidential and only the research team will be access the information. All the information will be stored on a password protected computer of the student researcher (Katherine Brain) and in a locked filing cabinet, both are securely located at the University of Newcastle. Data will be retained for a minimum of 5 years as per University of Newcastle requirements.

How will the information collected be used?
The information collected will be used to help develop a nutrition program for people who experience chronic pain. The results will be published in a journal article and in the PhD thesis of Katherine Brain. You will not be identified in any reports arising from the study. You can access a summary of the results of the research by emailing the student researcher, Katherine Brain (Katherine.Brain@uon.edu.au).

What do you need to do to participate?
Please read this Information Statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, please contact Katherine Brain (Email: Katherine.Brain@uon.edu.au, Phone: (02) 49218673) or the chief investigator Professor Clare Collins (Email: Clare.Collins@newcastle.edu.au, Phone (02) 49215646).

If you would like to participate or would like more information, please contact Katherine Brain (Email: Katherine.Brain@uon.edu.au or Phone: 49218673)

Thank you for considering this invitation.

Professor Clare Collins (Chief Investigator) Katherine Brain (Student Researcher)

Complaints about this research
This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 16/07/20/5.04

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email HNELHED-HREC@hnehealth.nsw.gov.au

Appendix 27. Questionnaire for staff focus groups

Thank you for participating in this focus group.

Before we get started, can you please answer the following questions?

We would like to know a bit more about people who participate in these focus groups (e.g. profession and length of time in practice).

1. What is your profession?

☐ Medical specialist

☐ Nurse

☐ Physiotherapist

☐ Psychologist

☐ Psychiatrist

☐ Other (please specify):_____

2. How long have you been working in your profession?

_____ Years

3. How long have you been working in your profession, in the area of chronic pain management?

_____ Years

The final questions relates to the introduction of a nutrition intervention for people who experience chronic pain.

4. On a scale of 1 (not very useful) to 10 (extremely useful) how useful would a nutrition intervention be to people experiencing chronic pain?

Appendix 28. Consent form for staff focus groups

Professor Clare Collins
Professor in Nutrition and Dietetics
NHMRC Senior Research Fellow
Co-director, Priority Research Centre in Physical Activity and Nutrition
Rm 310, Level 3 ATC Building
School of Health Sciences
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The University of Newcastle
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Ph: 02 49215646
Fax: 0249217053
Email: Clare.Collins@newcastle.edu.au

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Consent Form for the Research Project: *"Using focus groups to explore nutrition's role in chronic pain management"*

Document Version 2; dated 30/6/2016

I agree to participate in the above research project and give my consent freely.
I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I consent to completing a questionnaire, participating in a focus group and having it recorded.

Please note: the focus group discussions will be transcribed by an outside transcription service. Other projects at the University of Newcastle have also used this service in the past and have deemed this service as valid and reliable. The transcription services referred will be bound by a confidentiality agreement.

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

Please complete with your name, contact details, signature and date and return to the research team via email: Katherine.Brain@uon.edu.au

Or post:
Katherine Brain
HA15 Hunter Building
School of Health Sciences
The University of Newcastle
Callaghan NSW 2308

Print Name: _____

Contact details (email and/or phone): _____

Signature: _____ **Date:** _____

Please note: If you are unable to provide a signature and send back (eg. No scanning or printing facilities) and would like to provide a signature on the day of your focus group session please email Katherine.Brain@uon.edu.au and express your intention to do this.

Appendix 29. Statement of contribution and collaboration for Chapter 5: Exploring the attitudes and beliefs of nutrition's role in pain management through semi-structured focus groups with patients experiencing chronic pain

I attest that Research Higher Degree candidate Katherine Brain contributed to the following paper:

Brain K, Burrows TL, Rollo ME, Thompson DI, Hayes C, Hodson FJ and Collins CE. Exploring the attitudes and beliefs of nutrition's role in pain management through semi-structured focus groups with patients experiencing chronic pain. Healthcare [Under Review]

Katherine Brain contributed to the methodological design of the study including drafting the ethics application, the focus group protocol, recruitment materials and participant questionnaires. Katherine Brain also conducted the focus groups, analysed quantitative and qualitative data and drafted the manuscript. Associate Professor Tracy L Burrows, Dr Megan E Rollo, Dr Chris Hayes, Ms Fiona J Hodson and Professor Clare E Collins assisted with the development of the study design and contributed to the development of the ethics application and manuscript within their capacity as PhD supervisors. Professor Debbe I Thompson provided assistance in qualitative research methodologies and reviewed the focus group protocol. All authors approved the final manuscript.

Ms Katherine Brain Date: 14/12/18

Associated Professor Tracy L Burrows Date: 14/12/18

Dr Megan E Rollo Date: 14/12/18

Professor Debbe I Thompson Date: 16/12/2018

Dr Chris Hayes Date: 14/12/18

Ms Fiona J Hodson Date: 14/12/18

Professor Clare E Collins Date: 14/12/18

Professor Robert Callister Date: 18/12/2018

Deputy Head of Faculty of Health and Medicine (Research and Research Training)

Appendix 30. Information Statement for patient focus groups

Professor Clare Collins
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THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Information Statement for the Research Project:
Document Version 3; dated 25/7/2016

Using focus groups to explore nutrition's role in chronic pain management

Patients at Hunter Integrated Pain Service are invited to participate in the research project identified above which is being conducted by the research team from the University of Newcastle and Hunter Integrated Pain Service.

The research is part of Katherine Brain's PhD study at the University of Newcastle, supervised by Professor Clare Collins from the School Health Sciences at the University of Newcastle

Why is the research being done?
The aim of this research is to understand how nutrition contributes to and/or affects pain experiences. We also plan to find out what you would like included (or not included) in a nutrition program, as well as the factors that help and support you (motivators) and make it harder (barriers) to eating healthily. The information obtained from this research will inform the development of a nutrition program targeted to the needs of people experiencing pain.

Who can participate in the research?
We are seeking people who experience chronic pain, aged over 18 years who currently attend Hunter Integrated Pain Service.

What would you be asked to do?
If you agree to participate, you will be asked to attend a focus group where you will be asked to participate in discussions relating to nutrition and pain. The focus group questions will give participants the opportunity to discuss ideas on nutrition and how food relates to their pain experiences. All responses will be kept anonymous and confidential. The focus group will be audio-recorded and transcribed using an outside transcription service. This service has been used in other researcher projects conducted at the University of Newcastle and has been deemed valid and reliable. The transcription services referred will be bound by a confidentiality agreement. You will be given an opportunity to review and/or edit the transcribed interview contents. De-identified copies of the transcripts will be sent to you via email. Participants will also be asked to complete a short questionnaire which will ask for your age, gender and pain status and also ask questions around use and confidence in using the internet and technology.

What choice do you have?
Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you or affect your treatment at HIPS. If you do decide to participate, you may withdraw from the project at any time.

How much time will it take?
The focus group will take approximately 1 hour to complete and will be held at the John Hunter Hospital.

What are the risks and benefits of participating?
There is the possibility that some discussion may be considered sensitive and if you ever feel uncomfortable you can stop participating at any time. You can also contact NSW Mental Health Line 1800 011 511 should you wish to seek further support regarding any of the issues raised within the focus groups. Those who complete the focus groups will

provide valuable information to inform the design of a program that could benefit the health and wellbeing of people experiencing chronic pain. Parking and transport costs will be covered for those who attend. Refreshments will also be available.

How will your privacy be protected?
All of the information provided will remain confidential and only the research team will be access the information. All the information will be stored on a password protected computer of the student researcher (Katherine Brain) and in a locked filing cabinet, both are securely located at the University of Newcastle. Data will be retained for a minimum of 5 years as per University of Newcastle requirements.

How will the information collected be used?
The information collected will be used to help develop a nutrition program for people who experience chronic pain. The results will be published in a journal article and in the PhD thesis of Katherine Brain. You will not be identified in any reports arising from the study. You can access a summary of the results of the research by emailing the student researcher, Katherine Brain (food4pain@newcastle.edu.au).

What do you need to do to participate?
Please read this Information Statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, please contact Katherine Brain (Email: food4pain@newcastle.edu.au, Phone: (02) 49218673) or the chief investigator Professor Clare Collins (Email: Clare.Collins@newcastle.edu.au, Phone (02) 49215646).

If you would like to participate or would like more information, please contact Katherine Brain (Email: food4pain@newcastle.edu.au or Phone: 49218673)

Thank you for considering this invitation.

Professor Clare Collins (Chief Investigator) Katherine Brain (Student Researcher)

Complaints about this research
This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 16/07/20/5.04

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email HNELHED-HREC@hnehealth.nsw.gov.au

Appendix 31. Consent form for patient focus groups

Professor Clare Collins
Professor in Nutrition and Dietetics
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Co-director, Priority Research Centre in Physical Activity and Nutrition
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Email: Clare.Collins@newcastle.edu.au

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Consent Form for the Research Project: "*Using focus groups to explore nutrition's role in chronic pain management*"

Document Version 2; dated 25/7/2016

I agree to participate in the above research project and give my consent freely.
I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I consent to completing a questionnaire, participating in a focus group and having it recorded.

Please note: the focus group discussions will be transcribed by an outside transcription service. Other projects at the University of Newcastle have also used this service in the past and have deemed this service as valid and reliable. The transcription services referred will be bound by a confidentiality agreement.

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

Please complete with your name, contact details, signature and date and return to the research team via email: ffood4pain@newcastle.edu.au.

Or post:
Katherine Brain
HA15 Hunter Building
School of Health Sciences
The University of Newcastle
Callaghan NSW 2308

Print Name: _____

Contact details (email and/or phone): _____

Signature: _____ **Date:** _____

Please note: If you are unable to provide a signature and send back (eg. No scanning or printing facilities) and would like to provide a signature on the day of your focus group session please email food4pain@newcastle.edu.au and express your intention to do this.

Appendix 32. Questionnaire for patient focus groups

Thank you for participating in this focus group.

Before we get started, can you please answer the following questions?

Gender: ☐ Male ☐ Female Date of birth: / /

Where do you feel most of your pain? .....

How did the main pain begin?

☐ Injury at home ☐ After surgery ☐ Related to another illness
☐ Injury at work/school ☐ Motor vehicle crash ☐ No obvious cause
☐ Injury in another setting ☐ Related to cancer ☐ Other .....

How long have you had the main pain? (tick one box only)

☐ Less than 3 months ☐ 12 months to 2 years ☐ More than 5 years
☐ 3 to 12 months ☐ 2 to 5 years

Which statement best describes the pain? (tick one box only)

☐ The pain is always there and always has the same intensity
☐ The pain is always there but the intensity changes
☐ The pain comes and goes. I am pain-free for less than 6 hours at a time
☐ The pain comes and goes and lasts up to an hour at a time.
☐ The pain comes every few days or weeks

Do you have any of these medical problems?

☐ Heart disease ☐ Rheumatoid arthritis ☐ Anaemia or other blood disease
☐ High blood pressure ☐ Kidney disease ☐ Osteoarthritis/degenerative arthritis
☐ Lung disease ☐ Depression/Anxiety ☐ Ulcer or stomach disease
☐ Diabetes ☐ Cancer ☐ Stroke or other neurological condition
☐ Other medical problems (please specify) .....

We would like to ask you for your opinion and about your experience using the Internet for health information. Can you please answer the following questions?

1. How often do you estimate you access the Internet for personal and/or health related activities such as to search for information, browse websites, and/or check email or social media (e.g. Facebook, twitter) including any access that occurs through an "app"? *Please do not include work-related activities in your estimate.*

☐ Never
☐ Once per month or less
☐ Once per fortnight
☐ Once a week
☐ Once a day
☐ 2-4 times per day
☐ 5-10 times per day
☐ More than 10 times per day

2. Which of the following devices do you own? *(please tick all that apply)*

- ☐ Desktop computer
- ☐ Laptop computer
- ☐ Tablet computer (e.g. iPad, Microsoft Surface)
- ☐ Smartphone (e.g. iPhone, Samsung Galaxy)
- ☐ None of the above
- ☐ Other (please specify):_____

3. Of the devices you own, which ones do you use to access the Internet? *(please tick all that apply)*

- ☐ Desktop computer
- ☐ Laptop computer
- ☐ Tablet computer (e.g. iPad, Microsoft Surface)
- ☐ Smartphone (e.g. iPhone, Samsung Galaxy)
- ☐ None of the above
- ☐ Other (please specify):_____

For each statement below, tell me which response best reflects your opinion and experience right now.

4. I know **what** health resources are available on the Internet
   - ☐ Strongly disagree
   - ☐ Disagree
   - ☐ Undecided
   - ☐ Agree
   - ☐ Strongly agree

5. I know **where** to find helpful health resources on the Internet
   - ☐ Strongly disagree
   - ☐ Disagree
   - ☐ Undecided
   - ☐ Agree
   - ☐ Strongly agree

6. I know **how** to find helpful health resources on the Internet
   - ☐ Strongly disagree
   - ☐ Disagree
   - ☐ Undecided
   - ☐ Agree
   - ☐ Strongly agree

7. I know **how to use** the Internet to answer my questions about health
   - ☐ Strongly disagree
   - ☐ Disagree
   - ☐ Undecided
   - ☐ Agree
   - ☐ Strongly agree

8. I know how to use **the health information** I find on the internet to help me
   - ☐ Strongly disagree
   - ☐ Disagree
   - ☐ Undecided
   - ☐ Agree
   - ☐ Strongly agree

9. I have the skills I need to **evaluate** the health resources I find on the Internet
   - ☐ Strongly disagree
   - ☐ Disagree
   - ☐ Undecided
   - ☐ Agree
   - ☐ Strongly agree

10. I can tell **high quality** health resources from **low quality** health resources on the Internet
    - ☐ Strongly disagree
    - ☐ Disagree
    - ☐ Undecided
    - ☐ Agree
    - ☐ Strongly agree

11. I feel **confident** in using information from the Internet to make health decisions
    - ☐ Strongly disagree
    - ☐ Disagree
    - ☐ Undecided
    - ☐ Agree
    - ☐ Strongly agree

Appendix 33. Patient focus group protocol

As participants arrive

1. Ask them to read the information statement, ask any questions and sign the consent form (if they have not already done so)
2. Ask them to write a different name on their name tags (ensure it is not their own). Can be funny
3. Ask them to take a bathroom break now if they need to so as not to interrupt the session
4. Ask them to fill out the pre-focus group questionnaire (asking permission to access demographic data via their records stored on HIPS data base and use of technology)

Before starting focus group

1. Thank everyone for coming
2. Introduce myself and my role (guide discussion and ensure everyone has the opportunity to contribute)
3. Introduce moderator and their role (keep everything on track and make some notes in case there is a problem with the recording)
4. Reason for the interview/how the information will be used: Today I would like to discuss the reasons why people experiencing chronic pain do or do not eat healthy. We are also aiming to create a nutrition related treatment option for people who experience chronic pain and would like to know if you would like a nutrition program, and what you would like to see included in the program. It is really important to hear all your thoughts and opinions relating to nutrition and how it impacts on chronic pain (and vice versa). There are no right or wrong answers so please speak up, we really want to hear from everyone!
5. Interview procedure: we will be digitally recording today's conversation and making some notes. The recording and notes will remain confidential and secured in locked filing cabinet and will only be accessed by the research team. You will notice we have asked everyone to choose a different name so that you will not be identified and all comments will remain anonymous. I would like to ask that everyone respects the discussion today and that the conversation is kept confidential and not discussed outside the room. I would also like to ask that everyone speaks one at a time, avoid personal conversations as this will make it difficult to record the session.
6. Is everyone ready to get started? *Remind participants the tape recorder is starting*

1. *Let's start by quickly talking about everyone's favourite food*
2. *As I mentioned earlier, we are interested in finding out what you think about nutrition and its relationship to chronic pain. So let's continue to talk about food. When you hear the words "healthy eating", what is the first thing that comes to mind? (Ask for examples of healthy foods)*
3. *In your experience, how might chronic pain influence nutrition?* *Prompts: 1. Healthy food selection, 2. Unhealthy food selection, 3. Alcohol consumptions, 4. Meal patterns.* ***Probe to identify how***
4. *In what ways, if at all, might chronic pain affect behaviours related to nutrition?* *Prompts: 1. Food shopping, 2. Cooking, 3. Eating out, 4. Skipping meals, 5. Overeating, 6. Capability, 7. Opportunity, 8. Motivation.* ***Probe to identify how***
5. *In your experience, in what ways might chronic pain affect body weight* *Probe to identify what might make it difficult for people with chronic pain to: 1. Gain weight, 2. Lose weight, 3. Achieve a healthy body weight and 4. Maintain a healthy body weight.*
6. *What might help people with chronic pain achieve and maintain a healthy body weight?*
7. *What benefits, if any, would you expect from participating in a nutrition intervention?* *Prompts: 1. Reduction in pain, 2. Lose weight, 3. Feel better, 4. Increase nutrition knowledge/skills, 5. Build confidence.* ***Probe to identify more information***
8. *What barriers, if any, do you think you might face if you participated in a nutrition intervention?* *Prompts: 1. Motivation, 2. Accessibility, 3. Appropriateness of material, 4. Lack of knowledge/skills/confidence, 5. Fear.* ***Probe to identify more information***
9. *On a scale of 1 (not very useful) to 10 (extremely useful) how useful would a nutrition intervention be to people experiencing chronic pain?*

Probe to identify reasons for choosing this rating
10. If we offered a nutrition program to people experiencing chronic pain, what would you expect the program to include? What would you expect the program NOT to include?
11. How would you prefer the program to be delivered? *Prompts: 1. Group sessions, 2. Individual sessions, 3. In person, 4. Over the internet, 5. Mobile technology (text messaging and apps), 6. Combination (which ones?). Probe to identify which they would find most appealing*
12. Tell me about the ways in which you currently use technology to manage pain? *Prompts: 1. Phone, 2. Internet, 3. Smartphone apps, 4. Online support groups, 5. Wearable devices*
13. Tell me your thoughts about your ability to use technology? *Prompts: 1. Knowledge, 2. Skills, 3. Confidence, 4. Access, 5. Fear*
14. All things considered ***[moderator to provide overall summary]*** *is this an adequate summary? Did I correctly describe what was said? Finally have we missed anything? And is there anything that you came wanting to say and you didn't get the chance to say?*

Appendix 34. Statement of contribution and collaboration for Chapter 6: The effect of a pilot dietary intervention on pain outcomes in patients attending a tertiary chronic pain service

I attest that Research Higher Degree candidate Katherine Brain contributed to the following paper:

Brain K, Burrows TL, Rollo ME, Hayes C, Hodson FJ and Collins CE. ReJUICE your pain: The effect of a dietary intervention on pain outcomes in patients attending a tertiary chronic pain service. Nutrients. [Under Review].

Katherine Brain contributed to the methodological design of the study including drafting the ethics application, intervention protocol, recruitment materials and participant questionnaires. Katherine Brain also conducted recruitment, data collection, delivered the intervention, analysed the data and drafted the manuscript. Associate Professor Tracy L Burrows, Dr Megan E Rollo, Dr Chris Hayes, Ms Fiona J Hodson and Professor Clare E Collins assisted with the development of the study design and contributed to the development of the ethics application, intervention protocol and manuscript within their capacity as PhD supervisors. All authors approved the final manuscript.

Ms Katherine Brain Date: 12/12/2018

Associated Professor Tracy L Burrows Date: 12/12/2018

Dr Megan E Rollo Date: 12/12/2018

Dr Chris Hayes Date: 12/12/2018

Ms Fiona J Hodson Date: 12/12/2018

Professor Clare E Collins Date: 12/12/2018

Professor Robert Callister Date: 13/12/2018

Deputy Head of Faculty of Health and Medicine (Research and Research Training)

Appendix 35. Permission to reproduce the published manuscript: The effect of a pilot dietary intervention on pain outcomes in patients attending a tertiary chronic pain service

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Appendix 36. Permission to reproduce the ReJUICE your pain logo

From: Grace Perrot
To: Katherine Brain
Subject: RE: Permission to reprint logo in PhD thesis
Date: Thursday, 13 December 2018 10:10:17 AM
Attachments: image001.png
image002.png
image003.png

Hi Katherine,

I give you, permission to reprint the ReJUICE your pain logo in your PhD thesis and also, non-exclusive licence to copy and communicate the logo via the University of Newcastle's online institutional repository NOVA.

Thank you,

- Grace

Grace Perrot
B Nutr&Diet (Hons)
Research Assistant
School of Health Sciences
Faculty of Health and Medicine
Priority Research Centre in Physical Activity & Nutrition

P: 0437 878 243
E: Grace.Perrot@newcastle.edu.au

The University of Newcastle (UON)
University Drive, Callaghan NSW 2308 Australia

From: Katherine Brain <Katherine.Brain@uon.edu.au>
Sent: Thursday, 13 December 2018 9:11 AM
To: Grace Perrot <Grace.Perrot@newcastle.edu.au>
Subject: Permission to reprint logo in PhD thesis

Hi Grace,

As I have previously mentioned, I would like to reprint the ReJUICE your pain logo (attached) which you created for my intervention study.

I would like to reprint this in my PhD thesis and would like to ask for non-exclusive licence to copy and communicate the logo via the University of Newcastle's online institutional repository NOVA.

Thanks,

Katherine

Katherine Brain (APD) B Nutr&Diet (Hons)
PhD Candidate & Research Assistant
School Health Sciences Faculty of Health and Medicine
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The University of Newcastle (UON)
University Drive Callaghan NSW 2308 Australia

Appendix 37. ReJUICE your pain study logo

Appendix 38. Supplementary Table S1: CONSORT 2010 Checklist

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2 & 3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3 & 4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	3
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6 & 7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	4

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	4, 7 & 8
	13b	For each group, losses and exclusions after randomisation, together with reasons	4, 7 & 8
Recruitment	14a	Dates defining the periods of recruitment and follow-up	3
	14b	Why the trial ended or was stopped	3
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9, 11-15
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9-16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	9-16
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9-16
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A Nil adverse events
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	18
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16-19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	16-19

Other information			
Registration	23	Registration number and name of trial registry	7
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix 39. Information Statement for ReJUICE your pain study

Professor Clare Collins
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THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Information Statement for the Research Project:
Document Version 3; dated 22/11/2017
Prof Clare Collins, A/Prof Tracy Burrows, Dr Megan Rollo, Dr Chris Hayes, Ms Fiona Hodson, Prof Lisa Wood and Miss Katherine Brain

ReJUICE your pain: A nutrition intervention for people experiencing pain

Patients at Hunter Integrated Pain Service (HIPS) are invited to participate in the research project identified above which is being conducted by the research team from the University of Newcastle and Hunter Integrated Pain Service.

The research is part of Katherine Brain's PhD study at the University of Newcastle, supervised by Professor Clare Collins from the School of Health Sciences at the University of Newcastle

Why is the research being done?
The aim of this research is to explore the acceptability and efficacy of a nutrition intervention and how it affects pain experiences. We also plan to explore the effect of a bioactive juice on pain levels. The bioactive juice contains a natural substance thought to affect the severity of pain. The information obtained from this research will help to plan future nutrition management strategies for pain.

Who can participate in the research?
We are seeking people who experience chronic pain, aged over 18 years who currently attend Hunter Integrated Pain Service. Participants must also have regular access to the internet.

The study is not suitable for those who:
- Cannot comprehend English
- Are currently pregnant, breastfeeding or trying to conceive
- Have a pacemaker or cochlear implant
- Have dietary restrictions due to allergy or intolerance to fruit
- Have Type I Diabetes or Type 2 Diabetes controlled with insulin

What would you be asked to do?
The study will run for 6 weeks. You will be randomly allocated to one of four groups:

If you are allocated to Group 1 or Group 2 you will be asked to:
- Complete two short questionnaires to record the foods you consumed in the previous 24 hours.
- Complete the Australian Eating Survey (AES) on two occasions. The survey will ask you about the foods that you currently eat and take about 15 minutes to complete online.
- Immediately upon completion of each survey you will be sent an email with your dietary analysis report with feedback on the nutritional adequacy of your diet. The report will compare your intake to Australian recommendations.
- You will be asked to attend up to three video coaching sessions with a dietitian. Two are highly recommended and one is optional. This can be done on a computer, tablet, iPad or smartphone.
- During the 6 week period you will be asked to consume 1x250ml bottle of juice every day for 6 weeks which will be provided to you free of charge by the researchers. The juice will be provided to participants at their first measurement session. Group 1 and Group 2 participants will receive different juices.

If you are allocated to Group 3 or Group 4 you will be asked to:

- Complete two short questionnaires to record the foods you consumed in the previous 24 hours.
- Complete the Australian Eating Survey (AES) on two occasions. The survey asks you about the foods that you currently consume and takes 15-20 minutes to complete online, which you will access via a link sent in an email.
- During the 6 weeks you will be asked to consume 1x 250ml bottle of juice every day for 6 weeks. Group 3 and Group 4 participants will receive different juices.
- You *will not* be sent a copy of your dietary analysis report or receive video coaching sessions with the dietitian throughout the study.
- At the end of the study, you will be given access to your dietary analysis report and an opportunity to speak with the dietitian via video coaching.
- After receiving your dietary analysis report and completed your video coaching session you will be asked to complete a short online questionnaire to ask about your experience with the report and video coaching session.

All participants will be asked to do the following:

- Attend 2 measurement sessions: each taking approximately 1-1.5hr this will occur at the start and the completion of the study. These will be conducted at the University of Newcastle. At these sessions, the following measurements will occur:
    - An online questionnaire including demographic (e.g. age, gender, work status) and pain-related questions: the primary aim of this study is to determine if you experience a change in your pain experience. This questionnaire will allow the research team to determine if you have experienced a change and if the intervention has been successful.
    - The Yale Food Addiction Scale: This questionnaire will be included in the online questionnaire mentioned above and it will help identify how people may use food to help them cope with their pain.
    - Body composition, height, weight and waist circumference: throughout the study the research team wish to monitor changes in weight and body composition and determine if a weight change has an impact on pain severity.
    - Blood pressure & arterial stiffness: This will be measured using a cardioscope, which will measure blood pressure and the arterial stiffness (this means how elastic your arteries are) of the arteries near the heart. The purpose of measuring blood pressure and arterial stiffness is to see if participation in this study has any impact on each participant's blood pressure and arterial stiffness.
    - Skin carotenoid analysis: Non-invasive photos will be taken of your skin on three sites of the body, the palm of the hand, and two at the elbow. This will be taken using a spectrophotometer which measures skin carotenoids (this means how much of the carotenoid pigment is stored in your skin). The carotenoid pigment is found in the brightly coloured fruit and vegetables and are stored in the skin.
    - Fasting blood sample: the purpose of the blood test is to measure any changes in antioxidants, cholesterol and inflammation markers to allow the research team to determine if the intervention is having an effect on your health
- Participate in a phone interview. The interview will ask about your experiences in the study including feedback on the components that you were provided with during the study. You will be asked questions relating to reasons and expectations of participating and experience of the program components including the Australian Eating Survey, the video coaching sessions and the juice. The telephone interview will be conducted by a research assistant who is experienced in participant interviews. The interview will be recorded and transcribed by the researchers. You will have an opportunity to review and/or edit the contents of the transcribed interview recording and confirm you are happy with the contents.

All participants will be given a parking permit to attend the measurement sessions and a healthy breakfast will be provided to all participants after the blood sample has been taken.

What choice do you have?

Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you or affect your treatment at HIPS. If you do decide to participate, you may withdraw from the project at any time.

How much time will it take?

The study will take 6 weeks and will include completing the AES on 2 occasions, up to 3 video coaching sessions with a dietitian (2 compulsory and 1 optional session) and 2 measurement sessions at the University of Newcastle. The phone interview will take between 15-30 minutes to complete and the interview will be conducted at a time that is convenient to you.

What are the risks and benefits of participating?

The side effects of having blood taken may including bleeding or bruising at the needle insertion point and possible dizziness and/or fainting. You will be asked if you normally feel dizzy or faint when you have blood taken and steps will be taken to reduce the risk of this occurring. The blood collection will follow standardized procedures and samples will be collected by a qualified phlebotomist.

During the video coaching sessions with the dietitian, some discussion may be considered sensitive and if you ever feel uncomfortable you can stop participating at any time. The option to speak to another health professional will also be made available if this situation arises. You can also contact NSW Mental Health Line 1800 011 511 should you wish to seek further support regarding any of the issues raised in these sessions. All video coaching sessions will remain confidential.

Those who complete this research study may find they have a reduction in their pain experience and improvements in their overall wellbeing. Participating will provide valuable information to inform further work in this area that could benefit the health and wellbeing of all people experiencing chronic pain.

How will your privacy be protected?

All of the information provided will remain confidential and only the research team will have access to the information. The recordings will be uploaded and saved on the student researchers password protected computer. Once these have been uploaded the tape recordings will be immediately deleted. All the information will be stored on a password protected computer of the student researcher (Katherine Brain) and in a locked filing cabinet, both are securely located at the University of Newcastle. Data will be retained for a minimum of 5 years as per University of Newcastle requirements.

How will the information collected be used?

The information collected will be used to help develop a nutrition program for people who experience chronic pain. The results will be published in a journal article and in the PhD thesis of Katherine Brain. You will not be identified in any reports arising from the study. You can access a summary of the results of the research by emailing the student researcher, Katherine Brain (rejuicepain@newcastle.edu.au)

What do you need to do to participate?

Please read this Information Statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, please contact Katherine Brain (Email: rejuicepain@newcastle.edu.au, Phone: (02) 49218673) or the chief investigator Professor Clare Collins (Email: Clare.Collins@newcastle.edu.au, Phone (02) 49215646).

If you would like to participate or would like more information, please contact Katherine Brain (Email: rejuicepain@newcastle.edu.au or Phone: 49218673)

Thank you for considering this invitation.

Prof Clare Collins (Chief Investigator)

A/Prof Tracy Burrows (Co-Investigator)

Dr Megan Rollo (Co-Investigator)

Dr Chris Hayes (Co-Investigator)

Ms Fiona Hodson (Co-Investigator)

Prof Lisa Wood (Co-Investigator)

Miss Katherine Brain (Student Researcher)

Complaints about this research

This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference number 17/07/19/4.04

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email HNELHED-HREC@hnehealth.nsw.gov.au

Appendix 40. Consent form for ReJUICE your pain study

Professor Clare Collins
Professor in Nutrition and Dietetics
NHMRC Senior Research Fellow
Co-director, Priority Research Centre in Physical Activity and Nutrition
Rm 310, Level 3 ATC Building
School of Health Sciences
Faculty of Health
The University of Newcastle
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Email: Clare.Collins@newcastle.edu.au

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Consent Form for the Research Project: *ReJUICE your pain: A nutrition intervention for people experiencing chronic pain*

Document Version 2; dated 24/07/2017

I agree to participate in the above research project and give my consent freely.

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing. I understand that my participation (or withdrawal) will have no impact on my treatment with Hunter Integrated Pain Service or with the University of Newcastle

I consent to being randomly allocated to either a nutrition intervention or waitlist control group as well as completing two 24 hour recalls and the Australian Eating Survey (AES) on 2 occasions, consuming 1x 250ml bottle of juice per day for 6 weeks and coming along to 2 measurement sessions. If allocated to the intervention group, I understand that I will receive my AES feedback report during the study and will be asked to attend up to 3 telehealth sessions with a dietitian. If allocated to the waitlist control group, I understand that I will receive my AES feedback report and access the telehealth sessions with the dietitian at the end of the 6 week study.

I understand that all my information will remain confidential. I have had the opportunity to have questions answered to my satisfaction.

Please complete with your name, contact details, signature and date and return to the research team via email: rejuicepain@newcastle.edu.au

Or post:
Katherine Brain
HA15 Hunter Building
School of Health Sciences
The University of Newcastle
Callaghan NSW 2308

Or you can return your form, in person, at your baseline measurement session

Print Name: _____

Contact details (email and/or phone): _____

Signature: _____ **Date:** _____

Appendix 41. Personalised Dietary Consultation protocol for ReJUICE your pain study

Session 1 (Week 1), 30 minutes

Section (time)	Content	Behaviour change technique	Resources
Opening (2min)	Welcome, introduction and session overview	N/A	Nil
Consolidate participant information (3min)	Review session form 1 and clarify details Explore current strategies and previous attempts at dietary change (what has worked and what has not worked)	T18 Prompting focus on past success	Completed VC consultation form Baseline measures PNQ1
Review COM factors affecting behaviour (3min)	Discuss self-identified COM factors ability to eat healthier and their impact on behaviour	N/A	Completed VC consultation form PNQ1
Review food and nutrient intake (5min)	Discuss results in AES report – highlight areas that are meeting recommendations and area in need of improvement	T19 Provide feedback on performance T1 & T2 Provide information on the consequences of the behaviour in general and to the individual	Completed VC consultation form AES report
Negotiate personalised goals (5mins)	Discuss motives and goals of participation Set personalised goals 2X short-term and behaviour based (2-6 weeks). Encourage outcome based but may also be behavioural	T10 Prompt review of behaviour goal T5 Goal setting – behaviour T6 Goal setting – outcome	Completed VC consultation form PNQ1

Select intervention strategies and outline plan (10min)	Use the PNT to select behavioural interventions based on PNQ Discuss plan to achieve goals through change of C, O and/or M behaviour components Interventions will aim to facilitate achievement of goals with a small steps approach to behaviour change Briefly identify any major perceived barriers to implementation of plan and achieving goals Explore solutions to barriers and facilitators If relevant: suggest and explain importance dietary self-monitoring (either by hand or technology – e.g. Easy Diet Diary). Emphasise feedback on progress towards goal with be provided.	BCT's will vary depending on the C, O or M aspects of behaviour that are to be addressed T7 Action planning T9 Set graded tasks T8 Barrier identification/problem solving T16 Prompt self-monitoring of the behaviour	Completed VC consultation form PNT
Closing (2min)	Summarise strategies and goals	N/A	Completed VC consultation form Participant session summary form PNT

Session 2 (Week 3), 30 minutes

Section (time)	Content	Behaviour change technique	Resources
Opening (1min)	Greeting and outline session	N/A	Nil
Review progress towards goals (10min)	Review participants self-reported progress towards goals If on the second PNQ progress is rated at ≤5 for either goal Ask if the same COM factors (from VC consultation 1) are influencing behaviour If it's not – ask if other COM factors are impacting behaviour Identify any new factors that need to be addressed Review participants chosen COM factors from PNQ1 and ensure they are still the same Yes: skip to next step No: identify new behavioural factors Revise goals if needed	T10 Prompt review of behaviour goal T11 Prompt review of outcome goal T19 Prompt feedback on performance T1 & T2 Provide information on the consequences of the behaviour in general and to the individual T5 Goal setting – behaviour T6 Goal setting – outcome	Completed VC consultation form 1 AES report 1 PNQ2
Review intervention strategies and outline plan (10 mins)	Based on progress and effect of/or adherence to strategies	BCT's will vary depending on the C, O or M aspects of behaviour that are to be addressed	Completed VC consultation form 1 PNQ2 PNT

	Use PNT to select new behavioural interventions or alternative strategies based on PNQ2 Discuss plan to achieve goals through C, O and/or behaviour components Interventions aim to facilitate achievement of goals with a 'small steps' approach to behaviour change Briefly identify any major perceived barriers to implementation of plan and achieving goals Explore solutions to barriers and facilitators	T7 Action planning T9 Set graded tasks T8 Barrier identification/problem solving T16 Prompt self-monitoring of the behaviour	
Closing (2min)	Summarise strategies and goals for next week Offer optional session	N/A	Participant session summary form PNT

Session 3 (Week 5), 20 minutes (optional)

Section (time)	Content	Behaviour change technique	Resources
Opening (1min)	Greeting and outline session	N/A	Nil
Review goals (4min)	Review participants progress towards goals	T10 Prompt review of behaviour goals T11 Prompt review of outcome goals	Completed VC consultation form 1 Participant session summary form
Review intervention strategies and plan (10min)	Discuss plan and the implementation of strategies Discuss challenges Discuss and build on success strategies	T8 Barrier identification/problem solving T19 Prompting focus on past success T15 Prompting generalised focus of a target behaviour	Completed VC consultation form 1 Participant session summary form PNT
Review plan and review goals (4min)	Revise goals as needed Offer alternative strategies as needed	BCT's will vary depending on the C, O or M aspects of behaviour that are to be addressed T7 Action planning T9 Set graded tasks T8 Barrier identification/problem solving T16 Prompt self-monitoring of the behaviour	Completed VC consultation form 1 Participant session summary form PNT
Closing (1min)	Summarise strategies and goals for next 2 weeks	N/A	Completed VC consultation form 1 Participant session summary form PNT

Appendix 42. Supplementary Table S2: Nutrition information for fruit juices

	Cherry crush (per 100ml)	Apple juice (per 100ml)
Energy (kJ)	291	185
Protein (g)	1.6	0.1
Fat (total) (g)	<0.2	0.0
Carbohydrates (g)	14.7	12.0
Sugars (g)	14.7	11.7
Dietary fibre (g)	0.8	0.1
Sodium (mg)	<1	5
Vitamin C (mg)	<5	40
Total red count (mg/100g)	19.3	0

Appendix 43. Baseline Questionnaire for ReJUICE your pain study

Baseline questionnaire

Study ID_____
Version 2, Hunter Integrated Pain Service; Baseline Questionnaire; 17/8/2017

Section 1 - Personal Information

Q1 Please select your gender.
Female
Male

Q2 When were you born? (please provide as DD/MM/YYYY) _____

Q3 Where were you born?
Australia
New Zealand
Other: _____

Q4 Are you of Aboriginal, Torres Strait Islander or Maori origin? (You can tick more than one box)
No
Yes, Aboriginal
Yes, Torres Strait Islander
Yes, Maori

Q5 What is your current work status? (you can tick more than one box)
Full time paid work
Part time paid work
Retired
Home duties
Unemployed (due to pain)
Unemployed (not due to pain)
Volunteer work
At work - limited hours/duties
On leave from work due to pain
Retraining
Studying (e.g. school or University)

Q6 Does pain affect the number of hours you work or study?
Yes
No

Q7 Does pain affect the type of work you are able to do?
Yes
No

Q8 How did the main pain begin?
Injury at home
Injury at work/school
Injury in another setting
After surgery
Motor vehicle crash
Related to cancer
Related to another illness
No obvious cause
Other: _____

Q9 How long have you had the main pain?
Less than 3 months
3-12 months
12 months to 2 years
2-5 years
More than 5 years

Q10 Which statement best describes the pain?
The pain is always there and always has the same intensity
The pain is always there but the intensity changes
The pain comes and goes. I am pain free for less than 6 hours at a time
The pain comes and goes and lasts up to an hour at a time
The pain comes and goes every few days or weeks

Q11 Move the slider on the line below to indicate how bad you feel your pain is today.

	0 10 20 30 40 50 60 70 80 90 100
0 = no pain and 100 = very bad pain	

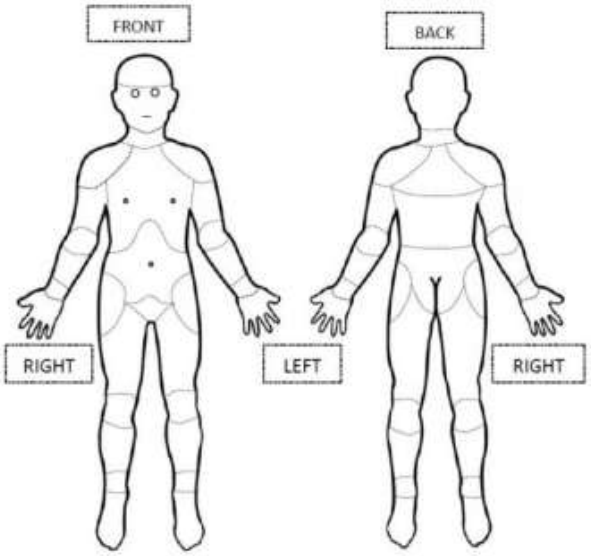
Q12 Do you have any of these medical problems? (you can tick more than one box)
Heart disease
High blood pressure
Lung disease
Diabetes
Rheumatoid arthritis
Kidney disease
Depression / Anxiety

Cancer
Anaemia or other blood disease
Osteoarthritis, degenerative arthritis
Ulcer or stomach disease
Stroke or other neurological condition
Other: _____
None

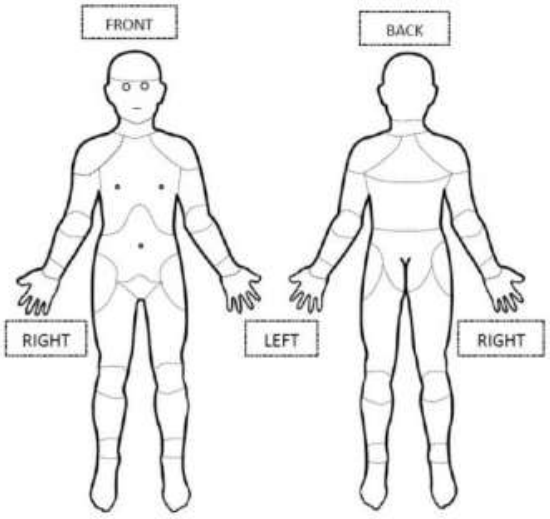
Q13 How many times in the past 3 months have you:
Seen a general practitioner (GP) about your pain _____
Seen a medical specialist (e.g. orthopedic surgeon etc) about pain _____
Seen health professionals other than doctors (e.g. physiotherapist, chiropractor, psychologist etc) about pain _____
Visited a hospital emergency department about pain? Include all visits, even if you were not admitted to the hospital _____
Been admitted to hospital as an inpatient because of pain _____
Had tests (e.g. X rays, scans) relating to pain _____

Section 2 - Brief Pain Inventory

Q1 On the diagram below, click the mouse in the region where it **hurts the most**.



Q2 On the diagram below, click the mouse in the regions where you feel pain.



Q3 Rate your pain by selecting the number that bests describes the following:
(select one number for each item, **0 = no pain** and **10 = pain as bad as you can imagine**)

	0	1	2	3	4	5	6	7	8	9	10
	0 = no pain						10 = pain as bad as you can image				
Your worst pain in the last week											
Your least pain in the last week											
Your pain on average											
Your pain right now											

Q4 During the past week, how much has pain interfered with the following:
(select one number for each item, where **0 = does not interfere** and **10 = completely interferes**)

	0	1	2	3	4	5	6	7	8	9	10
	0 = Does not interfere						10 = Completely interferes				
Your general activity											
Your mood											
Your walking ability											
Your normal work (both											

outside and inside the home)
Your relationship with other people
Your sleep
Your enjoyment of life

Section 3 – PSEQ

Q1 Rate how confident you are that you can do the following things **at present** despite the pain.
Select one of the numbers on the scale under each item where **0 = not at all confident and 6 = completely confident**.
Remember this questionnaire is not asking whether or not you have been doing these things, but rather how confident you are that you can do them at present, **despite the pain.**

	0 (not at all confident)	1	2	3	4	5	6 (completely confident)
I can enjoy things, despite the pain							
I can do most of the household chores (e.g. tidying- up, washing dishes etc) despite the pain							
I can socialize with my friends or family members as often as I used to do, despite the pain							
I can cope with my pain in most situations							
I can do some form of work, despite the pain (“work” includes housework, paid and unpaid work)							
I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain							
I can cope with my pain without medication							
I can still accomplish most of my goals in life, despite the pain							

I can live a normal lifestyle, despite the pain	
I can gradually become more active, despite the pain	

Section 4 - PCS

Q1 Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain

	Not at all	To a slight degree	To a moderate degree	To a great degree	All the time
I worry all the time about whether the pain will end					
I feel I can’t go on					
It’s terrible and I think it’s never going to get any better					
It’s awful and I feel it overwhelms me					
I feel I can’t stand it anymore					
I become afraid that the pain will get worse					
I keep thinking of other painful events					
I anxiously want the pain to go away					
I can’t seem to keep it out of my mind					
I keep thinking about how much it hurts					

I keep thinking about how badly I want the pain to stop
There's nothing I can do to reduce the intensity of the pain
I wonder whether something serious may happen

Section 5 - SF36

Q1 In general, would you say your health is:
Excellent
Very good
Good
Fair
Poor

Q2 **Compared to one year ago,** how would you rate your health in general **now**?
Much better now than one year ago
Somewhat better now than one year ago
About the same
Somewhat worse now than one year ago
Much worse now than one year ago

Q3 The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports			
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf			
Lifting or carrying groceries			
Climbing **several** flights of stairs			
Climbing **one** flight of stairs			
Bending, kneeling or stooping			
Walking more than a mile			
Walking **several** blocks			
Walking **one** block			
Bathing or dressing yourself			

Q4 During the **past 4 weeks** have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	Yes	No
Cut down the amount of time you spent on work or other activities		
Accomplished less than you would like		
Were limited in the kind of work or other activities		
Had difficulty performing the work or other activities (for example, it took extra effort)		

Q5 During the **past 4 weeks** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems?** (such as feeling depressed or anxious)

	Yes	No
Cut down the amount of time you spent on work or other activities		

Accomplished less than you would like	
Didn’t do work or other activities as carefully as usual	

Q6 During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?
Not at all
Slightly
Moderately
Quite a bit
Extremely

Q7 How much **bodily** pain have you had during the **past 4 weeks?**
None
Very mild
Mild
Moderate
Severe
Very severe

Q8 During the **past 4 weeks**, how much did **pain** interfere with your normal work? (including both work outside the home and housework)
Not at all
A little bit
Moderately
Quite a bit
Extremely

Q9 These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks…**

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Did you feel full of life?						
Have you been a very nervous person?						
Have you felt so down in the dumps						

that nothing could cheer you up?
Have you felt calm and peaceful?
Did you have a lot of energy?
Have you felt downhearted and blue?
Did you feel worn out?
Have you been a happy person?
Did you feel tired?

Q10 How TRUE or FALSE is **each** of the following statements for you.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get sick a little easier than other people					
I am as healthy as anybody I know					
I expect my health to get worse					
My health is excellent					

Appendix 44. Final Questionnaire for ReJUICE your pain study

Final Questionnaire

Study ID_____
Version 3, Hunter Integrated Pain Service, 22/11/17

Section 1 - VAS

Move the slider on the line below to indicate how bad you feel your pain is today.

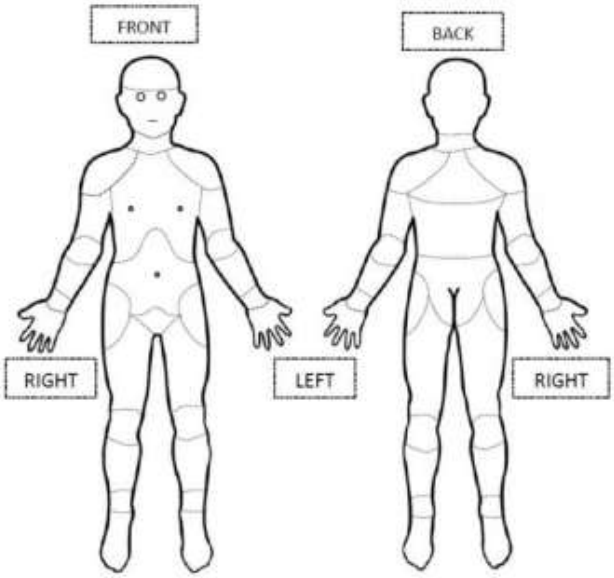
	0 10 20 30 40 50 60 70 80 90 100
0 = no pain and 100 = very bad pain	

Over the last 6 weeks has your pain changed? Has the intensity or frequency changed?
Yes, if yes please describe how your pain has changed _____
Don't know
No

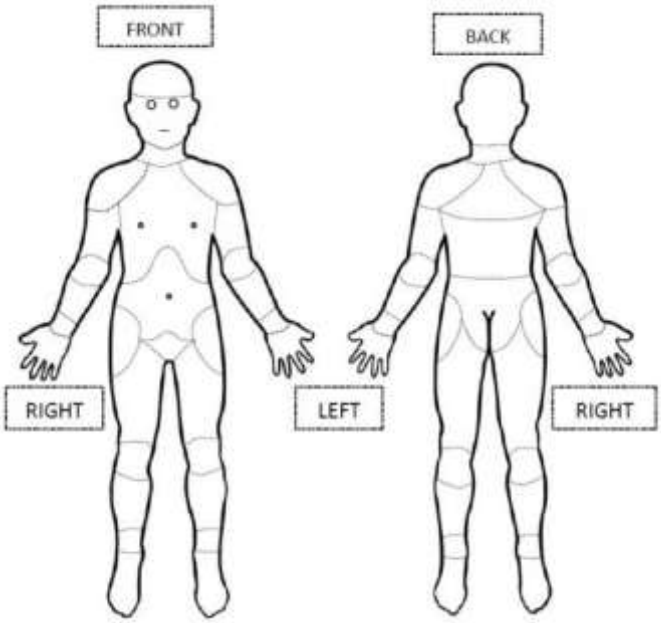
Section 2 - Brief Pain Inventory

You were asked to complete this at your baseline measurement session, the reason we are asking you to complete it again is to see if there has been any change in your pain experience over the last 6 weeks while you have been participating in our study.

Q1 On the diagram below, click the mouse in the region where it hurts the most.



Q2 On the diagram below, click the mouse in the regions where you feel pain.



Q3 Rate your pain by selecting the number that best describes the following:
(select one for each item, 0 = *no pain* and 10 = *pain as bad as you can imagine*)

	0 1 2 3 4 5 6 7 8 9 10 0 = no pain 10 = Pain as bad as you can imagine
Your *worst* pain this week?	
Your *least* pain this week?	
Your pain on average?	
Your pain right now?	

Q4 During the past week, how much has pain interfered with the following:
(select one number for each item, where 0 = *does not interfere* and 10 = *completely interferes)*

	0 1 2 3 4 5 6 7 8 9 10 0 = does not interfere 10 = completely interferes
Your general activity?	
Your mood?	
Your walking ability?	
Your normal work (both outside and inside home)?	
Your relationship with other people?	
Your sleep?	
Your enjoyment of life?	

Section 3 – PSEQ

Q1 Rate how confident you are that you can do the following things at present despite the pain. Select one of the numbers on the scale under each item where 0 = not at all confident and 6 = completely confident. Remember this questionnaire is not asking whether or not you have been doing these things, but rather how confident you are that you can do them at present, despite the pain.

	0 (not at all confident) 1 2 3 4 5 6 (completely confident)
I can enjoy things, despite the pain	

I can do most of the household chores (e.g. tidying- up, washing dishes etc) despite the pain
I can socialize with my friends or family members as often as I used to do, despite the pain
I can cope with my pain in most situations
I can do some form of work, despite the pain (“work” includes housework, paid and unpaid work)
I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain
I can cope with my pain without medication
I can still accomplish most of my goals in life, despite the pain
I can live a normal lifestyle, despite the pain
I can gradually become more active, despite the pain

Section 4 – PCS

Q1 Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain.

Using the scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain in the last 6 weeks

	Not at all	To a slight degree	To a moderate degree	To a great degree	All the time
I worry all the time about whether the pain will end					

I feel I can’t go on

It’s terrible and I think it’s never going to get any better

It’s awful and I feel it overwhelms me

I feel I can’t stand it anymore

I become afraid that the pain will get worse

I keep thinking of other painful events

I anxiously want the pain to go away

I can’t seem to keep it out of my mind

I keep thinking about how much it hurts

I keep thinking about how badly I want the pain to stop

There’s nothing I can do to reduce the intensity of the pain

I wonder whether something serious may happen

Section 5 - SF36

Q1 In general, would you say your health is:
Excellent
Very good
Good
Fair
Poor

Q2 Compared to 6 weeks ago, how would you rate your health in general now?
Much better now than 6 weeks ago
Somewhat better now than 6 weeks ago
About the same

Somewhat worse now than 6 weeks ago
Much worse now than 6 weeks ago

Q3 The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports			
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf			
Lifting or carrying groceries			
Climbing several flights of stairs			
Climbing one flight of stairs			
Bending, kneeling or stooping			
Walking more than a mile			
Walking several blocks			
Walking one block			
Bathing or dressing yourself			

Q4 During the past 4 weeks have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
Cut down the amount of time you spent on work or other activities		
Accomplished less than you would like		
Were limited in the kind of work or other activities		
Had difficulty performing the work or other activities (for example, it took extra effort)		

Q5 During the past 4 weeks have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems? (such as feeling depressed or anxious)

	Yes	No
Cut down the amount of time you spent on work or other activities		

Accomplished less than you would like
Didn’t do work or other activities as carefully as usual

Q6 During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?
Not at all
Slightly
Moderately
Quite a bit
Extremely

Q7 How much bodily pain have you had during the past 4 weeks?
None
Very mild
Mild
Moderate
Severe
Very severe

Q8 During the past 4 weeks, how much did pain interfere with your normal work? (including both work outside the home and housework)
Not at all
A little bit
Moderately
Quite a bit
Extremely

Q9 These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Did you feel full of life?						
Have you been a very nervous person?						
Have you felt so down in the dumps that nothing could cheer you up?						
Have you felt calm and peaceful?						

Did you have a lot of energy?	
Have you felt downhearted and blue?	
Did you feel worn out?	
Have you been a happy person?	
Did you feel tired?	

Q10 How TRUE or FALSE is each of the following statements for you.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get sick a little easier than other people					
I am as healthy as anybody I know					
I expect my health to get worse					
My health is excellent					

Section 6 – Satisfaction with study

Q1 Please indicate how satisfied you were with the overall ReJUICE your pain program?
Very Satisfied
Satisfied
Neutral
Unsatisfied
Very Unsatisfied

Q2 Please indicate how satisfied you were with each ReJUICE your pain program component.

	Very Satisfied	Satisfied	Neutral	Unsatisfied	Very Unsatisfied
Australian Eating Survey					
Feedback report from the Australian Eating Survey (Intervention Group Only)					

Video coaching sessions with dietitian (Intervention Group Only)	
The juice you were asked to consume	

Q3 Overall, my involvement in the ReJUICE your pain program has encouraged me to (Intervention Group Only):

	Strongly Agree	Agree	Neutral	Disagree	Strongly disagree
Read labels and nutrition information on food products					
Change the food products that I purchase					
Eat more fruit and vegetables					
Eat fewer discretionary foods (e.g. soft drinks, alcohol, cakes, pastries etc)					
Keep record of what I eat					
Set myself nutrition goals					
Download healthy eating/food apps					
Be mindful using food to cope with my pain					