BMJ Open

Healthy lifestyle program for Low back Pain (HeLP): Protocol for a randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-029290
Article Type:	Protocol
Date Submitted by the Author:	21-Jan-2019
Complete List of Authors:	Robson, Emma; Hunter New England Population Health, Kamper, Steven; University of Sydney, Centre for Pain, Health and Lifestyle, School of Public Health Davidson, Simon; Hunter New England Population Health; The University of Newcastle, Viana da Silva, Priscilla; Hunter New England Population Health; The University of Newcastle, Williams, Amanda; Hunter New England Population Health Lee, Hopin; Hunter New England Population Health; University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences Hodder, Rebecca; Hunter New England Local Health District, Hunter New England Population Health; The University of Newcastle, Hall, Alix; Hunter Medical Research Institute, University of Newcastle, School of Medicine and Public Health Gleadhill, Connor; Hunter New England Population Health; University of Sydney, Centre for Pain, Health and Lifestyle, School of Public Health Williams, Christopher; Hunter Medical Research Institute, University of Newcastle, School of Medicine and Public Health; Hunter New England Local Health District, Population Health
Keywords:	Back pain < ORTHOPAEDIC & TRAUMA SURGERY, Spine < ORTHOPAEDIC & TRAUMA SURGERY, PUBLIC HEALTH, PAIN MANAGEMENT, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY

Healthy lifestyle program for Low back Pain (HeLP): Protocol for a randomised controlled trial

Authors:
Emma Robson[1,2,3]
A/Prof Steven J Kamper[3,4]
Simon Davidson[1,2,3]
Priscilla Viana Silva[1, 2,3]
Amanda Williams[1,2,3]
Dr Rebecca Hodder[1,2,3,5]
Dr Hopin Lee[1,3,6]
Dr Alix Hall [5]
Connor Gleadhill[1,3,4]
Dr Christopher Williams[1,2,3,5]

Author Details

[1] Hunter New England Population Health, Locked Bag 10, Wallsend NSW, 2287, Australia.
[2] School of Medicine and Public Health, University of Newcastle, Newcastle NSW, 2308, Australia
[3] Centre for Pain, Health and Lifestyle, NSW, Australia
[4] University of Sydney, PO Box M179, Missenden Rd, Camperdown NSW, 2050, Australia
[5] Hunter Medical Research Institute, Locked Bag 1, Hunter Region Mc NSW, 2310, Australia
[6] Centre for Statistics in Medicine, Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK

Corresponding author: Emma Robson, Locked bag 10 Wallsend, NSW 2287, Australia.

Email: emma.robson@hnehealth.nsw.gov.au Phone: (02) 49246069

Word count: 3991

Abstract

Introduction: Low back pain is one of the most common and burdensome chronic conditions worldwide. Lifestyle factors, such as excess weight, physical inactivity, poor diet and smoking are linked to low back pain chronicity and disability. There are few high quality randomised controlled trials that investigate the effects of targeting lifestyle risk factors in people with chronic low back pain.

Methods and Analysis:

The aim of this study is to determine the effectiveness of a Healthy lifestyle program for Low back Pain (HeLP) targeting weight, physical activity, diet and smoking to reduce disability in patients with chronic low back pain compared to usual care. This is a randomised controlled trial, with participants stratified by BMI, allocated 1:1 to the HeLP intervention or usual physiotherapy care. HeLP involves three main components: i) clinical consultations with a physiotherapist and dietitian; ii) educational resources; and iii) telephone-based health coaching support for lifestyle risk factors. The primary outcome is disability (Roland Morris Disability Questionnaire), at 26 weeks. Secondary outcomes include pain, weight, quality of life and smoking status. Data will be collected at baseline, and weeks 6, 12, 26 and 52. Patients with chronic low back pain who have at least one health risk factor; overweight or obese; smoker; inadequate physical activity or fruit and vegetable consumption, will be recruited from primary or secondary care, or the community. Data will be analysed by intention-to-treat using linear mixed effects regression models. We will conduct three supplementary analysis: causal mediation analysis, compiler average causal effects analysis (CACE) and economic analyses.

Ethics and Dissemination: This study was approved by the Hunter New England Research Ethics Committee (Approval No. 17/02/15/4.05), and University of Newcastle Human Research Ethics Committee (Ref No. H-2017-0222). Outcomes of this trial and supplementary analyses will be disseminated through publications in peer-reviewed journals and conference presentations.

Trial Registration Number: ACTRN12617001288314.

Strengths and limitations of this study

- The first randomised controlled trial investigating a comprehensive lifestyle intervention involving physiotherapy, dietetics and telephone health coaching for patients with chronic low back pain.
- The trial includes collection of a large range of variables to enable investigation of clinical effectiveness, cost effectiveness and mechanisms of addressing lifestyle factors in chronic low back pain patients to help guide healthcare policy decisions and clinical practice.
- Choice of primary and secondary outcomes is based on importance to patients with the condition.

INTRODUCTION

Chronic low back pain is a worldwide public health problem with significant individual and economic burden.(1-7) In 2016, low back pain was the leading cause of disability globally, accounting for over 57.6 million years lived with disability (YLD).(1) Estimated total costs of back pain are significant, with direct costs of care estimated at £2.8 billion in the UK,(7) and $90 billion in the US.(5) In Australia annual costs exceed $4.8 billion and back pain reduces the country's Gross Domestic Product by $2.9 billion per year.(3) Health care consumption, medication use, productivity losses and forced early retirement contribute to these costs.(3, 5, 7)

Lifestyle risk factors, including excess weight, physical inactivity, poor diet and smoking contribute to the burden of low back pain.(8-12) Meta-analysis of 33 studies found obesity was associated with increased prevalence of chronic low back pain (OR 1.4, 95% CI 1.4, 1.6) and increased care-seeking for low back pain (OR 1.6, 95% CI 1.5, 1.7).(8) Another meta-analysis of 27 studies demonstrated associations between smoking and chronic low back pain (OR 1.8, CI 95% 1.3, 2.5).(11) Physical inactivity and poor diet contribute to obesity, and have an influence on chronic low back pain independently.(13-18) Despite some inconsistency in the literature, evidence suggests low levels of physical activity is associated with chronic low back pain,(13-15) as is diet-induced systematic inflammation.(16, 17)

Preliminary clinical studies suggest addressing such lifestyle factors can improve low back pain outcomes including disability.(12, 19-22) For example, a pre-post study of a weight loss program targeting diet and physical activity showed significant improvement in pain related disability in patients with low back pain.(19) Increasing physical activity and providing exercise are widely accepted core treatment recommendations for chronic low back pain management(23, 24) and reviews of the literature show exercise is effective in reducing disability (improvement of 2.5 points on 100 point scale, 95% CI 1.0, 3.9) compared to control.(25, 26) In relation to smoking, one cohort study involving 5333 smokers with low back pain also showed clinically significant reductions in pain (30% decrease) in those who quit smoking.(20)

Despite evidence suggesting the potential benefit of interventions targeting these lifestyle factors,(21, 22) there is only one similar randomised control trial evaluating a lifestyle

intervention for patients with chronic low back pain.(27, 28) This study found no effect, likely due to poor adherence to the treatment.

Objective

The primary aim of this trial is to determine the effectiveness of a multi-focused Healthy lifestyle program for Low back Pain (HeLP) to reduce disability in patients with chronic low back pain, compared to usual physiotherapy care. Secondary objectives are to determine the effectiveness of the intervention on pain intensity, patient weight, quality of life and smoking status.

We will also conduct three supplementary analyses to assess: i) treatment effect in those who complied with the intervention using Complier Average Causal Effects (CACE) analysis, ii) mediating effects of the intervention through pain, weight, smoking cessation, physical activity levels, diet, pain self-efficacy, and psychological distress, iii) cost effectiveness of the intervention from the health sector and societal perspectives.

METHODS AND ANALYSIS

Study Design

The study will be a parallel-group pragmatic randomised controlled trial with two groups (Fig 1.) Participants will be stratified by Body Mass Index (BMI) category and randomised 1:1 to either the HeLP intervention or usual physiotherapy care.

Setting

People with a main complaint of low back pain referred from primary care, or secondary care at a major tertiary referral hospital in the Hunter New England Local Health District, NSW, or self-referred from community advertisements, will be screened for eligibility.

Eligibility

Eligibility criteria are as follows:

- ≥ 18 years of age
- Chronic low back pain, defined as pain between the 12th rib and buttock crease, with or without leg pain, of more than 3 months duration(29);
- Pain intensity rating over the last week of ≥3 on an 11 point numerical rating scale (NRS) where "0" represents no pain and "10" represents worst possible pain,(30) or respond "moderately", "quite a bit" or "extremely" when asked how much back pain interferes with completing normal daily activities of living (modified item of Short Form Health Survey-36)(30);
- At least one health risk factor: overweight or obese (BMI of >25kg/m^2) (18); participate in less than 30 minutes of physical activity on 5 days of the week(31); current smoker; or eat less than 2 serves of fruit and 5 serves of vegetables per day.(32)

Exclusion criteria:

- Previous bariatric weight loss surgery;
- Currently undertaking weight loss or smoking cessation program or care (e.g. Dietetics for weight loss, Jenny Craig, Lite n Easy, Optifast, Weight Watchers, nicotine replacement therapy, Quitline);
- Back surgery in the previous 6 months or planned back surgery in the next 6 months;
- Known or suspected serious pathology causing back pain (i.e. rheumatoid arthritis, cancer, fracture or infection);
- Cannot actively engage in the intervention (unable to communicate, use a telephone or attend appointments, adapt meals or exercise);
- Comorbidity that does not allow safe completion of study procedures (e.g. uncontrolled blood pressure or heart conditions, uncontrolled diabetes);
- Pregnant or planning pregnancy in the next 12 months.

Details of the intervention and control

Trial design adheres to the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) recommendations,(33) and the intervention and control conditions are described

according to the Template for Intervention description and Replication (TIdieR) (Appendix 1).(34)

Intervention (HeLP)

Participants randomised to the intervention group will receive HeLP over a 6-month period. The intervention draws on cognitive behavioural therapy (CBT) and motivational interviewing (MI) to support pain management and facilitate positive behaviour change related to maintaining a healthy lifestyle (Table 1).

HeLP includes:

i) Consultations with a physiotherapist and dietitian;
ii) Provision of educational resources; and
iii) Telephone-based health coaching services for healthy lifestyle and smoking cessation (Table 2).

i) Consultations

This component was co-developed by a multidisciplinary team of investigators with expertise in physiotherapy, dietetics, psychology, nursing and health service management. Consultations aim to:

- Assess participants' back pain condition;
- Educate participants about back pain and lifestyle;
- Use behaviour change strategies to facilitate positive lifestyle changes (achieve a healthy body weight, increase physical activity, develop healthy eating habits, quit smoking);
- Initiate engagement in telephone support services;
- Reinforce positive behaviours and encourage self-regulation.

Mode and timing of consultation delivery

Participants will be offered to attend five clinical consultations of up to 60 minutes in duration; four with a registered physiotherapist, and one with a registered dietitian. Physiotherapy consultations will include an initial consultation and follow up consultations at 3, 6, and 12

weeks post randomisation. The dietitian consultation will occur at week 3, immediately after the physiotherapy consultation (Table 2). Consultations will be conducted face-to-face, however; if patients are not able to attend appointments face-to-face they may be offered telehealth consultations (telephone or video conference) to deliver clinical content. The delivery method for all consultations will be recorded.

Content (Initial consultation)

The initial consultation will involve three major components (Table 1):

1. History and physical assessment(24);
2. HeLP education (education about pain biology and links between pain and lifestyle);
3. Develop an individualised HeLP action plan to address lifestyle risks, incorporating behaviour change strategies and initiating a physical activity program.

Physical assessment, education and advice is built upon guideline recommendations and in line with back pain patients' expectations from physiotherapists.(23-25, 35-37) Education and advice is designed to improve participants' understanding of the biopsychosocial nature of low back pain by presenting information on the nature of pain biology,(38) address erroneous beliefs about back pain (e.g. that low back pain is always associated with pathology), and outline links between low back pain and health behaviour risks (weight, smoking etc). Advice aims to encourage pain self-management, negotiate a physical activity plan and provide a platform for patients to engage with additional support services for healthy lifestyle.

Behaviour change strategies are based on principles of MI and CBT.(37, 39-41) Evidence supports the use of CBT and MI in improving physical and behavioural outcomes in patients with back pain.(37) (39, 42) Behaviour change strategies include: assessing stage of change; goal setting with graded task assignment; and developing self-monitoring and regulation practices. Clinicians will work with patients to set tailored goals using graded task assignment, e.g. agreeing on an initial goal of 10 minutes walking per day, to increase to 30 minutes per day by week 6. Clinicians will encourage self-monitoring and regulation through goal evaluation and use of patient resources to monitor pain, activity and eating patterns. Patient understanding of, and participation in, telephone health coaching services will also be encouraged.

Content (follow up consultations)

Subsequent consultations (weeks 3, 6 and 12) will reinforce key messages, information and action plans provided in the initial consultation. Participants and clinicians will evaluate goals and progress, identify and address barriers to change, and encourage self-monitoring (Table 1).

The dietitian consultation will occur immediately after physiotherapy consult in week 3. The consultation will focus on achieving or maintaining healthy eating behaviours to assist in weight management. Education and advice will be based on Australian healthy eating(18, 32, 43, 44) and obesity management guidelines.(18, 32, 43) Education will be tailored to participants needs including information on recommended intake of the five key food groups, energy balance, portion sizes and general healthy lifestyle promotion.

Clinicians will support and encourage patients to achieve their lifestyle goals and engage with telephone health coaching services. Goals and content of clinical care will be provided in the initial referrals to the telephone coaching services.

Training for Intervention Delivery

The intervention clinicians will attend multiple training sessions (including piloting the intervention) prior to study commencement and offered to attend a 2-day Health Behaviour Change course.(45) Training involves background to the study, understanding intervention and appointment scheduling protocols for each consult, and behaviour change techniques. Clinicians will also learn how to use REDCap,(46) an electronic data capture tool to record patient appointment attendance and delivery of intervention components. An intervention checklist will be provided to guide intervention delivery and optimise fidelity. Intervention clinicians will be provided implementation support via regular face to face and email contact with the research team for the duration of the study.

TABLE 1: PHYSIOTHERAPY CONSULTATIONS

Physiotherapy	Component	Content	Purpose
Week 1 (initial)	Physical Assessment	- Patient history and physical assessment including assessing range of motion, evaluate strength, flexibility, pain characteristics. - Collect anthropometric measurements (height, weight)	Develop rapport Assess and address patients expectations for physiotherapy care
	Psychoeducation	- Introduce pain biology, concept of pain being multifactorial and does not equal damage, as well as fluctuating nature of pain conditions - Acknowledgement that pain is real - Discuss influence of lifestyle factors on back pain and consequences of being overweight, having a poor diet, inactivity, poor sleep and smoking - Introduce HeLP to support adoption of healthy lifestyle behaviours - Promote support services the GHS and Quitline	Correct erroneous pain beliefs, increase knowledge, provide rationale for need to change health behaviour.
	Behaviour change strategies	- Assess patients stage of change and motivations through questioning - Acknowledge general barriers to lifestyle change and program adherence - Establish and agree on commitment to change - Goal setting: establish patient management and lifestyle goals - Agree on graded exercises and physical activity (e.g. aim to start walking 10 minutes 5 times a week). - Discuss strategies to facilitate self-monitoring behaviours such as keeping activity, pain and diet diaries and attending follow up appointments	Initiate process of behaviour change, encourage safe engagement in physical activity, initiate engagement with support services.
Week 3 and 6	Psychoeducation	- Reinforce back pain education and lifestyle messages in first consultation	Increase knowledge
	Behaviour change strategies	- Evaluate goals and adapt with patient discussion and assessment of diaries - Problem solving: discuss patient barriers to meeting goals and strategies to overcome - Goal setting: Adapt or progress graded exercise and activity - Discuss participation in the GHS and Quit line services and encourage continued participation (if appropriate) - Encourage continual encouragement of self-monitoring	Reinforce positive behaviour, support behaviour change and self-monitoring behaviours.
Week 12	Physical Assessment	- Collect anthropometric measurements	Data collection
	Psychoeducation	- Reflect on information provided previously and patient experience	Initiate self-reflection and reinforce positive behaviours

	Behaviour change	- Reassess motivation to change and/or motivation to sustain behaviour change - Encourage completion of the GHS and or Quit line program - Goal setting for maintaining healthy lifestyle change - Negotiate strategies and problem solving for overcoming barriers to maintain changes	Goal setting for continued self-management and maintaining or further improving lifestyle behaviours, reinforce positive behaviours, identify skills and strategies to prevent relapse of unhealthy habits.
Dietitian Consult			
Week 3	Brief dietary assessment	- Assess patients diet using monitoring completed food diary or conduct brief diet history and eating behaviours	Build rapport
	Psychoeducation	- Reinforce HeLP messages: the importance of a healthy lifestyle in pain management and the role of diet in weight management and chronic pain. - Discuss five key food groups and Australia Guide to Healthy Eating, Australia Dietary Guideline recommendations - Introduce concepts of energy balance and portion size	Increase knowledge; reinforce alignment of health service perspectives for treating back pain, including support from GHS
	Behaviour Change strategies	- Assess patients stage of change and motivations through questioning - Goal setting: identify or confirm patient lifestyle and dietary goals - Acknowledge and discuss any barriers to change and reassure small lifestyle changes make a difference - Graded task assignment: Detail suitable strategies to improve dietary intake, balance energy intake and ensure adequate consumption of core food groups - Encourage participation and continued dietary support from the GHS - Encourage self-monitoring e.g. keep a food diary	Reinforce positive behaviour, initiate positive safe dietary changes, support behaviour change and use of support services.

Legend: GHS, Get Healthy Service.

II) Educational Resources

Patients will be provided with resources including an information booklet or access to a web based app, and a 5 minute video(47) reflecting education and key messages. The information booklet and app were co-developed by back pain experts, intervention physiotherapists and dietitians. The booklet and app were piloted with consumers and assessed for cultural safety, and changes were made according to feedback. The information booklet and app details pain education provided in the consults, healthy lifestyle information, information about support services, and diaries to record goals and encourage self-monitoring. The 5 minute video(47) will be sent to patients via SMS or email, viewing will also be prompted at the week 3 appointment.

III) Telephone health coaching

A) Healthy lifestyle coaching telephone service

All patients in the intervention group will be referred to the telephone-based "NSW Get Healthy Information and Coaching Service" immediately after their initial consultation (Table 2).

The Get Healthy Service (GHS) is a telephone-based health coaching initiative provided by the NSW Government. The service aims to support people to modify unhealthy behaviours; increase physical activity levels; make healthy dietary changes; reduce alcohol consumption and achieve and maintain a healthy body weight.(48, 49) There is evidence that the GHS is effective in reducing BMI, and waist circumference, and improves eating behaviours and physical activity in the general population.(49, 50)

Mode of and timing of delivery

The GHS involves up to 10 individually tailored phone calls over a 6-month period, delivered by qualified and specially-trained health professionals.(51) Calls are usually made bi-monthly for the first three months (n=6) to help facilitate behaviour change, with remaining calls tapering off for the following three months. Average call duration is 13 minutes.(49, 50) Patients can graduate early from the GHS if they complete 5 coaching calls and meet their health goals.

Content

Content is based on the Australian Guide to Healthy Eating, and National Physical Activity Guidelines.(31, 52) Coaches provide education, advice and counselling to achieve or maintain a healthy weight through modifying energy intake, and use strategies to improve intake of the five key food groups and achieve moderate physical activity of 30 minutes 5 days per week. The GHS aims to support, motivate and monitor the lifestyle goals patients established in their face-to-face consultations. Coaching uses MI techniques and self-regulation to support behaviour change.(50)

Training for intervention delivery

All GHS coaches are university qualified health professionals (dietitians, exercise physiologists, health psychologists). All coaches involved the trial will receive 3 hours of interactive face-to-face training, delivered by the principle investigators. Training is based on academic detailing, including educational outreach, technical assistance and provision of resources. Sessions include education about chronic pain and guideline recommended care for patients with low back pain; current evidence for low back pain management and links to health behaviour risks and lifestyle; and advice from professional experiences treating patients, including common barriers to care and engagement in lifestyle management. Coaches are instructed how to make links between lifestyle behaviours, weight management and back pain care, and complete mock case studies to facilitate integration of the training into usual coaching practice. Coaches will be provided with resources and training material to guide learning, and for use with patients. Coaches will be provided with contact details (telephone and email) and encouraged to contact principle investigators for ad hoc support for guidance about challenges, cases or management questions.

B) Smoking Cessation Program

Participants who identify as smokers at baseline will be referred to the NSW Quitline telephone smoking cessation program. Referral to Quitline will occur within the first 12 weeks of the intervention (Table 2), with the exact timing negotiated between the clinician and patient, based on patient preference, stage of change and consent.

Quitline is a telephone counselling service aiming to encourage participants to set a quit date and facilitate successful quit attempts. An evaluation of the Australian Quitline services showed that 88% of callers sampled had made a quit attempt since their initial call, and of those who had made a quit attempt, 38% had ceased smoking at six-month follow-up. Actual quit rates in those accessing Quitline after adjusting for non-responses was approximately 20%.(53)

Mode and timing of delivery

Those participating in Quitline receive an initial counselling call and are encouraged to set a quit date within the next month. Participants are offered a free counselling service of up to five calls from the day before the quit date to 30 days after the quit date. Call duration typically ranges from 10-20 minutes.(54, 55) "Quit kits" containing information about quitting smoking are posted to participants upon enrolment in Quitline.

Content

Quitline counselling sessions include an assessment of smoking status, identification of triggers for smoking, coping strategies and information on effective quitting aids. Strategies to support quitting are tailored to individual preferences. "Quit Kits" also include nicotine replacement therapies such as gum, lozenge and patches, guidance booklets and informational support.

Training for intervention delivery

All Quitline counsellors have a tertiary education qualification such as social work or psychology, and are trained in health education and counselling delivery using CBT and MI techniques.

Control (Usual Care Group)

The usual care group will be referred for usual physiotherapy care in a public hospital outpatient physiotherapy clinic.

Content

The usual care appointments may include a physical assessment, and guideline-based advice and education for back pain.(23, 24)

Mode of and timing of delivery

Up to three face-to-face usual care appointments will be provided by a registered physiotherapist.

Training for delivery

Usual care physiotherapists will deliver their usual practices of care, however they will be asked not to provide specific support for lifestyle-related health behaviours. Physiotherapists will record components of usual care on a standardised form, entered directly into the REDCap database.

Outcome Assessment

Patients will be asked to complete questionnaires at baseline (prior to randomisation), 6, 12, 26 and 52 weeks post randomisation (Table 2, Table 3). Baseline data will be collected via telephone. At weeks 6, 12, 26 and 52 patients will have the option of providing data online (via an email or SMS link), on a paper-based form, or transcribed by a trained telephone interviewer.

Objective height and weight will be collected at the initial consultation and weight will be measured again at 12 weeks (height measured at initial consultation only).

Baseline demographic characteristics

Baseline measures include: date of birth, gender, employment status, income, health insurance status, compensation status, previous episodes of back pain, duration of back pain, and presence of co-existing medical conditions (e.g. heart disease, stroke, diabetes, cancer, asthma, arthritis, depression).

Outcomes

Primary outcome

The primary outcome is disability at 26 weeks measured via the Roland Morris Disability Questionnaire; a validated self-report 24 item low back pain specific survey.(56)

Key secondary outcomes

Secondary outcomes include pain intensity, weight, measured according to ISAK protocols(57) (weeks 1 at initial appointment and week 12 appointment) and via self-report (baseline, weeks 6, 12, 26 and 52); quality of life measured by the Short Form12 version 2 and smoking status using NSW Population Health survey questions; collected at all data collection time points. (58)

Exploratory outcomes

Exploratory outcomes, including potential mediators and cost outcomes will be collected at all data collection time points (Table 3).

Process outcomes

Process evaluation includes measurement of intervention fidelity via clinician completion of a checklist to record the delivery of intervention components in both groups, and by observation of a random 10% of intervention consultations. We will also measure; dose of intervention (number of consultations attended and number of calls received), supplementary interventions, program completion, and reasons for drop out.

TABLE 2: TIMING OF INTERVENTION DELIVERY AND FOLLOW UP ASSESSMENTS

Component	Week
Intervention group	
Recruitment phone call: Eligibility screening, baseline data collection and randomisation	0
Initial consultation	1
Referral to NSW GHS weight management program	Following initial consultation
NSW GHS weight management program‡	1-26
Follow up consultations	3, 6, 12
Telephone interviews for outcome assessments	6, 12, 26 ,52
Referral to Quitline smoking cessation program	1-12 based on patient preference for timing
Quit line smoking cessation program	1-26 (depending on referral date)
Control	
Recruitment phone call: Eligibility screening, baseline data collection and randomisation	0
Usual physiotherapy care consultations	From week 1
Telephone interviews for outcome assessments	6, 12, 26 ,52

GHS, Get Healthy Service.

‡ *If patients miss calls, or put the program temporarily on hold the program may run longer than 26 weeks. If participants achieve goals they may also graduate early after 5 calls.*

TABLE 3: OUTCOME MEASURES

Domain	Measure	Time (weeks)
Primary		
Disability (endpoint 26 weeks)	Roland Morris Disability Questionnaire (RMDQ).(56)	0, 6, 12, 26, 52
Secondary		
Pain Intensity	11 point, 0-10 Numerical Rating Scale as the average pain over the last week where zero indicated no pain and ten indicates worst possible pain.(30)	0, 6, 12, 26, 52
Weight	Objective weight measured to the nearest 0.1kg by a trained assessor using International Society for the Advancement of Kinathropometry (ISAK) procedures.(57)	1, 12
	Self-reported weight (kg) is also collected at all-time points	0, 6, 12, 26, 52
Quality of Life	12-item Short Form Health Survey version 2 (0-100 scale; high score indicates greater quality of life).(58)	0, 6, 12, 26, 52
Smoking Status	2 items from the NSW Health survey (Which describes your smoking status and how many cigarettes smoked per day)	0, 6, 12, 26, 52
Exploratory Outcomes		
Physical Activity	International Physical Activity Questionnaire (IPAQ) reported as average hours and minutes spent participating in moderate to vigorous activity. (59)	0, 6, 12, 26, 52
Nutrition	21 item Food Frequency Questionnaire of intake over the past month (response options for fruit vegetable, discretionary choices, wholegrains and dairy categories: rarely or never, less than once a week, once a week, 2-3 times a week, 4-6 times a week, 1-2 times a day, 3-4 times a day, 5+ a day and response options for meat categories: rarely or never, less than once a week, once a week, 2-3 times a week, 4-6 times a week, 7+ times a week).(60)	0, 6, 12, 26, 52
Sleep Quality	Item-6 from the Pittsburgh Sleep Quality Index (response options: very bad, fairly bad, fairly good, very good)(61)	0, 6, 12, 26, 52
Pain Self Efficacy	2 item validated Pain Self-Efficacy Questionnaire (PSEQ-2) on a scale of 0-6 with zero indication not at all confident and 6 completely confident.(62)	0, 6, 12, 26, 52
Psychological Distress	Kessler 6 Questionnaire as how often a feeling was experiences over the past 30 days (response options: all of the time, most of the time, some of the time, a little of the time, none of the time).(63)	0, 6, 12, 26, 52
Alcohol Consumption	Alcohol Use Disorders Identification Test (AUDIT-C) (0-12 scale) high score greater risk of alcohol-related harm.(64)	0, 6, 12, 26, 52
Process and Economic measures		
Adverse Events	Open text question: "Have you developed any new medical conditions or an exacerbation of an existing condition?"	6, 52
Health Economics	Self-reported health and home care utilisation and medication use. Intervention costs: staff time, phone calls, referral and written materials. GHS and Quitline costs: number and call duration. Self-reported work absenteeism, presenteeism.	0, 6, 12, 26, 52

Recruitment Procedures

The recruitment process is detailed in the CONSORT diagram (Figure 1). Potentially eligible patients will be provided with a study information letter. The letter details the study procedures and informs patients they will be contacted by the research team to discuss participation. When patients are called, research personnel will screen for eligibility.

Eligible patients will verbally consent to participation and have baseline data collected over the phone. Written consent will be obtained at the initial consultation.

Randomisation procedures

Eligible consenting patients will complete baseline data collection over the phone with a trained interviewer, and be randomised via a concealed central randomisation service. Patients will be randomly allocated to the intervention or control group (1:1 ratio). A permuted 6:4 block randomization approach will be used so that the distribution of healthy weight, overweight and obese participants is equal across treatment conditions (intervention or control). Interviewers will be prompted by the system to input BMI category (healthy weight $\leq$24.9kg/m^2, overweight $\geq$25kg/m^2 - <30kg/m^2, obese $\geq$30kg/m^2) within the REDCap database which allocates participants to an experimental group based on a pre-specified randomisation schedule generated by an independent statistician.

Blinding

On study entry participants will be told that they will receive one of two treatment programs delivered by a physiotherapist. To reduce ascertainment bias, participants are not informed of the specific treatment details before allocation, nor provided detailed about the treatment to which they are not assigned. To reduce performance bias, the clinicians involved in the study deliver only the intervention, or the control. It is not possible for objective anthropometry outcomes to be blinded, as intervention and control physiotherapists will perform the measurements at the consults. Statisticians will conduct analyses blinded to treatment allocation using dummy coding for treatment group. Analyses will be conducted according to a pre-specified, published analysis plan. Treatment group will be unblinded at the completion of analysis.

Data Analysis

Data will be analysed using the intention to treat principle with the number of analyses restricted and specified a priori. Data integrity will be monitored by regularly scrutinising data files for omissions and errors. All manually entered data will be double checked.

Sample size

Sample size was calculated using the method of Twisk for mixed models. With 4 repeated observations, an estimated intra-cluster correlation (correlation between the observations) of 0.5, alpha of 5%, and allowing for up to 18% loss to follow up. A total of 346 patients (173 per group) provides over 80% power to detect between group differences of 3 points (SD 5) on Roland Morris Disability Questionnaire (RMDQ)(65) at 26 weeks. This is the smallest worthwhile effect that would justify implementation of the intervention. We ignored the increase in statistical power due to stratification and including baseline covariates in the analysis.

Effect estimates

A linear mixed effects regression model will be used to estimate the effectiveness of the intervention in reducing self-reported disability compared to control over 26 weeks of follow-up. A time by treatment group interaction term will be included as a fixed effect to assess the between group differences in adjusted mean disability scores at each time-point. Baseline disability scores will be included as a fixed effect in the model. Treatment group, time, BMI category, and potential confounders (participant characteristics) will also be included as fixed effects. A random subject-level intercept will be used to account for the repeated measures of the data. If more than 10% of the data is missing the pattern of missing data will be examined and an appropriate method of multiple imputation (depending on the data) will be used. Sensitivity analysis will involve comparing complete case, to imputed data analyses. A secondary analysis will explore the differential effects of the intervention on primary outcome for normal weight vs. overweight/obese. The sample size provides sufficient power to detect a differential effect of 2 points on the RMDQ between normal weight and overweight/obese

patients. This question will be evaluated using a linear mixed effects model including a three way, fixed effect interaction term; treatment group, time, and BMI category.

We pre-specify four key secondary outcomes for interpretation to reduce the possibility of Type I error. Treatment effects will be estimated using linear mixed effects, and logistic mixed effects regression models. Adjusted mean differences (continuous variables) or differences in proportions (dichotomous variables) will be assessed for each outcome at each follow-up point, with 26 weeks post randomization being considered the primary end-point of the study. Exploratory analyses will be conducted on outcomes of health behaviors, self-efficacy and psychological distress. The same fixed and random effects pre-specified for the main outcome model will be used in all secondary and exploratory analyses.

Supplementary analyses

Three pre-planned supplementary analyses will be undertaken. We will publish detailed protocols on open science repositories prior to unblinding of data. Analyses will include:

Complier Average Causal Effect (CACE) analyses will be conducted for the primary and key secondary outcomes.(66) The threshold for compliance will be attendance at least 2 intervention consultations and 5 or more completed GHS telephone calls (unless earlier graduation from the GHS program).

Causal mediation analysis will be used to investigate treatment mechanisms.(67) We will assess the mediating effects of physical activity, diet, pain, self-efficacy, weight, and symptoms of psychological distress on low back pain disability.

Three economic analyses will be conducted. First, a cost model comparing the costs associated with the control and intervention pathways. Second, a cost-utility analysis from the perspective of the health sector including individual health care utilisation costs (healthcare service and medication use). Third, a cost-utility analysis from a societal perspective including the additional non healthcare costs (e.g. carer or community service costs) and costs associated with work absenteeism and presenteeism. Costs will be based standard published rates and self-reported (out of pocket) costs. Health state utilities (to estimate QALYs), will be obtained from SF-12 score and transformed into health state utilities via the SF-6D algorithm.

Patient and Public Involvement

Development of the research question and the intervention design was based on previously conducted randomised controlled trials and data from patients on the orthopaedic surgical waitlist at the John Hunter Hospital, Newcastle Australia in 2014.(28, 68) Patients were involved in pilot stages of the study to provide feedback on physiotherapy care, health coaching and resources. Patients will not be involved in recruitment of participants or conduct of the study. Results of this study will available to the public and patients in published in open access peer reviewed journals.

AUTHOR CONTRIBUTION: CW and SK designed the project and secured funding. CW, ER, AW, RH, SD, AH designed the consultation content, trained relevant research staff, developed materials, data collection tools and databases. AH contributed to the randomisation schedule and statistical analysis protocol. SD, ER and CG are involved in delivery of the intervention. ER drafted the manuscript and all authors revised it critically for important intellectual content and approved the final version.

FUNDING: This work was supported by an National Health and Medical Research Council (NHMRC) project grant (Grant Number APP1100992).

COMPETING INTERESTS: None declared.

ETHICAL APPROVAL: This study was approved by the Hunter New England Research Ethics Committee (Approval No. 17/02/15/4.05), and University of Newcastle Human Research Ethics Committee (Ref No. H-2017-0222). The study was prospectively registered with the Australian New Zealand Clinical Trial Registry (ACTRN12617001288314).

DATA SHARING: De-identified data with accompanying data dictionaries will be made available on request. All analysis protocols will be made publicly available and published in open access peer reviewed journals. Proposals for data use may be submitted to the Principle investigator 12 months following publication of results.

ACKNOWLEDGEMENTS: The authors would like to thank the Physiotherapy Department at the Royal Newcastle Centre, John Hunter Hospital for assisting in the intervention delivery. We would also like to thank the Hunter New England Population Health Computer Assisted Telephone Interviewing CATI team for undertaking recruitment and data collection and the wider Hunter Population Health facility for provision of necessary resources.

References

1. Vos T, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet. 2017;390:1211-59.10.1016/S0140-6736(17)31833-0
2. Hoy D, March L, Brooks P, et al. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. Ann Rheum Dis. 2014;73(6):968-74.10.1136/annrheumdis-2013-204428
3. Schofield D, Shrestha R, Percival R, et al. The personal and national costs of early retirement because of spinal disorders: impacts on income, taxes, and government support payments. Spine J 2012;12:1111–8.
4. Henschke N, Kamper S, Maher C. The Epidemiology and Economic Consequences of Pain. 2015;90.
5. Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. The Spine Journal. 2007:8-20
6. Arthritis and Osteoporosis Victoria. A problem worth solving: the rising cost of musculoskeletal condtions in Australia. 2013
7. Hong J, Reed C, Novick D, et al. Costs associated with treatment of chronic low back pain: an analysis of the UK General Practice Research Database. Spine (Phila Pa 1976). 2013;38(1):75-82.10.1097/BRS.0b013e318276450f
8. Shiri R, Karppinen J, Leino-Arjas P, et al. The association between obesity and low back pain: a meta-analysis. Am J Epidemiol. 2009;171(2):135-54.10.1093/aje/kwp356
9. Heuch I, Heuch I, Hagen K, et al. Body mass index as a risk factor for developing chronic low back pain: a follow-up in the Nord-Trondelag Health Study. Spine (Phila Pa 1976). 2013;38(2):133-9.10.1097/BRS.0b013e3182647af2
10. Suri P, Boyko EJ, Smith NL, et al. Modifiable risk factors for chronic back pain: insights using the co-twin control design. Spine J. 2017;17(1):4-14.10.1016/j.spinee.2016.07.533
11. Shiri R, Karppinen J, Leino-Arjas P, et al. The association between smoking and low back pain: a meta-analysis. Am J Med. 2010;123(1):87 e7-35.10.1016/j.amjmed.2009.05.028
12. Bohman T, Alfredsson L, Jensen I, et al. Does a healthy lifestyle behaviour influence the prognosis of low back pain among men and women in a general population? A population-based cohort study. BMJ Open. 2014;4(12):e005713.10.1136/bmjopen-2014-005713
13. Lin CW, McAuley JH, Macedo L, et al. Relationship between physical activity and disability in low back pain: a systematic review and meta-analysis. Pain. 2011;152(3):607-13.10.1016/j.pain.2010.11.034
14. Heneweer H, Vanhees L, Picavet HS. Physical activity and low back pain: a U-shaped relation? Pain. 2009;143(1-2):21-5.10.1016/j.pain.2008.12.033
15. Shiri R, Falah-Hassani K. Does leisure time physical activity protect against low back pain? Systematic review and meta-analysis of 36 prospective cohort studies. Br J Sports Med. 2017;51(19):1410-8.10.1136/bjsports-2016-097352
16. Seaman DR. The diet-induced proinflammatory state. Journal of Manipulative and Physiological Therapeutics. 2002;25(3):168-79.10.1067/mmt.2002.122324
17. Macphail K. C-reactive protein, chronic low back pain and, diet and lifestyle. International Musculoskeletal Medicine. 2015;37(1):29-32.10.1179/1753615415y.0000000001

18. National Health and Medical Research Council. Clinical Practice Guidelines for the management of overweight and obesity in Adults, Adolescents and Children in Australia. Melbourne: National Health and Medical Research Council. 2013
19. Roffey D, Ashdown L, Dornan H, et al. Pilot evaluation of a multidisciplinary, medically supervised, nonsurgical weight loss program on the severity of low back pain in obese adults. The Spine Journal. 2011;11 197-204
20. Behrend C PM, Coyne E, et al. Smoking Cessation Related to Improved Patient-Reported Pain Scores Following Spinal Care. J Bone Joint Surg Am 2012; 94:2161–6.
21. Dean E, Soderlund A. What is the role of lifestyle behaviour change associated with non-communicable disease risk in managing musculoskeletal health conditions with special reference to chronic pain? BMC Musculoskelet Disord. 2015;16:87.10.1186/s12891-015-0545-y
22. Wai EK, Rodriguez S, Dagenais S, et al. Evidence-informed management of chronic low back pain with physical activity, smoking cessation, and weight loss. Spine J. 2008;8(1):195-202.10.1016/j.spinee.2007.10.024
23. Wong JJ, Cote P, Sutton DA, et al. Clinical practice guidelines for the noninvasive management of low back pain: A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. European journal of pain. 2017;21(2):201-16.10.1002/ejp.931
24. National Institute for Health and Care Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management. 2016
25. Gordon R, Bloxham S. A Systematic Review of the Effects of Exercise and Physical Activity on Non-Specific Chronic Low Back Pain. Healthcare (Basel). 2016;4(2).10.3390/healthcare4020022
26. Hayden J, van Tulder M, Malmivaara A, et al. Exercise therapy for treatment of non-specific low back pain (review). Cochrane Database Syst Rev. 2005(3).10.1002/14651858.CD000335.pub2.
27. Williams A, Wiggers J, O'Brien KM, et al. A randomised controlled trial of a lifestyle behavioural intervention for patients with low back pain, who are overweight or obese: study protocol. BMC Musculoskelet Disord. 2016;17:70.10.1186/s12891-016-0922-1
28. Williams. A, Wiggers. J, O'Brien. K, et al. The effectiveness of a healthy lifestyle intervention, for chronic low back pain: a randomised controlled trial. Pain. 2018
29. Krismer M, van Tulder M, et al. Strategies for prevention and management of musculoskeletal conditions: Low back pain (non-specific). Best Pract Res Clin Rheumatol. 2007;21(1):77-91.10.1016/j.berh.2006.08.004
30. Hawker G, Mian S, Kendzerska T, et al. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). Arthritis Care Research. Novmber 2011;63(11):S240-S52
31. Australian Government Department of Health. Australia's Physical Activity and Sedentary Behaviour Guidelines for Adults. 2017
32. National Health and Medical Research Council. Australian Dietary Guidelines. Canberra: National Health and Medical Research Council. 2013
33. Chan A, Tetzlaff J, Gøtzsche P, et al. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ 2013;346:e:7586.
34. Hoffmann T, Glasziou P, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014;348:g(1687.)

35. Verbeek J, Sengers M, Riemens L, et al. Patient expectations of treatment for back pain: A Systematic Review of Qualitative and Quantitative Studies. SPINE. 2004;29(20):2309–18
36. Kamper S, Haanstra T, Simmons K, et al. What Do Patients with Chronic Spinal Pain Expect from Their Physiotherapist? . Physiotherapy Australia 70(1)
37. Sveinsdottir V, Eriksen HR, Reme SE. Assessing the role of cognitive behavioral therapy in the management of chronic nonspecific back pain. J Pain Res. 2012;5:371-80.10.2147/JPR.S25330
38. Moseley GL, Butler DS. Fifteen Years of Explaining Pain: The Past, Present, and Future. The journal of pain : official journal of the American Pain Society. 2015;16(9):807-13.10.1016/j.jpain.2015.05.005
39. Vong SK, Cheing GL, Chan F, et al. Motivational enhancement therapy in addition to physical therapy improves motivational factors and treatment outcomes in people with low back pain: a randomized controlled trial. Arch Phys Med Rehabil. 2011;92(2):176-83.10.1016/j.apmr.2010.10.016
40. Hall K, Gibbie T, Lubman D. Motivational interviewing techniques Facilitating behaviour change in the general practice setting. Australian Family Physician 2012;41(9)
41. British Association for Behvioural and Cognitive Psychotherapies. What is CBT? 2012
42. Henschke N, Ostelo RW, van Tulder MW, et al. Behavioural treatment for chronic low-back pain. Cochrane Database Syst Rev. 2010(7):CD002014.10.1002/14651858.CD002014.pub3
43. Australian Government national Health and Medical Research Council Department of Health and Ageing. Australian Guide to Healthy Eating.
44. National Health and Medical Research Council. Summary Guide for the Management of Overweight and Obesity in Primary Care. Melbourne: National Health and Medical Research Council. 2013
45. Health Change Australia. HealthChange® Methodology and Training Options. 2018
46. Harris P, Taylor R, Thielke R, et al. Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, . J Biomed Inform. 2009;42(2):377-81
47. Mosely L, Moen D. Tame the Beast: Its time to rethink persistant pain.
48. O'Hara B, Phongsavan P, Eakin E, et al. Effectiveness of Australia's Get Healthy Information and Coaching Service: maintenance of self-reported anthropometric and behavioural changes after program completion. BMC Public Health. 2013;13:175
49. O'Hara BJ, Phongsavan P, Venugopal K, et al. Effectiveness of Australia's Get Healthy Information and Coaching Service(R): translational research with population wide impact. Prev Med. 2012;55(4):292-8.10.1016/j.ypmed.2012.07.022
50. O'Hara B, Gale J, McGill B, et al. Weight-Related Goal Setting in a Telephone-Based Preventive ealth-Coaching Program: Demonstration of Effectiveness. American Journal of Health Promotion. 2017;31(6):491-501.10.1177/0890117116660776
51. O'Hara BJ, Phongsavan P, Rissel C, et al. Role of general practice in the utilisation of the NSW Get Healthy Information and Coaching Service. Aust J Prim Health. 2015;21(2):182-8.10.1071/PY13154
52. Brown W, Bauman A, Bull F, et al. Development of Evidence - based Physical Activity Recommendations for Adults (18–64 years). Report prepared for the Australian Government Department of Health; Content/health-pubhlth-strateg-phys-act-guidelies/$File/DEB-PAR-Adults-18- 64years.pdf. Aug 2012

53. Greenhalgh E, Stillman S, Ford C. Cessation assistance: Telephone- and Internet-based interventions. Tobacco in Australia: Facts and issues Melbourne: Cancer Council Victoria; 2016 2016
54. Tzelepis F, Paul CL, Wiggers J, et al. A randomised controlled trial of proactive telephone counselling on cold-called smokers' cessation rates. Tobacco control. 2011;20(1):40-6.10.1136/tc.2010.035956
55. NSW Government Cancer Insititute NSW. NSW Quitline. 2017
56. Roland M, Morris R. A study of the natural history of back pain. Part 1: Development of a reliable and sensitive measure of disability in low back pain. Spine (Phila Pa 1976). 1983;8:141-4
57. International Society for the Advancement of Kinanthropometry. International Standards for Antrhopometric Assessment. Underdale: ISAK. 2001.
58. Ware J, Kosinski M, Turner-bowker D, et al. User's Manual for the SF- 12v2 Health Survey (With a Supplement Documenting SF-12 Health Survey). Lincoln: QualityMetric Incorporated. 2002
59. Craig C, Marshall A, Sjostrom M, et al. International Physical Activity Questionnaire: 12-Country Reliability and Validity. Medicine & Science in Sports & Exercise. 2003;35(8):1381-95
60. Cleghorn CL, Harrison RA, Ransley JK, et al. Can a dietary quality score derived from a short-form FFQ assess dietary quality in UK adult population surveys? Public health nutrition. 2016;19(16):2915-23.10.1017/S1368980016001099
61. Buysse D, Reynolds C, Monk T, et al. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res. 1989;28:193–213
62. Nicholas MK, McGuire BE, Asghari A. A 2-item short form of the Pain Self-efficacy Questionnaire: development and psychometric evaluation of PSEQ-2. The journal of pain : official journal of the American Pain Society. 2015;16(2):153-63.10.1016/j.jpain.2014.11.002
63. Kessler R, Barker P, Colpe L, et al. Screening for serious mental illness in the general population. Archives of General Psychiatry 2003;60(2):184-9.
64. Bush K, Kivlahan D, McDonell M, et al. The AUDIT Acohol Consumption Questions (AUDIT-C): a Brief screening test for problem drinking. Arch Internal Med 1998;3:1789-95
65. Maughan EF, Lewis JS. Outcome measures in chronic low back pain. Eur Spine J. 2010;19(9):1484-94.10.1007/s00586-010-1353-6
66. Dunn G, Maracy M, Tomenson B. Estimating treatment eff ects from randomized clinical trials with noncompliance and loss to follow-up: the role of instrumental variable methods. Stat Methods Med Res. 2005;14(369-95)
67. H. Lee GM, J.H. McAuley, S.J. Kamper, M. Hübscher, G.L. Moseley, L. Wolfenden, R.K. Hodder, C.M. Williams. Causal mechanisms in the clinical course and treatment of back pain. Best Practice & Research Clinical Rheumatology. 2017.http://dx.doi.org/10.1016/j.berh.2017.04.001
68. O'Brien KM, Wiggers J, Williams A, et al. Telephone-based weight loss support for patients with knee osteoarthritis: a pragmatic randomised controlled trial. Osteoarthritis Cartilage. 2018;26(4):485-494(4):485-94.10.1016/j.joca.2018.01.003

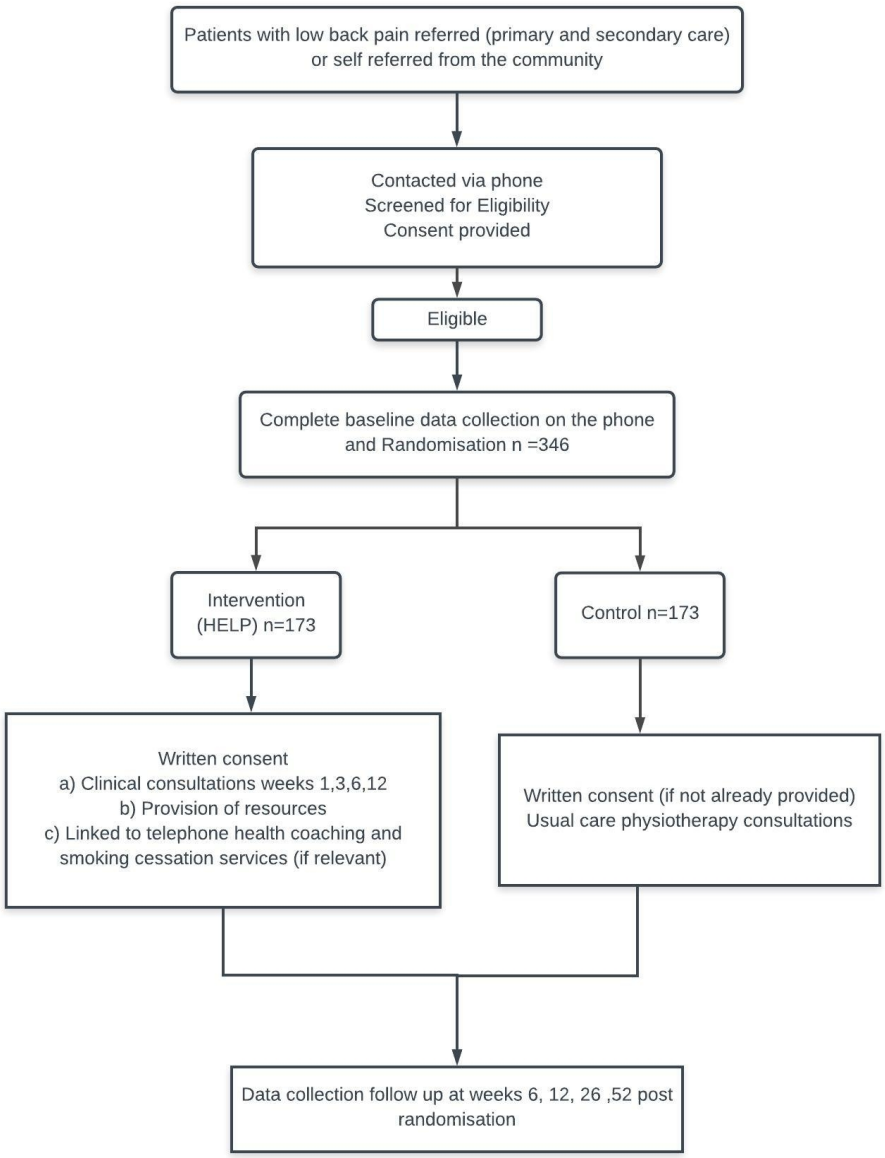


Figure 1: Participant flow consort diagram

209x269mm (160 x 160 DPI)

TIDieR Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	P1 (title) P2- (abstract)	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	P4-5 (introduction, objectives)	
	WHAT	7.	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	P9 P12-14	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	P8-14	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	P7 and 9 P12-13 P14	Clinicians Get Healthy Quit line
	HOW		

6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	P7, 12, 14 and Table 2.	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	P5	
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Table 2	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	P8, P9, P12, P14	
	MODIFICATIONS	N/A	
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	
	HOW WELL	**Checklist**	
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	P9	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

SPIRIT Checklist.docx

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	P 2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	P 23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	P1
	5b	Name and contact information for the trial sponsor	P1, 23
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	P23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	P4-5
	6b	Explanation for choice of comparators	P 14
Objectives	7	Specific objectives or hypotheses	P 5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	P 5

Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P7-14 T 1&2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	As per Ethics
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	P 9, T3
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P15-16 T3
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	T2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P 19
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	P5
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	P 19

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	P 19
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	P 19
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	P 19
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	P 19
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	T1, T2, T3
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P 1
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P 19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P 20
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P 21
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	P 20
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	As per Ethics
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	P 2
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	As per ethics P2
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P 18
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	As per Ethics
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	P 23
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	P23
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P 22
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P 23

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	As per Ethics
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Healthy lifestyle program for Low back Pain (HeLP): Protocol for a randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-029290.R1
Article Type:	Protocol
Date Submitted by the Author:	04-Apr-2019
Complete List of Authors:	Robson, Emma; Hunter New England Population Health, Kamper, Steven; University of Sydney, Centre for Pain, Health and Lifestyle, School of Public Health Davidson, Simon; Hunter New England Population Health; The University of Newcastle, Viana da Silva, Priscilla; Hunter New England Population Health; The University of Newcastle, Williams, Amanda; Hunter New England Population Health Hodder, Rebecca; Hunter New England Local Health District, Hunter New England Population Health; The University of Newcastle, Lee, Hopin; Hunter New England Population Health; University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences Hall, Alix; Hunter Medical Research Institute, University of Newcastle, School of Medicine and Public Health Gleadhill, Connor; Hunter New England Population Health; University of Sydney, Centre for Pain, Health and Lifestyle, School of Public Health Williams, Christopher; University of Newcastle, School of Medicine and Public Health; Hunter New England Local Health District, Population Health
Primary Subject Heading:	Public health
Secondary Subject Heading:	Patient-centred medicine, Rehabilitation medicine, Research methods, Sports and exercise medicine, Smoking and tobacco
Keywords:	Back pain < ORTHOPAEDIC & TRAUMA SURGERY, Spine < ORTHOPAEDIC & TRAUMA SURGERY, PUBLIC HEALTH, PAIN MANAGEMENT, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY

Healthy lifestyle program for Low back Pain (HeLP): Protocol for a randomised controlled trial

Authors:
Emma Robson[1,2,3]
A/Prof Steven J Kamper[3,4]
Simon Davidson[1,2,3]
Priscilla Viana Silva[1, 2,3]
Amanda Williams[1,2,3]
Dr Rebecca Hodder[1,2,3,5]
Dr Hopin Lee[1,3,6]
Dr Alix Hall [5]
Connor Gleadhill[1,3,4]
Dr Christopher M Williams[1,2,3,5]

Author Details

[1] Hunter New England Population Health, Locked Bag 10, Wallsend NSW, 2287, Australia.
[2] School of Medicine and Public Health, University of Newcastle, Newcastle NSW, 2308, Australia
[3] Centre for Pain, Health and Lifestyle, NSW, Australia
[4] University of Sydney, PO Box M179, Missenden Rd, Camperdown NSW, 2050, Australia
[5] Hunter Medical Research Institute, Locked Bag 1, Hunter Region Mc NSW, 2310, Australia
[6] Centre for Statistics in Medicine, Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK

Corresponding author:

Dr Christopher Williams,

Locked bag 10 Wallsend, NSW 2287, Australia.

Email: christopher.m.williams@hnehealth.nsw.gov.au

Phone: (02) 49246121

Word count: 3991

Abstract

Introduction: Low back pain is one of the most common and burdensome chronic conditions worldwide. Lifestyle factors, such as excess weight, physical inactivity, poor diet and smoking are linked to low back pain chronicity and disability. There are few high quality randomised controlled trials that investigate the effects of targeting lifestyle risk factors in people with chronic low back pain.

Methods and Analysis:

The aim of this study is to determine the effectiveness of a Healthy lifestyle program for Low back Pain (HeLP) targeting weight, physical activity, diet and smoking to reduce disability in patients with chronic low back pain compared to usual care. This is a randomised controlled trial, with participants stratified by BMI, allocated 1:1 to the HeLP intervention or usual physiotherapy care. HeLP involves three main components: i) clinical consultations with a physiotherapist and dietitian; ii) educational resources; and iii) telephone-based health coaching support for lifestyle risk factors. The primary outcome is disability (Roland Morris Disability Questionnaire), at 26 weeks. Secondary outcomes include pain, weight, quality of life and smoking status. Data will be collected at baseline, and weeks 6, 12, 26 and 52. Patients with chronic low back pain who have at least one health risk factor; overweight or obese; smoker; inadequate physical activity or fruit and vegetable consumption, will be recruited from primary or secondary care, or the community. Data will be analysed by intention-to-treat using linear mixed effects regression models. We will conduct three supplementary analysis: causal mediation analysis, compiler average causal effects analysis (CACE) and economic analyses.

Ethics and Dissemination: This study was approved by the Hunter New England Research Ethics Committee (Approval No. 17/02/15/4.05), and University of Newcastle Human Research Ethics Committee (Ref No. H-2017-0222). Outcomes of this trial and supplementary analyses will be disseminated through publications in peer-reviewed journals and conference presentations.

Trial Registration Number: ACTRN12617001288314.

Strengths and limitations of this study

- The first randomised controlled trial investigating a comprehensive lifestyle intervention involving physiotherapy, dietetics and telephone health coaching for patients with chronic low back pain.
- The trial includes collection of a large range of variables to enable investigation of clinical effectiveness, cost effectiveness and mechanisms of addressing lifestyle factors in chronic low back pain patients to help guide healthcare policy decisions and clinical practice.
- Choice of primary and secondary outcomes is based on importance to patients with the condition.

INTRODUCTION

Chronic low back pain is a worldwide public health problem with significant individual and economic burden.(1-7) In 2016, low back pain was the leading cause of disability globally, accounting for over 57.6 million years lived with disability (YLD).(1) Estimated total costs of back pain are significant, with direct costs of care estimated at £2.8 billion in the UK,(7) and $90 billion in the US.(5) In Australia annual costs exceed $4.8 billion and back pain reduces the country's Gross Domestic Product by $2.9 billion per year.(3) Health care consumption, medication use, productivity losses and forced early retirement contribute to these costs.(3, 5, 7)

Lifestyle risk factors, including excess weight, physical inactivity, poor diet and smoking contribute to the burden of low back pain.(8-12) Meta-analysis of 33 studies found obesity was associated with increased prevalence of chronic low back pain (OR 1.4, 95% CI 1.4, 1.6) and increased care-seeking for low back pain (OR 1.6, 95% CI 1.5, 1.7).(8) Another meta-analysis of 27 studies demonstrated associations between smoking and chronic low back pain (OR 1.8, CI 95% 1.3, 2.5).(11) Physical inactivity and poor diet contribute to obesity, and have an influence on chronic low back pain independently.(13-18) Despite some inconsistency in the literature, evidence suggests low levels of physical activity is associated with chronic low back pain,(13-15) as is diet-induced systematic inflammation.(16, 17)

Preliminary clinical studies suggest addressing such lifestyle factors can improve low back pain outcomes including disability.(12, 19-22) For example, a pre-post study of a weight loss program targeting diet and physical activity showed significant improvement in pain related disability in patients with low back pain.(19) Increasing physical activity and providing exercise are widely accepted core treatment recommendations for chronic low back pain management(23, 24) and reviews of the literature show exercise is effective in reducing disability (improvement of 2.5 points on 100 point scale, 95% CI 1.0, 3.9) compared to control.(25, 26) In relation to smoking, one cohort study involving 5333 smokers with low back pain also showed clinically significant reductions in pain (30% decrease) in those who quit smoking.(20)

Despite evidence suggesting the potential benefit of interventions targeting these lifestyle factors,(21, 22) there is only one similar randomised control trial evaluating a lifestyle

intervention for patients with chronic low back pain.(27, 28) This study found no effect, likely due to poor adherence to the treatment.

Objective

The primary aim of this trial is to determine the effectiveness of a multi-focused Healthy lifestyle program for Low back Pain (HeLP) to reduce disability in patients with chronic low back pain, compared to usual physiotherapy care. Secondary objectives are to determine the effectiveness of the intervention on pain intensity, patient weight, quality of life and smoking status.

We will also conduct three supplementary analyses to assess: i) treatment effect in those who complied with the intervention using Complier Average Causal Effects (CACE) analysis, ii) mediating effects of the intervention through pain, weight, smoking cessation, physical activity levels, diet, pain self-efficacy, and psychological distress, iii) cost effectiveness of the intervention from the health sector and societal perspectives.

METHODS AND ANALYSIS

Study Design

The study will be a parallel-group pragmatic randomised controlled trial with two groups (Fig 1.) Participants will be stratified by Body Mass Index (BMI) category and randomised 1:1 to either the HeLP intervention or usual physiotherapy care.

Setting

People with a main complaint of low back pain referred from primary care, or secondary care at a major tertiary referral hospital in the Hunter New England Local Health District, NSW, or self-referred from community advertisements, will be screened for eligibility.

Eligibility

Eligibility criteria are as follows:

- ≥ 18 years of age
- Chronic low back pain, defined as pain between the 12th rib and buttock crease, with or without leg pain, of more than 3 months duration(29);
- Pain intensity rating over the last week of ≥3 on an 11 point numerical rating scale (NRS) where "0" represents no pain and "10" represents worst possible pain,(30) or respond "moderately", "quite a bit" or "extremely" when asked how much back pain interferes with completing normal daily activities of living (modified item of Short Form Health Survey-36)(30);
- At least one health risk factor: overweight or obese (BMI of >25kg/m^2) (18); participate in less than 30 minutes of physical activity on 5 days of the week(31); current smoker; or eat less than 2 serves of fruit and 5 serves of vegetables per day.(32)

Exclusion criteria:

- Previous bariatric weight loss surgery;
- Currently undertaking weight loss or smoking cessation program or care (e.g. Dietetics for weight loss, Jenny Craig, Lite n Easy, Optifast, Weight Watchers, nicotine replacement therapy, Quitline);
- Back surgery in the previous 6 months or planned back surgery in the next 6 months;
- Known or suspected serious pathology causing back pain (i.e. rheumatoid arthritis, cancer, fracture or infection);
- Cannot actively engage in the intervention (unable to communicate, use a telephone or attend appointments, adapt meals or exercise);
- Comorbidity that does not allow safe completion of study procedures (e.g. uncontrolled blood pressure or heart conditions, uncontrolled diabetes);
- Pregnant or planning pregnancy in the next 12 months.

Details of the intervention and control

Trial design adheres to the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) recommendations,(33) and the intervention and control conditions are described

according to the Template for Intervention description and Replication (TIdieR) (Appendix 1).(34)

Intervention (HeLP)

Participants randomised to the intervention group will receive HeLP over a 6-month period. The intervention draws on cognitive behavioural therapy (CBT) and motivational interviewing (MI) to support pain management and facilitate positive behaviour change related to maintaining a healthy lifestyle (Table 1).

HeLP includes:

i) Consultations with a physiotherapist and dietitian;
ii) Provision of educational resources; and
iii) Telephone-based health coaching services for healthy lifestyle and smoking cessation (Table 2).

i) Consultations

This component was co-developed by a multidisciplinary team of investigators with expertise in physiotherapy, dietetics, psychology, nursing and health service management. Consultations aim to:

- Assess participants' back pain condition;
- Educate participants about back pain and lifestyle;
- Use behaviour change strategies to facilitate positive lifestyle changes (achieve a healthy body weight, increase physical activity, develop healthy eating habits, quit smoking);
- Initiate engagement in telephone support services;
- Reinforce positive behaviours and encourage self-regulation.

Mode and timing of consultation delivery

Participants will be offered to attend five clinical consultations of up to 60 minutes in duration; four with a registered physiotherapist, and one with a registered dietitian. Physiotherapy consultations will include an initial consultation and follow up consultations at 3, 6, and 12

weeks post randomisation. The dietitian consultation will occur at week 3, immediately after the physiotherapy consultation (Table 2). Consultations will be conducted face-to-face, however; if patients are not able to attend appointments face-to-face they may be offered telehealth consultations (telephone or video conference) to deliver clinical content. The delivery method for all consultations will be recorded.

Content (Initial consultation)

The initial consultation will involve three major components (Table 1):

1. History and physical assessment(24);
2. HeLP education (education about pain biology and links between pain and lifestyle);
3. Develop an individualised HeLP action plan to address lifestyle risks, incorporating behaviour change strategies and initiating a physical activity program.

Physical assessment, education and advice is built upon guideline recommendations and in line with back pain patients' expectations from physiotherapists.(23-25, 35-37) Education and advice is designed to improve participants' understanding of the biopsychosocial nature of low back pain by presenting information on the nature of pain biology,(38) address erroneous beliefs about back pain (e.g. that low back pain is always associated with pathology), and outline links between low back pain and health behaviour risks (weight, smoking etc). Advice aims to encourage pain self-management, negotiate a physical activity plan and provide a platform for patients to engage with additional support services for healthy lifestyle.

Behaviour change strategies are based on principles of MI and CBT.(37, 39-41) Evidence supports the use of CBT and MI in improving physical and behavioural outcomes in patients with back pain.(37) (39, 42) Behaviour change strategies include: assessing stage of change; goal setting with graded task assignment; and developing self-monitoring and regulation practices. Clinicians will work with patients to set tailored goals using graded task assignment, e.g. agreeing on an initial goal of 10 minutes walking per day, to increase to 30 minutes per day by week 6. Clinicians will encourage self-monitoring and regulation through goal evaluation and use of patient resources to monitor pain, activity and eating patterns. Patient understanding of, and participation in, telephone health coaching services will also be encouraged.

Content (follow up consultations)

Subsequent consultations (weeks 3, 6 and 12) will reinforce key messages, information and action plans provided in the initial consultation. Participants and clinicians will evaluate goals and progress, identify and address barriers to change, and encourage self-monitoring (Table 1).

The dietitian consultation will occur immediately after physiotherapy consult in week 3. The consultation will focus on achieving or maintaining healthy eating behaviours to assist in weight management. Education and advice will be based on Australian healthy eating(18, 32, 43, 44) and obesity management guidelines.(18, 32, 43) Education will be tailored to participants needs including information on recommended intake of the five key food groups, energy balance, portion sizes and general healthy lifestyle promotion.

Clinicians will support and encourage patients to achieve their lifestyle goals and engage with telephone health coaching services. Goals and content of clinical care will be provided in the initial referrals to the telephone coaching services.

Training for Intervention Delivery

The intervention clinicians will attend multiple training sessions (including piloting the intervention) prior to study commencement and offered to attend a 2-day Health Behaviour Change course.(45) Training involves background to the study, understanding intervention and appointment scheduling protocols for each consult, and behaviour change techniques. Clinicians will also learn how to use REDCap,(46) an electronic data capture tool to record patient appointment attendance and delivery of intervention components. An intervention checklist will be provided to guide intervention delivery and optimise fidelity. Intervention clinicians will be provided implementation support via regular face to face and email contact with the research team for the duration of the study.

TABLE 1: PHYSIOTHERAPY CONSULTATIONS

Physiotherapy	Component	Content	Purpose
Week 1 (initial)	Physical Assessment	- Patient history and physical assessment including assessing range of motion, evaluate strength, flexibility, pain characteristics. - Collect anthropometric measurements (height, weight)	Develop rapport Assess and address patients expectations for physiotherapy care
	Psychoeducation	- Introduce pain biology, concept of pain being multifactorial and does not equal damage, as well as fluctuating nature of pain conditions - Acknowledgement that pain is real - Discuss influence of lifestyle factors on back pain and consequences of being overweight, having a poor diet, inactivity, poor sleep and smoking - Introduce HeLP to support adoption of healthy lifestyle behaviours - Promote support services the GHS and Quitline	Correct erroneous pain beliefs, increase knowledge, provide rationale for need to change health behaviour.
	Behaviour change strategies	- Assess patients stage of change and motivations through questioning - Acknowledge general barriers to lifestyle change and program adherence - Establish and agree on commitment to change - Goal setting: establish patient management and lifestyle goals - Agree on graded exercises and physical activity (e.g. aim to start walking 10 minutes 5 times a week). - Discuss strategies to facilitate self-monitoring behaviours such as keeping activity, pain and diet diaries and attending follow up appointments	Initiate process of behaviour change, encourage safe engagement in physical activity, initiate engagement with support services.
Week 3 and 6	Psychoeducation	- Reinforce back pain education and lifestyle messages in first consultation	Increase knowledge
	Behaviour change strategies	- Evaluate goals and adapt with patient discussion and assessment of diaries - Problem solving: discuss patient barriers to meeting goals and strategies to overcome - Goal setting: Adapt or progress graded exercise and activity - Discuss participation in the GHS and Quit line services and encourage continued participation (if appropriate) - Encourage continual encouragement of self-monitoring	Reinforce positive behaviour, support behaviour change and self-monitoring behaviours.
Week 12	Physical Assessment	- Collect anthropometric measurements	Data collection
	Psychoeducation	- Reflect on information provided previously and patient experience	Initiate self-reflection and reinforce positive behaviours

	Behaviour change	- Reassess motivation to change and/or motivation to sustain behaviour change - Encourage completion of the GHS and or Quit line program - Goal setting for maintaining healthy lifestyle change - Negotiate strategies and problem solving for overcoming barriers to maintain changes	Goal setting for continued self-management and maintaining or further improving lifestyle behaviours, reinforce positive behaviours, identify skills and strategies to prevent relapse of unhealthy habits.
Dietitian Consult			
Week 3	Brief dietary assessment	- Assess patients diet using monitoring completed food diary or conduct brief diet history and eating behaviours	Build rapport
	Psychoeducation	- Reinforce HeLP messages: the importance of a healthy lifestyle in pain management and the role of diet in weight management and chronic pain. - Discuss five key food groups and Australia Guide to Healthy Eating, Australia Dietary Guideline recommendations - Introduce concepts of energy balance and portion size	Increase knowledge; reinforce alignment of health service perspectives for treating back pain, including support from GHS
	Behaviour Change strategies	- Assess patients stage of change and motivations through questioning - Goal setting: identify or confirm patient lifestyle and dietary goals - Acknowledge and discuss any barriers to change and reassure small lifestyle changes make a difference - Graded task assignment: Detail suitable strategies to improve dietary intake, balance energy intake and ensure adequate consumption of core food groups - Encourage participation and continued dietary support from the GHS - Encourage self-monitoring e.g. keep a food diary	Reinforce positive behaviour, initiate positive safe dietary changes, support behaviour change and use of support services.

Legend: GHS, Get Healthy Service.

II) Educational Resources

Patients will be provided with resources including an information booklet or access to a web based app, and a 5 minute video(47) reflecting education and key messages. The information booklet and app were co-developed by back pain experts, intervention physiotherapists and dietitians. The booklet and app were piloted with consumers and assessed for cultural safety, and changes were made according to feedback. The information booklet and app details pain education provided in the consults, healthy lifestyle information, information about support services, and diaries to record goals and encourage self-monitoring. The 5 minute video(47) will be sent to patients via SMS or email, viewing will also be prompted at the week 3 appointment.

III) Telephone health coaching

A) Healthy lifestyle coaching telephone service

All patients in the intervention group will be referred to the telephone-based "NSW Get Healthy Information and Coaching Service" immediately after their initial consultation (Table 2).

The Get Healthy Service (GHS) is a telephone-based health coaching initiative provided by the NSW Government. The service aims to support people to modify unhealthy behaviours; increase physical activity levels; make healthy dietary changes; reduce alcohol consumption and achieve and maintain a healthy body weight.(48, 49) There is evidence that the GHS is effective in reducing BMI, and waist circumference, and improves eating behaviours and physical activity in the general population.(49, 50)

Mode of and timing of delivery

The GHS involves up to 10 individually tailored phone calls over a 6-month period, delivered by qualified and specially-trained health professionals.(51) Calls are usually made bi-monthly for the first three months (n=6) to help facilitate behaviour change, with remaining calls tapering off for the following three months. Average call duration is 13 minutes.(49, 50) Patients can graduate early from the GHS if they complete 5 coaching calls and meet their health goals.

Content

Content is based on the Australian Guide to Healthy Eating, and National Physical Activity Guidelines.(31, 52) Coaches provide education, advice and counselling to achieve or maintain a healthy weight through modifying energy intake, and use strategies to improve intake of the five key food groups and achieve moderate physical activity of 30 minutes 5 days per week. The GHS aims to support, motivate and monitor the lifestyle goals patients established in their face-to-face consultations. Coaching uses MI techniques and self-regulation to support behaviour change.(50)

Training for intervention delivery

All GHS coaches are university qualified health professionals (dietitians, exercise physiologists, health psychologists). All coaches involved the trial will receive 3 hours of interactive face-to-face training, delivered by the principle investigators. Training is based on academic detailing, including educational outreach, technical assistance and provision of resources. Sessions include education about chronic pain and guideline recommended care for patients with low back pain; current evidence for low back pain management and links to health behaviour risks and lifestyle; and advice from professional experiences treating patients, including common barriers to care and engagement in lifestyle management. Coaches are instructed how to make links between lifestyle behaviours, weight management and back pain care, and complete mock case studies to facilitate integration of the training into usual coaching practice. Coaches will be provided with resources and training material to guide learning, and for use with patients. Coaches will be provided with contact details (telephone and email) and encouraged to contact principle investigators for ad hoc support for guidance about challenges, cases or management questions.

B) Smoking Cessation Program

Participants who identify as smokers at baseline will be referred to the NSW Quitline telephone smoking cessation program. Referral to Quitline will occur within the first 12 weeks of the intervention (Table 2), with the exact timing negotiated between the clinician and patient, based on patient preference, stage of change and consent.

Quitline is a telephone counselling service aiming to encourage participants to set a quit date and facilitate successful quit attempts. An evaluation of the Australian Quitline services showed that 88% of callers sampled had made a quit attempt since their initial call, and of those who had made a quit attempt, 38% had ceased smoking at six-month follow-up. Actual quit rates in those accessing Quitline after adjusting for non-responses was approximately 20%.(53)

Mode and timing of delivery

Those participating in Quitline receive an initial counselling call and are encouraged to set a quit date within the next month. Participants are offered a free counselling service of up to five calls from the day before the quit date to 30 days after the quit date. Call duration typically ranges from 10-20 minutes.(54, 55) "Quit kits" containing information about quitting smoking are posted to participants upon enrolment in Quitline.

Content

Quitline counselling sessions include an assessment of smoking status, identification of triggers for smoking, coping strategies and information on effective quitting aids. Strategies to support quitting are tailored to individual preferences. "Quit Kits" also include nicotine replacement therapies such as gum, lozenge and patches, guidance booklets and informational support.

Training for intervention delivery

All Quitline counsellors have a tertiary education qualification such as social work or psychology, and are trained in health education and counselling delivery using CBT and MI techniques.

Control (Usual Care Group)

The usual care group will be referred for usual physiotherapy care in a public hospital outpatient physiotherapy clinic.

Content

The usual care appointments may include a physical assessment, and guideline-based advice and education for back pain.(23, 24)

Mode of and timing of delivery

Up to three face-to-face usual care appointments will be provided by a registered physiotherapist.

Training for delivery

Usual care physiotherapists will deliver their usual practices of care, however they will be asked not to provide specific support for lifestyle-related health behaviours. Physiotherapists will record components of usual care on a standardised form, entered directly into the REDCap database.

Outcome Assessment

Patients will be asked to complete questionnaires at baseline (prior to randomisation), 6, 12, 26 and 52 weeks post randomisation (Table 2, Table 3). Baseline data will be collected via telephone. At weeks 6, 12, 26 and 52 patients will have the option of providing data online (via an email or SMS link), on a paper-based form, or transcribed by a trained telephone interviewer.

Objective height and weight will be collected at the initial consultation and weight will be measured again at 12 weeks (height measured at initial consultation only).

Baseline demographic characteristics

Baseline measures include: date of birth, gender, employment status, income, health insurance status, compensation status, previous episodes of back pain, duration of back pain, and presence of co-existing medical conditions (e.g. heart disease, stroke, diabetes, cancer, asthma, arthritis, depression).

Outcomes

Primary outcome

The primary outcome is disability at 26 weeks measured via the Roland Morris Disability Questionnaire; a validated self-report 24 item low back pain specific survey.(56)

Key secondary outcomes

Secondary outcomes include pain intensity, weight, measured according to ISAK protocols(57) (weeks 1 at initial appointment and week 12 appointment) and via self-report (baseline, weeks 6, 12, 26 and 52); quality of life measured by the Short Form12 version 2 and smoking status using NSW Population Health survey questions; collected at all data collection time points. (58)

Exploratory outcomes

Exploratory outcomes, including potential mediators and cost outcomes will be collected at all data collection time points (Table 3).

Process outcomes

Process evaluation includes measurement of intervention fidelity via clinician completion of a checklist to record the delivery of intervention components in both groups, and by observation of a random 10% of intervention consultations. We will also measure; dose of intervention (number of consultations attended and number of calls received), supplementary interventions, program completion, and reasons for drop out.

TABLE 2: TIMING OF INTERVENTION DELIVERY AND FOLLOW UP ASSESSMENTS

Component	Week
Intervention group	
Recruitment phone call: Eligibility screening, baseline data collection and randomisation	0
Initial consultation	1
Referral to NSW GHS weight management program	Following initial consultation
NSW GHS weight management program‡	1-26
Follow up consultations	3, 6, 12
Telephone interviews for outcome assessments	6, 12, 26 ,52
Referral to Quitline smoking cessation program	1-12 based on patient preference for timing
Quit line smoking cessation program	1-26 (depending on referral date)
Control	
Recruitment phone call: Eligibility screening, baseline data collection and randomisation	0
Usual physiotherapy care consultations	From week 1
Telephone interviews for outcome assessments	6, 12, 26 ,52

GHS, Get Healthy Service.

‡ *If patients miss calls, or put the program temporarily on hold the program may run longer than 26 weeks. If participants achieve goals they may also graduate early after 5 calls.*

TABLE 3: OUTCOME MEASURES

Domain	Measure	Time (weeks)
Primary		
Disability (endpoint 26 weeks)	Roland Morris Disability Questionnaire (RMDQ).(56)	0, 6, 12, 26, 52
Secondary		
Pain Intensity	11 point, 0-10 Numerical Rating Scale as the average pain over the last week where zero indicated no pain and ten indicates worst possible pain.(30)	0, 6, 12, 26, 52
Weight	Objective weight measured to the nearest 0.1kg by a trained assessor using International Society for the Advancement of Kinathropometry (ISAK) procedures.(57)	1, 12
	Self-reported weight (kg) is also collected at all-time points	0, 6, 12, 26, 52
Quality of Life	12-item Short Form Health Survey version 2 (0-100 scale; high score indicates greater quality of life).(58)	0, 6, 12, 26, 52
Smoking Status	2 items from the NSW Health survey (Which describes your smoking status and how many cigarettes smoked per day)	0, 6, 12, 26, 52
Exploratory Outcomes		
Physical Activity	International Physical Activity Questionnaire (IPAQ) reported as average hours and minutes spent participating in moderate to vigorous activity. (59)	0, 6, 12, 26, 52
Nutrition	21 item Food Frequency Questionnaire of intake over the past month (response options for fruit vegetable, discretionary choices, wholegrains and dairy categories: rarely or never, less than once a week, once a week, 2-3 times a week, 4-6 times a week, 1-2 times a day, 3-4 times a day, 5+ a day and response options for meat categories: rarely or never, less than once a week, once a week, 2-3 times a week, 4-6 times a week, 7+ times a week).(60)	0, 6, 12, 26, 52
Sleep Quality	Item-6 from the Pittsburgh Sleep Quality Index (response options: very bad, fairly bad, fairly good, very good)(61)	0, 6, 12, 26, 52
Pain Self Efficacy	2 item validated Pain Self-Efficacy Questionnaire (PSEQ-2) on a scale of 0-6 with zero indication not at all confident and 6 completely confident.(62)	0, 6, 12, 26, 52
Psychological Distress	Kessler 6 Questionnaire as how often a feeling was experiences over the past 30 days (response options: all of the time, most of the time, some of the time, a little of the time, none of the time).(63)	0, 6, 12, 26, 52
Alcohol Consumption	Alcohol Use Disorders Identification Test (AUDIT-C) (0-12 scale) high score greater risk of alcohol-related harm.(64)	0, 6, 12, 26, 52
Process and Economic measures		
Adverse Events	Open text question: "Have you developed any new medical conditions or an exacerbation of an existing condition?"	6, 52
Health Economics	Self-reported health and home care utilisation and medication use. Intervention costs: staff time, phone calls, referral and written materials. GHS and Quitline costs: number and call duration. Self-reported work absenteeism, presenteeism.	0, 6, 12, 26, 52

Recruitment Procedures

The recruitment process is detailed in the CONSORT diagram (Figure 1). Potentially eligible patients will be provided with a study information letter. The letter details the study procedures and informs patients they will be contacted by the research team to discuss participation. When patients are called, research personnel will screen for eligibility.

Eligible patients will verbally consent to participation and have baseline data collected over the phone. Written consent will be obtained at the initial consultation.

Randomisation procedures

Eligible consenting patients will complete baseline data collection over the phone with a trained interviewer, and be randomised via a concealed central randomisation service. Patients will be randomly allocated to the intervention or control group (1:1 ratio). A permuted 6:4 block randomization approach will be used so that the distribution of healthy weight, overweight and obese participants is equal across treatment conditions (intervention or control). Interviewers will be prompted by the system to input BMI category (healthy weight $\leq$24.9kg/m^2, overweight $\geq$25kg/m^2 - <30kg/m^2, obese $\geq$30kg/m^2) within the REDCap database which allocates participants to an experimental group based on a pre-specified randomisation schedule generated by an independent statistician.

Blinding

On study entry participants will be told that they will receive one of two treatment programs delivered by a physiotherapist. To reduce ascertainment bias, participants are not informed of the specific treatment details before allocation, nor provided detailed about the treatment to which they are not assigned. To reduce performance bias, the clinicians involved in the study deliver only the intervention, or the control. It is not possible for objective anthropometry outcomes to be blinded, as intervention and control physiotherapists will perform the measurements at the consults. Statisticians will conduct analyses blinded to treatment allocation using dummy coding for treatment group. Analyses will be conducted according to a pre-specified, published analysis plan. Treatment group will be unblinded at the completion of analysis.

Data Analysis

Data will be analysed using the intention to treat principle with the number of analyses restricted and specified a priori. Data integrity will be monitored by regularly scrutinising data files for omissions and errors. All manually entered data will be double checked.

Sample size

Sample size was calculated using the method of Twisk for mixed models. With 4 repeated observations, an estimated intra-cluster correlation (correlation between the observations) of 0.5, alpha of 5%, and allowing for up to 18% loss to follow up. A total of 346 patients (173 per group) provides over 80% power to detect between group differences of 3 points (SD 5) on Roland Morris Disability Questionnaire (RMDQ)(65) at 26 weeks. This is the smallest worthwhile effect that would justify implementation of the intervention. We ignored the increase in statistical power due to stratification and including baseline covariates in the analysis.

Effect estimates

A linear mixed effects regression model will be used to estimate the effectiveness of the intervention in reducing self-reported disability compared to control over 26 weeks of follow-up. A time by treatment group interaction term will be included as a fixed effect to assess the between group differences in adjusted mean disability scores at each time-point. Baseline disability scores will be included as a fixed effect in the model. Treatment group, time, BMI category, and potential confounders (participant characteristics) will also be included as fixed effects. A random subject-level intercept will be used to account for the repeated measures of the data. If more than 10% of the data is missing the pattern of missing data will be examined and an appropriate method of multiple imputation (depending on the data) will be used. Sensitivity analysis will involve comparing complete case, to imputed data analyses. A secondary analysis will explore the differential effects of the intervention on primary outcome for normal weight vs. overweight/obese. The sample size provides sufficient power to detect a differential effect of 2 points on the RMDQ between normal weight and overweight/obese

patients. This question will be evaluated using a linear mixed effects model including a three way, fixed effect interaction term; treatment group, time, and BMI category.

We pre-specify four key secondary outcomes for interpretation to reduce the possibility of Type I error. Treatment effects will be estimated using linear mixed effects, and logistic mixed effects regression models. Adjusted mean differences (continuous variables) or differences in proportions (dichotomous variables) will be assessed for each outcome at each follow-up point, with 26 weeks post randomization being considered the primary end-point of the study. Exploratory analyses will be conducted on outcomes of health behaviors, self-efficacy and psychological distress. The same fixed and random effects pre-specified for the main outcome model will be used in all secondary and exploratory analyses.

Supplementary analyses

Three pre-planned supplementary analyses will be undertaken. We will publish detailed protocols on open science repositories prior to unblinding of data. Analyses will include:

Complier Average Causal Effect (CACE) analyses will be conducted for the primary and key secondary outcomes.(66) The threshold for compliance will be attendance at least 2 intervention consultations and 5 or more completed GHS telephone calls (unless earlier graduation from the GHS program).

Causal mediation analysis will be used to investigate treatment mechanisms using data collected at baseline, 12 weeks and 26 weeks.(67) We will assess the mediating effects of physical activity, diet, pain, self-efficacy, weight, and symptoms of psychological distress on low back pain disability.

Three economic analyses will be conducted. First, a cost model comparing the costs associated with the control and intervention pathways. Second, a cost-utility analysis from the perspective of the health sector including individual health care utilisation costs (healthcare service and medication use). Third, a cost-utility analysis from a societal perspective including the additional non healthcare costs (e.g. carer or community service costs) and costs associated with work absenteeism and presenteeism. Costs will be based standard published rates and self-reported (out of pocket) costs. Health state utilities (to estimate QALYs), will be obtained from SF-12 score and transformed into health state utilities via the SF-6D algorithm.

Patient and Public Involvement

Development of the research question and the intervention design was based on previously conducted randomised controlled trials and data from patients on the orthopaedic surgical waitlist at the John Hunter Hospital, Newcastle Australia in 2014.(28, 68) Patients were involved in pilot stages of the study to provide feedback on physiotherapy care, health coaching and resources. Patients will not be involved in recruitment of participants or conduct of the study. Results of this study will available to the public and patients in published in open access peer reviewed journals.

Ethics and Dissemination

This study was approved by the Hunter New England Research Ethics Committee (Approval No. 17/02/15/4.05), and University of Newcastle Human Research Ethics Committee (Ref No. H-2017-0222). Outcomes of this trial and supplementary analyses will be disseminated through publications in peer-reviewed journals and conference presentations.

FIGURE LEGEND

Figure 1. Planned flow of participants through the HeLP trial.

HELP; Healthy lifestyle program for Low back Pain.

AUTHOR CONTRIBUTION: CW and SK designed the project and secured funding. CW, ER, AW, RH, SD, AH designed the consultation content, trained relevant research staff, developed materials, data collection tools and databases. AH contributed to the randomisation schedule and statistical analysis protocol. SD, ER and CG are involved in delivery of the intervention. ER drafted the manuscript and all authors revised it critically for important intellectual content and approved the final version.

FUNDING: This work was supported by an National Health and Medical Research Council (NHMRC) project grant (Grant Number APP1100992).

COMPETING INTERESTS: None declared.

ETHICAL APPROVAL: This study was approved by the Hunter New England Research Ethics Committee (Approval No. 17/02/15/4.05), and University of Newcastle Human Research Ethics Committee (Ref No. H-2017-0222). The study was prospectively registered with the Australian New Zealand Clinical Trial Registry (ACTRN12617001288314).

DATA SHARING: De-identified data with accompanying data dictionaries will be made available on request. All analysis protocols will be made publicly available and published in open access peer reviewed journals. Proposals for data use may be submitted to the Principle investigator 12 months following publication of results.

ACKNOWLEDGEMENTS: The authors would like to thank the Physiotherapy Department at the Royal Newcastle Centre, John Hunter Hospital for assisting in the intervention delivery. We would also like to thank the Hunter New England Population Health Computer Assisted Telephone Interviewing CATI team for undertaking recruitment and data collection and the wider Hunter Population Health facility for provision of necessary resources.

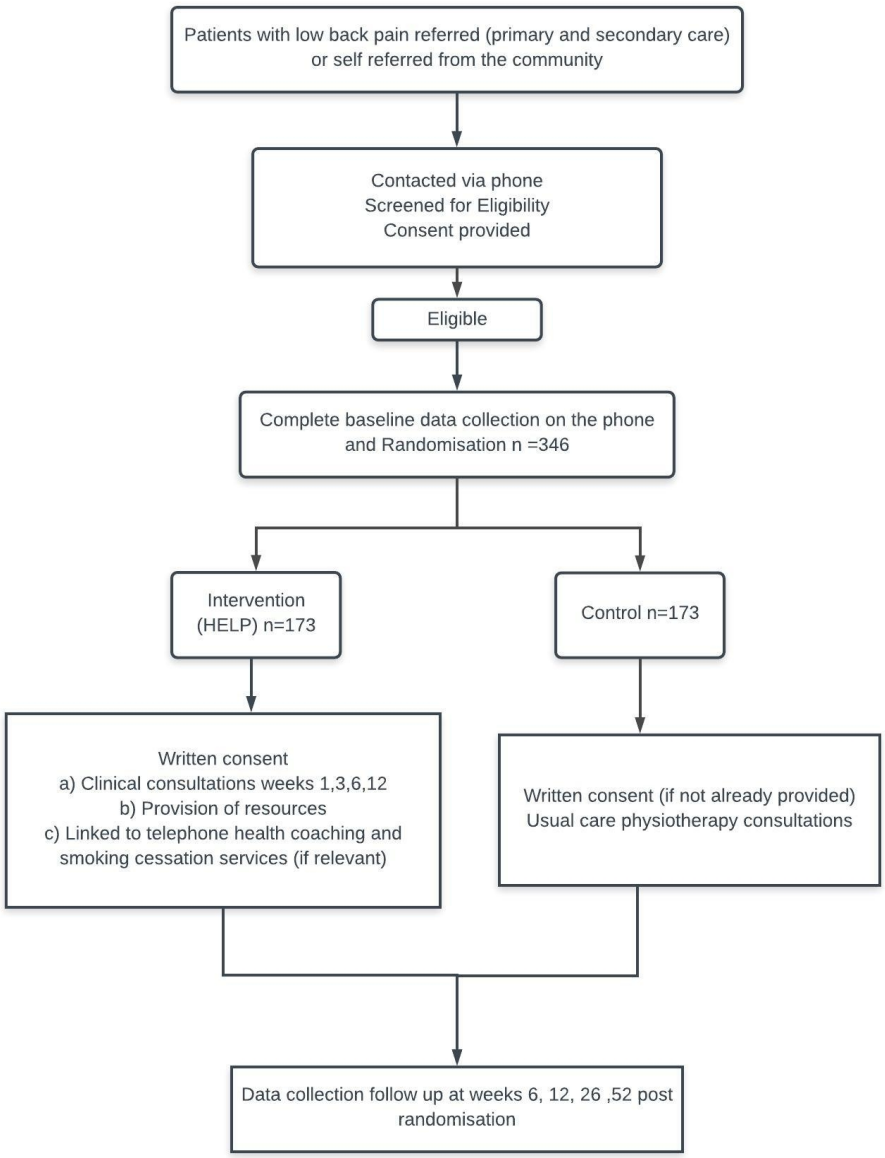
References

1. Vos T, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet. 2017;390:1211-59.10.1016/S0140-6736(17)31833-0
2. Hoy D, March L, Brooks P, et al. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. Ann Rheum Dis. 2014;73(6):968-74.10.1136/annrheumdis-2013-204428
3. Schofield D, Shrestha R, Percival R, et al. The personal and national costs of early retirement because of spinal disorders: impacts on income, taxes, and government support payments. Spine J 2012;12:1111–8.
4. Henschke N, Kamper S, Maher C. The Epidemiology and Economic Consequences of Pain. 2015;90.
5. Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. The Spine Journal. 2007:8-20
6. Arthritis and Osteoporosis Victoria. A problem worth solving: the rising cost of musculoskeletal condtions in Australia. 2013
7. Hong J, Reed C, Novick D, et al. Costs associated with treatment of chronic low back pain: an analysis of the UK General Practice Research Database. Spine (Phila Pa 1976). 2013;38(1):75-82.10.1097/BRS.0b013e318276450f
8. Shiri R, Karppinen J, Leino-Arjas P, et al. The association between obesity and low back pain: a meta-analysis. Am J Epidemiol. 2009;171(2):135-54.10.1093/aje/kwp356
9. Heuch I, Heuch I, Hagen K, et al. Body mass index as a risk factor for developing chronic low back pain: a follow-up in the Nord-Trondelag Health Study. Spine (Phila Pa 1976). 2013;38(2):133-9.10.1097/BRS.0b013e3182647af2
10. Suri P, Boyko EJ, Smith NL, et al. Modifiable risk factors for chronic back pain: insights using the co-twin control design. Spine J. 2017;17(1):4-14.10.1016/j.spinee.2016.07.533
11. Shiri R, Karppinen J, Leino-Arjas P, et al. The association between smoking and low back pain: a meta-analysis. Am J Med. 2010;123(1):87 e7-35.10.1016/j.amjmed.2009.05.028
12. Bohman T, Alfredsson L, Jensen I, et al. Does a healthy lifestyle behaviour influence the prognosis of low back pain among men and women in a general population? A population-based cohort study. BMJ Open. 2014;4(12):e005713.10.1136/bmjopen-2014-005713
13. Lin CW, McAuley JH, Macedo L, et al. Relationship between physical activity and disability in low back pain: a systematic review and meta-analysis. Pain. 2011;152(3):607-13.10.1016/j.pain.2010.11.034
14. Heneweer H, Vanhees L, Picavet HS. Physical activity and low back pain: a U-shaped relation? Pain. 2009;143(1-2):21-5.10.1016/j.pain.2008.12.033
15. Shiri R, Falah-Hassani K. Does leisure time physical activity protect against low back pain? Systematic review and meta-analysis of 36 prospective cohort studies. Br J Sports Med. 2017;51(19):1410-8.10.1136/bjsports-2016-097352
16. Seaman DR. The diet-induced proinflammatory state. Journal of Manipulative and Physiological Therapeutics. 2002;25(3):168-79.10.1067/mmt.2002.122324
17. Macphail K. C-reactive protein, chronic low back pain and, diet and lifestyle. International Musculoskeletal Medicine. 2015;37(1):29-32.10.1179/1753615415y.0000000001

18. National Health and Medical Research Council. Clinical Practice Guidelines for the management of overweight and obesity in Adults, Adolescents and Children in Australia. Melbourne: National Health and Medical Research Council. 2013
19. Roffey D, Ashdown L, Dornan H, et al. Pilot evaluation of a multidisciplinary, medically supervised, nonsurgical weight loss program on the severity of low back pain in obese adults. The Spine Journal. 2011;11 197-204
20. Behrend C PM, Coyne E, et al. Smoking Cessation Related to Improved Patient-Reported Pain Scores Following Spinal Care. J Bone Joint Surg Am 2012; 94:2161–6.
21. Dean E, Soderlund A. What is the role of lifestyle behaviour change associated with non-communicable disease risk in managing musculoskeletal health conditions with special reference to chronic pain? BMC Musculoskelet Disord. 2015;16:87.10.1186/s12891-015-0545-y
22. Wai EK, Rodriguez S, Dagenais S, et al. Evidence-informed management of chronic low back pain with physical activity, smoking cessation, and weight loss. Spine J. 2008;8(1):195-202.10.1016/j.spinee.2007.10.024
23. Wong JJ, Cote P, Sutton DA, et al. Clinical practice guidelines for the noninvasive management of low back pain: A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. European journal of pain. 2017;21(2):201-16.10.1002/ejp.931
24. National Institute for Health and Care Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management. 2016
25. Gordon R, Bloxham S. A Systematic Review of the Effects of Exercise and Physical Activity on Non-Specific Chronic Low Back Pain. Healthcare (Basel). 2016;4(2).10.3390/healthcare4020022
26. Hayden J, van Tulder M, Malmivaara A, et al. Exercise therapy for treatment of non-specific low back pain (review). Cochrane Database Syst Rev. 2005(3).10.1002/14651858.CD000335.pub2.
27. Williams A, Wiggers J, O'Brien KM, et al. A randomised controlled trial of a lifestyle behavioural intervention for patients with low back pain, who are overweight or obese: study protocol. BMC Musculoskelet Disord. 2016;17:70.10.1186/s12891-016-0922-1
28. Williams. A, Wiggers. J, O'Brien. K, et al. The effectiveness of a healthy lifestyle intervention, for chronic low back pain: a randomised controlled trial. Pain. 2018
29. Krismer M, van Tulder M, et al. Strategies for prevention and management of musculoskeletal conditions: Low back pain (non-specific). Best Pract Res Clin Rheumatol. 2007;21(1):77-91.10.1016/j.berh.2006.08.004
30. Hawker G, Mian S, Kendzerska T, et al. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). Arthritis Care Research. Novmber 2011;63(11):S240-S52
31. Australian Government Department of Health. Australia's Physical Activity and Sedentary Behaviour Guidelines for Adults. 2017
32. National Health and Medical Research Council. Australian Dietary Guidelines. Canberra: National Health and Medical Research Council. 2013
33. Chan A, Tetzlaff J, Gøtzsche P, et al. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ 2013;346:e:7586.
34. Hoffmann T, Glasziou P, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014;348:g(1687.)

35. Verbeek J, Sengers M, Riemens L, et al. Patient expectations of treatment for back pain: A Systematic Review of Qualitative and Quantitative Studies. SPINE. 2004;29(20):2309–18
36. Kamper S, Haanstra T, Simmons K, et al. What Do Patients with Chronic Spinal Pain Expect from Their Physiotherapist? . Physiotherapy Australia 70(1)
37. Sveinsdottir V, Eriksen HR, Reme SE. Assessing the role of cognitive behavioral therapy in the management of chronic nonspecific back pain. J Pain Res. 2012;5:371-80.10.2147/JPR.S25330
38. Moseley GL, Butler DS. Fifteen Years of Explaining Pain: The Past, Present, and Future. The journal of pain : official journal of the American Pain Society. 2015;16(9):807-13.10.1016/j.jpain.2015.05.005
39. Vong SK, Cheing GL, Chan F, et al. Motivational enhancement therapy in addition to physical therapy improves motivational factors and treatment outcomes in people with low back pain: a randomized controlled trial. Arch Phys Med Rehabil. 2011;92(2):176-83.10.1016/j.apmr.2010.10.016
40. Hall K, Gibbie T, Lubman D. Motivational interviewing techniques Facilitating behaviour change in the general practice setting. Australian Family Physician 2012;41(9)
41. British Association for Behvioural and Cognitive Psychotherapies. What is CBT? 2012
42. Henschke N, Ostelo RW, van Tulder MW, et al. Behavioural treatment for chronic low-back pain. Cochrane Database Syst Rev. 2010(7):CD002014.10.1002/14651858.CD002014.pub3
43. Australian Government national Health and Medical Research Council Department of Health and Ageing. Australian Guide to Healthy Eating.
44. National Health and Medical Research Council. Summary Guide for the Management of Overweight and Obesity in Primary Care. Melbourne: National Health and Medical Research Council. 2013
45. Health Change Australia. HealthChange® Methodology and Training Options. 2018
46. Harris P, Taylor R, Thielke R, et al. Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, . J Biomed Inform. 2009;42(2):377-81
47. Mosely L, Moen D. Tame the Beast: Its time to rethink persistant pain.
48. O'Hara B, Phongsavan P, Eakin E, et al. Effectiveness of Australia's Get Healthy Information and Coaching Service: maintenance of self-reported anthropometric and behavioural changes after program completion. BMC Public Health. 2013;13:175
49. O'Hara BJ, Phongsavan P, Venugopal K, et al. Effectiveness of Australia's Get Healthy Information and Coaching Service(R): translational research with population wide impact. Prev Med. 2012;55(4):292-8.10.1016/j.ypmed.2012.07.022
50. O'Hara B, Gale J, McGill B, et al. Weight-Related Goal Setting in a Telephone-Based Preventive ealth-Coaching Program: Demonstration of Effectiveness. American Journal of Health Promotion. 2017;31(6):491-501.10.1177/0890117116660776
51. O'Hara BJ, Phongsavan P, Rissel C, et al. Role of general practice in the utilisation of the NSW Get Healthy Information and Coaching Service. Aust J Prim Health. 2015;21(2):182-8.10.1071/PY13154
52. Brown W, Bauman A, Bull F, et al. Development of Evidence - based Physical Activity Recommendations for Adults (18–64 years). Report prepared for the Australian Government Department of Health; Content/health-pubhlth-strateg-phys-act-guidelies/$File/DEB-PAR-Adults-18- 64years.pdf. Aug 2012

53. Greenhalgh E, Stillman S, Ford C. Cessation assistance: Telephone- and Internet-based interventions. Tobacco in Australia: Facts and issues Melbourne: Cancer Council Victoria; 2016 2016
54. Tzelepis F, Paul CL, Wiggers J, et al. A randomised controlled trial of proactive telephone counselling on cold-called smokers' cessation rates. Tobacco control. 2011;20(1):40-6.10.1136/tc.2010.035956
55. NSW Government Cancer Insititute NSW. NSW Quitline. 2017
56. Roland M, Morris R. A study of the natural history of back pain. Part 1: Development of a reliable and sensitive measure of disability in low back pain. Spine (Phila Pa 1976). 1983;8:141-4
57. International Society for the Advancement of Kinanthropometry. International Standards for Antrhopometric Assessment. Underdale: ISAK. 2001.
58. Ware J, Kosinski M, Turner-bowker D, et al. User's Manual for the SF- 12v2 Health Survey (With a Supplement Documenting SF-12 Health Survey). Lincoln: QualityMetric Incorporated. 2002
59. Craig C, Marshall A, Sjostrom M, et al. International Physical Activity Questionnaire: 12-Country Reliability and Validity. Medicine & Science in Sports & Exercise. 2003;35(8):1381-95
60. Cleghorn CL, Harrison RA, Ransley JK, et al. Can a dietary quality score derived from a short-form FFQ assess dietary quality in UK adult population surveys? Public health nutrition. 2016;19(16):2915-23.10.1017/S1368980016001099
61. Buysse D, Reynolds C, Monk T, et al. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res. 1989;28:193–213
62. Nicholas MK, McGuire BE, Asghari A. A 2-item short form of the Pain Self-efficacy Questionnaire: development and psychometric evaluation of PSEQ-2. The journal of pain : official journal of the American Pain Society. 2015;16(2):153-63.10.1016/j.jpain.2014.11.002
63. Kessler R, Barker P, Colpe L, et al. Screening for serious mental illness in the general population. Archives of General Psychiatry 2003;60(2):184-9.
64. Bush K, Kivlahan D, McDonell M, et al. The AUDIT Acohol Consumption Questions (AUDIT-C): a Brief screening test for problem drinking. Arch Internal Med 1998;3:1789-95
65. Maughan EF, Lewis JS. Outcome measures in chronic low back pain. Eur Spine J. 2010;19(9):1484-94.10.1007/s00586-010-1353-6
66. Dunn G, Maracy M, Tomenson B. Estimating treatment eff ects from randomized clinical trials with noncompliance and loss to follow-up: the role of instrumental variable methods. Stat Methods Med Res. 2005;14(369-95)
67. H. Lee GM, J.H. McAuley, S.J. Kamper, M. Hübscher, G.L. Moseley, L. Wolfenden, R.K. Hodder, C.M. Williams. Causal mechanisms in the clinical course and treatment of back pain. Best Practice & Research Clinical Rheumatology. 2017.http://dx.doi.org/10.1016/j.berh.2017.04.001
68. O'Brien KM, Wiggers J, Williams A, et al. Telephone-based weight loss support for patients with knee osteoarthritis: a pragmatic randomised controlled trial. Osteoarthritis Cartilage. 2018;26(4):485-494(4):485-94.10.1016/j.joca.2018.01.003



111x143mm (300 x 300 DPI)

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	P1 (title) P2- (abstract)	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	P4-5 (introduction, objectives)	
	WHAT	7.	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	P9 P12-14	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	P8-14	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	P7 and 9 P12-13 P14	Clinicians Get Healthy Quit line
	HOW		

6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	P7, 12, 14 and Table 2.	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	P5	
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Table 2	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	P8, P9, P12, P14	
	MODIFICATIONS	N/A	
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	
	HOW WELL	**Checklist**	
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	P9	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	P 2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	P 23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	P1
	5b	Name and contact information for the trial sponsor	P1, 23
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	P23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	P4-5
	6b	Explanation for choice of comparators	P 14
Objectives	7	Specific objectives or hypotheses	P 5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	P 5

Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P7-14 T 1&2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	As per Ethics
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	P 9, T3
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P15-16 T3
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	T2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P 19
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	P5
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	P 19

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	P 19
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	P 19
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	P 19
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	P 19
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	T1, T2, T3
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P 1
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P 19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P 20
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P 21
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	P 20
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	As per Ethics
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	P 2
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	As per ethics P2
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P 18
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	As per Ethics
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	P 23
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	P23
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P 22
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P 23

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	As per Ethics
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

BMJ Open

Healthy lifestyle program for Low back Pain (HeLP): Protocol for a randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-029290.R2
Article Type:	Protocol
Date Submitted by the Author:	30-Jun-2019
Complete List of Authors:	Robson, Emma; Hunter New England Population Health, Kamper, Steven; University of Sydney, Centre for Pain, Health and Lifestyle, School of Public Health Davidson, Simon; Hunter New England Population Health; The University of Newcastle, Viana da Silva, Priscilla; Hunter New England Population Health; The University of Newcastle, Williams, Amanda; Hunter New England Population Health Hodder, Rebecca; Hunter New England Local Health District, Hunter New England Population Health; The University of Newcastle, Lee, Hopin; Hunter New England Population Health; University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences Hall, Alix; Hunter Medical Research Institute, University of Newcastle, School of Medicine and Public Health Gleadhill, Connor; Hunter New England Population Health; University of Sydney, Centre for Pain, Health and Lifestyle, School of Public Health Williams, Christopher; University of Newcastle, School of Medicine and Public Health; Hunter New England Local Health District, Population Health
Primary Subject Heading:	Public health
Secondary Subject Heading:	Patient-centred medicine, Rehabilitation medicine, Research methods, Sports and exercise medicine, Smoking and tobacco
Keywords:	Back pain < ORTHOPAEDIC & TRAUMA SURGERY, Spine < ORTHOPAEDIC & TRAUMA SURGERY, PUBLIC HEALTH, PAIN MANAGEMENT, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY

Healthy lifestyle program for Low back Pain (HeLP): Protocol for a randomised controlled trial

Authors:
Emma Robson[1,2,3]
A/Prof Steven J Kamper[3,4]
Simon Davidson[1,2,3]
Priscilla Viana Silva[1, 2,3]
Amanda Williams[1,2,3]
Dr Rebecca Hodder[1,2,3,5]
Dr Hopin Lee[1,3,6]
Dr Alix Hall [5]
Connor Gleadhill[1,3,4]
Dr Christopher M Williams[1,2,3,5]

Author Details

[1] Hunter New England Population Health, Locked Bag 10, Wallsend NSW, 2287, Australia.
[2] School of Medicine and Public Health, University of Newcastle, Newcastle NSW, 2308, Australia
[3] Centre for Pain, Health and Lifestyle, NSW, Australia
[4] University of Sydney, PO Box M179, Missenden Rd, Camperdown NSW, 2050, Australia
[5] Hunter Medical Research Institute, Locked Bag 1, Hunter Region Mc NSW, 2310, Australia
[6] Centre for Statistics in Medicine, Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK

Corresponding author:

Dr Christopher Williams,

Locked bag 10 Wallsend, NSW 2287, Australia.

Email: christopher.m.williams@hnehealth.nsw.gov.au

Phone: (02) 49246121

Word count: 3991

Abstract

Introduction: Low back pain is one of the most common and burdensome chronic conditions worldwide. Lifestyle factors, such as excess weight, physical inactivity, poor diet and smoking are linked to low back pain chronicity and disability. There are few high quality randomised controlled trials that investigate the effects of targeting lifestyle risk factors in people with chronic low back pain.

Methods and Analysis:

The aim of this study is to determine the effectiveness of a Healthy lifestyle program for Low back Pain (HeLP) targeting weight, physical activity, diet and smoking to reduce disability in patients with chronic low back pain compared to usual care. This is a randomised controlled trial, with participants stratified by BMI, allocated 1:1 to the HeLP intervention or usual physiotherapy care. HeLP involves three main components: i) clinical consultations with a physiotherapist and dietitian; ii) educational resources; and iii) telephone-based health coaching support for lifestyle risk factors. The primary outcome is disability (Roland Morris Disability Questionnaire), at 26 weeks. Secondary outcomes include pain, weight, quality of life and smoking status. Data will be collected at baseline, and weeks 6, 12, 26 and 52. Patients with chronic low back pain who have at least one health risk factor; overweight or obese; smoker; inadequate physical activity or fruit and vegetable consumption, will be recruited from primary or secondary care, or the community. Data will be analysed by intention-to-treat using linear mixed effects regression models. We will conduct three supplementary analysis: causal mediation analysis, compiler average causal effects analysis (CACE) and economic analyses.

Ethics and Dissemination: This study was approved by the Hunter New England Research Ethics Committee (Approval No. 17/02/15/4.05), and University of Newcastle Human Research Ethics Committee (Ref No. H-2017-0222). Outcomes of this trial and supplementary analyses will be disseminated through publications in peer-reviewed journals and conference presentations.

Trial Registration Number: ACTRN12617001288314.

Strengths and limitations of this study

- The first randomised controlled trial investigating a comprehensive lifestyle intervention involving physiotherapy, dietetics and telephone health coaching for patients with chronic low back pain.
- The trial includes collection of a large range of variables to enable investigation of clinical effectiveness, cost effectiveness and mechanisms of addressing lifestyle factors in chronic low back pain patients to help guide healthcare policy decisions and clinical practice.
- Choice of primary and secondary outcomes is based on importance to patients with the condition.

INTRODUCTION

Chronic low back pain is a worldwide public health problem with significant individual and economic burden.(1-7) In 2016, low back pain was the leading cause of disability globally, accounting for over 57.6 million years lived with disability (YLD).(1) Estimated total costs of back pain are significant, with direct costs of care estimated at £2.8 billion in the UK,(7) and $90 billion in the US.(5) In Australia annual costs exceed $4.8 billion and back pain reduces the country's Gross Domestic Product by $2.9 billion per year.(3) Health care consumption, medication use, productivity losses and forced early retirement contribute to these costs.(3, 5, 7)

Lifestyle risk factors, including excess weight, physical inactivity, poor diet and smoking contribute to the burden of low back pain.(8-12) Meta-analysis of 33 studies found obesity was associated with increased prevalence of chronic low back pain (OR 1.4, 95% CI 1.4, 1.6) and increased care-seeking for low back pain (OR 1.6, 95% CI 1.5, 1.7).(8) Another meta-analysis of 27 studies demonstrated associations between smoking and chronic low back pain (OR 1.8, CI 95% 1.3, 2.5).(11) Physical inactivity and poor diet contribute to obesity, and have an influence on chronic low back pain independently.(13-18) Despite some inconsistency in the literature, evidence suggests low levels of physical activity is associated with chronic low back pain,(13-15) as is diet-induced systematic inflammation.(16, 17)

Preliminary clinical studies suggest addressing such lifestyle factors can improve low back pain outcomes including disability.(12, 19-22) For example, a pre-post study of a weight loss program targeting diet and physical activity showed significant improvement in pain related disability in patients with low back pain.(19) Increasing physical activity and providing exercise are widely accepted core treatment recommendations for chronic low back pain management(23, 24) and reviews of the literature show exercise is effective in reducing disability (improvement of 2.5 points on 100 point scale, 95% CI 1.0, 3.9) compared to control.(25, 26) In relation to smoking, one cohort study involving 5333 smokers with low back pain also showed clinically significant reductions in pain (30% decrease) in those who quit smoking.(20)

Despite evidence suggesting the potential benefit of interventions targeting these lifestyle factors,(21, 22) there is only one similar randomised control trial evaluating a lifestyle

intervention for patients with chronic low back pain.(27, 28) This study found no effect, likely due to poor adherence to the treatment.

Objective

The primary aim of this trial is to determine the effectiveness of a multi-focused Healthy lifestyle program for Low back Pain (HeLP) to reduce disability in patients with chronic low back pain, compared to usual physiotherapy care. Secondary objectives are to determine the effectiveness of the intervention on pain intensity, patient weight, quality of life and smoking status.

We will also conduct three supplementary analyses to assess: i) treatment effect in those who complied with the intervention using Complier Average Causal Effects (CACE) analysis, ii) mediating effects of the intervention through pain, weight, smoking cessation, physical activity levels, diet, pain self-efficacy, and psychological distress, iii) cost effectiveness of the intervention from the health sector and societal perspectives.

METHODS AND ANALYSIS

Study Design

The study will be a parallel-group pragmatic randomised controlled trial with two groups (Fig 1.) Participants will be stratified by Body Mass Index (BMI) category and randomised 1:1 to either the HeLP intervention or usual physiotherapy care.

Setting

People with a main complaint of low back pain referred from primary care, or secondary care at a major tertiary referral hospital in the Hunter New England Local Health District, NSW, or self-referred from community advertisements, will be screened for eligibility.

Eligibility

Eligibility criteria are as follows:

- ≥ 18 years of age
- Chronic low back pain, defined as pain between the 12th rib and buttock crease, with or without leg pain, of more than 3 months duration(29);
- Pain intensity rating over the last week of ≥3 on an 11 point numerical rating scale (NRS) where "0" represents no pain and "10" represents worst possible pain,(30) or respond "moderately", "quite a bit" or "extremely" when asked how much back pain interferes with completing normal daily activities of living (modified item of Short Form Health Survey-36)(30);
- At least one health risk factor: overweight or obese (BMI of >25kg/m^2) (18); participate in less than 30 minutes of physical activity on 5 days of the week(31); current smoker; or eat less than 2 serves of fruit and 5 serves of vegetables per day, as a proxy of overall diet quality.(32)

Exclusion criteria:

- Previous bariatric weight loss surgery;
- Currently undertaking weight loss or smoking cessation program or care (e.g. Dietetics for weight loss, Jenny Craig, Lite n Easy, Optifast, Weight Watchers, nicotine replacement therapy, Quitline);
- Back surgery in the previous 6 months or planned back surgery in the next 6 months;
- Known or suspected serious pathology causing back pain (i.e. rheumatoid arthritis, cancer, fracture or infection);
- Cannot actively engage in the intervention (unable to communicate, use a telephone or attend appointments, adapt meals or exercise);
- Comorbidity that does not allow safe completion of study procedures (e.g. uncontrolled blood pressure or heart conditions, uncontrolled diabetes);
- Pregnant or planning pregnancy in the next 12 months.

Details of the intervention and control

Trial design adheres to the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) recommendations,(33) and the intervention and control conditions are described

according to the Template for Intervention description and Replication (TIdieR) (Appendix 1).(34)

Intervention (HeLP)

Participants randomised to the intervention group will receive HeLP over a 6-month period. The intervention draws on cognitive behavioural therapy (CBT) and motivational interviewing (MI) to support pain management and facilitate positive behaviour change related to maintaining a healthy lifestyle (Table 1).

HeLP includes:

i) Consultations with a physiotherapist and dietitian;
ii) Provision of educational resources; and
iii) Telephone-based health coaching services for healthy lifestyle and smoking cessation (Table 2).

i) Consultations

This component was co-developed by a multidisciplinary team of investigators with expertise in physiotherapy, dietetics, psychology, nursing and health service management. Consultations aim to:

- Assess participants' back pain condition;
- Educate participants about back pain and lifestyle;
- Use behaviour change strategies to facilitate positive lifestyle changes (achieve a healthy body weight, increase physical activity, develop healthy eating habits, quit smoking);
- Initiate engagement in telephone support services;
- Reinforce positive behaviours and encourage self-regulation.

Mode and timing of consultation delivery

Participants will be offered to attend five clinical consultations of up to 60 minutes in duration; four with a registered physiotherapist, and one with a registered dietitian. Physiotherapy consultations will include an initial consultation and follow up consultations at 3, 6, and 12

weeks post randomisation. The dietitian consultation will occur at week 3, immediately after the physiotherapy consultation (Table 2). Consultations will be conducted face-to-face, however; if patients are not able to attend appointments face-to-face they may be offered telehealth consultations (telephone or video conference) to deliver clinical content. The delivery method for all consultations will be recorded.

Content (Initial consultation)

The initial consultation will involve three major components (Table 1):

1. History and physical assessment(24);
2. HeLP education (education about pain biology and links between pain and lifestyle);
3. Develop an individualised HeLP action plan to address lifestyle risks, incorporating behaviour change strategies and initiating a physical activity program.

Physical assessment, education and advice is built upon guideline recommendations and in line with back pain patients' expectations from physiotherapists.(23-25, 35-37) Education and advice is designed to improve participants' understanding of the biopsychosocial nature of low back pain by presenting information on the nature of pain biology,(38) address erroneous beliefs about back pain (e.g. that low back pain is always associated with pathology), and outline links between low back pain and health behaviour risks (weight, smoking etc). Advice aims to encourage pain self-management, negotiate a physical activity plan and provide a platform for patients to engage with additional support services for healthy lifestyle.

Behaviour change strategies are based on principles of MI and CBT.(37, 39-41) Evidence supports the use of CBT and MI in improving physical and behavioural outcomes in patients with back pain.(37) (39, 42) Behaviour change strategies include: assessing stage of change; goal setting with graded task assignment; and developing self-monitoring and regulation practices. Clinicians will work with patients to set tailored goals using graded task assignment, e.g. agreeing on an initial goal of 10 minutes walking per day, to increase to 30 minutes per day by week 6. Clinicians will encourage self-monitoring and regulation through goal evaluation and use of patient resources to monitor pain, activity and eating patterns. Patient understanding of, and participation in, telephone health coaching services will also be encouraged.

Content (follow up consultations)

Subsequent consultations (weeks 3, 6 and 12) will reinforce key messages, information and action plans provided in the initial consultation. Participants and clinicians will evaluate goals and progress, identify and address barriers to change, and encourage self-monitoring (Table 1).

The dietitian consultation will occur immediately after physiotherapy consult in week 3. The consultation will focus on achieving or maintaining healthy eating behaviours to assist in weight management. Education and advice will be based on Australian healthy eating(18, 32, 43, 44) and obesity management guidelines.(18, 32, 43) Education will be tailored to participants needs including information on recommended intake of the five key food groups, energy balance, portion sizes and general healthy lifestyle promotion.

Clinicians will support and encourage patients to achieve their lifestyle goals and engage with telephone health coaching services. Goals and content of clinical care will be provided in the initial referrals to the telephone coaching services.

Training for Intervention Delivery

The intervention clinicians will attend multiple training sessions (including piloting the intervention) prior to study commencement and offered to attend a 2-day Health Behaviour Change course.(45) Training involves background to the study, understanding intervention and appointment scheduling protocols for each consult, and behaviour change techniques. Clinicians will also learn how to use REDCap,(46) an electronic data capture tool to record patient appointment attendance and delivery of intervention components. An intervention checklist will be provided to guide intervention delivery and optimise fidelity. Intervention clinicians will be provided implementation support via regular face to face and email contact with the research team for the duration of the study.

TABLE 1: PHYSIOTHERAPY CONSULTATIONS

Physiotherapy	Component	Content	Purpose
Week 1 (initial)	Physical Assessment	- Patient history and physical assessment including assessing range of motion, evaluate strength, flexibility, pain characteristics. - Collect anthropometric measurements (height, weight)	Develop rapport Assess and address patients expectations for physiotherapy care
	Psychoeducation	- Introduce pain biology, concept of pain being multifactorial and does not equal damage, as well as fluctuating nature of pain conditions - Acknowledgement that pain is real - Discuss influence of lifestyle factors on back pain and consequences of being overweight, having a poor diet, inactivity, poor sleep and smoking - Introduce HeLP to support adoption of healthy lifestyle behaviours - Promote support services the GHS and Quitline	Correct erroneous pain beliefs, increase knowledge, provide rationale for need to change health behaviour.
	Behaviour change strategies	- Assess patients stage of change and motivations through questioning - Acknowledge general barriers to lifestyle change and program adherence - Establish and agree on commitment to change - Goal setting: establish patient management and lifestyle goals - Agree on graded exercises and physical activity (e.g. aim to start walking 10 minutes 5 times a week). - Discuss strategies to facilitate self-monitoring behaviours such as keeping activity, pain and diet diaries and attending follow up appointments	Initiate process of behaviour change, encourage safe engagement in physical activity, initiate engagement with support services.
Week 3 and 6	Psychoeducation	- Reinforce back pain education and lifestyle messages in first consultation	Increase knowledge
	Behaviour change strategies	- Evaluate goals and adapt with patient discussion and assessment of diaries - Problem solving: discuss patient barriers to meeting goals and strategies to overcome - Goal setting: Adapt or progress graded exercise and activity - Discuss participation in the GHS and Quit line services and encourage continued participation (if appropriate) - Encourage continual encouragement of self-monitoring	Reinforce positive behaviour, support behaviour change and self-monitoring behaviours.
Week 12	Physical Assessment	- Collect anthropometric measurements	Data collection
	Psychoeducation	- Reflect on information provided previously and patient experience	Initiate self-reflection and reinforce positive behaviours

	Behaviour change	- Reassess motivation to change and/or motivation to sustain behaviour change - Encourage completion of the GHS and or Quit line program - Goal setting for maintaining healthy lifestyle change - Negotiate strategies and problem solving for overcoming barriers to maintain changes	Goal setting for continued self-management and maintaining or further improving lifestyle behaviours, reinforce positive behaviours, identify skills and strategies to prevent relapse of unhealthy habits.
Dietitian Consult			
Week 3	Brief dietary assessment	- Assess patients diet using monitoring completed food diary or conduct brief diet history and eating behaviours	Build rapport
	Psychoeducation	- Reinforce HeLP messages: the importance of a healthy lifestyle in pain management and the role of diet in weight management and chronic pain. - Discuss five key food groups and Australia Guide to Healthy Eating, Australia Dietary Guideline recommendations - Introduce concepts of energy balance and portion size	Increase knowledge; reinforce alignment of health service perspectives for treating back pain, including support from GHS
	Behaviour Change strategies	- Assess patients stage of change and motivations through questioning - Goal setting: identify or confirm patient lifestyle and dietary goals - Acknowledge and discuss any barriers to change and reassure small lifestyle changes make a difference - Graded task assignment: Detail suitable strategies to improve dietary intake, balance energy intake and ensure adequate consumption of core food groups - Encourage participation and continued dietary support from the GHS - Encourage self-monitoring e.g. keep a food diary	Reinforce positive behaviour, initiate positive safe dietary changes, support behaviour change and use of support services.

Legend: GHS, Get Healthy Service.

II) Educational Resources

Patients will be provided with resources including an information booklet or access to a web based app, and a 5 minute video(47) reflecting education and key messages. The information booklet and app were co-developed by back pain experts, intervention physiotherapists and dietitians. The booklet and app were piloted with consumers and assessed for cultural safety, and changes were made according to feedback. The information booklet and app details pain education provided in the consults, healthy lifestyle information, information about support services, and diaries to record goals and encourage self-monitoring. The 5 minute video(47) will be sent to patients via SMS or email, viewing will also be prompted at the week 3 appointment.

III) Telephone health coaching

A) Healthy lifestyle coaching telephone service

All patients in the intervention group will be referred to the telephone-based "NSW Get Healthy Information and Coaching Service" immediately after their initial consultation (Table 2).

The Get Healthy Service (GHS) is a telephone-based health coaching initiative provided by the NSW Government. The service aims to support people to modify unhealthy behaviours; increase physical activity levels; make healthy dietary changes; reduce alcohol consumption and achieve and maintain a healthy body weight.(48, 49) There is evidence that the GHS is effective in reducing BMI, and waist circumference, and improves eating behaviours and physical activity in the general population.(49, 50)

Mode of and timing of delivery

The GHS involves up to 10 individually tailored phone calls over a 6-month period, delivered by qualified and specially-trained health professionals.(51) Calls are usually made bi-monthly for the first three months (n=6) to help facilitate behaviour change, with remaining calls tapering off for the following three months. Average call duration is 13 minutes.(49, 50) Patients can graduate early from the GHS if they complete 5 coaching calls and meet their health goals.

Content

Content is based on the Australian Guide to Healthy Eating, and National Physical Activity Guidelines.(31, 52) Coaches provide education, advice and counselling to achieve or maintain a healthy weight through modifying energy intake, and use strategies to improve intake of the five key food groups and achieve moderate physical activity of 30 minutes 5 days per week. The GHS aims to support, motivate and monitor the lifestyle goals patients established in their face-to-face consultations. Coaching uses MI techniques and self-regulation to support behaviour change.(50)

Training for intervention delivery

All GHS coaches are university qualified health professionals (dietitians, exercise physiologists, health psychologists). All coaches involved the trial will receive 3 hours of interactive face-to-face training, delivered by the principle investigators. Training is based on academic detailing, including educational outreach, technical assistance and provision of resources. Sessions include education about chronic pain and guideline recommended care for patients with low back pain; current evidence for low back pain management and links to health behaviour risks and lifestyle; and advice from professional experiences treating patients, including common barriers to care and engagement in lifestyle management. Coaches are instructed how to make links between lifestyle behaviours, weight management and back pain care, and complete mock case studies to facilitate integration of the training into usual coaching practice. Coaches will be provided with resources and training material to guide learning, and for use with patients. Coaches will be provided with contact details (telephone and email) and encouraged to contact principle investigators for ad hoc support for guidance about challenges, cases or management questions.

B) Smoking Cessation Program

Participants who identify as smokers at baseline will be referred to the NSW Quitline telephone smoking cessation program. Referral to Quitline will occur within the first 12 weeks of the intervention (Table 2), with the exact timing negotiated between the clinician and patient, based on patient preference, stage of change and consent.

Quitline is a telephone counselling service aiming to encourage participants to set a quit date and facilitate successful quit attempts. An evaluation of the Australian Quitline services showed that 88% of callers sampled had made a quit attempt since their initial call, and of those who had made a quit attempt, 38% had ceased smoking at six-month follow-up. Actual quit rates in those accessing Quitline after adjusting for non-responses was approximately 20%.(53)

Mode and timing of delivery

Those participating in Quitline receive an initial counselling call and are encouraged to set a quit date within the next month. Participants are offered a free counselling service of up to five calls from the day before the quit date to 30 days after the quit date. Call duration typically ranges from 10-20 minutes.(54, 55) "Quit kits" containing information about quitting smoking are posted to participants upon enrolment in Quitline.

Content

Quitline counselling sessions include an assessment of smoking status, identification of triggers for smoking, coping strategies and information on effective quitting aids. Strategies to support quitting are tailored to individual preferences. "Quit Kits" also include nicotine replacement therapies such as gum, lozenge and patches, guidance booklets and informational support.

Training for intervention delivery

All Quitline counsellors have a tertiary education qualification such as social work or psychology, and are trained in health education and counselling delivery using CBT and MI techniques.

Control (Usual Care Group)

The usual care group will be referred for usual physiotherapy care in a public hospital outpatient physiotherapy clinic.

Content

The usual care appointments may include a physical assessment, and guideline-based advice and education for back pain.(23, 24)

Mode of and timing of delivery

Up to three face-to-face usual care appointments will be provided by a registered physiotherapist.

Training for delivery

Usual care physiotherapists will deliver their usual practices of care, however they will be asked not to provide specific support for lifestyle-related health behaviours. Physiotherapists will record components of usual care on a standardised form, entered directly into the REDCap database.

Outcome Assessment

Patients will be asked to complete questionnaires at baseline (prior to randomisation), 6, 12, 26 and 52 weeks post randomisation (Table 2, Table 3). Baseline data will be collected via telephone. At weeks 6, 12, 26 and 52 patients will have the option of providing data online (via an email or SMS link), on a paper-based form, or transcribed by a trained telephone interviewer.

Objective height and weight will be collected at the initial consultation and weight will be measured again at 12 weeks (height measured at initial consultation only).

Baseline demographic characteristics

Baseline measures include: date of birth, gender, employment status, income, health insurance status, compensation status, previous episodes of back pain, duration of back pain, and presence of co-existing medical conditions (e.g. heart disease, stroke, diabetes, cancer, asthma, arthritis, depression).

Outcomes

Primary outcome

The primary outcome is disability at 26 weeks measured via the Roland Morris Disability Questionnaire; a validated self-report 24 item low back pain specific survey.(56)

Key secondary outcomes

Secondary outcomes include pain intensity, weight, measured according to ISAK protocols(57) (weeks 1 at initial appointment and week 12 appointment) and via self-report (baseline, weeks 6, 12, 26 and 52); quality of life measured by the Short Form12 version 2 and smoking status using NSW Population Health survey questions; collected at all data collection time points. (58)

Exploratory outcomes

Exploratory outcomes, including potential mediators and cost outcomes will be collected at all data collection time points (Table 3).

Process outcomes

Process evaluation includes measurement of intervention fidelity via clinician completion of a checklist to record the delivery of intervention components in both groups, and by observation of a random 10% of intervention consultations. We will also measure; dose of intervention (number of consultations attended and number of calls received), supplementary interventions, program completion, and reasons for drop out.

TABLE 2: TIMING OF INTERVENTION DELIVERY AND FOLLOW UP ASSESSMENTS

Component	Week
Intervention group	
Recruitment phone call: Eligibility screening, baseline data collection and randomisation	0
Initial consultation	1
Referral to NSW GHS weight management program	Following initial consultation
NSW GHS weight management program‡	1-26
Follow up consultations	3, 6, 12
Telephone interviews for outcome assessments	6, 12, 26 ,52
Referral to Quitline smoking cessation program	1-12 based on patient preference for timing
Quit line smoking cessation program	1-26 (depending on referral date)
Control	
Recruitment phone call: Eligibility screening, baseline data collection and randomisation	0
Usual physiotherapy care consultations	From week 1
Telephone interviews for outcome assessments	6, 12, 26 ,52

GHS, Get Healthy Service.

‡ *If patients miss calls, or put the program temporarily on hold the program may run longer than 26 weeks. If participants achieve goals they may also graduate early after 5 calls.*

TABLE 3: OUTCOME MEASURES

Domain	Measure	Time (weeks)
Primary		
Disability (endpoint 26 weeks)	Roland Morris Disability Questionnaire (RMDQ).(56)	0, 6, 12, 26, 52
Secondary		
Pain Intensity	11 point, 0-10 Numerical Rating Scale as the average pain over the last week where zero indicated no pain and ten indicates worst possible pain.(30)	0, 6, 12, 26, 52
Weight	Objective weight measured to the nearest 0.1kg by a trained assessor using International Society for the Advancement of Kinathropometry (ISAK) procedures.(57)	1, 12
	Self-reported weight (kg) is also collected at all-time points	0, 6, 12, 26, 52
Quality of Life	12-item Short Form Health Survey version 2 (0-100 scale; high score indicates greater quality of life).(58)	0, 6, 12, 26, 52
Smoking Status	2 items from the NSW Health survey (Which describes your smoking status and how many cigarettes smoked per day)	0, 6, 12, 26, 52
Exploratory Outcomes		
Physical Activity	International Physical Activity Questionnaire (IPAQ) reported as average hours and minutes spent participating in moderate to vigorous activity. (59)	0, 6, 12, 26, 52
Nutrition	21 item Food Frequency Questionnaire of intake over the past month (response options for fruit vegetable, discretionary choices, wholegrains and dairy categories: rarely or never, less than once a week, once a week, 2-3 times a week, 4-6 times a week, 1-2 times a day, 3-4 times a day, 5+ a day and response options for meat categories: rarely or never, less than once a week, once a week, 2-3 times a week, 4-6 times a week, 7+ times a week).(60)	0, 6, 12, 26, 52
Sleep Quality	Item-6 from the Pittsburgh Sleep Quality Index (response options: very bad, fairly bad, fairly good, very good)(61)	0, 6, 12, 26, 52
Pain Self Efficacy	2 item validated Pain Self-Efficacy Questionnaire (PSEQ-2) on a scale of 0-6 with zero indication not at all confident and 6 completely confident.(62)	0, 6, 12, 26, 52
Psychological Distress	Kessler 6 Questionnaire as how often a feeling was experiences over the past 30 days (response options: all of the time, most of the time, some of the time, a little of the time, none of the time).(63)	0, 6, 12, 26, 52
Alcohol Consumption	Alcohol Use Disorders Identification Test (AUDIT-C) (0-12 scale) high score greater risk of alcohol-related harm.(64)	0, 6, 12, 26, 52
Process and Economic measures		
Adverse Events	Open text question: "Have you developed any new medical conditions or an exacerbation of an existing condition?"	6, 52
Health Economics	Self-reported health and home care utilisation and medication use. Intervention costs: staff time, phone calls, referral and written materials. GHS and Quitline costs: number and call duration. Self-reported work absenteeism, presenteeism.	0, 6, 12, 26, 52

Recruitment Procedures

The recruitment process is detailed in the CONSORT diagram (Figure 1). Potentially eligible patients will be provided with a study information letter. The letter details the study procedures and informs patients they will be contacted by the research team to discuss participation. When patients are called, research personnel will screen for eligibility.

Eligible patients will verbally consent to participation and have baseline data collected over the phone. Written consent will be obtained at the initial consultation.

Randomisation procedures

Eligible consenting patients will complete baseline data collection over the phone with a trained interviewer, and be randomised via a concealed central randomisation service. Patients will be randomly allocated to the intervention or control group (1:1 ratio). A permuted 6:4 block randomization approach will be used so that the distribution of healthy weight, overweight and obese participants is equal across treatment conditions (intervention or control). Interviewers will be prompted by the system to input BMI category (healthy weight $\leq$24.9kg/m^2, overweight $\geq$25kg/m^2 - <30kg/m^2, obese $\geq$30kg/m^2) within the REDCap database which allocates participants to an experimental group based on a pre-specified randomisation schedule generated by an independent statistician.

Blinding

On study entry participants will be told that they will receive one of two treatment programs delivered by a physiotherapist. To reduce ascertainment bias, participants are not informed of the specific treatment details before allocation, nor provided detailed about the treatment to which they are not assigned. To reduce performance bias, the clinicians involved in the study deliver only the intervention, or the control. It is not possible for objective anthropometry outcomes to be blinded, as intervention and control physiotherapists will perform the measurements at the consults. Statisticians will conduct analyses blinded to treatment allocation using dummy coding for treatment group. Analyses will be conducted according to a pre-specified, published analysis plan. Treatment group will be unblinded at the completion of analysis.

Data Analysis

Data will be analysed using the intention to treat principle with the number of analyses restricted and specified a priori. Data integrity will be monitored by regularly scrutinising data files for omissions and errors. All manually entered data will be double checked.

Sample size

Sample size was calculated using the method of Twisk for mixed models. With 4 repeated observations, an estimated intra-cluster correlation (correlation between the observations) of 0.5, alpha of 5%, and allowing for up to 18% loss to follow up. A total of 346 patients (173 per group) provides over 80% power to detect between group differences of 3 points (SD 5) on Roland Morris Disability Questionnaire (RMDQ)(65) at 26 weeks. This is the smallest worthwhile effect that would justify implementation of the intervention. We ignored the increase in statistical power due to stratification and including baseline covariates in the analysis.

Effect estimates

A linear mixed effects regression model will be used to estimate the effectiveness of the intervention in reducing self-reported disability compared to control using all data points over 26 weeks of follow-up. A time by treatment group interaction term will be included as a fixed effect to assess the between group differences in adjusted mean disability scores at each time-point. Baseline disability scores will be included as a fixed effect in the model. Treatment group, time, BMI category, and potential confounders (participant characteristics) will also be included as fixed effects. A random subject-level intercept will be used to account for the repeated measures of the data. If more than 10% of the data is missing the pattern of missing data will be examined and an appropriate method of multiple imputation (depending on the data) will be used. Sensitivity analysis will involve comparing complete case, to imputed data analyses. A secondary analysis will explore the differential effects of the intervention on primary outcome for normal weight vs. overweight/obese. The sample size provides sufficient power to detect a differential effect of 2 points on the RMDQ between normal weight and

overweight/obese patients. This question will be evaluated using a linear mixed effects model including a three way, fixed effect interaction term; treatment group, time, and BMI category.

We pre-specify four key secondary outcomes for interpretation to reduce the possibility of Type I error. Treatment effects will be estimated using linear mixed effects, and logistic mixed effects regression models. Adjusted mean differences (continuous variables) or differences in proportions (dichotomous variables) will be assessed for each outcome at each follow-up point, with 26 weeks post randomization being considered the primary end-point of the study. Exploratory analyses will be conducted on outcomes of health behaviors, self-efficacy and psychological distress. The same fixed and random effects pre-specified for the main outcome model will be used in all secondary and exploratory analyses.

Supplementary analyses

Three pre-planned supplementary analyses will be undertaken. We will publish detailed protocols on open science repositories prior to unblinding of data. Analyses will include:

Complier Average Causal Effect (CACE) analyses will be conducted for the primary and key secondary outcomes.(66) The threshold for compliance will be attendance at least 2 intervention consultations and 5 or more completed GHS telephone calls (unless earlier graduation from the GHS program).

Causal mediation analysis will be used to investigate treatment mechanisms using data collected at baseline, 12 weeks and 26 weeks.(67) We will assess the mediating effects of physical activity, diet, pain, self-efficacy, weight, and symptoms of psychological distress on low back pain disability.

Three economic analyses will be conducted. First, a cost model comparing the costs associated with the control and intervention pathways. Second, a cost-utility analysis from the perspective of the health sector including individual health care utilisation costs (healthcare service and medication use). Third, a cost-utility analysis from a societal perspective including the additional non healthcare costs (e.g. carer or community service costs) and costs associated with work absenteeism and presenteeism. Costs will be based standard published rates and self-reported (out of pocket) costs. Health state utilities (to estimate QALYs), will be obtained from SF-12 score and transformed into health state utilities via the SF-6D algorithm.

Patient and Public Involvement

Development of the research question and the intervention design was based on previously conducted randomised controlled trials and data from patients on the orthopaedic surgical waitlist at the John Hunter Hospital, Newcastle Australia in 2014.(28, 68) Patients were involved in pilot stages of the study to provide feedback on physiotherapy care, health coaching and resources. Patients will not be involved in recruitment of participants or conduct of the study. Results of this study will available to the public and patients in published in open access peer reviewed journals.

Ethics and Dissemination

This study was approved by the Hunter New England Research Ethics Committee (Approval No. 17/02/15/4.05), and University of Newcastle Human Research Ethics Committee (Ref No. H-2017-0222). Outcomes of this trial and supplementary analyses will be disseminated through publications in peer-reviewed journals and conference presentations.

FIGURE LEGEND

Figure 1. Planned flow of participants through the HeLP trial.

HELP; Healthy lifestyle program for Low back Pain.

AUTHOR CONTRIBUTION: CW designed the project and secured funding, contributed to ethical approval, design of consultation content, trained relevant research staff, development of patient resources, data collection tools, procedures and databases; contributed to statistical analysis protocol, contributed to drafting the manuscript, critically revision of intellectual content and approved the final version.

SK designed the project and secured funding, contributed to ethical approval, design of consultation content, trained relevant research staff, development of patient resources, data collection tools, procedures and databases; contributed to statistical analysis protocol, contributed to drafting the manuscript, critically revision of intellectual content and approved the final version.

ER contributed to ethical approval, design of consultation content, trained relevant research staff, development of patient resources, data collection tools, procedures and databases; contributed to statistical analysis protocol; delivery of the intervention; and contributed to drafting the manuscript, critically revision of intellectual content and approved the final version.

AW contributed to ethical approval, design of consultation content, trained relevant research staff, development of patient resources, data collection tools, procedures and databases; and critically revision of intellectual content and approved the final version of the protocol.

RH contributed to ethical approval, design of consultation content, trained relevant research staff, development of patient resources, data collection tools, procedures and databases; and critically revision of intellectual content and approved the final version of the protocol.

SD contributed to ethical approval, design of consultation content, trained relevant research staff, development of patient resources, data collection tools, procedures and databases; contributed to statistical analysis protocol; delivery of the intervention; and contributed to drafting the manuscript, critically revision of intellectual content and approved the final version.

PVS contributed to ethical approval, design of consultation content, trained relevant research staff, development of patient resources, data collection tools, procedures and databases; contributed to statistical analysis protocol; delivery of the intervention; and contributed to drafting the manuscript, critically revision of intellectual content and approved the final version.

AH contributed to development of data collection tools, procedures and databases; developed the randomisation schedule and statistical analysis protocol; and contributed to drafting the manuscript, critically revision of intellectual content and approved the final version.

CG contributed to ethical approval, design of consultation content, trained relevant research staff, development of patient resources, data collection tools, procedures and databases; contributed to statistical analysis protocol; delivery of the intervention; and contributed to drafting the manuscript, critically revision of intellectual content and approved the final version.

HL contributed to ethical approval, design of consultation content, trained relevant research staff, development of patient resources, data collection tools, procedures and databases; contributed to statistical analysis protocol; delivery of the intervention; and contributed to drafting the manuscript, critically revision of intellectual content and approved the final version, designed the consultation content, trained relevant research staff, developed materials, data collection tools and databases.

FUNDING: This work was supported by a National Health and Medical Research Council (NHMRC) project grant (Grant Number APP1100992).

COMPETING INTERESTS: None declared.

ETHICAL APPROVAL: This study was approved by the Hunter New England Research Ethics Committee (Approval No. 17/02/15/4.05), and University of Newcastle Human Research Ethics Committee (Ref No. H-2017-0222). The study was prospectively registered with the Australian New Zealand Clinical Trial Registry (ACTRN12617001288314).

DATA SHARING: De-identified data with accompanying data dictionaries will be made available on request. All analysis protocols will be made publicly available and published in open access peer reviewed journals. Proposals for data use may be submitted to the Principle investigator 12 months following publication of results.

ACKNOWLEDGEMENTS: The authors would like to thank the Physiotherapy Department at the Royal Newcastle Centre, John Hunter Hospital for assisting in the intervention delivery. We would also like to thank the Hunter New England Population Health Computer Assisted Telephone Interviewing CATI team for undertaking recruitment and data collection and the wider Hunter Population Health facility for provision of necessary resources.

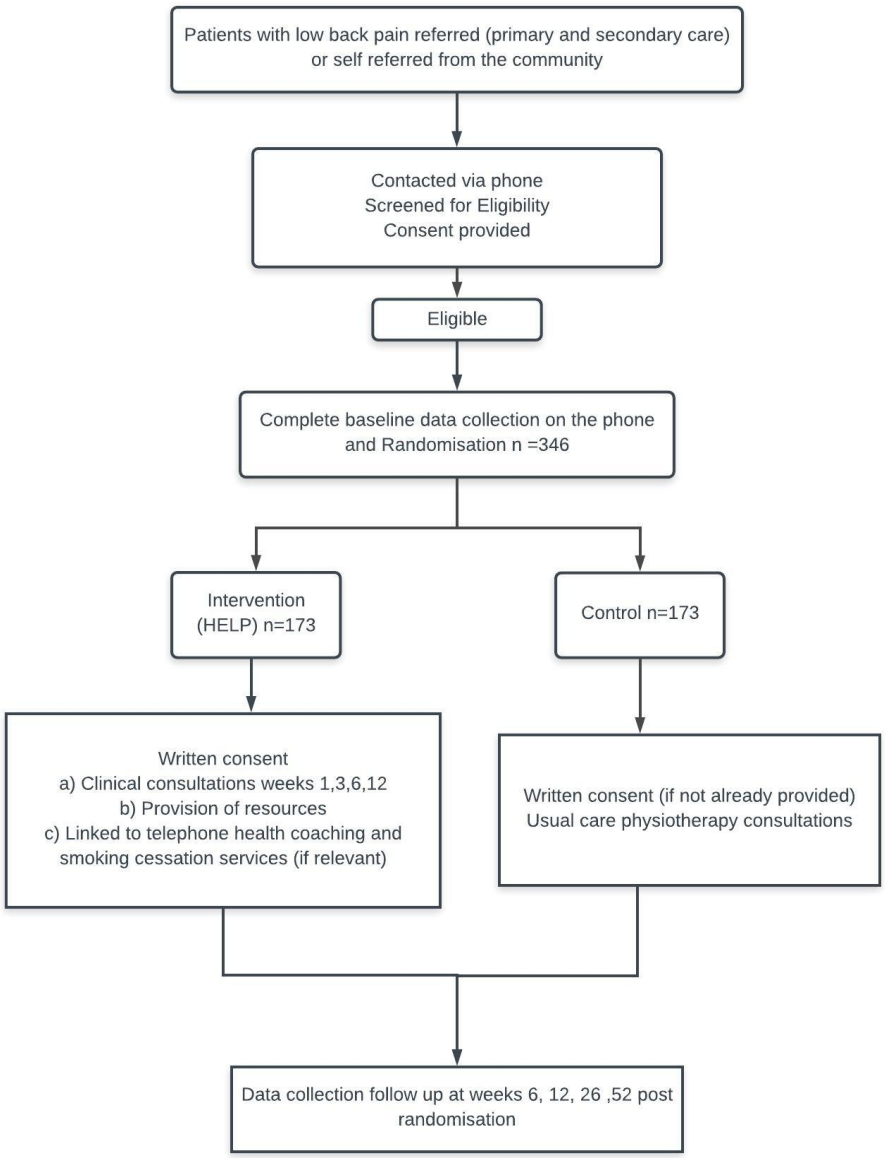
References

1. Vos T, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet. 2017;390:1211-59.10.1016/S0140-6736(17)31833-0
2. Hoy D, March L, Brooks P, et al. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. Ann Rheum Dis. 2014;73(6):968-74.10.1136/annrheumdis-2013-204428
3. Schofield D, Shrestha R, Percival R, et al. The personal and national costs of early retirement because of spinal disorders: impacts on income, taxes, and government support payments. Spine J 2012;12:1111–8.
4. Henschke N, Kamper S, Maher C. The Epidemiology and Economic Consequences of Pain. 2015;90.
5. Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. The Spine Journal. 2007:8-20
6. Arthritis and Osteoporosis Victoria. A problem worth solving: the rising cost of musculoskeletal condtions in Australia. 2013
7. Hong J, Reed C, Novick D, et al. Costs associated with treatment of chronic low back pain: an analysis of the UK General Practice Research Database. Spine (Phila Pa 1976). 2013;38(1):75-82.10.1097/BRS.0b013e318276450f
8. Shiri R, Karppinen J, Leino-Arjas P, et al. The association between obesity and low back pain: a meta-analysis. Am J Epidemiol. 2009;171(2):135-54.10.1093/aje/kwp356
9. Heuch I, Heuch I, Hagen K, et al. Body mass index as a risk factor for developing chronic low back pain: a follow-up in the Nord-Trondelag Health Study. Spine (Phila Pa 1976). 2013;38(2):133-9.10.1097/BRS.0b013e3182647af2
10. Suri P, Boyko EJ, Smith NL, et al. Modifiable risk factors for chronic back pain: insights using the co-twin control design. Spine J. 2017;17(1):4-14.10.1016/j.spinee.2016.07.533
11. Shiri R, Karppinen J, Leino-Arjas P, et al. The association between smoking and low back pain: a meta-analysis. Am J Med. 2010;123(1):87 e7-35.10.1016/j.amjmed.2009.05.028
12. Bohman T, Alfredsson L, Jensen I, et al. Does a healthy lifestyle behaviour influence the prognosis of low back pain among men and women in a general population? A population-based cohort study. BMJ Open. 2014;4(12):e005713.10.1136/bmjopen-2014-005713
13. Lin CW, McAuley JH, Macedo L, et al. Relationship between physical activity and disability in low back pain: a systematic review and meta-analysis. Pain. 2011;152(3):607-13.10.1016/j.pain.2010.11.034
14. Heneweer H, Vanhees L, Picavet HS. Physical activity and low back pain: a U-shaped relation? Pain. 2009;143(1-2):21-5.10.1016/j.pain.2008.12.033
15. Shiri R, Falah-Hassani K. Does leisure time physical activity protect against low back pain? Systematic review and meta-analysis of 36 prospective cohort studies. Br J Sports Med. 2017;51(19):1410-8.10.1136/bjsports-2016-097352
16. Seaman DR. The diet-induced proinflammatory state. Journal of Manipulative and Physiological Therapeutics. 2002;25(3):168-79.10.1067/mmt.2002.122324
17. Macphail K. C-reactive protein, chronic low back pain and, diet and lifestyle. International Musculoskeletal Medicine. 2015;37(1):29-32.10.1179/1753615415y.0000000001

18. National Health and Medical Research Council. Clinical Practice Guidelines for the management of overweight and obesity in Adults, Adolescents and Children in Australia. Melbourne: National Health and Medical Research Council. 2013
19. Roffey D, Ashdown L, Dornan H, et al. Pilot evaluation of a multidisciplinary, medically supervised, nonsurgical weight loss program on the severity of low back pain in obese adults. The Spine Journal. 2011;11 197-204
20. Behrend C PM, Coyne E, et al. Smoking Cessation Related to Improved Patient-Reported Pain Scores Following Spinal Care. J Bone Joint Surg Am 2012; 94:2161–6.
21. Dean E, Soderlund A. What is the role of lifestyle behaviour change associated with non-communicable disease risk in managing musculoskeletal health conditions with special reference to chronic pain? BMC Musculoskelet Disord. 2015;16:87.10.1186/s12891-015-0545-y
22. Wai EK, Rodriguez S, Dagenais S, et al. Evidence-informed management of chronic low back pain with physical activity, smoking cessation, and weight loss. Spine J. 2008;8(1):195-202.10.1016/j.spinee.2007.10.024
23. Wong JJ, Cote P, Sutton DA, et al. Clinical practice guidelines for the noninvasive management of low back pain: A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. European journal of pain. 2017;21(2):201-16.10.1002/ejp.931
24. National Institute for Health and Care Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management. 2016
25. Gordon R, Bloxham S. A Systematic Review of the Effects of Exercise and Physical Activity on Non-Specific Chronic Low Back Pain. Healthcare (Basel). 2016;4(2).10.3390/healthcare4020022
26. Hayden J, van Tulder M, Malmivaara A, et al. Exercise therapy for treatment of non-specific low back pain (review). Cochrane Database Syst Rev. 2005(3).10.1002/14651858.CD000335.pub2.
27. Williams A, Wiggers J, O'Brien KM, et al. A randomised controlled trial of a lifestyle behavioural intervention for patients with low back pain, who are overweight or obese: study protocol. BMC Musculoskelet Disord. 2016;17:70.10.1186/s12891-016-0922-1
28. Williams. A, Wiggers. J, O'Brien. K, et al. The effectiveness of a healthy lifestyle intervention, for chronic low back pain: a randomised controlled trial. Pain. 2018
29. Krismer M, van Tulder M, et al. Strategies for prevention and management of musculoskeletal conditions: Low back pain (non-specific). Best Pract Res Clin Rheumatol. 2007;21(1):77-91.10.1016/j.berh.2006.08.004
30. Hawker G, Mian S, Kendzerska T, et al. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). Arthritis Care Research. Novmber 2011;63(11):S240-S52
31. Australian Government Department of Health. Australia's Physical Activity and Sedentary Behaviour Guidelines for Adults. 2017
32. National Health and Medical Research Council. Australian Dietary Guidelines. Canberra: National Health and Medical Research Council. 2013
33. Chan A, Tetzlaff J, Gøtzsche P, et al. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ 2013;346:e:7586.
34. Hoffmann T, Glasziou P, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014;348:g(1687.)

35. Verbeek J, Sengers M, Riemens L, et al. Patient expectations of treatment for back pain: A Systematic Review of Qualitative and Quantitative Studies. SPINE. 2004;29(20):2309–18
36. Kamper S, Haanstra T, Simmons K, et al. What Do Patients with Chronic Spinal Pain Expect from Their Physiotherapist? . Physiotherapy Australia 70(1)
37. Sveinsdottir V, Eriksen HR, Reme SE. Assessing the role of cognitive behavioral therapy in the management of chronic nonspecific back pain. J Pain Res. 2012;5:371-80.10.2147/JPR.S25330
38. Moseley GL, Butler DS. Fifteen Years of Explaining Pain: The Past, Present, and Future. The journal of pain : official journal of the American Pain Society. 2015;16(9):807-13.10.1016/j.jpain.2015.05.005
39. Vong SK, Cheing GL, Chan F, et al. Motivational enhancement therapy in addition to physical therapy improves motivational factors and treatment outcomes in people with low back pain: a randomized controlled trial. Arch Phys Med Rehabil. 2011;92(2):176-83.10.1016/j.apmr.2010.10.016
40. Hall K, Gibbie T, Lubman D. Motivational interviewing techniques Facilitating behaviour change in the general practice setting. Australian Family Physician 2012;41(9)
41. British Association for Behvioural and Cognitive Psychotherapies. What is CBT? 2012
42. Henschke N, Ostelo RW, van Tulder MW, et al. Behavioural treatment for chronic low-back pain. Cochrane Database Syst Rev. 2010(7):CD002014.10.1002/14651858.CD002014.pub3
43. Australian Government national Health and Medical Research Council Department of Health and Ageing. Australian Guide to Healthy Eating.
44. National Health and Medical Research Council. Summary Guide for the Management of Overweight and Obesity in Primary Care. Melbourne: National Health and Medical Research Council. 2013
45. Health Change Australia. HealthChange® Methodology and Training Options. 2018
46. Harris P, Taylor R, Thielke R, et al. Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, . J Biomed Inform. 2009;42(2):377-81
47. Mosely L, Moen D. Tame the Beast: Its time to rethink persistant pain.
48. O'Hara B, Phongsavan P, Eakin E, et al. Effectiveness of Australia's Get Healthy Information and Coaching Service: maintenance of self-reported anthropometric and behavioural changes after program completion. BMC Public Health. 2013;13:175
49. O'Hara BJ, Phongsavan P, Venugopal K, et al. Effectiveness of Australia's Get Healthy Information and Coaching Service(R): translational research with population wide impact. Prev Med. 2012;55(4):292-8.10.1016/j.ypmed.2012.07.022
50. O'Hara B, Gale J, McGill B, et al. Weight-Related Goal Setting in a Telephone-Based Preventive ealth-Coaching Program: Demonstration of Effectiveness. American Journal of Health Promotion. 2017;31(6):491-501.10.1177/0890117116660776
51. O'Hara BJ, Phongsavan P, Rissel C, et al. Role of general practice in the utilisation of the NSW Get Healthy Information and Coaching Service. Aust J Prim Health. 2015;21(2):182-8.10.1071/PY13154
52. Brown W, Bauman A, Bull F, et al. Development of Evidence - based Physical Activity Recommendations for Adults (18–64 years). Report prepared for the Australian Government Department of Health; Content/health-pubhlth-strateg-phys-act-guidelies/$File/DEB-PAR-Adults-18- 64years.pdf. Aug 2012

53. Greenhalgh E, Stillman S, Ford C. Cessation assistance: Telephone- and Internet-based interventions. Tobacco in Australia: Facts and issues Melbourne: Cancer Council Victoria; 2016 2016
54. Tzelepis F, Paul CL, Wiggers J, et al. A randomised controlled trial of proactive telephone counselling on cold-called smokers' cessation rates. Tobacco control. 2011;20(1):40-6.10.1136/tc.2010.035956
55. NSW Government Cancer Insititute NSW. NSW Quitline. 2017
56. Roland M, Morris R. A study of the natural history of back pain. Part 1: Development of a reliable and sensitive measure of disability in low back pain. Spine (Phila Pa 1976). 1983;8:141-4
57. International Society for the Advancement of Kinanthropometry. International Standards for Antrhopometric Assessment. Underdale: ISAK. 2001.
58. Ware J, Kosinski M, Turner-bowker D, et al. User's Manual for the SF- 12v2 Health Survey (With a Supplement Documenting SF-12 Health Survey). Lincoln: QualityMetric Incorporated. 2002
59. Craig C, Marshall A, Sjostrom M, et al. International Physical Activity Questionnaire: 12-Country Reliability and Validity. Medicine & Science in Sports & Exercise. 2003;35(8):1381-95
60. Cleghorn CL, Harrison RA, Ransley JK, et al. Can a dietary quality score derived from a short-form FFQ assess dietary quality in UK adult population surveys? Public health nutrition. 2016;19(16):2915-23.10.1017/S1368980016001099
61. Buysse D, Reynolds C, Monk T, et al. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res. 1989;28:193–213
62. Nicholas MK, McGuire BE, Asghari A. A 2-item short form of the Pain Self-efficacy Questionnaire: development and psychometric evaluation of PSEQ-2. The journal of pain : official journal of the American Pain Society. 2015;16(2):153-63.10.1016/j.jpain.2014.11.002
63. Kessler R, Barker P, Colpe L, et al. Screening for serious mental illness in the general population. Archives of General Psychiatry 2003;60(2):184-9.
64. Bush K, Kivlahan D, McDonell M, et al. The AUDIT Acohol Consumption Questions (AUDIT-C): a Brief screening test for problem drinking. Arch Internal Med 1998;3:1789-95
65. Maughan EF, Lewis JS. Outcome measures in chronic low back pain. Eur Spine J. 2010;19(9):1484-94.10.1007/s00586-010-1353-6
66. Dunn G, Maracy M, Tomenson B. Estimating treatment eff ects from randomized clinical trials with noncompliance and loss to follow-up: the role of instrumental variable methods. Stat Methods Med Res. 2005;14(369-95)
67. H. Lee GM, J.H. McAuley, S.J. Kamper, M. Hübscher, G.L. Moseley, L. Wolfenden, R.K. Hodder, C.M. Williams. Causal mechanisms in the clinical course and treatment of back pain. Best Practice & Research Clinical Rheumatology. 2017.http://dx.doi.org/10.1016/j.berh.2017.04.001
68. O'Brien KM, Wiggers J, Williams A, et al. Telephone-based weight loss support for patients with knee osteoarthritis: a pragmatic randomised controlled trial. Osteoarthritis Cartilage. 2018;26(4):485-494(4):485-94.10.1016/j.joca.2018.01.003



111x143mm (300 x 300 DPI)

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	P1 (title) P2- (abstract)	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	P4-5 (introduction, objectives)	
	WHAT	7.	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	P9 P12-14	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	P8-14	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	P7 and 9 P12-13 P14	Clinicians Get Healthy Quit line
	HOW		

6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	P7, 12, 14 and Table 2.	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	P5	
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Table 2	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	P8, P9, P12, P14	
	MODIFICATIONS	N/A	
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	
	HOW WELL	**Checklist**	
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	P9	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	P 2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	P 23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	P1
	5b	Name and contact information for the trial sponsor	P1, 23
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	P23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	P4-5
	6b	Explanation for choice of comparators	P 14
Objectives	7	Specific objectives or hypotheses	P 5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	P 5

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P7-14 T 1&2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	As per Ethics
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	P 9, T3
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P15-16 T3
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	T2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P 19
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	P5

Methods: Assignment of interventions (for controlled trials)

Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	P 19

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	P 19
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	P 19
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	P 19
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	P 19
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	T1, T2, T3
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P 1
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P 19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P 20
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P 21
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	P 20
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	As per Ethics
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	P 2
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	As per ethics P2
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P 18
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	As per Ethics
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	P 23
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	P23
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P 22
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P 23

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	As per Ethics
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.