Journal of Yoga & Physical Therapy
ISSN: 2157-7595

Hartfiel et al., J Yoga Phys Ther 2014, 4:2
DOI: 10.4172/2157-7595.1000161

Research Article Open Access

The Cost-Effectiveness of Yoga for Preventing and Reducing Back Pain at Work: Trial Protocol

[1]*, Rhiannon Tudor Edwards[1] and Ceri Phillips[2]

[1]Centre for Health Economics and Medicines Evaluation, UK
[2]Swansea University, UK

Abstract

Recent evidence suggests that yoga can be effective for reducing back pain. One recent randomised controlled trial (RCT) reported that yoga was cost-effective, from a societal perspective, for reducing back pain. Our study will be the first RCT to investigate the cost-effectiveness of yoga, from the perspective of the employer, for preventing and reducing back pain at work.

Our study population will include 120 NHS staff members recruited from three hospital sites. Participants who meet the inclusion criteria will be randomised to receive either an eight-week yoga programme or an education programme consisting of evidence-based back care information. The yoga group will attend a weekly sixty minute yoga session and then practise at home using a back care DVD and an illustrated yoga booklet.

Outcome measures will be collected at baseline, at eight weeks, and at six months. The Roland Morris Disability Questionnaire (RMDQ) will be the primary outcome measure for back pain. Sickness absence data, the EQ5D-5L and ICECAP-A will be used for the economic evaluation. Secondary outcome measures will assess back pain, wellbeing, quality of life, mood and resilience.

The economic evaluation will be calculated using return-on-investment analysis (ROI) for the employer perspective and cost-effectiveness analysis (CEA) for the societal perspective. Qualitative data will be collected to determine the facilitators and barriers for successfully implementing a yoga programme at work.

Keywords: Yoga; Back pain; Work place; Occupational health

Background

Back pain is one of the major factors associated with sickness absence, costing British industry an estimated £14 billion per year [1]. The Office for National Statistics reported that musculoskeletal conditions, including back and neck pain, was the main cause of sickness absence in 2013 with a total of 31 million days lost [2]. Research indicates that few workplace interventions are effective for preventing and reducing back pain [3]. Group exercise programmes, however, have been shown to have a positive effect on the health of employees [4] and are reported to be more cost-effective than one-to-one spinal manipulation treatments provided by physiotherapists, chiropractors and osteopaths [5].

Yoga is a promising from of group exercise, which includes physical activity, breathing exercises, relaxation techniques and meditation practices to enhance mindfulness and mind-body awareness [6]. Recent evidence suggests that yoga for reducing back pain can be effective [7,8], and cost-effective from a societal perspective [9].

Although there are several published RCTs investigating the effectiveness of yoga delivered in workplace settings [10-15], none have examined whether yoga is cost-effective from the perspective of the employer. The purpose of this study is to measure the financial return of a workplace yoga programme for preventing and reducing back pain - one of the major causes of sickness absence in the UK.

Trial Objectives

The primary objectives of this study are to:

1) Design and deliver a yoga-based back care programme to employees of all ages and fitness levels;
2) Conduct an RCT investigating the effectiveness and cost-effectiveness of a workplace yoga programme for preventing and reducing back pain;
3) Investigate the factors that influence the implementation and impact of a yoga programme at work.

Methods

Trial design

This study will be a multi-site pragmatic RCT offered to NHS employees from three hospital sites. Participants will be randomly allocated to receive either an eight-week yoga programme or an educational programme consisting of *The Back Book* and *How to Manage Stress*. Six qualified yoga instructors will be selected to deliver the eight week programme.

Recruitment and participants

This study will be open to all NHS staff, with and without back pain, between 18 – 65 years of age and who are able to attend one yoga class per week. The classes will be offered after work, from 5.30 – 6.30 pm at the three different hospital locations.

***Corresponding author:** Ned Hartfiel, Centre for Health Economics and Medicines Evaluation, Bangor University, Neuadd Ardudwy, Bangor, Gwynedd, UK LL57 2PZ, Tel: 44 (0)1248 388314 ext 8606; E-mail: ned.hartfiel@bangor.ac.uk

Received December 11, 2013; **Accepted** March 10, 2014; **Published** March 15, 2014

Citation: Hartfiel N, Edwards RT, Phillips C (2014) The Cost-Effectiveness of Yoga for Preventing and Reducing Back Pain at Work: Trial Protocol. J Yoga Phys Ther 4: 161. doi:10.4172/2157-7595.1000161

The NHS Occupational Health and Wellbeing Unit will recruit employees via an e-newsletter and an all-staff e-mail which will explain the details of the trial. Interested NHS staff members will then receive a participant information sheet, a consent form and a health questionnaire.

The participation information sheet will invite participants allocated to the yoga group to attend one 60 minute yoga class each week and to practice at home for 20 minutes, 3x per week using a DVD and illustrated booklet. Attendance at the yoga classes and adherence to home practice will be monitored weekly. The health questionnaire will ask participants for demographic information including whether they are full- or part-time employees, their use of the health service, changes in medication, and any other health conditions (e.g., recent surgery, pregnancy, spinal disc problems, etc) that could prevent safe participation in the yoga programme. The health questionnaire will also include valid and reliable outcome measures for collecting baseline data on back pain, wellbeing, quality of life, mood and resilience.

Exclusion criteria, site preference and randomisation

To insure safety and prevent bias, participants who are currently experiencing the following conditions will be excluded from this study: 1) pregnancy; 2) recent spinal disc problems or major surgery; 3) practicing yoga or yoga-related activities (such as pilates or tai chi); 4) leaving the NHS within six months. Health questionnaires will be reviewed by research team members, including physiotherapists and yoga instructors, who will assess the risk and eligibility of participants.

Eligible participants will be randomised to either the yoga programme or the education programme. An equal allocation of 1:1 will be used to ensure balance in the overall number of participants in the yoga and education groups. Randomisation will be conducted by the North Wales Organisation for Randomised Trial in Health (NWORTH). After randomisation, the NHS Occupational Health and Wellbeing Unit will inform participants of their group allocation.

Sample size

A sample size calculation was performed which determined that a minimum of 116 participants will be needed for this study. This calculation was based on a 2012 pilot study published in *Occupational Medicine* entitled "yoga for reducing perceived stress and back pain at work" [10]. This study found that a change in RMDQ scores of 1.17 was statistically significant for employees with little disability, and that the standard deviation of the difference in change scores was calculated to be 1.95 points resulting in an effect size calculation of 0.76. Using this effect size calculation, Cohen's power of analysis test [16] and assuming 80% power, the current study will require a total sample size of 87 complete cases. If we assume a 25% attrition rate, then we will need to recruit 116 participants for this study.

Interventions

The yoga intervention will include an eight-week programme consisting of sixty minute yoga classes offered at the workplace, plus a back care DVD and an illustrated yoga booklet for home practice. The back care programme taught in this study was developed by a panel of physiotherapists, osteopaths and senior Dru Yoga instructors. This panel agreed on a progressive programme of yoga techniques, which could be easily learned in a sixty minute class setting at the workplace and then practised at home by participants. Dru Yoga was the chosen intervention because it is a safe and therapeutic form of yoga that can be practised by most people [17]. Dru Yoga is characterised by graceful movements, directed breathing, and relaxation methods that include affirmation and visualisation techniques. The sixty minute Dru Yoga classes will be divided into four stages: activation exercises, energy block release sequences, back care postures and relaxation techniques. The participants allocated to the education group will receive two evidence-based booklets (approximately 20 pages each): *The Back Book* [18] and *How to Manage Stress* [19]. Produced by The Stationery Office, *The Back Book* presents information about how to prevent back pain. *How to Manage Stress* is distributed by Mind, one of the leading mental health charities in the UK. At the conclusion of this study, the education group will also receive a back care DVD, an illustrated yoga booklet, and a four week series of yoga classes.

Outcome measures

The health questionnaire, completed by all participants in both groups before randomisation, will contain valid and reliable scales for measuring back pain, wellbeing, quality of life, mood and resilience. Participants in both the yoga and education groups will complete the health questionnaire at baseline, at eight weeks, and at 6 months. The Roland Morris Disability Questionnaire (RMDQ) will be the primary outcome measure for back pain [20]. The RMDQ has been found to be sensitive to change, reliable and valid [21]. Secondary measures will include the Keele STarT Back Screening Tool [22], the WHO-5 wellbeing scale [23], the Exercise-Induced Feeling Inventory (EFI) to measure mood [24], and the Resilience Scale (RS-14) [25].

The economic evaluation will include both a return-on-investment and cost-effectiveness analysis. Return-on-investment from the employer perspective will be completed by obtaining sickness absence data from the NHS Electronic Staff Records (ESRs) for all participants in our study during the eight week intervention and six month follow up period. Cost-effectiveness analysis will be calculated using the EQ5D-5L [26] and ICECAP-A [27] for both groups. For the yoga group, class attendance and home practice records will measure adherence to the protocol.

Qualitative data will be collected from twenty-minute group interviews with a convenience sample of yoga participants at each of the three hospital sites. In addition, interviews with a purposive sample of yoga instructors and hospital administrators will be conducted to provide insights into how the trial was delivered and how participants experienced receiving the intervention. These insights into the context, dosage, fidelity and implementation will help inform the future delivery of yoga programmes at work.

Bias and adverse events

Although randomisation will help eliminate selection bias, participants who are randomised to the education group may withdraw from the study, especially if yoga is their preferred intervention. To minimise attrition bias, incentives will be provided to the education group for completing the questionnaires at eight weeks and at six months. At eight weeks, the education group will be offered a free yoga mat for completing the end-programme questionnaire. At six months, the education group will receive a four week series of yoga classes, a back care DVD and an illustrated yoga booklet. In addition to providing incentives, the NHS Office of Occupational Health and Wellbeing will send reminder e-mails to all participants in both groups who fail to complete questionnaires. If participants withdraw from the study, the research team will attempt to collect information on their reasons for leaving and record any adverse events due to practising yoga. Additional information on adverse effects due to

practising yoga will be collected during the focus group interviews with yoga participants after the completion of the eight-week programme.

Analysis

Statistical and economic analysis plan

An intention-to-treat analysis of variance (ANOVA) approach will be used to determine the effectiveness of the yoga programme for reducing back pain and improving wellbeing. Multiple linear regressions will be used when appropriate. Significance will be assessed at $p < 0.05$ for the RMDQ, Keele STarT, WHO-5, EFI, and RS-14 The effect of the yoga intervention on all domains will be corrected using a false discovery rate (FDR) approach ($Q<0.05$) [28].

Primary and secondary outcome measure scores will be summarised descriptively (i.e. mean, SD, median, minimum and maximum) at baseline, eight weeks (primary end point) and six months for both the yoga and education groups. The difference in mean scores between the yoga and education groups at eight weeks and six months (and the corresponding 95% confidence interval) will be determined.

The economic analysis plan will include a return-on-investment (ROI) analysis from the perspective of the employer and a cost-effectiveness analysis (CEA) from a societal perspective.

Return-on-investment analysis

The ROI analysis will consider only the costs relevant to the employer, such as the cost of the intervention and the savings from the number of sickness absence days reduced. Costs will be defined as the costs for setting up and delivering the eight week yoga programme. The benefits will be defined as the difference in the absenteeism costs due to back pain between the yoga and education groups.

Cost-effectiveness analysis

The CEA will measure the costs and benefits of the yoga group and the education group. Mean differences in total costs and benefits between the yoga and education groups at eight weeks and at the six month follow-up period will be calculated. Incremental cost-effectiveness ratios (ICERs) will be determined by dividing the difference in total costs by the difference in total benefits for both groups. Subgroup analysis considering the degree of back pain at baseline, the adherence to the yoga programme, and the location of the programme will also be conducted.

Measurement of costs

The health questionnaires completed by participants at baseline, eight weeks and six months will collect data on "health service use". This data will include visits to GPs, practice nurses, and other health professionals (e.g. physiotherapists). The data will be analysed as to whether it is related to back pain or not. In order to estimate total costs, unit costs will be assigned for each visit to a health care professional. Unit costs will be obtained from national published sources such as the Personal Social Services Research Unit (PSSRU) [29] and the NHS Reference Cost 2012-13 [30].

Measurement of benefit

The EQ5D-5L profiles for each participant will be scored using a "crosswalk" between the EQ5D-3L value sets and the new EQ5D-5L. Mean scores and measures of dispersion will be calculated for both groups. Quality-adjusted life years (QALYs) will be calculated using area under the curve analysis, weighting quantity of life (years) by quality of life (weighted health utility index) [31].

Uncertainty and sensitivity analysis

A summary measure of the uncertainty of costs and effects will be presented using cost-effectiveness acceptability curves (CEAC). The CEAC will show a range of probabilities of an intervention being cost-effectiveness at different ceiling thresholds (i.e. maximum amount that decision makers are willing to pay for a unit of benefit). To test the robustness of the results, a series of sensitivity analyses will be conducted to explore the variability in estimating cost-effectiveness.

Qualitative analysis

Qualitative thematic analysis of interviews with yoga participants will be aim to identify the elements of satisfaction or dissatisfaction, and the degree of impact of the yoga programme. Interviews will be digitally recorded, subject to the permission of each participant, and where appropriate transcribed verbatim. Anonymous direct quotations will be used when appropriate to describe key findings.

Ethical Review

Ethical approval for this trial was obtained from the School of Sport, Health and Exercise Sciences at Bangor University. R&D approval was granted by a NHS Internal Review Panel.

Acknowledgement

The trial is funded by the Welsh Health Economics Support Services.

References

1. Tilbrook HE, Cox H, Hewitt CE, Kang'ombe AR, Chuang LH, et al. (2011) Yoga for Chronic Low Back Pain: A Randomized Trial. Annals of Internal Medicine 155: 569-578.
2. Chuang LH, Soares MO, Tilbrook H, Cox H, Hewitt CE, et al. (2012) A Pragmatic Multicentered Randomized Controlled Trial of Yoga for Chronic Low Back Pain: Economic Evaluation. Spine (Phila Pa 1976). 37: 1593-1601.
3. CBI (2011) Confederation of British Industry. Workplace Health and Absence Survey: Healthy Returns? London, UK.
4. Office for National Statistics. Full Report: Sickness Absence in the Labour Market, February 2014. London, UK.
5. Van Poppel MN, Hooftman WE, Koes BW (2004) An update of a systematic review of controlled clinical trials on the primary prevention of back pain at the workplace. Occup Med (Lond) 54: 345–352.
6. Kreis J, Bödeker W (2004) Health-related and Economic Benefits of Workplace Health Promotion and Prevention – Summary of the Scientific Evidence. Essen: BKK Bundesverband, 2004.
7. UK BEAM Trial Team (2004) United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: effectiveness of physical treatments for back pain in primary care. BMJ 329: 1377–1384.
8. Posadzki P, Ernst E (2011) Yoga for low back pain: a systematic review of randomized clinical trials. Clin Rheumatol 30: 1257–1262.
9. Mohan G (2006) Exploring yoga as therapy. Int J Yoga Therapy 16: 13–19.
10. Hartfiel N, Burton C, Rycroft-Malone J, Clarke G, Havenhand J, et al. (2012) Yoga for reducing perceived stress and back pain at work. Occup Med (Lond) 62: 606-612.
11. Wolever RQ, Bobinet KJ, McCabe K, Mackenzie ER, Fekete E, et al. (2012) Effective and viable mind-body stress reduction in the workplace: a randomized controlled trial. J Occup Health Psychol 17: 246-258.
12. Strijk JE, Proper KI, van der Beek AJ, van Mechelen W (2012) A worksite vitality intervention to improve older workers' lifestyle and vitality-related outcomes: results of a randomised controlled trial. J Epidemiol Community Health 66: 1071-1088.
13. Cheema BS, Houridis A, Busch L, Raschke-Cheema V, Melville GW, et al. (2011) Effect of an office worksite-based yoga program on heart rate variability: a randomized controlled trial. BMC Complement Altern Med 13: 82.

14. Hartfiel N, Havenhand J, Khalsa SB, Clarke G, Krayer A (2011) The effectiveness of yoga for the improvement of well-being and resilience to stress in theworkplace. Scand J Work Environ Health 37: 70-76.

15. van Dongen JM, Strijk JE, Proper KI, van Wier MF, van Mechelen W, et al. (2013) A cost-effectiveness and return-on-investment analysis of a worksite vitality intervention among older hospital workers: results of a randomized controlled trial. J Occup Environ Med 55: 337-346.

16. Cohen J (1992) Quantitative methods in psychology: A power primer. Psychological Bulletin 112: 155-159.

17. Barrington C, Goswami A, Jones A. Dru Yoga: Stillness in Motion. Bangor, Dru Publications, UK.

18. Burton K, Klaber-Moffett J, Main C, Roland M, Waddell G (2002) The Back Book, 2nd (edn). TSO Publishers, Norwich, UK.

19. Darton K (2012) How to Manage Stress. Mind; London,UK.

20. Roland M, Morris R (1983) 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 8: 141–144.

21. Roland M, Fairbank J (2000) The Roland-Morris disability questionnaire and the Oswestry disability questionnaire. Spine 25: 3115–3124.

22. Hill JC, Dunn KM, Lewis M, Mullis R, Main CJ, et al. (2008) A primary care back pain screening tool: identifying patient subgroups for initial treatment. Arthritis Rheum 59: 632–641.

23. Bech P, Olsen RL, Kjoller M, Rasmussen NK (2003) Measuring well-being rather than the absence of distress symptoms: a comparison of the SF-36 Mental Health subscale and the WHO-Five Well-Being Scale. Int J Meth Psychiatr Res 12: 85-91.

24. Gauvin L, Rejeski WJ (1993) The Exercise-Induced Feeling Inventory: Development and initial validation. J Sport Exer Psychol 15: 403–423.

25. Wagnild GM, Young HM (1993) Development and psychometric evaluation of the Resilience Scale. J Nurs Meas1: 165-178.

26. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, et al. (2011) Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L) Qual Life Res 20: 1727–1736.

27. Al-Janabi H, Flynn TN, Coast J (2012) Development of a self-report measure of capability wellbeing for adults: the ICECAP-A. Qual Life Res 21: 167-176.

28. Benjamini Y, Hochberg Y (1995) Controlling the false discovery rate: a practical and powerful approach to multiple testing J R Stat Soc B 57: 289–300.

29. Lesley Curtis (2012) Personal Social Service Research Unit (PSSRU). Unit costs of health and social care 2012.

30. Department of Health. Reference Costs 2012-13. London, UK.

31. Horsman J, Furlong W, Feeny D, Torrance G (2003) The Health Utilities Index (HUI®): concepts, measurement properties and applications. Health Qual Life Outcomes 1: 54.