The effectiveness of a healthy lifestyle intervention, for chronic low back pain: a randomised controlled trial

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Abstract

We assessed the effectiveness of a 6-month healthy lifestyle intervention, on pain intensity in patients with chronic low back pain who were overweight or obese. We conducted a pragmatic randomised controlled trial (RCT), embedded within a cohort multiple RCT of patients on a waiting list for outpatient orthopaedic consultation at a tertiary hospital in NSW, Australia. Eligible patients with chronic low back pain (>3 months in duration) and BMI ≥27kg/m^2 and <40kg/m^2 were randomly allocated, using a central concealed random allocation process, to receive advice and education and referral to a 6-month telephone-based healthy lifestyle coaching service, or usual care. The primary outcome was pain intensity measured using an 11-point numerical rating scale, at baseline, 2 weeks and monthly for 6 months. Data analysis was by intention-to-treat according to a pre-published analysis plan. Between May 13 and October 27, 2015, 160 patients were randomly assigned in a 1:1 ratio to the intervention or usual care. We found no difference between groups for pain intensity over 6 months (area under the curve, mean difference= 6.5, 95%CI -8.0 to 21.0; p=0.38) or any secondary outcome. In the intervention group 41% (n=32) of participants reported an adverse event compared with 56% (n=45) in the control group. Our findings show providing education and advice and telephone-based healthy lifestyle coaching did not benefit patients with low back pain who were overweight or obese, compared to usual care. The intervention did not influence the targeted healthy lifestyle behaviours proposed to improve pain in this patient group.

Key words

Low back pain, lifestyle, obesity, randomised controlled trial

Background

Low back pain is the leading cause of disability worldwide and imposes considerable economic burden.[13,36] There is strong evidence that the development and persistence of low back pain is linked to 'lifestyle risks', such as overweight and obesity.[34] Clinical practice guidelines recommend patients with low back pain should be advised to engage in physical activity,[23,30] and there is widespread suggestion that managing lifestyle risks such as weight, should be a key focus of care for patients with low back pain.[14,38] Systematic review evidence suggests that targeting lifestyle risk factors reduces pain and disability in other musculoskeletal conditions such as knee osteoarthritis (OA).[11] A meta-analysis of randomised controlled trials (RCTs) showed that behavioural weight loss interventions lead to moderate improvements in pain and physical function for patients with knee OA who were overweight or obese.[12] Furthermore, patients who achieve at least a 5% weight loss, experience a significant reduction in disability.[12] In contrast to knee OA, no RCTs have assessed the impact of lifestyle interventions on patient outcomes for low back pain.[38] This means that despite the known links between lifestyle risks and low back pain, there is currently no evidence about the effectiveness of lifestyle management to guide clinical practice recommendations for low back pain.

There are several theories for why targeting lifestyle risk factors could improve patient-reported outcomes such as pain and disability for people with low back pain. Weight loss may reduce mechanical load on the spine, reduce systemic inflammation, [14,32] or reduce mood or emotional distress which is thought to exacerbate the effect of weight on the experience of pain.[10] Furthermore, increased physical activity and a better diet (i.e. less energy-dense nutrient-poor foods), may influence these processes by contributing to weight loss.[14]

In view of this, we aimed to assess the effectiveness of a healthy lifestyle intervention, which targeted weight, physical activity and diet behaviours, to reduce pain intensity for patients with chronic low back pain who were overweight or obese, compared to usual care. The trial also aimed to determine if the intervention approach improved disability, weight, body mass

index (BMI), physical activity, diet, sleep quality, global rating of symptom change, emotional distress, quality of life and health care use, compared to usual care.

Methods

Study design and participants

The study was a two-arm pragmatic parallel group randomised controlled trial, part of a cohort multiple RCT.[31] Details of the study are reported in the study protocol and statistical analysis plan.[26,40] Protocol deviations are specified in Text S1 in the supplementary file. The study was conducted at the John Hunter Hospital, New South Wales (NSW), Australia. Patients with musculoskeletal conditions, who were on the waiting list for outpatient consultation with an orthopaedic specialist, were invited to participate in the cohort study involving telephone assessments. All patients in the cohort were informed that regular surveys were being conducted as part of hospital audit processes and to track patient health while waiting for consultation. During one of the telephone assessments, participants of the cohort study with chronic low back pain were assessed for eligibility for the RCT. Eligible consenting patients were randomised to study conditions: i) offered the intervention (intervention group), or ii) remained in the cohort follow up (usual care control group).

Participant inclusion criteria were: a primary complaint of chronic low back pain (defined as: pain between the 12th rib and buttock crease with or without leg pain for longer than 3 months)[2]; with an average low back pain intensity ≥3 of 10 on a 0-10 numerical rating scale (NRS) over the past week, or moderate level of interference in activities of daily living (adaptation of item 8 on SF36); 18 years or older; overweight or obese (BMI ≥27kg/m^2 and <40kg/m^2) based on self-reported weight and height; and access to a telephone. Exclusion criteria were: known or suspected serious pathology as the cause of back pain as advised by their general practitioner (e.g. fracture, cancer, infection, inflammatory arthritis, cauda equine syndrome); previous obesity surgery; currently participating in any prescribed, medically supervised or commercial weight loss program; back surgery in the last 6 months or booked for surgery in the next 6 months; unable to comply with the study protocol that required

adaption of meals or exercise due to non-independent living arrangements; any medical or physical impairment precluding safe participation in exercise, such as uncontrolled hypertension; unable to speak and read English sufficiently to complete the study procedures.

Ethical approval was obtained from the Hunter New England Human Research Ethics Committee (approval No. 13/12/11/5.18) and the University of Newcastle Human Research Ethics Committee (approval No. H-2015-0043). This study adheres to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Randomisation and masking

The randomisation schedule was prepared *a priori* by an independent investigator using SAS 9.3 through the SURVEYSELECT procedure. Patients were randomised into study conditions (offered the intervention, or usual care control) in a 1:1 ratio, using a central concealed random allocation process. Specifically, when a patient was deemed eligible they were allocated the next available study identification number which corresponded with study identification numbers of the randomisation schedule. At this point the patient was considered randomised to study. After baseline assessment, interviewers opened a pre-packed opaque envelope labelled with the corresponding study identification number and contained the participant's group status. The envelopes were arranged by a research assistant, who was not involved in the study. Outcome assessors conducting follow up data collection telephone interviews and trial statisticians were masked to group allocation. Due to the design of the study (i.e. cohort multiple RCT)[31] participants were not aware of alternate study conditions.

Interventions

Participants randomised to the intervention group were offered a healthy lifestyle intervention involving: brief telephone advice, offer of a clinical consultation followed by referral to a 6-month telephone-based health coaching service. The approach was based on formative

evaluation which identified telephone services as the most preferred method by patients to support lifestyle change and weight loss.[41] Participants in the intervention group remained on the waiting list for orthopaedic specialist consultation and could attend a consultation during the study period. Patients were free to access care outside the study as they saw fit.

The *brief telephone advice* was provided by trained telephone interviewers after baseline assessment, immediately after randomisation. This advice included information that a broad range of factors contribute to the experience of low back pain, followed by description of the potential benefits of weight loss and physical activity for reducing low back pain.

The *clinical consultation* was a face-to-face consultation (up to one hour) conducted in a community health centre with the study physiotherapist, who was not involved in data collection. As detailed in our protocol,[40] the consultation was informed by Self Determination Theory and involved two broad approaches; (i) clinical assessment followed by low back pain education and advice, and (ii) behaviour change techniques.[1]

In brief, the patient education and advice aimed to improve understanding about low back pain,correct erroneous beliefs about the cause of back pain, (i.e. provide information about the nature of the condition, that persistent low back pain is multifactorial with multiple influences and not usually the result of pathological tissue damage), reduce pain related fear and distress that may hamper participation in the intervention, as well as describe the broader influences of back pain including lifestyle risks (overweight, inactivity, nutrition, smoking, alcohol, and poor sleep). The education and advice included information about the role of weight loss and physical activity in managing low back pain symptoms and introduced the telephone health coaching service as a way to support weight loss, physical activity and diet. The behaviour change techniques were incorporated to facilitate intentions to change and adopt healthy lifestyle habits for back pain self-management, using the following techniques: intention formation[1] (by encouraging commitment from the participant to engage with the coaching service and confirming that monitoring of participation and lifestyle behaviours would occur throughout the program); setting graded tasks and specific

behaviour goals[1]; prompting barrier identification[1] (by discussing patient specific potential barriers to behaviour change) and prompting self-monitoring of behaviour and outcomes.[1]

The *telephone-based health coaching service* was the NSW Get Healthy Service (GHS) (www.gethealthynsw.com.au).[27] The service involves 10 individually tailored coaching calls, based on national Healthy Eating and Physical Activity guidelines,[6,24] delivered over 6 months by qualified health professionals.[27] The GHS is a public health telephone-based service to support individuals to modify eating behaviours, increase physical activity, achieve and maintain a healthy weight, and where appropriate, referral to smoking cessation services. The GHS is funded by the NSW government and provided free to all residents of the state. A pre-post study showed the GHS to be effective for reducing weight, BMI and waist circumference in the general population, for those adherent to the program.[27]

Participant referrals to GHS were sent by the researchers via fax or email and indicated that referred participants were patients with low back pain. The GHS directly contacted the participants. All GHS health coaches were trained in evidence-based advice for low back pain by a study investigator (CW). This training involved a 2-hour interactive workshop and information resources to facilitate adaption of advice for study participants. The workshop and resources were based on information contained in international clinical practice guidelines for low back pain and included topics of diagnosis, prognosis, pain related distress, evidence-based management strategies and the role of a healthy lifestyle and weight loss.

Participants randomised to the control group continued on the usual care pathway (i.e. remained on the waiting list to have an orthopaedic specialist consultation and could progress to consultation if scheduled) and took part in data collection during the study period. No other active intervention was provided as part of the study however; no restrictions were placed upon the use of other health services during the study period. Control participants were informed that a new clinical service would be available in approximately 6 months involving clinical assessment and support from other services for

their back pain should they need it. No other details about the new service, or that other patients had started this service were disclosed.

Outcome measures

The primary outcome was average self-reported back pain intensity, over the 6 month follow up. At baseline, and weeks 2, 6, 10, 14, 18, 22 and 26 participants were asked to report the 'average pain intensity experienced in their back over the past week' on a Numerical Rating Scale (NRS), where 0 was 'no pain' and 10 was the 'worst possible pain'. The NRS is a widely used and validated measure.[16] Pain intensity was chosen as the primary outcome as it is recommend as a core outcome for clinical trials in non-specific low back pain and is a key priority for patients.[9]

Secondary outcomes were: self-reported weight (kg); low back pain disability, using the Roland Morris Disability Questionnaire (0-24 scale; high score indicates greater disability)[33]; quality of life, using the 12-item Short Form Health Survey (physical and mental health component scores (0-100 scale; high score indicates greater quality of life))[39]; sleep quality using item 6 from the Pittsburgh Sleep Quality Index (very bad, fairly bad, fairly good, very good)[7]; physical activity, using the Active Australia Survey (average minutes spent participating in moderate-to-vigorous physical activity per week)[4]; diet, using a short food frequency questionnaire (serves of fruit (0-1, 2 or more); serves of vegetables (0-2, 3-4, 5 or more); serves of discretionary foods e.g. processed meats, salty snacks, confectionary, sugar sweetened beverages (more than once per week, once per week or less))[8]; alcohol consumption using the Alcohol Use Disorders Identification Test (0-12 scale; high score indicates greater risk of alcohol-related harm)[5]; smoking prevalence (have you smoked any tobacco in the last 4 weeks? (including cigarettes, roll your own, pipes, cigars or any other tobacco products))[35]; back pain beliefs, using the one-item Survey of Pain Attitudes (0-28 scale; a high score indicates worse pain attitude)[19] and health care utilisation over the last 6 weeks including medication use and type of health service for back pain, all measured at 0,6,26 weeks.

Emotional distress, using the Depression Anxiety Stress Scale-21 (0-63 scale; high score indicates greater severity)[22] and the physical component of the Fear Avoidance Beliefs Questionnaire (0-24 scale; a high score indicates greater degree of fear-avoidance beliefs)[37] were measured at 0 and 26 weeks. Global rating of symptom change, using the Global Perceived Effect Scale (-5 'vastly worse' to 5 'completely recovered')[21] was measured at 6 and 26 weeks.

Objective weight (kg) and waist circumference were measured by a trained research assistant using International Society for the Advancement of Kinanthropometry procedures[17] at 26 weeks only. BMI was calculated as weight /height squared (kg/m^2) using self-reported and objective measures of weight separately.

Commencement date and the number of health coaching calls received were reported directly by the GHS. Participants were asked to report any adverse events (any new medical conditions or an exacerbation of another condition) during the intervention period in the 6 and 26 week questionnaires.

Data collection

Participants were asked to complete questionnaires (primary and secondary outcomes); at baseline, 6 weeks, and 26 weeks post randomisation. Baseline data was collected during a telephone interview from eligible participants prior to random allocation. Week 6 and week 26 questionnaires were completed via telephone by telephone interviewers blind to group allocation or mailed in the post as per participant preference. Participants were also asked to provide self-reported primary outcome data at weeks 2, 10, 14, 18 and 22 via telephone or text message, as per participant preference. Participants were asked to attend a clinical appointment with a research assistant at 6 months at which time objective weight and waist circumference were measured. At baseline, current time on the waiting list for consultation (days) and triage classification, was obtained from hospital records.

Statistical analysis

Sample size calculations estimated that a sample of 80 participants per group allowing for 15% loss to follow up would provide 90% power to detect a clinically meaningful difference of 1.5 in pain intensity (NRS) (equivalent to a 39 point difference in the AUC), with a standard deviation of 2.3, and a two-sided alpha of 0.025. Weight loss was the mechanism hypothesised to influence pain, therefore we also powered for self-reported weight as a secondary outcome. Therefore, using the reduced alpha of 0.025 to account for multiplicity,[29] the sample provided 80% power to detect a 6% reduction in self-reported weight, which has been hypothesised to lead to a clinically meaningful reduction in symptoms for other musculoskeletal conditions.[11] In these calculations the increase in statistical power conferred by reducing error variance through repeated outcome measures over time and the correlation among repeated measures have been conservatively ignored.

All outcomes were analysed under the intention-to-treat principle. The primary outcome was examined as the average self-reported pain intensity over 6 months defined as the area under the curve (AUC) of all pain intensity scores. AUC for pain intensity represents cumulative average pain intensity over time (i.e. average pain intensity score at each time point multiplied by the time elapsed since the previous observation) in each treatment group. For interpretation, dividing the AUC result by the number of weeks of follow-up (i.e. 26) will give the mean between group differences in the NRS.

For participants with <10% missing pain intensity values, the missing values were interpolated and an AUC computed. For participants with 10% or greater missing data an AUC was not computed. Multiple imputation using the chained equations method was used to impute missing AUC data. The imputation model included a range of covariates believed to be associated with missingness or the outcome itself (baseline knee pain intensity, time since onset of pain, waiting time and baseline BMI). The primary outcome analysis assessed the between-group differences in AUC using an independent sample Students t-test. Statistical significance was defined as p values less than 0.025.

Continuous secondary outcomes were assessed using baseline-adjusted hierarchical linear models with fixed effects for treatment group, time, group*time interaction, baseline value of the outcome, and random subject-level intercepts. Continuous outcomes measured at baseline and week 26 were assessed using baseline-adjusted ANCOVA at 26 weeks. Continuous outcomes measured at week 26 only were assessed using 2 sample t-tests. Categorical secondary outcomes were assessed using General Estimating Equations with fixed effects for treatment group, time, and group*time interaction. Dichotomous outcomes utilised the binomial distribution (with logit link), ordinal outcomes utilised the multinomial distribution (with cumulative logit link), and count outcomes utilised the negative-binomial distribution (with a log link function). Adverse events were classified according to the International Classification of Diseases version 10 by research personnel; the proportion of participants reporting an adverse event was compared between groups using the chi-squared test. A secondary analysis of the primary outcome used hierarchical linear models to assess between group differences in the trajectory of pain intensities over the follow-up period, modelled using growth curve modelling. Sensitivity analysis for the primary outcome analysis (AUC) used linear regression models adjusting for baseline prognostic variables, knee pain intensity, time since onset of pain, waiting time and BMI. Statistical significance in these models was defined as p values less than 0.01 to account for multiple comparisons.[29]

The analysis plan was approved and published prior to analysis of data.[26] Independent statistician(s) who were blinded to allocation completed the statistical analyses as per the published protocol using SAS V9.4 (SAS Institute, Cary, North Carolina, USA). The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12615000478516).

Results

Patients were recruited and randomly assigned to study groups between May 13 and October 27, 2015. Of 521 patients screened, 179 were eligible, and 160 (89.4%) provided

consent and were randomised to either the lifestyle intervention (n=80) or usual care (n=80) (Figure 1). One participant was excluded after randomisation as he was found to be ineligible. Participants had a mean age of 56.7 (SD 13.4) years and 94 (59.1%) were female. The mean baseline pain intensity was 6.7 (SD 1.7) and mean pain duration was 15.8 (SD 14.2) years. The mean self-reported weight at baseline was 91.4 (SD 15.6) kilograms. Participant characteristics at baseline were similar between groups (Table 1).

The completeness of the primary outcome data, back pain intensity, over the follow-up period was 87.7%. Missingness for primary outcome data was associated with a lower baseline weight (mean difference= -8.0kg, 95%CI -3.0 to -13.1; p=0.002). At 26 weeks, 22 participants in the intervention group and 13 participants in the control group, did not complete data collection (Figure 1). There were no meaningful differences in baseline characteristics between participants lost to follow-up and participants who completed 26 week follow-up.

Pain intensity over the 6-month follow-up period was not significantly different between groups (AUC mean difference= 6.5 of total pain scores, 95%CI -8.0 to 21.0; p=0.38; equivalent to a 0.25 point difference on the pain intensity NRS 95%CI -0.31 to 0.81) (Table 2). Similarly, there were no significant differences between groups for any secondary outcome during follow-up (Table 3).

Adverse events per group are reported in Table S1 in the supplementary file. The proportion of participants reporting an adverse event was not different between groups; 41% (n=32) and 56% (n=45) for the intervention and control group respectively. The number and type of health services and medications used were similar across groups (Table S2 and S3 in the supplementary file).

In regard to intervention adherence; 37 (46.8%) participants from the intervention group attended the single consultation with the study physiotherapist. GHS service data showed that 76 participants (96.2%) in the intervention group commenced GHS coaching calls (received at least one call), 38 (48.1%) participants received at least 3 calls (median 3;

interquartile range: 1 to 9), and 33 (41.8%) participants receiving 6 or more calls. The mean number calls conducted with participants was 5.1 (SD 4.5). Twenty-three participants (29.1%) attended the clinical consult and received 6 or more GHS calls.

Analysis of the pain intensity trajectory found no significant between group difference in mean pain intensity over 6 months (-0.08, 95% CI -0.04 to 0.21; p=0.19) (Figure 2, Table 2). We also noted no between group difference in the primary outcome when adjusted for prognostic variables (baseline pain intensity, time since onset of pain, waiting time, baseline BMI), (AUC mean difference= 6.2, 95% CI -6.3 to 18.8; p=0.32).

After consideration of the adherence results we undertook a post-hoc analysis to assess the effect of receiving the clinical consult and 6 or more GHS calls in the intervention group (i.e. 29% of participants) compared to the control group. This analysis showed no between group difference for pain intensity or self-reported weight (Table S4 and S5 in the supplementary file).

Discussion

We have shown that a healthy lifestyle intervention involving brief telephone advice, offer of a clinical consultation involving detailed education, and referral to a 6-month telephone-based health coaching service targeting weight loss, physical activity and diet, did not improve pain intensity for patients with low back pain who were overweight or obese. The intervention did not reduce self-reported weight, the hypothesised mechanism to influence pain, nor did the intervention improve other secondary outcomes including physical activity, diet, disability, sleep quality, emotional distress, global rating of symptom change, quality of life or health care use.

Strengths and limitations of this study

Several study features ensured low risk of bias including central randomisation and allocation concealment, blinding of outcome assessors and statisticians, and pre-publication of a study protocol and statistical analysis plan.[26,40] The cohort multiple RCT design

meant that patients were not aware of the alternate study group. This mimics real world heath care, reduces participant performance bias, and minimises sampling bias by reducing non-consent.[31]

A potential limitation of the trial is that participants were recruited from one tertiary hospital. Although this hospital has a wide referral base of general practitioners (n >1300), from a large health district (population size >900,000), the single centre design may impact generalisability of the findings. Due to the pragmatic design of the study, it was not feasible to collect objective weight across the intervention period so our measurement of weight relied on self-report. Measuring objective weight across all time points may have increased the validity of our assessment of weight outcomes.

Our intervention included several pragmatically delivered components. The overall adherence to these components was low. Around half (47%) of the intervention group attended the initial consult, and although 96% of patients commenced the GHS, just 42% received 6 or more (of 10) GHS calls. Only 29% attended the consult *and* received 6 or more calls. Poor engagement with the intervention may explain why the intervention failed to provide benefits to participants. However, in our post-hoc analysis we did not note any signal of an effect on pain intensity or weight loss for participants who received the clinical consultation and 6 or more GHS calls.

While our approach was based on formative evaluation, which indicated telephone services as the most preferred method to support healthy lifestyle and weight loss,[41] for patients with low back pain who are overweight, it remains unclear how to encourage patient adherence and support patients to make lifestyle changes. In the general population, telephone services have been shown to be as effective as face-to-face services when addressing lifestyle risks.[15] In our study, we used a non-disease specific healthy lifestyle intervention designed for the general population. Current best practice guidelines for weight loss and behaviour change recommend tailored support to cater for the needs of different

patient groups and to provide support for at least 3 months.[25] Although our study aimed to provide up to 6 months of support, it is possible that patients with long standing chronic low back pain require more intensive and disease specific support to adequately manage their pain and facilitate lifestyle changes; for example such as that offered in multidisciplinary pain management programs.[20] Certainly, patients with low back pain who are overweight may encounter additional challenges to engaging in positive behaviour changes. Combined with mobility restrictions, patients with chronic pain are often fearful that physical activity will make their condition worse.[28] There is also evidence that patients may use food to help cope with their pain, as eating certain foods can elicit a chemical response in the brain providing feelings of comfort.[3,18] In our study, it is unclear if these additional challenges contributed to poor adherence and led to no effect, or if a lack of benefit from participating in the service resulted in poor adherence or drop out over time. Future studies should appropriately identify how to optimise low back pain patient involvement in health behaviour change to elicit and assess any potential effect of lifestyle focussed care.

Lifestyle risks such as overweight and obesity have been shown to increase persistent low back pain and health care seeking for low back pain.[34] Accordingly, targeting lifestyle as part of the management of low back pain is widely recommended.[14,38] However, there is no direct evidence that addressing lifestyle and weight in particular, benefits these patients.[38] Evidence from other musculoskeletal conditions, indicates clinically meaningful weight loss of 6% of body weight leads to reduced pain intensity.[11] As our intervention did not affect patients' weight we cannot confirm whether targeting this, or other aspects of lifestyle, has a meaningful influence on patients with low back pain.

Given the link between lifestyle risks and chronic low back pain, it is surprising no other trials in this area have been conducted.[38] Currently, there is no evidence to guide the clinical management of patients with these comorbid health issues. This is a significant oversight as patients with low back pain who are also overweight and have other poor lifestyle behaviours are likely to face additional challenges managing these coexisting health issues. As together

they are likely to elicit a greater burden on the health of individuals and across the population, there is a need for research which aims to understand the interaction between lifestyle and back pain, and as well develop integrative management approaches to guide the development of effective interventions.

Conclusions

Our study provides high quality evidence that a healthy lifestyle intervention involving brief advice, clinical education and advice, and referral to a telephone-based health coaching service was not effective in reducing back pain intensity, weight, disability and other outcomes in low back pain patients who were overweight or obese. Clinical education and advice coupled with referral to non-disease specific telephone-based healthy lifestyle coaching service is unlikely to provide benefits to this patient group.

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Conflict of interest statement

The authors have no conflict of interest to declare.

References

[1] Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. Health Psychol. Off. J. Div. Health Psychol. Am. Psychol. Assoc. 2008;27:379–387.

[2] Airaksinen O, Brox JI, Cedraschi C, Hildebrandt J, Klaber-Moffett J, Kovacs F, Mannion a F, Reis S, Staal JB, Ursin H, Zanoli G. Chapter 4: European guidelines for the management of chronic nonspecific low back pain. Eur. Spine J. 2006;15:S192-300.

[3] Amy Janke E, Kozak AT. "The More Pain I Have, the More I Want to Eat": Obesity in the Context of Chronic Pain. Obes. Silver Spring 2012;20:2027–2034.

[4] Australian Institute of Health and Welfare (AIHW). The Active Australia Survey: a guide and manual for implementation, analysis and reporting. Canberra, Australia: AIHW, 2003 p.

[5] Babor TF, Higgins-Biddle JC, Saunders JB, Monteiro MG. AUDIT. The alcohol use disorders identification test: guidelines for use in primary care (2nd Ed). 1992.

[6] Brown W, Bauman A, Bull F, Burton N. Development of Evidence-Based Physical Activity Recommendations for Adults (18 - 64 years). Report prepared for the Australian Government Department of Health, 2012.

[7] Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res. 1989;28:193–213.

[8] Centre for Epidemiology Research. NSW Population Health Survey. Sydney NSW: NSW Department of Health, 2014.

[9] Chiarotto A, Deyo RA, Terwee CB, Boers M, Buchbinder R, Corbin TP, Costa LOP, Foster NE, Grotle M, Koes BW, Kovacs FM, Lin C-WC, Maher CG, Pearson AM, Peul WC, Schoene ML, Turk DC, Tulder MW van, Ostelo RW. Core outcome domains for clinical trials in non-specific low back pain. Eur. Spine J. 2015;24:1127–1142.

[10] Chou L, Brady SRE, Urquhart DM, Teichtahl AJ, Cicuttini FM, Pasco JA, Brennan-Olsen SL, Wluka AE. The Association Between Obesity and Low Back Pain and Disability Is Affected by Mood Disorders. Medicine (Baltimore) 2016;95. doi:10.1097/MD.0000000000003367.

[11] Christensen R, Bartels EM, Astrup A, Bliddal H. Effect of weight reduction in obese patients diagnosed with knee osteoarthritis: a systematic review and meta-analysis. Ann. Rheum. Dis. 2007;66:433–439.

[12] Christensen R, Bartels EM, Astrup A, Bliddal H. Effect of weight reduction in obese patients diagnosed with knee osteoarthritis: a systematic review and meta-analysis. Ann. Rheum. Dis. 2007;66:433–439.

[13] Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. Spine J. Off. J. North Am. Spine Soc. 2008;8:8–20.

[14] Dean E, Söderlund 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.

[15] Goode AD, Reeves MM, Eakin EG. Telephone-delivered interventions for physical activity and dietary behavior change: an updated systematic review. Am. J. Prev. Med. 2012;42:81–8.

[16] Hawker GA, Mian S, Kendzerska T, French M. 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 Res. 2011;63:240–252.

[17] International Society for the Advancement of Kinanthropometry (ISAK). International Standards for Anthropometric Assessment. Underdale, S.A.: ISAK, 2001.

[18] Janke EA, Jones E, Hopkins CM, Ruggieri M, Hruska A. Catastrophizing and anxiety sensitivity mediate the relationship between persistent pain and emotional eating. Appetite 2016;103:64–71.

[19] Jensen MP, Keefe FJ, Lefebvre JC, Romano JM, Turner JA. One-and two-item measures of pain beliefs and coping strategies. Pain 2003;104:453–469.

[20] Kamper SJ, Apeldoorn AT, Chiarotto A, Smeets RJ, Ostelo RW, Guzman J, van Tulder MW. Multidisciplinary biopsychosocial rehabilitation for chronic low back pain. Cochrane Libr. 2014.

[21] Kamper SJ, Ostelo RWJG, Knol DL, Maher CG, de Vet HCW, Hancock MJ. Global Perceived Effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced by current status. J. Clin. Epidemiol. 2010;63:760–766.

[22] Lovibond PF, Lovibond SH. The structure of negative emotional states: Comparison of the depression anxiety stress scales (DASS) with the Beck Depression and Anxiety Inventories. Behav. Res. Ther. 1995;33:335–343.

[23] National Guideline Centre (UK). Low Back Pain and Sciatica in Over 16s: Assessment and Management. London: National Institute for Health and Care Excellence (UK), 2016.

[24] National Health and Medical Research Council (NHMRC). Australian Dietary Guidelines. Canberra: NHMRC, 2013.

[25] National Institute for Health and Care Excellence (NICE). Weight management: lifestyle services for overweight or obese adults. (Clinical Guideline PH53). 2014.

[26] O'Brien KM, Williams A, Wiggers J, Wolfenden L, Yoong S, Campbell E, Kamper SJ, McAuley J, Attia J, Oldmeadow C, Williams CM, O'Brien KM, Williams A, Wiggers J, Wolfenden L, Yoong S, Campbell E, Kamper SJ, McAuley J, Attia J, Oldmeadow C, Williams CM. Effectiveness of a healthy lifestyle intervention for low back pain and osteoarthritis of the knee: protocol and statistical analysis plan for two randomised controlled trials. Braz. J. Phys. Ther. 2016;20:477–489.

[27] O'Hara BJ, Phongsavan P, Venugopal K, Eakin EG, Eggins D, Caterson H, King L, Allman-Farinelli M, Haas M, Bauman AE. Effectiveness of Australia's Get Healthy Information and Coaching Service®: translational research with population wide impact. Prev. Med. 2012;55:292–8.

[28] Okifuji A, Hare BD. The association between chronic pain and obesity. J. Pain Res. 2015;8:399–408.

[29] Proschan MA, Waclawiw MA. Practical guidelines for multiplicity adjustment in clinical trials. Control. Clin. Trials 2000;21:527–539.

[30] Qaseem A, Wilt TJ, McLean RM, Forciea MA, for the Clinical Guidelines Committee of the American College of Physicians. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. Ann. Intern. Med. 2017;166:514.

[31] Relton C, Torgerson D, O'Cathain A, Nicholl J. Rethinking pragmatic randomised controlled trials: introducing the "cohort multiple randomised controlled trial" design. BMJ 2010;340:963–967.

[32] Roffey D, Budiansky A, J. Coyle M, Wai E. Obesity and Low Back Pain: Is There a Weight of Evidence to Support a Positive Relationship? 2013;2.

[33] Roland M, Morris R. A study of the natural history of back pain: part I: development of a reliable and sensitive measure of disability in low-back pain. spine 1983;8:141–144.

[34] Shiri R, Karppinen J, Leino-Arjas P, Solovieva S, Viikari-Juntura E. The association between obesity and low back pain: a meta-analysis. Am. J. Epidemiol. 2010;171:135–54.

[35] Shiri R, Karppinen J, Leino-Arjas P, Solovieva S, Viikari-Juntura E. The association between smoking and low back pain: a meta-analysis. Am. J. Med. 2010;123:87.e7-35.

[36] Vos T, Allen C, Arora M, Barber RM, Bhutta ZA, Brown A, Carter A, Casey DC, Charlson FJ, Chen AZ, others. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. The Lancet 2016;388:1545–1602.

[37] Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain 1993;52:157–168.

[38] Wai EK, Rodriguez S, Dagenais S, Hall H. Evidence-informed management of chronic low back pain with physical activity, smoking cessation, and weight loss. Spine J. Off. J. North Am. Spine Soc. 2008;8:195–202.

[39] Ware J, Kosinski M, Bjorner J, Turner-Bowker D, Gandek B, Maruish M. User's Manual for the SF-12v2 Health Survey (with a Supplement Documenting SF-12 Health Survey). Boston, MA: Lincoln, RI: QualityMetric Incorporated, 2002.

[40] Williams A, Wiggers J, O'Brien KM, Wolfenden L, Yoong S, Campbell E, Robson E, McAuley J, Haskins R, Kamper SJ. 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;17:1.

[41] Williams CM, Williams A, O'Brien K, Wolfenden L, Wiggers J. Preventative care strategies for common risk factors of chronic disease and musculoskeletal pain in patients waiting for specialist consultation. Obes. Res. Clin. Pract. 2014;8, Supplement 1:115.

Figure 1: Trial profile

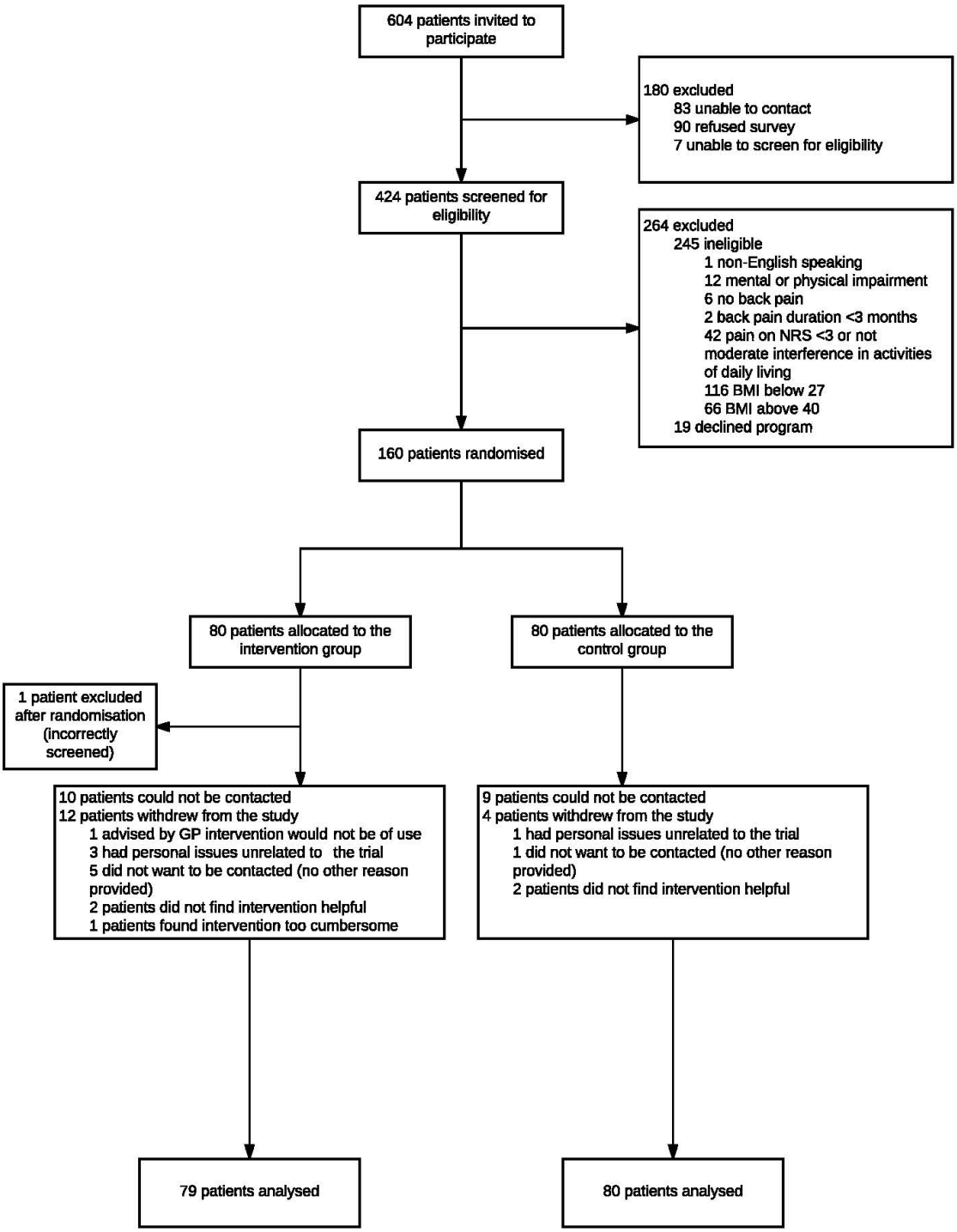

Figure 2: Mean pain intensity over the follow-up period

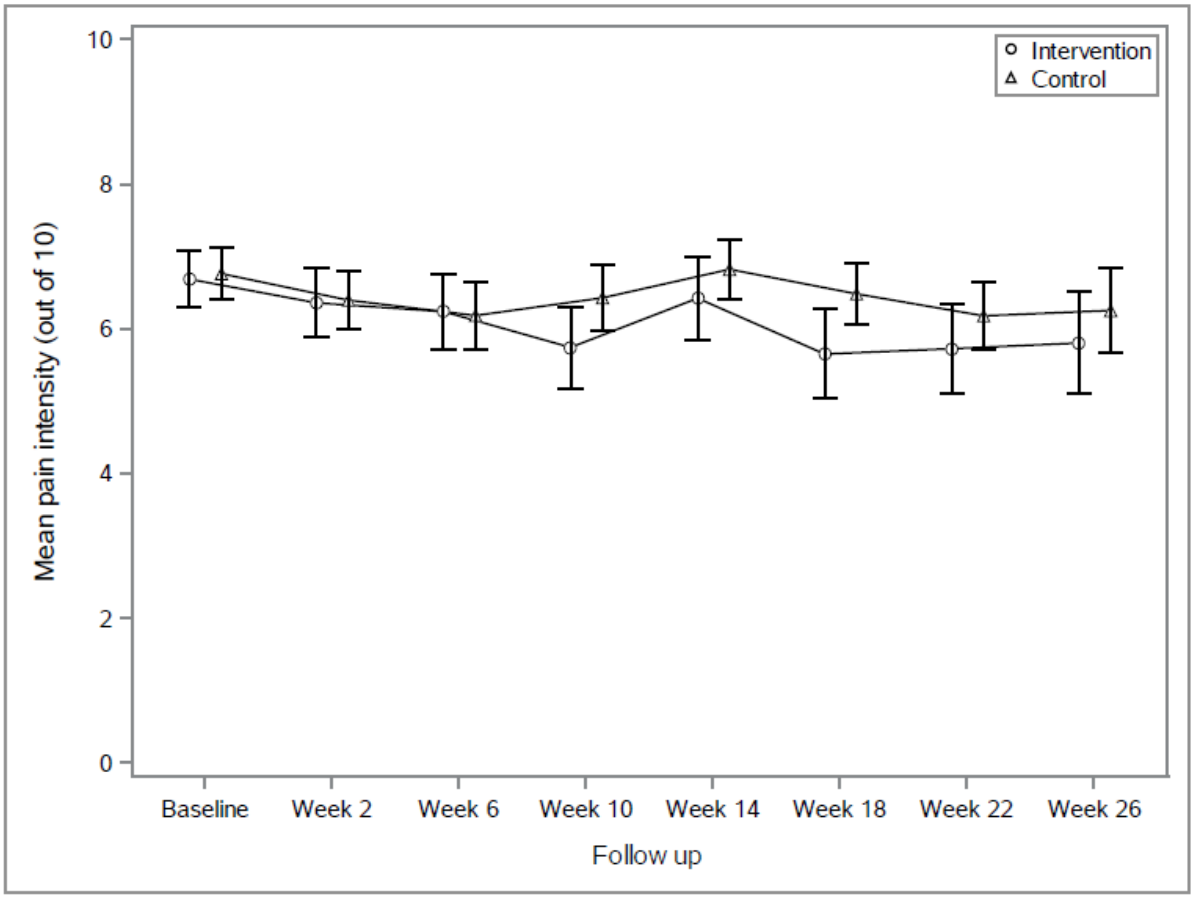

Table 1: Baseline characteristics

	Intervention (n=79)	Control (n=80)
Demographic characteristics		
Age (years), mean (SD)	56.0 (13.3)	57.4 (13.6)
Gender (male), n (%)	31 (39.2)	34 (42.5)
Aboriginal and/or Torres Strait Islander status, n (%)	7 (8.9)	5 (6.3)
Employment status, n (%)		
Employed	17 (21.5)	17 (21.3)
Unemployed	15 (19.0)	9 (11.3)
Retired	27 (34.2)	29 (36.3)
Can't work (health reasons)	20 (25.3)	25 (31.3)
Country of origin (Australia), n (%)	69 (87.3)	68 (85.0)
Highest level of education, n (%)		
>High school	27 (34.2)	31 (38.8)
Private health insurance, n (%)	6 (7.6)	9 (11.3)
Other co-existing medical conditions needing medication, n (%)	67 (84.8)	68 (85.0)
Current time on the waiting list for consultation (days), median (IQR)	685 (255 -1289)	525 (184 -1185)
Triage classification, n (%)*		
Non-urgent	5 (6.3)	3 (3.8)
Semi-urgent	64 (81.0)	66 (82.5)
Urgent	8 (10.1)	9 (11.3)
Clinical characteristics		
Pain intensity (NRS), mean (SD)	6.7 (1.8)	6.8 (1.6)
Pain duration (how long have you been troubled with your pain) (years), mean (SD)	13.0 (11.9)	18.5 (15.7)
Disability and function (RMDQ), mean (SD)	14.7 (5.2)	15.8 (5.1)
Self-reported weight, mean (SD)	91.9 (16.5)	90.8 (14.6)
Subjective BMI, mean (SD)	32.4 (3.5)	32.1 (3.6)
Quality of Life (SF12.v2), mean (SD)		
Physical component score (PCS)	31.3 (9.2)	29.2 (9.6)
Mental component score (MCS)	46.7 (13.9)	46.1 (13.8)
Emotional distress (DASS-21), mean (SD)		
Depression subscale	11.3 (10.9)	9.9 (9.1)
Anxiety subscale	9.3 (7.7)	9.0 (7.8)
Stress subscale	13.3 (9.3)	13.6 (9.0)
Poor sleep quality (item 6, Pittsburgh Sleep Quality Index), n (%)†	11 (14)	24 (30)
Physical activity (mins MVPA/week), mean (SD)	73.9 (219.3)	146.7 (504.0)
Diet, n (%)		
Daily fruit intake (<2 serves)	40 (51)	41 (51)
Daily vegetable intake (<5 serves)	64 (81)	67 (84)
Consumes discretionary foods more than once a week	9 (11)	11 (14)
Alcohol consumption (AUDIT), mean (SD)	2.2 (2.5)	2.2 (2.6)
Smoking prevalence, n (%)	17 (22)	21 (26)
Pain attitudes (SOPA), mean (SD)	16.9 (4.7)	16.5 (4.7)
Fear avoidance beliefs (FABQ), mean (SD)	17.2 (5.5)	17.5 (6.0)

Health care utilisation, n (%)		
Medication use for back pain	66 (84)	63 (79)
Health care visits for back pain	37 (47)	47 (59)

Abbreviations: NRS=numerical rating scale; RMDQ=Roland Morris Disability Questionnaire; BMI=Body Mass Index; SF12.v2= Short Form Health Survey version 2; PCS=Physical Component Score; MCS=Mental Component Score; DASS-21=Depression Anxiety Stress Scale; MVPA=Moderate-to-Vigorous Physical Activity; AUDIT=Alcohol Use Disorders Identification Test; SOPA= Survey of Pain Attitudes; FABQ= Fear Avoidance Beliefs Questionnaire

*Note that these percentages do not add up to 100% because n=4 participants had no triage classification recorded (Intervention n=2, Control n=2)

†Item 6 from the Pittsburgh Sleep Quality Index dichotomised as very bad and fairly bad versus very good and fairly good

Table 2: Analyses of primary outcome (pain intensity)

Analysis	Outcome	Intervention mean (95%CI) (n=79)	Control mean (95%CI) (n=80)	Mean difference* (95%CI)	p value
Primary (ITT, MI)	Area under the pain intensity curve (AUC)	156.8 (146.2 to 167.5)	163.4 (153.6 to 173.1)	6.5 (-8.0 to 21.0)	0.38
Secondary	Pain intensity score	**Intervention mean (SD) (n=79)**	**Control mean (SD) (n=80)**	**Mean difference* (95%CI)**	**p value**
	Baseline	6.7 (1.8)	6.8 (1.6)		
	Week 2	6.4 (2.1)	6.4 (1.9)	0.0 (-0.6 to 0.6)	1.00
	Week 6	6.2 (2.1)	6.2 (2.1)	-0.1 (-0.8 to 0.5)	0.72
	Week 10	5.7 (2.4)	6.4 (2.0)	0.6 (0.0 to 1.3)	0.05
	Week 14	6.4 (2.3)	6.8 (1.8)	0.4 (-0.2 to 1.1)	0.20
	Week 18	5.6 (2.5)	6.5 (1.8)	0.8 (0.2 to 1.5)	0.01
	Week 22	5.7 (2.5)	6.2 (2.0)	0.4 (-0.3 to 1.1)	0.24
	Week 26	5.8 (2.7)	6.3 (2.4)	0.3 (-0.4 to 1.0)	0.36
	Monthly trend			0.08 (-0.04 to 0.21)	0.19

Abbreviations: ITT=Intention to treat, MI= Multiple Imputation, AUC= Area under the curve
*Mean difference= control-intervention

Table 3: Analyses of secondary outcomes

Outcome	Time point	Intervention	Control	
		Mean(SD)	Mean(SD)	Mean difference* (95% CI)
Disability score (RMDQ)	Baseline	14.7 (5.2); n=79	15.8 (5.1); n=80	
	Week 6	14.2 (5.6); n=57	15.8 (5.1); n=69	0.8 (-0.6, 2.2)
	Week 26	13.9 (6.5); n=38	14.7 (5.9); n=55	-0.1 (-1.7, 1.5)
Self-reported weight	Baseline	91.9 (16.5); n=79	90.8 (14.6); n=80	
	Week 6	93.9 (18.0); n=62	90.2 (15.0); n=72	-0.3 (-1.9, 1.2)
	Week 26	93.5 (17.4); n=54	93.3 (16.8); n=63	1.8 (0.2, 3.5)
Objective weight	Baseline†	98.5 (18.6); n=25	-	-
	Week 26	96.1 (15.7); n=13	97.9 (20.3); n=26	1.8 (-11.2, 14.8)
Subjective BMI	Baseline	32.4 (3.5); n=79	32.1 (3.6); n=80	
	Week 6	32.8 (4.1); n=62	32.0 (4.1); n=72	-0.1 (-0.6, 0.5)
	Week 26	32.7 (4.3); n=54	32.5 (4.6); n=63	0.6 (0.0, 1.2)
Objective BMI	Week 26	33.3 (4.3); n=12	35.2 (6.5); n=26	1.8 (-2.3, 6.0)
Objective waist circumference	Week 26	121.0 (21.9); n=10	110.8 (17.7); n=23	-10.1 (-24.8, 4.6)
Quality of life PCS (SF12v2)	Baseline	31.3 (9.2); n=79	29.2 (9.6); n=79	
	Week 6	31.8 (9.1); n=57	30.3 (10.6); n=69	-0.3 (-3.0, 2.4)
	Week 26	32.1 (10.9); n=43	30.5 (10.1); n=61	-0.6 (-3.5, 2.4)
Quality of life MCS (SF12v2)	Baseline	46.7 (13.9); n=79	46.1 (13.8); n=79	
	Week 6	46.6 (11.0); n=57	45.0 (11.6); n=69	-0.9 (-4.3, 2.4)
	Week 26	46.5 (13.8); n=43	44.3 (13.3); n=61	-1.7 (-5.4, 2.0)
Global rating of symptom change (GPE)	Week 6	4.3 (1.8); n=58	4.5 (1.8); n=70	0.2 (-0.5, 0.9)
	Week 26	4.9 (2.2); n=41	4.2 (1.9); n=58	-0.6 (-1.3, 0.2)
DASS-21, Depression	Baseline	11.3 (10.9); n=79	9.9 (9.1); n=79	
	Week 26	13.1 (11.2); n=43	11.9 (11.1); n=61	0.5 (-2.7, 3.7)
DASS-21, Anxiety	Baseline	9.3 (7.7); n=79	9.0 (7.8); n=79	
	Week 26	9.8 (8.3); n=43	9.4 (9.0); n=61	-0.3 (-3.2, 2.7)
DASS-21, Stress	Baseline	13.3 (9.3); n=79	13.6 (9.0); n=79	
	Week 26	14.3 (10.7); n=43	13.8 (11.1); n=61	-0.2 (-3.9, 3.4)
Physical activity (MVPA/week)	Baseline	73.9 (219.3); n=79	146.7 (504.0); n=80	
	Week 6	95.8 (208.3); n=59	130.6 (382.1); n=71	-7.1 (-150.0, 135.8)
	Week 26	229.2 (755.1); n=43	148.6 (400.0); n=61	-99.3 (-260.2, 61.5)
Alcohol consumption (AUDIT)	Baseline	2.2 (2.5); n=79	2.2 (2.6); n=80	
	Week 6	2.3 (2.8); n=58	2.3 (2.6); n=70	-0.1 (-0.5, 0.4)
	Week 26	2.2 (2.6); n=43	2.3 (2.7); n=58	0.1 (-0.4, 0.6)
Pain attitudes (SOPA)	Baseline	16.9 (4.7); n=79	16.5 (4.7); n=80	
	Week 6	16.2 (4.2); n=59	16.1 (4.7); n=71	0.3 (-1.3, 1.8)
	Week 26	16.9 (5.5); n=43	15.8 (5.3); n=61	-0.5 (-2.3, 1.2)
Fear avoidance beliefs scale (FABQ)	Baseline	17.2 (5.5); n=79	17.5 (6.0); n=79	
	Week 26	15.4 (7.4); n=43	16.6 (6.4); n=60	1.0 (-1.4, 3.5)
Outcome	**Time point**	**Intervention**	**Control**	

		n/N (%)	n/N (%)	OR (95% CI) Ref = Control
Poor sleep quality‡	Baseline	11/79 (14)	24/80 (30)	
	Week 6	7/58 (12)	15/71 (21)	0.59 (0.23, 1.51)
	Week 26	5/43 (12)	8/61 (13)	1.04 (0.37, 2.96)
Diet – Daily fruit intake (0 -1 serves)§	Baseline	40/79 (51)	41/80 (51)	
	Week 6	24/59 (41)	37/71 (52)	0.63 (0.32, 1.24)
	Week 26	16/43 (37)	25/61 (41)	0.79 (0.38, 1.63)
Diet – Daily vegetable intake (0-2 serves)	Baseline	35/79 (44)	37/80 (46)	
	Week 6	27/59 (46)	37/71 (52)	-
	Week 26	21/42 (50)	29/61 (48)	-
Diet – Daily vegetable intake (3-4 serves)	Baseline	29/79 (37)	30/80 (38)	
	Week 6	27/59 (46)	22/71 (31)	-
	Week 26	17/42 (40)	20/61 (33)	-
Diet – Daily vegetable intake‖	Week 6	-	-	0.96 (0.50, 1.82)
	Week 26	-	-	1.30 (0.62, 2.72)
Diet – Consumes discretionary foods more than once a week	Baseline	73/79 (92)	73/80 (91)	
	Week 6	51/58 (88)	60/71 (85)	1.17 (0.44, 3.12)
	Week 26	37/43 (86)	52/61 (85)	1.11 (0.36, 3.41)
Smoking prevalence	Baseline	17/79 (22)	21/80 (26)	
	Week 6	11/59 (19)	14/71 (20)	0.93 (0.43, 2.00)
	Week 26	4/43 (9)	11/61 (18)	0.56 (0.24, 1.27)
Participants using other healthcare for back pain	Baseline	37/79 (47)	47/80 (59)	
	Week 6	24/60 (40)	39/72 (54)	0.56 (0.28, 1.12)
	Week 26	14/38 (37)	25/56 (45)	0.73 (0.33, 1.65)
Attended orthopaedic consultation for back pain	Baseline	4/79 (5)	6/80 (8)	
	Week 6	3/60 (5)	4/72 (6)	-
	Week 26	0/38 (0)	2/56 (4)	-
Participants using medication for back pain	Baseline	66/79 (84)	63/80 (79)	
	Week 6	44/60 (73)	58/72 (81)	0.64 (0.29, 1.44)
	Week 26	27/38 (71)	45/56 (80)	0.54 (0.20, 1.44)

Abbreviations: RMDQ=Roland Morris Disability Questionnaire; BMI=Body Mass Index; SF12.v2= Short Form Health Survey version 2; PCS=Physical Component Score; MCS=Mental Component Score; GPE=Global Perceived Effect scale; DASS-21=Depression Anxiety Stress Scale; MVPA=Moderate-to-Vigorous Physical Activity; AUDIT=Alcohol Use Disorders Identification Test; SOPA= Survey of Pain Attitudes; FABQ= Fear Avoidance Beliefs Questionnaire
*Mean difference = control – intervention, adjusted for baseline values (where baseline value exists)
†Measured for intervention group only at the clinical consultation
‡Item 6 from the Pittsburgh Sleep Quality Index dichotomised as very bad and fairly bad versus very good and fairly good
§Reference = 2 or more serves
‖Vegetable intake categories = 0-2 serves, 3-4 serves, 5 or more serves; OR is the proportional odds of reporting a lower category of vegetable intake for the intervention group

Supplementary file

Text S1: Summary of changes to the original study protocol and statistical analysis plan

Deviations from the original protocol:

1. In the original study protocol we stated that we would use linear mixed models to assess the primary outcome. Based on further statistical advice we changed the analysis to examine the between-group differences in the area under the curve (AUC). These changes were made prior to undertaking the analysis and are documented in the published statistical analysis plan
2. The protocol stated that we would report process data including the length and timing of the Get Healthy Service coaching calls and achievement of participant identified goals. We were unable to report this data as it was not available from the Get Healthy Service provider.
3. The original study protocol stated that we would report subjective body mass index (BMI) at baseline and 26 weeks only. However as detailed in our statistical analysis plan we reported subjective BMI at baseline, 6 weeks and 26 weeks. We reported data for BMI at baseline, 6 weeks and 26 weeks.

Deviations from statistical analysis plan:

1. The statistical analysis plan stated that we would analyse the number of adverse events between groups using a Fishers exact test. This test was chosen as the event rate of adverse events was expected to be low. As numbers were larger than expected a Chi-squared test was used.
2. In the statistical analysis plan a table was provided for the secondary outcomes. The table layout included an 'overall' row for each secondary outcome. This row was removed as it was irrelevant given the analyses we undertook.
3. After considering the results we conducted post hoc analyses to further explore intervention adherence. These analyses are explicitly identified as 'post hoc' in our manuscript.

Table S1: Details of adverse events by group

ICD-10 codes	Intervention (n=79)	Control (n=80)
Week 6		
C26 Malignant neoplasm of other and ill-defined digestive organs	0	1
E07 Other disorders of thyroid	0	1
F32 Depressive episode	0	1
G03 Meningitis due to other and unspecified causes	0	1
G47 Sleep disorders	0	2
H81 Disorders of vestibular function	1	1
H83 Other diseases of inner ear	0	1
I51 Complications and ill-defined descriptions of heart disease	0	1
J11 Influenza, virus not identified	2	0
J40 Bronchitis, not specified as acute or chronic	0	2
J45 Asthma	1	0
K57 Diverticular disease of intestine	0	1
K85 Acute pancreatitis	0	1
M06 Other rheumatoid arthritis	1	0
M25 Other joint disorders, not elsewhere classified	5	7
M54 Dorsalgia	5	3
M79 Other soft tissue disorders, not elsewhere classified	1	0
N28 Other disorders of kidney and ureter, not elsewhere classified	0	2
N30 Cystitis	1	0
N39 Other disorders of urinary system	3	0
R19 Other symptoms and signs involving the digestive system and abdomen	1	1
R20 Disturbances of skin sensation	2	2
R52 Pain, not elsewhere classified	1	2
S32 Fracture of lumbar spine and pelvis	0	1
S50 Superficial injury of forearm	0	1
T12 Fracture of lower limb, level unspecified	0	1
W19 Unspecified fall	0	1
Total week 6	24	34
Week 26		

E14 Unspecified diabetes mellitus	1	0
F32 Depressive episode	0	1
G71 Primary disorders of muscles	0	1
H54 Visual impairment including blindness (binocular or monocular)	1	0
I10 Essential (primary) hypertension	0	1
I51 Complications and ill-defined descriptions of heart disease	0	1
I61 Intracerebral haemorrhage	1	0
I80 Phlebitis and thrombophlebitis	1	0
I83 Varicose veins of lower extremities	0	1
J11 Influenza, virus not identified	0	1
K74 Fibrosis and cirrhosis of liver	0	1
M06 Other rheumatoid arthritis	0	2
M25 Other joint disorders, not elsewhere classified	1	7
M54 Dorsalgia	5	8
M79 Other soft tissue disorders, not elsewhere classified	0	3
M99 Biomechanical lesions, not elsewhere classified	0	1
N39 Urinary tract infection, site not specified	1	0
R01 Cardiac murmurs and other cardiac sounds	1	0
R19 Other symptoms and signs involving the digestive system and abdomen	1	1
R20 Disturbances of skin sensation	0	1
S39 Other and unspecified injuries of abdomen, lower back and pelvis	0	1
S86 Injury of muscle and tendon at lower leg level	0	1
Total week 26	13	32

Adverse event; any new medical condition or exacerbation of and old medical conditions during the defined reporting period

Table S2: Descriptions of concomitant healthcare services used for low back pain*

Service category	Time point	Intervention	Control
		n (%)	n (%)
General Practitioner	Baseline	28 (58)	35 (56)
	Week 6	19 (51)	21 (40)
	Week 26	13 (87)	19 (53)
Medical specialist	Baseline	0 (0)	1 (2)
	Week 6	0 (0)	1 (2)
	Week 26	0 (0)	1 (3)
Chiropractor	Baseline	1 (2)	6 (10)
	Week 6	1 (3)	6 (11)
	Week 26	0 (0)	2 (6)
Physiotherapy	Baseline	5 (10)	5 (8)
	Week 6	3 (8)	7 (13)
	Week 26	0 (0)	4 (11)
Dietitian	Baseline	0 (0)	0 (0)
	Week 6	1 (3)	0 (0)
	Week 26	1 (7)	0 (0)
Other allied health	Baseline	1 (2)	1 (2)
	Week 6	1 (3)	0 (0)
	Week 26	0 (0)	2 (6)
Massage therapy	Baseline	2 (4)	1 (2)
	Week 6	2 (5)	4 (8)
	Week 26	0 (0)	0 (0)
Alternative medicine	Baseline	0 (0)	2 (3)
	Week 6	1 (3)	1 (2)
	Week 26	0 (0)	2 (6)
Emergency	Baseline	1 (2)	4 (6)
	Week 6	1 (3)	2 (4)
	Week 26	0 (0)	2 (6)
Hospital admission	Baseline	1 (2)	0 (0)
	Week 6	0 (0)	1 (2)
	Week 26	0 (0)	0 (0)
Spinal injection	Baseline	2 (4)	0 (0)
	Week 6	2 (5)	1 (2)
	Week 26	0 (0)	0 (0)
Imaging	Baseline	3 (6)	1 (2)
	Week 6	2 (5)	0 (0)
	Week 26	0 (0)	0 (0)
Physical activity services	Baseline	0 (0)	0 (0)
	Week 6	1 (3)	2 (4)
	Week 26	1 (7)	1 (3)

Community services	Baseline	0 (0)	1 (2)
	Week 6	0 (0)	1 (2)
	Week 26	0 (0)	0 (0)
Orthopaedic surgeon consultation	Baseline	4 (8)	6 (10)
	Week 6	3 (8)	4 (8)
	Week 26	0 (0)	2 (6)
Pain clinic	Baseline	0 (0)	0 (0)
	Week 6	0 (0)	2 (4)
	Week 26	0 (0)	0 (0)
Other	Baseline	0 (0)	0 (0)
	Week 6	0 (0)	0 (0)
	Week 26	0 (0)	1 (3)

Data are the number of reported health services accessed by participants. Emergency refers to participants who presented to emergency department but were not admitted. Other allied health professional includes Back Fit, osteopath, psychologist, exercise physiologist and diabetes clinic. Alternative medicine refers to Bowen therapy, naturopath and acupuncture. Physical activity services refer to hydrotherapy and aqua aerobics. Community services refer to patient transport and home care. Other refers to Lite n' Easy.
*Sample size at baseline n=159 (79 intervention, 80 control), 6 weeks=132 (60 intervention, 72 control), 26 weeks n=94 (38 intervention, 56 control).

Table S3: Descriptions of concomitant medications used for low back pain*

Service category	Time point	Intervention	Control
		n (%)	n (%)
Paracetamol	Baseline	32 (28)	26 (24)
	Week 6	25 (28)	38 (33)
	Week 26	15 (30)	28 (29)
Paracetamol with opioid	Baseline	21 (18)	13 (12)
	Week 6	14 (16)	8 (7)
	Week 26	4 (8)	6 (6)
Paracetamol with other combinations	Baseline	2 (2)	2 (2)
	Week 6	2 (2)	1 (1)
	Week 26	2 (4)	1 (1)
Anticonvulsant	Baseline	13 (11)	13 (12)
	Week 6	8 (9)	12 (10)
	Week 26	7 (14)	14 (14)
Muscle relaxant	Baseline	1 (1)	5 (5)
	Week 6	0 (0)	2 (2)
	Week 26	0 (0)	2 (2)
NSAID	Baseline	17 (15)	5 (5)
	Week 6	16 (18)	9 (8)
	Week 26	9 (18)	10 (10)
NSAID with opioid	Baseline	6 (5)	7 (6)
	Week 6	8 (9)	8 (7)
	Week 26	1 (2)	4 (4)
Opioid	Baseline	19 (17)	33 (30)
	Week 6	15 (17)	35 (30)
	Week 26	12 (24)	24 (24)
Psychoactive	Baseline	3 (3)	3 (3)
	Week 6	0 (0)	2 (2)
	Week 26	0 (0)	3 (3)
Other	Baseline	1 (1)	2 (2)
	Week 6	0 (0)	1 (1)
	Week 26	0 (0)	6 (6)

Data are the number of reported medications used by participants. NSAID with opioid refers to any NSAID-opioid combination medicine. Paracetamol with opioid refers to any paracetamol-opioid combination. Other refers to Antihypertensive, cholesterol lowering, topical gels and creams, alternative medicines or supplements e.g. glucosamine, calcium channel blocker, herbal medicine (unspecified), folic acid, fish oil, and emu oil.
Abbreviations: NSAID=non-steroidal anti-inflammatory drug.
*Sample size at baseline n=159 (79 intervention, 80 control), 6 weeks=132 (60 intervention, 72 control), 26 weeks n=94 (38 intervention, 56 control).

Table S4: Post hoc analyses of pain intensity

Analysis	Outcome	Intervention mean (95%CI) (n=23)	Control mean (95%CI) (n=80)	Mean difference* (95%CI)	p value
Primary (ITT, MI)	Area under the pain intensity curve (AUC)	154·3 (137·9 to 170·7)	163·4 (153·9 to 172·8)	9·0 (-10·1 to 28·2)	0·35
Secondary	Pain intensity score	**Intervention mean (SD) (n=23)**	**Control mean (SD) (n=80)**	**Mean difference* (95%CI)**	**p value**
	Baseline	6·7 (1·4)	6·8 (1·6)		
	Week 2	6·4 (1·9)	6·4 (1·9)	-0·0 (-0·9 to 0·9)	0·92
	Week 6	6·3 (2·4)	6·2 (2·1)	-0·1 (-1·0 to 0·8)	0·79
	Week 10	5·8 (2·7)	6·4 (2·0)	0·6 (-0·3 to 1·5)	0·21
	Week 14	6·3 (2·2)	6·8 (1·8)	0·5 (-0·4 to 1·4)	0·31
	Week 18	5·9 (2·1)	6·5 (1·8)	0·6 (-0·4 to 1·5)	0·24
	Week 22	5·8 (2·7)	6·2 (2·0)	0·4 (-0·5 to 1·3)	0·44
	Week 26	5·2 (2·9)	6·3 (2·4)	0·9 (-0·0 to 1·9)	0·05
	Monthly trend			0·14 (-0·05 to 0·33)	0·16

Abbreviations: ITT=Intention to treat, MI= Multiple Imputation, AUC= Area under the curve
*Mean difference= control-intervention

Table S5: Post hoc analyses of subjective weight

Outcome	Time point	Intervention (n=23)	Control (n=80)	
		Mean(SD)	**Mean(SD)**	**Mean difference* (95% CI)**
Subjective weight	Baseline	97·7 (17·5)	90·8 (14·6)	
	Week 6	98·6 (17·7)	90·2 (15·0)	-0·9 (-3·1, 1·4)
	Week 26	99·2 (18·4)	93·3 (16·8)	1·1 (-1·4, 3·5)

*Mean difference= control-intervention, adjusted for baseline values