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Extended Research Article

Supporting self-management with an internet intervention for low back pain in primary care: a RCT (SupportBack 2)

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Scientific summary

Supporting self-management with an internet intervention for low back pain in primary care: a RCT (SupportBack 2)

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Scientific summary

Background

Low back pain (LBP) is highly prevalent and causes substantial disability. First-line recommendations for those with LBP are to remain active and to self-manage. However, behavioural self-management can be complex. Widely accessible, effective support for self-management is needed to ensure that those with LBP can rapidly access optimal care. Internet interventions, accessible from any device with an internet connection, may provide a means of delivering behavioural self-management support for LBP in UK primary care. Where internet interventions have been delivered previously, remote healthcare professional (HCP) support has been shown to increase the effectiveness. As this HCP element adds costs, it is important to determine if it is necessary in the delivery of internet interventions for LBP.

Objectives

1. To determine the clinical and cost-effectiveness of an internet intervention provided with and without physiotherapist telephone support, on LBP-related disability compared to usual care, in a UK primary care setting.
2. To use a mixed-methods process evaluation to explore issues with the implementation of the interventions, potential mechanisms and contextual factors affecting outcomes.

Methods

The study design was a three parallel-arm, multicentre randomised controlled trial with a nested mixed-methods process evaluation. The study was set in UK primary care. Inclusion criteria were as follows: patients over the age of 18, experiencing current LBP with or without sciatica, with access to the internet and the ability to read or understand English without assistance and provide informed consent. Exclusion criteria: indicators of serious spinal pathology, spinal surgery with the past 6 months and pregnancy. Participants were recruited via list searches, or opportunistically through automated electronic pop-ups triggered in consultations, or where pop-up technology was not implemented, through recruitment packs provided within appropriate consultations.

The three trial arms comprised: (1) Usual care for LBP, which included the option for unrestricted range of care including general practitioner consultations, medication and all referrals or to pain clinics. (2) Usual care for LBP as described, and access to the 'SupportBack' internet intervention. SupportBack was primarily a six-session internet intervention (accessible from any device with an internet connection), designed to provide accessible behavioural support for the self-management of LBP. The focus was on increasing activity, including walking and gentle back exercises. The intervention also included a range of modules on LBP-related topics, such as mood, work, sleep and flare-ups. (3) Usual care for LBP, access to the internet intervention, plus up to three brief telephone calls from a physiotherapist. The calls were designed to address concerns, support use of the interventions and provide motivation to adhere to activity goals.

The primary outcome was LBP-related disability over 12 months as measured by the Roland–Morris Disability Questionnaire (RMDQ). The RMDQ was measured at 6 weeks, 3, 6 and 12 months, and a repeated-measures model was used in the primary analysis. Secondary analyses included RMDQ scores at each time point, proportion of participants reaching ≥ 30% reduction in RMDQ (minimum clinically important difference, MCID) at 12 months, and a number of related measures including pain intensity, days in pain per months, pain self-efficacy, kinesiophobia, catastrophising and physical activity. Health-related quality of life was measured with the EuroQol-5 Dimensions, five-level version (EQ-5D-5L) for the health economic analysis; this was used to generate quality-adjusted life-years (QALYs).

For the power calculation, we used a between-group MCID of 1.5 on the RMDQ, which we proposed as important in the context of low-intensity interventions. For the repeated-measures primary outcome, a difference of 1.5 points

on the RMDQ over the follow-up period of 12 months, assuming a standard deviation of 5 in line with the feasibility trial gave an effect size of 0.30. Alpha was set to 0.025 for the primary analysis to allow both interventions to be independently compared with usual care. Using the four repeated measures, an assumed correlation between repeated measures of 0.7, 90% power and allowing for 20% lost to follow-up resulted in a sample size of 806. Randomisation was fully automated using a concealed computer-generated random allocation sequence. Participants were block randomised to the three arms, stratified by recruitment centre and LBP-related disability (less than four on the RMDQ).

The primary analysis for the RMDQ score over time was conducted using a multilevel mixed-model framework with observations at 6 weeks, 3, 6 and 12 months (level 1) nested within participants (level 2). The analysis was adjusted for baseline RMDQ score, stratification factors, pain duration, Subgroups for Targeted Treatment (STarT) Back risk subgroup. Multilevel models were also used for secondary outcomes. A health economic analysis was undertaken from an NHS perspective. Resource use was measured using general practice patient notes review. EQ-5D-5L scores at baseline, 6 weeks and 12 months were used to estimate QALYs. Results were presented in terms of cost per QALY (a cost–utility study). We also used improvement in the RMDQ between 12 months and baseline to estimate cost-effectiveness in terms of cost-per-point improvement in RMDQ. Incremental costs and effects were estimated using regression-based methods. Because of missing data, multiple imputation was used in the base-case analysis.

A mixed-methods process evaluation was conducted which included a nested qualitative study with participants, a qualitative study with the trial support physiotherapists and a quantitative study examining the use and implementation of the interventions as well as mediation analyses. In both qualitative studies, we used telephone interviews, which were transcribed verbatim and analysed using thematic analyses.

Results

Practices and patients

We recruited 179 primary care practices from 6 regional Clinical Research Networks across the UK. Eleven thousand one hundred and ninety-six potential participants were invited into the study via invitation packs. Of those invited, 2693 (24%) responded. Following screening and sending of a study system link, 825 participants were randomised (7%): 274 to usual primary care, 275 to usual care + internet intervention and 276 to usual care + internet intervention + physiotherapist support. Across the arms, follow-up rates were 83% at 6 weeks, 72% at 3 months, 70% at 6 months and 79% at 12 months. Participant baseline demographic and clinical characteristics were well balanced at baseline across the three arms. Practice notes review data were received for 717 participants (87%) of the trial sample.

Clinical outcomes

There was a small reduction in RMDQ over 12 months compared to usual care following the internet intervention without physiotherapist support [adjusted mean difference of −0.5, 97.5% confidence interval (CI) −1.2 to 0.2; $p = 0.085$] and the internet intervention with physiotherapist support (−0.6, 97.5% CI −1.2 to 0.1; $p = 0.048$). These differences were not statistically significant at the level of 0.025. Overall, there were no significant differences between the interventions and usual care with regard to pain intensity (measured as current pain, least pain in the last 2 weeks and average pain over the last 2 weeks) in a repeated-measures model, over 12 months. Participants in both intervention arms reported a significant reduction of around a day less in pain per month, over 12 months, compared to usual care. At 6 weeks, both interventions significantly improved pain self-efficacy and satisfaction with care for back pain. At 12 months, there were small but significant reductions in kinesiophobia in both intervention arms, compared to usual care. There were no serious adverse events associated with the interventions.

Health economic outcomes

Estimates for the cost of the intervention were £16 and £61 for the internet and internet plus telephone-support groups, respectively. The base-case analysis estimated incremental costs compared to control of −£16 and £96 and incremental QALYs compared to control were 0.011 and 0.013 for the internet and internet plus support groups, respectively. The intervention without support dominated usual care, being both more effective and less costly. Estimates of uncertainty suggested that both interventions were more likely than the usual primary care group to be cost-effective at values of a QALY between £20,000 and £30,000, with the internet group the most likely to be

cost-effective at these values. Results suggest that the interventions may represent efficient use of NHS resources, particularly the internet – only intervention at the National Institute for Health and Care Excellence threshold of 20,000–30,000 per QALY.

Process evaluation

In the nested participant qualitative study, 46 participants were interviewed at a range of time points following randomisation (n = 15 after 3 months, n = 14 after 6 months, n = 17 after 12 months) across all three arms. Participants had diverse LBP histories and were generally positive regarding the online aspects of the intervention. For those who perceived benefit, SupportBack appeared to affect outcomes through specific behavioural support for physical activity, that the participants could choose for themselves. For those who did not report benefit, there were pre-existing barriers, or a lack of perceived benefit when activities were tried. This led to disengagement. Participants in the support arm were positive about calls they received from the physiotherapists; they found them motivating and reassuring. In the physiotherapist qualitative study, five trial physiotherapists were interviewed. Overall, physiotherapists felt well-supported and reported few problems in delivering the telephone support. Some described the perceived limitations of the telephone method and lack of physical contact. Others felt that the telephone contact increased the activation of the participants. Physiotherapists described the benefits of the interactive nature of the internet intervention, and some described the benefit of a 6-week staged delivery of self-management support and behavioural advice.

The quantitative process evaluation study showed that the use of the intervention was higher in the intervention + support arm (86% completing at least session 1 of the internet intervention) than in the intervention without support arm (66% completing at least session 1), where session 1 was the core session introducing rationales and core activities. Physiotherapist telephone support was also delivered at acceptable levels, with 71% in this arm receiving at least two phone calls (the agreed amount for the core of the telephone intervention). Lower or higher usage of the internet intervention was not significantly related to RMDQ outcome in either intervention arm. Usage was also not related to pain self-efficacy at 6 weeks. The conditions to explore whether pain self-efficacy was a mediator of LBP-related disability were satisfied in the intervention without a support arm. Following an instrumental variable approach, pain self-efficacy did not mediate RMDQ outcome at 12 months in the intervention without support arm. Finally, following planned subgroup analyses, there was no evidence that baseline risk of persistent disability, pain duration or deprivation indices impacted the effect of the interventions compared to usual care.

Conclusions

In the SupportBack 2 trial, we showed that an internet intervention, delivered with and without physiotherapist telephone support, had a small and non-significant impact on LBP-related disability across 12 months. The interventions were safe, and generally were delivered and used as intended. Our health economic analysis showed that both interventions were likely to be cost-effective compared to the usual primary care alone group. Additionally, the intervention without support dominated usual primary care, being more effective and less costly. Clinicians will need to balance our findings on clinical effectiveness, cost-effectiveness, and safety with the likely accessibility of the intervention when considering use with patients.

Future research

As these internet interventions were used as intended and safe, future research should focus on increasing effectiveness. In this study, there was little indication of a subgroup identifiable at baseline who benefited more than others. Research to increase effectiveness needs to acknowledge the inherent complexity and heterogeneity of LBP as a condition, that likely compounds with the complexity in mechanistic processes underlying digitally supported self-management. Through our process work, it seemed that those who reported a lack of benefit early in their use of the intervention went on to disengage. Rapidly adaptive interventions that respond to early lack of response may merit consideration in future research.

Trial registration

This trial is registered as ISRCTN14736486.

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