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Running is acceptable and efficacious in adults with non-specific chronic low back pain: the ASTEROID randomised controlled trial

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ABSTRACT

Objectives: Running is one of the most accessible forms of exercise, yet its suitability for adults with chronic low back pain (LBP) is unknown. This study assessed the efficacy and acceptability of running in adults with chronic LBP.

Methods: This two-arm parallel (1:1) individually randomised controlled trial allocated 40 participants (mean [SD] age: 33 [6] years, female: 50%) with non-specific chronic LBP to a 12-week intervention or waitlist control. The intervention was a progressive run-walk interval program comprising three 30-minute sessions per week, that were digitally delivered and remotely supported by an exercise physiologist. Efficacy outcomes were self-reported pain intensity (100-point visual analogue scale) and disability (Oswestry Disability Index). Acceptability outcomes were attrition, adherence and adverse events.

Results: At 12-week follow-up, the intervention improved average pain intensity (mean net difference [95%CI]: -15.30 [-25.33, -5.27] points, P=0.003), current pain intensity (-19.35 [-32.01, -6.69] points, P=0.003) and disability (-5.20 [-10.12, -0.24] points, P=0.038), compared to control. There was no attrition and mean (SD) training adherence was 70% (20%; i.e. 2.1 of 3 sessions per week). Nine non-serious adverse events deemed likely study-related were reported (lower limb injury/pain: n=7, syncope associated with an underlying condition: n=1, LBP: n=1).

Conclusions: A run-walk program was considered an acceptable intervention by participants to improve pain intensity and disability in individuals aged 18-45 years with non-specific chronic LBP when compared to control. An individualised and conservative run-walk program should be considered a suitable form of physical activity for adults with chronic LBP.

SUMMARY BOX

What is already known on this topic: Recreational running is associated with lower rates of low back pain and healthier spinal tissue. However, it is unclear if running is acceptable or effective for individuals with pre-existing low back pain.

What this study adds: A 12-week run-walk interval training program was acceptable and efficacious for reducing pain intensity and disability in individuals aged 18-45 years with chronic low back pain.

How this study might affect research, practice or policy: Given the potential health benefits, running should be considered a suitable form of exercise training for adults with chronic low back pain. More research is needed to confirm the efficacy of running training to treat low back pain and provide clinically meaningful improvement.

INTRODUCTION

Low back pain (LBP) is a major healthcare challenge affecting 7.5% of people worldwide[1] and is responsible for an estimated 69 million years lived with a disability (i.e. healthy years lost).[2] Chronic LBP (i.e. pain ≥12 weeks) often involves substantial individual burden, with higher levels of disability, reduced physical activity and poorer aerobic fitness, compared to pain-free controls.[3–5] Exercise training is recommended as treatment in individuals with chronic LBP to reduce pain intensity and disability and minimise the negative health consequences of the condition.[6] Aerobic exercise improves pain intensity, disability and mental health in individuals with LBP.[7] However, commonly studied aerobic interventions, such as walking, may not provide sufficient intensity to optimise improvements in pain intensity and disability similar to that seen in other active interventions (e.g. resistance training).[8]

In individuals with chronic LBP, high-intensity exercise training (i.e. ≥85% VO_{2max} or heart rate reserve) is associated with greater improvements in disability, aerobic capacity and training adherence than moderate-intensity exercise.[9–11] However, most evidence on high-intensity aerobic exercise in individuals with LBP pertains to cycling interventions.[9–12] This bias towards cycling over running interventions may be due to a perceived stigma amongst individuals with chronic LBP that running is unsafe compared to lower impact exercise such as swimming and cycling.[13] Despite these safety concerns, recreational runners have lower rates of LBP and healthier spinal tissue than non-runners.[14,15] Additionally, running is an inexpensive and highly accessible form of aerobic activity popular amongst adults (e.g. ranked the third most popular physical activity in Australia).[16] As such, running has been proposed as an intervention for individuals with LBP that may lead to reduced pain intensity and better health outcomes.[17,18]

Only two randomised controlled trials (RCT) have compared a running intervention to a control group or other active intervention in individuals with LBP.[19,20] In an RCT of 320 retired athletes (mean [SD] age: 37.6 [5.4] years) with non-specific chronic LBP, six months of running (30 minutes, five days per week) led to within-group reductions in pain intensity, yet was less effective than tai chi and no different to a non-exercise control.[20] However, no details were provided regarding the running intervention other than frequency. Furthermore, all groups received concurrent 'hands-on' treatment consisting of massage, adjustments and acupuncture, making it difficult to ascertain the benefits and harms of completing a running program in isolation.[20] In a second pilot RCT (n=20) designed to test the effect of high-intensity aerobic exercise in adults with non-specific chronic LBP (mean [SD] age: 42.4 [12.7] years), 12 weeks of supervised treadmill running (30-50 minutes, three times per week at 85% heart rate reserve) led to greater within-group reductions in pain and disability than electrotherapy treatment (ultrasound, transcutaneous electrical nerve stimulation or laser).[19] These results are promising; however, the certainty of between-group differences is limited given the small sample size. Both RCTs[19,20] provided limited information on attrition and adverse events, which is necessary to assess the acceptability of a running intervention.

Prior studies provide preliminary evidence that a running intervention may be acceptable for individuals with chronic LBP; however, limited reporting of adverse events and attrition, and the lack of a true no-treatment control prevent confirmation of treatment efficacy and acceptability. Additionally, it is unclear whether these findings can be generalised to more accessible forms of running, such as unsupervised, overground running (i.e. not on a treadmill). This study aimed to assess the efficacy (subjective pain intensity and disability) and acceptability of a digitally-delivered and community-based running intervention in individuals with chronic LBP compared to waitlist control.

METHODS

Trial design

This two-arm parallel (1:1) 12-week RCT examined the efficacy and acceptability of a digitally delivered progressive run-walk interval training program compared to waitlist control in adults (n=40) with non-specific chronic LBP. The full study protocol is described in detail elsewhere;[21] no changes were made to the methods after trial commencement. Data collection was completed at Imaging @ Olympic Park (Melbourne, Australia), where all participants completed online questionnaires (v13.8.2, REDCap, Nashville, United States of America) at baseline, 6- and 12-week follow-up. Ethics approval was granted by Deakin University Human Research Ethics Committee (ID: 2022-162) on 26 September 2022. Participants provided written informed consent prior to participating in the study, which was conducted in line with the Declaration of Helsinki. This study is reported in line with the Consolidated Standards of Reporting Trials (CONSORT) Statement (Supplemental File 1).[22]

Participants

Adults aged 18-45 years with non-specific chronic LBP (≥3 months; experienced on most days in an average week, with or without leg pain) were recruited from the Melbourne metropolitan region via web-based advertising.[21] Participants who registered their interest through the study website were screened via phone to assess eligibility. Exclusion criteria consisted of: (a) history of spinal surgery, spine trauma (e.g. fracture or motor vehicle accident), cauda equina symptoms, known structural scoliosis requiring surgical consultation, symptomatic radiculopathy (diagnosed via medical professional or leg pain greater than back pain),

inflammatory spondyloarthropathies, or non-musculoskeletal causes of LBP (e.g. infection, visceral pain), (b) inability to communicate in English, (c) pregnancy, lactating or less than 1-year postnatal, (d) current or prior elite athletes (e.g. member of Australian Institute of Sport, State Institutes or Academies of Sport or the national squad of any sport),[23] (e) any absolute contraindications for magnetic resonance imaging, (f) participation in running or sport that involves running in the last three months (>1 session per month), (g) having experienced a lower limb injury in the last six weeks, (h) any absolute contraindications for exercise training or deemed higher risk of adverse event due to physical activity per the Adult Pre-Exercise Screening System,[24] and (i) unable to access or operate a smartphone with a cellular internet connection.

Intervention

Participants randomised to exercise training were prescribed three 30-minute exercise training sessions per week over 12 weeks (36 total sessions) by an accredited (Exercise and Sports Science Australia) exercise physiologist from the research team.[21] Training sessions were self-directed, completed in the local community and consisted of a progressive interval-based run-walk training program preceded by an optional 5-minute warm-up of mobility exercises (Supplemental File 2). Run-walk training data were captured using Runkeeper (v14.7, ASICS Runner App, Boston, United States of America), a fitness app that uses global positioning system to track the location and pace of users. The participants received support and guidance during brief 10-15-minute video consultations (Zoom Video Communications, California, United States of America), weekly (weeks 1-4) and fortnightly (weeks 6-12). Participants could also contact the exercise physiologist as required outside of these scheduled appointments via phone or text messaging. Throughout the intervention, participants received educational

content, delivered via email using REDCap, covering the following topics: (a) ideal running speed, (b) footwear selection, (c) the safety of running, and (d) dealing with setbacks (Supplemental File 3). Participants were recommended to complete training sessions on a flat track without large hills. No restrictions were provided regarding the type of training surface (e.g. dirt, grass, paved). In addition to the intervention, participants could manage their LBP as usual (e.g. general practitioner management, over-the-counter pharmacotherapy) and engage in other physical activity if desired.

The exercise training program consisted of short running intervals interspersed with rest periods of walking (Table 1). Participants started the program at stage one, two or three as determined by their tolerance to a 2-minute run test during the initial physical assessment. During this test, participants were instructed to run at a slow to moderate pace for as long as they were comfortable, up to a maximum of two minutes. Participants who could jog comfortably for (a) 0-44 seconds started at stage one of the program; (b) 45-89 seconds started at stage two of the program; and (c) 90-120 seconds started at stage three of the program. Participant could also self-select their starting stage (one, two or three) if desired. During each training session, participants self-selected their chosen number of repeats to complete (between 6 and 10). Participants progressed to the next stage (maximum one stage per week) if they could complete the upper repeat range (i.e. ten repeats) and completed at least two training sessions that week. In collaboration with the exercise physiologist, participants also had the option to remain at the current stage or regress to a lower stage of the interval program if deemed necessary (e.g. significantly increased LBP, other injury/soreness, following periods of poor adherence). Throughout the intervention, participants were advised to jog at a slow to moderate speed (10 km/h) during the running portion of the training session and to walk at a self-selected pace between each bout. Running speeds between 7-8km/h have been shown to

correspond with high-intensity exercise zones (i.e. ≥85% VO_{2max} or heart rate reserve) in adults with non-specific chronic LBP.[19,25]

Waitlist control

Participants randomised to control were asked to manage their LBP as usual (e.g. general practitioner management, over-the-counter pharmacotherapy) and avoid commencing a running program.[21] Otherwise, no restrictions on physical activity were imposed. Following completion of the study, waitlist participants were offered the same exercise training program and 1-on-1 consultation with an exercise physiologist as per the intervention group.

Outcomes

The pre-specified primary outcomes of average pain intensity and disability[21] were recorded at baseline, six weeks and 12 weeks electronically via online questionnaire (REDCap) in addition to the habitual physical activity. Data relating to the co-primary outcome of lumbar intervertebral disc T2 will be reported elsewhere given the nuanced steps involved in the acquisition and processing of these images. Secondary outcomes pertaining to acceptability were recorded throughout the intervention. The run distance, speed and surface (grass, gravel, paved, trail or mixed) of each training session were recorded using Runkeeper, which participants accessed via their smartphone.

Pain intensity

Current, average and worst LBP intensity was measured on a 100-point visual analogue scale (VAS) with endpoints representing "no pain" (0 points) and "worst pain imaginable" (100 points).[26] Average and worst LBP intensity were based on the last seven days. The VAS demonstrates excellent test-retest reliability when measuring pain intensity (ICC=0.90).[27] A 20-point reduction was considered the minimum clinically meaningful difference.[28]

Disability

The Oswestry Disability Index measures self-reported disability due to LBP.[29] Questions are rated from 0-5 points, with higher scores indicating greater disability due to LBP. The total score (0-50 points) is doubled and represented as a score out of 100. The Oswestry Disability Index has good to excellent test-retest reliability (ICC=0.84-0.94).[30] A 10-point reduction was considered the minimum clinically meaningful difference.[31]

Habitual physical activity

Habitual physical activity was measured using the International Physical Activity Questionnaire.[32] The questionnaire asks about the frequency/duration of vigorous and moderate intensity physical activity, walking and sitting over the past seven days. Total weekly physical activity was calculated by weighting each type of activity by its energy requirement in metabolic equivalent to produce a score in metabolic equivalent (MET) minutes.[32]

Acceptability

The following acceptability data were documented throughout the study via REDCap: recruitment ([1] enrolled participants compared to total screened potential participants, [2] reasons for ineligibility or declined participation, [3] enrolment timeline, [4] advertising spend, strategy, engagement and results), attrition ([1] number of participants available for follow-up, [2] reasons for loss to follow-up), adherence ([1] overall training session attendance, [2] weekly training volume completed), and combined usability of Runkeeper and the run-walk program (10-item System Usability Scale).[33]

Adverse events

The number, seriousness and nature of adverse events were recorded throughout the intervention, with participants instructed to inform the research team immediately should any adverse event occur. Moreover, participants allocated to exercise training were asked about adverse events during the weekly/fortnightly video call with an exercise physiologist from the study team. Serious adverse events were defined as any untoward medical occurrence that resulted in death, was life-threatening or required hospitalisation.[34] Non-serious adverse events were defined as any other untoward medical occurrence, such as increased pain or injury that resulted in a missed training session. Adverse events were classified as likely study-related if they were deemed definitely, probably or possibly related to the exercise training intervention.

Sample size

The sample size of 40 participants (n=20 per group) was based on *a priori* statistical power calculations and adjustment for attrition to detect the smallest between-group net differences of interest in pain intensity and disability.[21] To detect a between-group net difference in pain

intensity of d=1.00 based on a clinically meaningful change of 20 mm,[28] SD of 20 mm[35] and test-retest reliability of r=0.57,[27] 16 total participants were required (n=8 per group). To detect a between-group net difference in disability of d=0.52 based on a clinically meaningful change of 10 points,[36] SD of 19.2 points[37] and test-retest reliability of r=0.83,[36] 20 total participants were required (n=10 per group). All power calculations were conducted using G*Power (version 3.1.9.7).[38]

Randomisation

Participants were randomly assigned to either exercise training or waitlist control (1:1) using block randomisation with random block lengths (2-6 per block) and stratification for sex using the 'blockrand' package in R (v4.1.2, The R Foundation, Vienna, Austria).[39] An author with no participant contact (SDT) created and employed the randomisation schedule using sequentially numbered, opaque, sealed envelopes.

Blinding

Given the nature of the intervention, neither participants nor team members administering the intervention were blinded to treatment allocation. Given the primary outcomes of interest were subjective pain intensity and disability, the participant was considered the assessor; therefore, it was not possible to blind the outcome assessor in this analysis.

Statistical methods

All analyses were conducted using Stata (v17, StataCorp, College Station, United States of America). Separate linear mixed models with random effects (participants) were used to evaluate within- and between-group (intervention and control) changes in efficacy outcomes (pain intensity and disability) over time. All linear mixed models employed restricted maximum likelihood estimations and adopted an intention-to-treat approach.[40] An α of 0.05 was adopted for all analyses. The statistical analysis and presentation are consistent with the CHecklist for statistical Assessment of Medical Papers (CHAMP) statement.[41]

Equity, diversity, and inclusion statement

Our author team comprised seven women and nine men, including junior, mid-career and senior researchers from a variety of disciplines and located across four countries in Australasia, North America and Europe. The study population included equal numbers of women and men with non-specific chronic LBP from Melbourne, Australia. We did not purposefully recruit people from marginalised communities.

RESULTS

Participant flow

Collectively, 322 individuals registered their interest in the study from October 2022 to January 2023 and 155 were screened for eligibility. Of those, 94 (60.6%) did not meet the inclusion criteria and 21 declined to participate (Figure 1). Forty participants (female: n=20; male: n=20) were randomised to the exercise intervention or waitlist control. No participants withdrew from the study.

Recruitment

This study was conducted from December 2022 to May 2023. The trial ended when all recruited participants finished the 12-week follow-up period. A total of AU$887.83 was spent on social media advertising (Facebook and Instagram) over 32 days, resulting in 152,250 impressions and 1,889 link clicks at AU$0.47 per click. Audience targeting was limited to adults aged 18-45 years old living within a 37km radius of our data collection site (Imaging @ Olympic Park, Melbourne, Australia). From 322 expressions of interest, most reported hearing of the study via Facebook or Instagram (87%), followed by 'online' (5%), a friend (5%), Deakin University (e.g. student or past participant; 2%) or a health professional (1%).

Baseline data

The descriptive characteristics of participants at baseline are presented in Table 2. Mean (SD) age at baseline was 32.8 (6.2) years, average LBP intensity was 39.7 (21.1) points (moderate

pain),[42] disability was 22.0 (9.1) points (moderate disability)[29] and habitual physical activity was 3273 (5750) MET-minutes. Fewer than half (45%) reported having previously run for exercise or fitness prior to their back injury and among those that did, the longest they had previously run was 11.1 (9.8) km.

Acceptability and adherence

Mean (SD) training adherence was 70.4% (20.4%), equivalent to 2.1 out of 3 sessions per week, running speed was 9.5 (1.8) km per hour and running distance (i.e. not including walking) was 2.0 (1.2) km per session, increasing from 1.1 (0.4) to 2.7 (1.6) km per session from week one to week 12 (Figure 2). This equated to a total of 105 hours spent running across the intervention group. Runs were most often completed on paved surfaces (57%), followed by grass (16%), gravel (12%), trail (9%) and mixed (6%) surfaces. Participants reported high system usability towards Runkeeper and the run-walk program with a mean (SD) score of 94.5 (8.6) points out of 100.

Outcomes and estimation

Changes in pain intensity and disability are presented in Table 3. Between-group differences favouring the intervention group (better health outcomes) were detected for average pain intensity at six (β [95% CI]: -10.17 [-20.29, -0.05] points, P=0.049) and 12 weeks (-15.30 [-25.33, -5.27] points, P=0.003), current pain intensity at 12 weeks (-19.35 [-32.01, -6.69] points, P=0.003) and disability at 12 weeks (-5.20 [-10.12, -0.24] points, P=0.038).

From baseline to six weeks, mean (95% CI) within-group average pain intensity (-11.50 [-18.59, -4.41] points; P=0.001), current pain intensity (-14.45 [-23.40, -5.50] points; P=0.002), worst pain intensity (-10.35 [-18.03, -2.67] points; P=0.008) and disability (-4.60 [-8.08, -1.12] points; P=0.010) decreased in the intervention group only. Similarly, from baseline to 12 weeks, mean (95% CI) within-group average pain intensity (-15.00 [-22.09, -7.91] points; P<0.001), current pain intensity (-16.55 [-25.50, -7.60] points; P<0.001), worst pain intensity (-14.65 [-22.33, -6.97] points; P<0.001) and disability (-6.90 [-10.38, -3.42] points; P<0.001) decreased in the intervention group only.

Adverse events

Nine adverse events deemed likely study-related were reported across nine individuals and 105 hours spent running in the intervention group (Supplemental Table 1), of which all were non-serious; seven (78%) were related to lower limb injury/pain (knee or ankle), one (11%) to cardiac syncope associated with an underlying condition and one (11%) to an increase of LBP. Study-related adverse events accounted for a total of 20 missed training sessions (2 training sessions per adverse event; range: 1-3 training sessions), with all except one participant returning to running within a week of experiencing a study-related adverse event.

DISCUSSION

In adults with non-specific chronic LBP, a 12-week progressive run-walk interval training program resulted in reductions in average pain intensity, current pain intensity and disability compared to waitlist control. Moreover, there was no attrition and high adherence to the exercise program. While nine adverse events deemed likely study-related were reported in the intervention group, only one was related to an increase in LBP, and all participants returned to training with an average of only two to three missed running sessions.

This study is the first to compare a running-based intervention to a true no-treatment control in individuals with non-specific chronic LBP, with findings indicating that a run-walk intervention may be effective for reducing pain intensity and disability despite between-group differences not reaching clinically meaningful cut-off scores. Results of a similar magnitude were shown in a previous study of 20 individuals with chronic LBP, whereby three months of continuous treadmill running resulted in greater within-group reductions in pain intensity (-21.6 points; McGill Pain Questionnaire, range: 0-78 points) and disability (-4.2 points; Roland-Morris Disability Questionnaire, range: 0-24 points) compared to electrotherapy.[19] In contrast, Weifen et al.[20] showed that six months of 'jogging' was less effective than tai-chi and no different to a non-exercise control group for pain intensity in individuals with chronic LBP. A key difference in this latter study is that both intervention and control groups received concurrent 'hands-on' passive treatment consisting of massage, adjustments and acupuncture. Despite a within-group pain intensity reduction of 19.8 points (100-point scale) in the running group, the unknown interaction between running and 'hands-on' treatment makes it difficult to determine the effect of the exercise component. While the most optimal running protocol for people with non-specific chronic LBP is yet to be determined, these collective findings

demonstrate early efficacy and confirm the need for further research into this highly accessible and inexpensive mode of exercise training.

The run-walk interval training program in the current study was deemed acceptable, as evidenced by the high adherence, strong recruitment pathways and a lack of attrition. Acceptability was supported by the digital platform used to deliver and monitor exercise prescription, rated very highly by participants on system usability. Despite this, adherence in the current study was lower than in two prior RCTs in individuals with chronic LBP,[19,25] which reported 90% and 98% adherence to a continuous running program; however, these interventions were completed in person while the current study was digitally delivered and remotely supported, which may in part account for this difference. Notably, a systematic review of 11 studies found that supervised exercise results in better adherence than non-supervised training in adults with chronic LBP.[43] Among digitally delivered beginners running programs for the general population, other 9-, 10- and 13-week studies have reported similar or lower adherence than the current results with rates of 70%,[44] 53%[45] and 66%,[46] respectively. This indicates that a digitally delivered, community-based run-walk intervention is acceptable for adults aged 18-45 years with non-specific chronic LBP and pain should not be a barrier to participating in running at rates similar to individuals without LBP.

In addition to adequate adherence, the run-walk intervention in the current study appeared safe for individuals with non-specific chronic LBP, with only one LBP-related adverse event deemed likely study-related from a total of 105 hours spent running. However, there were seven reported adverse events deemed likely study-related, which involved lower limb injury/pain and one report of syncope (associated with an underlying cardiac condition first experienced after screening). An average of only 2 sessions were missed per adverse event (20 missed

sessions total from a cohort of 20 participants) and most were resolved within one week. All prior studies utilising a running intervention in individuals with LBP have not reported on adverse events.[19,20,25] However, similar results were seen in a 10-week beginners run-walk interval program for healthy individuals, whereby 34 participants missed 39 sessions due to injury.[45] In a larger study, 33% of 141 healthy individuals reported sustaining an injury throughout a 9-week beginners run-walk program.[44] This is slightly less than 45% of participants reporting an adverse event in our study, albeit over a 12-week intervention. Despite limited evidence, these results combined suggest that individuals with non-specific chronic LBP have a similar risk of injury completing a run-walk program as the general population. Additionally, with most adverse events resolving within one week, there appeared to be no detrimental impact on program progression or attrition. Regardless, consideration should be given to preventing lower limb pain or injury when undertaking a run-walk program in individuals with non-specific chronic LBP. Additionally, future research into running interventions for non-specific chronic LBP may explore the effect of adding gait retraining, as this is shown to lower ground impact forces and reduce injuries in novice runners.[47] Overall, these findings suggest that running is both acceptable and safe for adults with non-specific chronic LBP. Given the potential health benefits,[48] run-walk interval training should be considered a suitable form of physical activity for individuals with non-specific chronic LBP who are interested in running or have previously avoided running due to safety concerns.

Clinical implications

Despite appearing safe, it is unclear if running should be used as part of treatment for individuals with non-specific chronic LBP. The reductions in pain intensity and disability observed in our intervention group approached, yet did not reach, pre-defined minimum

clinically meaningful cut-off scores (i.e. a decrease of 20 points[49] for pain intensity or 10 points[31] for disability). We do, however, acknowledge that the magnitude of the effect sizes we established a priori to serve as thresholds for clinical meaningfulness were large and potentially unlikely to be detected following exercise interventions and within adults with non-specific chronic LBP with low baseline values, such as those observed in our current study. Our study was the first to test the acceptability of a run-walk interval training program in individuals with non-specific chronic LBP, with previous studies utilising continuous running interventions.[19,20,25] Therefore, a conservative starting volume (running duration) and gradual stage progressions were chosen to allow participants adequate time to adapt to the training stimulus. In a systematic review of 17 trials comparing various modes of aerobic exercise training in adults with chronic LBP,[50] higher frequency (≥5 days per week) and longer duration (≥12 weeks) interventions were more likely to result in clinically meaningful changes to pain intensity and disability than lower dose programs. Therefore, it is possible that utilising a higher training load in the current study could have led to greater improvements in pain intensity and disability. A higher training load could be achieved by extending the intervention (e.g. six months) and utilising a similar conservative protocol over the first three months before increasing the training load thereafter. By comparing run-walk interval training programs completed at various intensities, volumes and rates of progression, future studies can assess if a greater stimulus can achieve a clinically meaningful effect without compromising attrition, adherence or safety. While these results fall short of evidence to support recommending conservative run-walk interval training programs to reduce non-specific chronic LBP, this intervention may be considered part of an overall treatment plan for adults with non-specific chronic LBP.

Limitations

Overall, our results provide promising new findings that are strengthened by the use of validated outcome measures, zero attrition and an intervention that clinicians can readily implement in clinical practice. However, the study is not without limitations. First, participants in the intervention group reported average pain intensity of 33.5 points at baseline (i.e. mild pain, ≤34 points).[42] In contrast, the average pain intensity of adults with non-specific chronic LBP across 89 exercise interventions included in a recent network meta-analysis[7] was 49.9 points at baseline (i.e. moderate pain, 35-74 points).[42] It is unclear how a cohort with moderate or severe average pain intensity would respond to a run-walk interval training program or if it would be acceptable. Future studies would benefit from setting stricter inclusion criteria to ensure a higher average baseline pain intensity and more generalisable findings to adults with non-specific chronic LBP. Second, compared to the intervention group, who met weekly or fortnightly with an exercise physiologist over the 12 weeks, the control group did not have contact with the researchers between testing sessions (baseline, 6 and 12 weeks). Therefore, we cannot quantify the non-specific effects of the intervention due to regular coaching and support, which are likely small, yet clinically important.[51] Future studies comparing a run-walk intervention should include an active control to minimise performance bias and determine whether running should be considered alongside current treatment options for non-specific chronic LBP. Third, study volunteers likely responded to the advertisement due to a pre-existing preference for running, which may have influenced results. However, fewer than half of the participants reported having previously run for exercise or fitness prior to their back injury. Therefore, the impact on results due to recruitment bias was likely minimal. Fourth, our results are specific to interval-based running in adults aged 18-45 years and may not be generalisable beyond this age range. For example, it is unclear how older adults with non-specific chronic LBP that is exacerbated with extension (e.g. lumbar stenosis) would respond

538 to an interval-based running program. Fifth, it is unclear if a lack of regression to the mean (i.e.
539 no change from baseline to follow up) in the control group may have inflated the true
540 intervention effect. Reductions in pain intensity at follow up due to regression to the mean are
541 likely to be present when LBP participants are care seeking due to higher than average levels
542 of pain intensity (e.g. in healthcare settings).[52] In contrast, exercise interventions where
543 participants are required to undertake conceptually challenging tasks (e.g. running) are less
544 likely to recruit participants with higher than average pain levels. This is evidenced by a lower
545 average baseline pain intensity in our study compared to that seen in other exercise trials.[7]
546 Therefore, the lack of regression to the mean in the control group observed in our study likely
547 reflects a true lack of treatment effect. Finally, these results pertain to individuals with non-
548 specific chronic LBP. Individuals with acute LBP are recommended to maintain regular
549 physical activity to optimise recovery.[6] However, there are currently no guidelines to indicate
550 when it is safe to return to running or run-walk interval training following a new occurrence of
551 LBP. To minimise the risk of injury or pain 'flare', we recommend individuals with
552 non-specific chronic LBP work closely with a suitably qualified health professional (e.g. an
553 exercise physiologist or physiotherapist) when returning to running or commencing a new
554 exercise training program.

CONCLUSION

A digitally delivered and remotely supported 12-week progressive run-walk intervention was deemed acceptable and may improve pain intensity and disability in adults with non-specific chronic LBP. Running appeared safe, with no attrition, minimal risk of increasing LBP and a similar overall risk of adverse event compared to the general population. While it is unclear if running should be used to treat non-specific chronic LBP, given the potential health benefits, a conservative run-walk program likely represents a suitable form of exercise training for individuals with non-specific chronic LBP who enjoy running or have avoided running in the past due to safety concerns.

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Conflicts of interest

The authors declare that they have no competing interests.

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Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

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TABLES

Table 1. Interval training program.

Stage	Run interval (seconds)	Walk interval (seconds)	Repeats		Total session time (minutes)		Total running time per session (minutes)		Total running time per week (minutes)*	Increase in weekly running time from previous week
			Lower	Upper	Minimum	Maximum	Minimum	Maximum		
1^	15	120	6	10	13.5	22.5	1.5	2.5	4.5	NA
2^	30	120	6	10	15	25	3	5	9	100.00%
3^	45	115	6	10	16	26.7	4.5	7.5	13.5	50.00%
4	60	90	6	10	15	25	6	10	18	33.33%
5	75	75	6	10	15	25	7.5	12.5	22.5	25.00%
6	90	60	6	10	15	25	9	15	27	20.00%
7	105	45	6	10	15	25	10.5	17.5	31.5	16.67%
8	120	45	6	10	16.5	27.5	12	20	36	14.29%
9	135	45	6	8	18	24	13.5	18	40.5	12.50%
10	150	30	6	8	18	24	15	20	45	11.11%
11	165	30	6	8	19.5	26	16.5	22	49.5	10.00%
12	180	30	6	8	21	28	18	24	54	9.09%
13	180	15	6	8	22.5	30	18	24	54	0.00%

^ Participants started at stage one (n=3), two (n=3) or three (n=14) depending on baseline running capacity and progressed to the next stage once they completed the upper repeat range. * Total running time per week was calculated based on three sessions per week at the lower repeat range. NA: not applicable.

Table 2. Descriptive characteristics of participants at baseline randomised to the run-walk intervention or control.

	Intervention (n=20)	**Control (n=20)**
Age, years	33.6 (5.3)	32.2 (7.0)
Female, n (%)	10 (50)	10 (50)
Pain, visual analogue scale (0-100)		
Current	30.8 (23.3)	40.1 (20.9)
Average [a]	33.5 (20.6)	46.0 (20.1)
Worst [a]	50.6 (22.5)	65.9 (17.9)
Disability, Oswestry Disability Index (0-100)	20.8 (8.5)	23.1 (9.7)
Low back pain duration, years [b]	3.2 (2.8)	4.9 (5.8)
Body mass index	29.6 (6.9)	29.0 (7.5)
Habitual Physical Activity, IPAQ	2281 (2599)	4265 (7683)
Employment status, n (%)		
Employed	18 (90)	18 (90)
Unemployed	2 (10)	1 (5)
Homemaker	0 (0)	1 (5)
Retired	0 (0)	0 (0)
Smoking status, n (%)		
Current	2 (10)	0 (0)
Former	1 (5)	3 (15)
Never smoked	17 (85)	17 (85)

Data are mean (SD) or count (percentage within-group). [a] Average and worst low back pain intensity over the last seven days. [b] Duration since onset of current episode of low back pain. IPAQ: International Physical Activity Questionnaire – short form.

Table 3. Changes in pain intensity and disability over time.

	Intervention (n=20)			Control (n=20)			Group-by-time	
Variable	**Mean (SE)**	**Δ Mean (95% CI)**	**P**	**Mean (SE)**	**Δ Mean (95% CI)**	**P**	**β (95% CI)**	**P**
VAS, current								
Baseline	30.80 (4.37)			40.10 (4.37)				
6-week	16.35 (4.37)	-14.45 (-23.40, -5.50)	**0.002**	36.03 (4.46)	-4.07 (-13.18, 5.04)	0.381	-10.38 (-23.15, 2.39)	0.111
12-week	14.25 (4.37)	-16.55 (-25.50, -7.60)	**<0.001**	42.90 (4.37)	2.80 (-6.15, 11.75)	0.540	-19.35 (-32.01, -6.69)	**0.003**
VAS, average								
Baseline	33.50 (3.87)			45.95 (3.87)				
6-week	22.00 (3.87)	-11.50 (-18.59, -4.41)	**0.001**	44.62 (3.93)	-1.33 (-8.55, 5.89)	0.718	-10.17 (-20.29, -0.05)	**0.049**
12-week	18.50 (3.87)	-15.00 (-22.09, -7.91)	**<0.001**	46.25 (3.87)	0.30 (-6.79, 7.39)	0.934	-15.30 (-25.33, -5.27)	**0.003**
VAS, worst								
Baseline	50.55 (4.61)			65.85 (4.61)				
6-week	40.20 (4.61)	-10.35 (-18.03, -2.67)	**0.008**	60.74 (4.67)	-5.11 (-12.93, 2.70)	0.200	-5.24 (-16.19, 5.72)	0.349
12-week	35.90 (4.61)	-14.65 (-22.33, -6.97)	**<0.001**	59.50 (4.61)	-6.35 (-14.03, 1.33)	0.105	-8.30 (-19.16, 2.56)	0.134
ODI								
Baseline	20.80 (2.12)			23.10 (2.12)				
6-week	16.20 (2.12)	-4.60 (-8.08, -1.12)	**0.010**	20.83 (2.15)	-2.72 (-5.81, 1.27)	0.209	-2.33 (-7.29, 2.63)	0.358
12-week	13.90 (2.12)	-6.90 (-10.38, -3.42)	**<0.001**	21.40 (2.12)	-1.70 (-5.18, 1.78)	0.338	-5.20 (-10.12, -0.24)	**0.038**

Data are sample size, estimated marginal mean (SE), within-group mean change (Δ) from baseline (95% CI), within-group P-value, group-by-time β coefficient (95% CI) and group-by-time P-value from linear mixed models. Observed mean (SD) are presented in Supplemental Table 2. ODI: Oswestry Disability Index; VAS: visual analogue scale.

FIGURES

Figure 1. CONSORT participant flow diagram. MRI: magnetic resonance imaging.

Figure 2. Mean (SD) distance (km) run per training session (i.e. does not include walking distance). Grey lines represent individual participant data, with gaps between lines indicating zero adherence in the respective weeks.