Combined exercise Intervention protocol validation in sedentary workers health risk with Nonspecific Chronic low back pain People

Ejercicio combinado Validación del protocolo de intervención en trabajadores sedentarios con riesgo para la salud con dolor lumbar crónico inespecífico Personas

*Saina Swathi, *Senthil Purushothaman, *Shazia Neelam, **Vinosh Kumar Purushothaman, ***Sivakumar Chinnusamy,

****T.G.Tilak Francis

*Chettinad Academy of Research and Education (India), **INTI International University (Malaysia), ***The Tamilnadu Dr MGR Medical University (India), ****Rajiv Gandhi University of Health Sciences (India)

Abstract. Background: Most chronic low back pain is nonspecific as the cause of the pain is unknown. Hence exercise protocol focussing on one area of fitness is not appropriate. A general exercise programme that combines muscular strength, flexibility and aerobic fitness would benefit the rehabilitation of Nonspecific Chronic Low Back Pain and its health risk. The present study aimed to validate the content of the combined exercise intervention protocol. Methods: The development and expert judgement stages are part of the content validation process. The development of the exercise protocol was based on a comprehensive literature review. The protocol was created in a step-by-step progressive manner. Exercises for flexibility (20 minutes), stabilisation and strengthening (20 minutes), and aerobic (20 minutes) make up the three main parts of the exercise protocol. 12 independent professionals with a minimum of 10 years of experience were invited. Ten of the twelve specialists consented to take part in the study. In India, all of the professionals were engaged in orthopaedic and musculoskeletal physical therapy. There are two professors, three associate professors, and five senior physiotherapists among the experts. Responses were gathered by mail. During the validation phase, The Exercise protocol was graded by the experts on relevance and ease of performance using a 5-point scale. After collecting the responses content validity index and kappa values were calculated. Results: 37 out of 39 items in the combined exercise intervention protocol showed good agreement. Treadmill walking with 60-75% and 80% and above target heart rate showed a kappa value of 0.66 for relevance and 0.50 for ease of performance. Conclusions: The designed exercise protocol exhibited good content validity.

Keywords: Non-specific back pain, sedentary individual, health risk, content validation, exercise protocol.

Resumen. Antecedentes: la mayoría del dolor lumbar crónico es inespecífico ya que se desconoce la causa del dolor. Por lo tanto, no es apropiado un protocolo de ejercicio que se centre en un área del fitness. Un programa de ejercicio general que combine fuerza muscular, flexibilidad y aptitud aeróbica beneficiaría la rehabilitación del dolor lumbar crónico inespecífico y su riesgo para la salud. El presente estudio tuvo como objetivo validar el contenido del protocolo de intervención de ejercicio combinado. Métodos: Las etapas de desarrollo y juicio de expertos forman parte del proceso de validación de contenido. El desarrollo del protocolo de ejercicio se basó en una revisión exhaustiva de la literatura. El protocolo se creó de manera progresiva paso a paso. Los ejercicios de flexibilidad (20 minutos), estabilización y fortalecimiento (20 minutos) y aeróbicos (20 minutos) conforman las tres partes principales del protocolo de ejercicio. Fueron invitados 12 profesionales independientes con un mínimo de 10 años de experiencia. Diez de los doce especialistas aceptaron participar en el estudio. En la India, todos los profesionales se dedicaban a la fisioterapia ortopédica y musculoesquelética. Entre los expertos hay dos profesores, tres profesores asociados y cinco fisioterapeutas experimentados. Las respuestas se recogieron por correo. Durante la fase de validación, los expertos calificaron el protocolo del ejercicio según su relevancia y facilidad de ejecución utilizando una escala de 5 puntos. Después de recopilar las respuestas, se calcularon el índice de validez de contenido y los valores kappa. Resultados: 37 de 39 ítems del protocolo de intervención con ejercicio combinado mostraron una buena concordancia. Caminar en cinta rodante con 60-75% y 80% y por encima de la frecuencia cardíaca objetivo mostró un valor kappa de 0,66 para relevancia y 0,50 para facilidad de rendimiento. Conclusiones: El protocolo de ejercicio diseñado exhibió buena validez de contenido. Palabras clave: Dolor de espalda inespecífico, individuo sedentario, riesgo para la salud, validación de contenido, protocolo de ejercicio.

Fecha recepción: 09-04-24. Fecha de aceptación: 07-10-24 Senthil Purushothaman senthilp101010@gmail.com

Introduction

Low back pain (LBP) is a problem worldwide with a lifetime prevalence of 84%. Nonspecific low back pain is defined as low back pain not attributable to a recognisable known specific pathology(1). All age groups are affected by low back pain but the impact on quality of life is lower in adolescents than in adults. This is due to there is increase in the prevalence of low back pain among young and middleaged people(2). Most of these people belong to working age those who experience LBP at least once in their lives(3). Nowadays due to modernisation and the increase of electronic media, all working-age people spend their prolonged time in front of laptops in a sitting position and adapting to a sedentary lifestyle. A sedentary lifestyle with a lack of physical activity results in loss of muscle power and strength and can be a predictor of LBP leading to recurrent low back pain(4). Chronic low back pain causes maladaptation in multiple domains such as the psychological, behavioural, and neuromuscular domains. Mainly fear of pain or harm results in a decrease in physical activity causing motor weakness and motor control deficits(5). A network meta-analysis collectively finds that active exercise therapies may be an effective treatment of non-specific chronic low back pain in adults. Clinical practice guidelines often recommend education along with exercise as a first line of treatment, but there is low-quality evidence that which specific mode of exercise training is best in treating Nonspecific chronic low back pain (NSCLBP)(6). Nonspecific chronic low back pain is not considered a homogeneous condition. As it is multifactorial. Hence a specific intervention programme may not be appropriate which focuses on one area of fitness. A general exercise programme which combines muscular strength, Flexibility and aerobic fitness may be beneficial for the rehabilitation of NSCLBP. Further research is needed(7). The proposed exercise protocol was designed based on principles of exercise combining all three components, flexibility, strength and aerobic fitness. The present study aimed to validate the content of a combined exercise intervention protocol which will be further assessed in my future study for sedentary workers both male and female suffering from non-specific chronic low back pain of age 20-40 years and with low level of physical activity and exclusion criteria for my future study will be subjects with red flag signs, neurological abnormalities, systemic diseases and structural deformities and pregnant women. The designed protocol requires a validation process for its relevance and ease of performance by experts. The term validity refers to a test/Protocol measuring what it intends to measure.

Methods

The process of content validation involves the development and expert judgement stage the protocol consists of three components focusing on improving flexibility, stabilization and strength training and increasing aerobic fitness and it was designed progressively with an extensive literature review. Totally 12 independent professionals with a minimum of 10 years of experience were selected for the validation process. Ten of the twelve specialists consented to take part in the study. In India, all of the professionals were engaged in orthopaedic and musculoskeletal physical therapy. There are two professors, three associate professors, and five senior physiotherapists among the experts. Responses were gathered by Google form and through the mail.

Combined Exercise Intervention Protocol (CEIP)

This structured CEIP is given for 12 weeks along with pain neuroscience education for sedentary workers suffering from non-specific chronic low back pain. This exercise protocol consists of 3 main components namely flexibility exercises, stabilization and strengthening exercises and aerobic exercises given 20 minutes each with 2-5 minutes resting interval. The first main component is flexibility exercises mainly focusing on large muscles around the lumbar region. These exercises start with a 15-second hold for 3 sets. later on, based on the patient's ability holding time was increased to 30 sec. The second component is stabilization and strengthening exercises. Under these exercises, there are sub-components such as kinaesthetic training, Lumbar muscle activation by drawing in maneuvre for transverse abdominis using pressure bio feedback unit and multifidus muscle activation in prone and side-lying position. Limb loading exercises without and with resistance both in supine as well as in prone position targeting both abdominals as well as lumbar extensors, resistance exercises with positional changes, functional training and perturbation training, were included. Finally, the protocol consists of a third component of aerobic exercises starting with low intensity at week 1 with a target heart rate of 40-50% and ending with moderate intensity at a target heart rate of 70-80% at week 12. All the components were progressed gradually with an increase in the intensity once the subject is comfortable with the previous week exercises. The exercise protocol is meant for a sedentary population those who are with lack of physical activity and suffer from non-specific chronic low back pain. Hence the protocol needs content validation.

Procedure of validation

The primary investigator invited 12 independent experts with a minimum of 10 years of experience in Musculoskeletal physiotherapy. Out of twelve, ten experts agreed to participate in the study. These professionals were placed diversely all over India. The process of validation includes preparing a Google form along with the exercise protocol sending it through electronic media and collecting responses. In the Google form, the process of validation included a rating of experts in a 5-point Likert grading on two parameters namely relevance and ease of performance. The scale was scored as 1=strongly disagree,2=mildly disagree,3=neutral,4= agree,5=strongly agree. The score 4 and 5 were acceptable for calculation. If scored less than 3, experts were requested for suggestions. Based on experts' advice on the exercise protocol the level of agreement, content validation index (CVI) and kappa value were calculated.

CVI calculated: Nr/N, No of experts responded (Nr) by Number of experts (N).

The cut-off level for acceptance of CVI is >0.78. Further highlights that if the level of agreement is greater than 78% among the experts the exercise is considered with good agreement and to be included in the protocol.

A modified kappa was calculated to confirm the relevance of the exercise protocol. The interpretation of kappa values was proposed as Fair=0.40 to 0.60, Good=0.60 to 0.74 and excellent=0.75 to 1.00

Results

Reports from the 10 experts are collected. As per the reports from the expert's content validity index and kappa values have been calculated. The protocol has three main components flexibility exercises, stabilization and strengthening exercises and aerobic exercises which are progressively increased in intensity. Stabilization and strengthening components consist of sub-components such as kinaesthetic training, deep muscle activation, resistance exercises, functional training and perturbation training. He whole exercise protocol comprises 39 items and was graded by all experts with excellent level of agreement, except two items from the aerobic exercise component, 38 and 39 items Treadmill walking with 60-75% of target heart rate showed a kappa value of 0.66 for relevance and ease of performance and 80% and above target heart rate showed a kappa value of 0.50 for relevance and ease of performance and only 6 to 7 experts agreed for high intensity. The experts suggested that the literature supports both moderate to high-intensity exercises for chronic low back pain but when it comes to the sedentary population those who are not in any form of physical activity earlier, exhaustion, compliance, and Adherence play an important role. It will be better to start the aerobic component with low intensity at week 1 and end with moderate intensity at week 12. Hence the treadmill walking is started with an intensity which is comfortable to

the patients and later on it is progressed gradually.

The entire combined exercise intervention protocol exhibited a good level of agreement. In the flexibility component, all the exercises except hamstring stretching showed 100% agreement. At the same time, hamstring stretching showed a CVI of 90% in relevance. In stabilization and strength training components Except for pelvic lifts and thoracic elevation, all the exercises got 100 % agreement whereas pelvic lifts got 90% agreement in relevance and 80% agreement in ease of performance. When it comes to aerobic exercises treadmill walking at 40-55% of the target heart rate got 80% of agreement, at 60-75% of heart rate got 70% of agreement and for 80% of the target heart rate got 60 % of agreement (Table 1).

Table 1.

Content validation of Combined Exercise Intervention Protocol

Contents of Combine Exercise Intervention protocol	Relevance		Ease of Performance	
I. FLEXIBILITY EXERCISE COMPONENT	CVI	KAPPA	CVI	KAPPA
1. Single knee to Chest (Right and Left)	100	1.00	100	1.00
2. Double Knee to Chest	100	1.00	100	1.00
3. Hamstring stretching (Right and Left)	90	0.89	100	1.00
4. Piriformis stretching (Right and Left)	100	1.00	100	1.00
5. Tensor fascia Lata Stretching.	100	1.00	100	1.00
6. Abdominal stretching	100	1.00	100	1.00
7. Cat camel stretching.	100	1.00	100	1.00
8. Quadratus lumborum stretching	100	1.00	100	1.00
9. Quadriceps muscle stretching	100	1.00	100	1.00
II. STABILIZATION EXERCISES COMPONENT	100	1.00	100	1.00
10. Kinesthetic training.	100	1.00	100	1.00
1. Drawing in maneuver (Deep segmental muscle activation for transverse abdominis), Multifidus muscle activation.	100	1.00	100	1.00
12. Progressive limb loading exercises for abdominals and trunk extensors. (Without resistance)	100	1.00	100	1.00
13. Progressive limb loading exercises for abdominals and trunk extensors. (With resistance)	100	1.00	100	1.00
Resistant exercises with positional changes 14. Supine - Curl ups	100	1.00	100	1.00
15. Diagonal curl-ups	100	1.00	100	1.00
16. Double knee to chest	100	1.00	100	1.00
17. Pelvic lifts	90	0.89	80	0.79
18. Bilateral straight leg raising and lowering	100	1.00	100	1.00
Sitting and standing 19. Flexion of trunk	100	1.00	100	1.00
20. Extension of trunk	100	1.00	100	1.00
21. Rotation with extension.	100	1.00	100	1.00
Prone position 22. Thoracic elevation	100	1.00	80	0.79
23. Leg lifts	100	1.00	100	1.00
Side-lying 24. Side bending exercises	100	1.00	100	1.00
25. Side planks	90	0.89	80	0.79
Functional training 26. Modified bridging exercises.	100	1.00	100	1.00
27. Push-ups.	100	1.00	100	1.00
28. Wall slides	100	1.00	100	1.00
29. Partial squats/mini squats	100	1.00	100	1.00
30. Lounges-partial	100	1.00	100	1.00
31. Step up-Step down activities.	100	1.00	100	1.00
Pertubation training 32. Curl ups	100	1.00	100	1.00
33. Rolling out	100	1.00	100	1.00
34. Push ups	100	1.00	100	1.00
35. Wall slides	100	1.00	100	1.00
36. Foam roller Alternate arm and leg movements	100	1.00	100	1.00
III. AEROBIC EXERCISE COMPONENT 37. Treadmill walking (40 – 55% of Target Heart Rate)	100	1.00	80	1.00
38. Treadmill walking $(60 - 75\% \text{ of Target Heart Rate})$	70	0.66	70	0.66
39. Treadmill walking (80% of Target Heart Rate)	60	0.50	60	0.50

Discussion

The designing of the exercise protocol includes a literature review, face validity and content validation by experts. The present study aimed to validate the content of the exercise protocol. Before content validation, a group of experts evaluated the face validity of the protocol. Depending upon the suggestions of experts resting intervals were included between the components of exercise hence duration was changed from 60-90 minutes. Pre-analysis of the patients by a general physician and regular monitoring of the individuals during and after the exercise is also considered, as even a moderate amount of physical activity can trigger cardiac events in individuals who are largely sedentary(8). All the stretching exercises in the flexibility component exhibit excellent levels of agreement in relevance and ease of performance. Improving the flexibility of the lumbar spine and increasing the range of motion of the spine helps to reduce back pain and assist with movement(9). the stretching programme comprises both lumbar flexion and lumbar extension exercises along with stretching of individual muscles such as the Hamstrings, Piriformis, Tensor fascia Lata, quadratus lumborum and Quadriceps which are prone to tightness due to prolonged sitting in sedentary workers and causes low back pain(10)(11)(12).

The stabilization and strength training components were considered to possess excellent agreement among the experts. Motor weakness and motor control deficits are widely reported in individuals with NSCLBP. These are seen as a result of psychological and behavioural adaptations such as fear avoidance beliefs and pain self-efficacy which causes a reduction in physical activity and functional movements(5). To achieve a desirable outcome in reducing disability, and functional limitations and improving quality of life, this component included exercises in a progressive manner starting from kinesthetic training, Muscle activation using an assistive device pressure biofeedback unit, resistance exercises, functional training and perturbation training(13). The aerobic component in the form of walking is incorporated into the exercise protocol to improve the functional status reducing fear of movement and helping the individuals with low back pain to conduct activities of daily living(14)(15). Treadmill walking starting at a moderate intensity at week 1 and ending with a high intensity at week 12 was included in the exercise protocol. Experts agreed with the relevance and ease of performance for moderate levels of intensity but not for high intensity although the high intensity of exercise is supported by different studies for NSCLBP, as the exercise protocol is meant for individuals with sedentary behaviour. To reduce the risks, enhance the compliance and to get optimal benefits. patients are encouraged to start treadmill walking with an intensity of either low or moderate which is comfortable for them(16). later on it gradually progressed week by week with regular and careful monitoring of the individual. To improve therapeutic outcomes, Previous studies suggested that the exercises should be a multicomponent targeting the strength flexibility neuronal firing patterns, voluntary control of spine, stabilizing muscles must be studied hence the combined exercise protocol was designed including flexibility exercises, Kinesthetic training, Resistance exercises, functional training and aerobic exercises (17)(18)(19)(20). Thus, the designed CEIP was well appreciated by the majority of experts. The present study's limitation includes experts recruited only from India for validation.

Conclusion

The designed exercise protocol exhibited good content validity in its use in sedentary workers suffering from nonspecific chronic low back pain and its health risk.

Acknowledgements

We need to thank the Physiotherapy experts and other faculties who have given their suggestions and spending their valuable time towards this study.

References

- Balagué, F., Mannion, A. F., Pellisé, F., & Cedraschi, C. (2012). Non-specific low back pain. Lancet (London, England), 379(9814), 482–491. https://doi.org/10.1016/S0140-6736(11)60610-7
- Hoy, D., March, L., Brooks, P., Blyth, F., Woolf, A., Bain, C., Williams, G., Smith, E., Vos, T., Barendregt, J., Murray, C., Burstein, R., & Buchbinder, R. (2014). The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. Annals of the rheumatic diseases, 73(6), 968–974. https://doi.org/10.1136/annrheumdis-2013-204428
- Vujcic, I., Stojilovic, N., Dubljanin, E., Ladjevic, N., Ladjevic, I., & Sipetic-Grujicic, S. (2018). Low Back Pain among Medical Students in Belgrade (Serbia): A Cross-Sectional Study. Pain research & management, 2018, 8317906. https://doi.org/10.1155/2018/8317906
- Citko, A., Górski, S., Marcinowicz, L., & Górska, A. (2018). Sedentary Lifestyle and Nonspecific Low Back Pain in Medical Personnel in North-East Poland. Bio-Med research international, 2018, 1965807. https://doi.org/10.1155/2018/1965807
- Farragher JB, Williams G, Pranata A, El-Ansary D, Parry S, Bryant AL (2021) Adaptations Associated with Non-Specific Chronic Low Back Pain: A Narrative Review. Int J Phys Med Rehabil. 9:602. https://doi.org/ 10.35248/2329-9096.21.9.602
- Owen, P. J., Miller, C. T., Mundell, N. L., Verswijveren,
 S. J. J. M., Tagliaferri, S. D., Brisby, H., Bowe, S. J.,
 & Belavy, D. L. (2020). Which specific modes of exercise training are most effective for treating low back pain? Network meta-analysis. British journal of sports medicine, 54(21), 1279–1287. https://doi.org/10.1136/bjsports-2019-100886
- Gordon, R., & Bloxham, S. (2016). A Systematic Review of the Effects of Exercise and Physical Activity on Non-Specific Chronic Low Back Pain. Healthcare (Basel, Switzerland), 4(2), 22. https://doi.org/10.3390/healthcare4020022
- Yang Y. J. (2019). An Overview of Current Physical Activity Recommendations in Primary Care. Korean journal of family medicine, 40(3), 135–142. https://doi.org/10.4082/kjfm.19.0038
- Gordon, R., & Bloxham, S. (2016). A Systematic Review of the Effects of Exercise and Physical Activity on Non-Specific Chronic Low Back Pain. Healthcare (Basel, Switzerland), 4(2), 22.

https://doi.org/10.3390/healthcare4020022 Nourbakhsh, M. R., Arabloo, A. M., & Salavati, M. (2006). The relationship between pelvic cross syndrome and chronic low back pain. Journal of back and musculoskeletal rehabilitation, 19(4), 119-128.https://doi.org/10.3233/BMR-2006-19403

- Dahiya, T., Verma, T., Fatima, A., Verma, R., & Bhushan, B. (2022). Incidence of Piriformis Tightness and to determine correlation with gluteus medius weakness in Indian IT Professionals: A cross sectional study. International Journal of Health Sciences, 6(S6), 4137–4146. https://doi.org/10.53730/ijhs.v6nS6.10578
- Bae, H. I., Kim, D. Y., & Sung, Y. H. (2017). Effects of a static stretch using a load on low back pain patients with shortened tensor fascia lata. Journal of exercise rehabilitation, 13(2), 227-231. https://doi.org/10.12965/jer.1734910.455
- Kisner, C., & Thorp, J. N. (2018). The spine: Exercise and manipulation interventions. Kisner C, Colby LA, Borstad J. Therapeutic Exercise Foundations and Techniques Seventh Edition. Philadephia: FA Davis Company, p491-545.
- Sitthipornvorakul, E., Klinsophon, T., Sihawong, R., & Janwantanakul, P. (2018). The effects of walking intervention in patients with chronic low back pain: A metaanalysis of randomized controlled trials. Musculoskeletal Science and Practice, 34, 38-46. https://doi.org/10.1016/j.msksp.2017.12.003
- Bolivar, A. A., Villamizar, J. A. F., & Castelblanco, Y. S. (2021). Aerobic capacity: musicalized physical activity, older adult, health promotion.
- Balagué, F., Mannion, A. F., Pellisé, F., & Cedraschi, C.

(2012). Non-specific low back pain. The lancet, 379(9814), 482-491. https://doi.org/10.1016/S0140-6736(11)60610-7

Mbada, C. E., Ayanniyi, O., Ogunlade, S. O., Orimolade, E. A., Oladiran, A. B., & Ogundele, A. O. (2014). Influence of Mckenzie protocol and two modes of endurance exercises on health-related quality of life of patients with long-term mechanical low-back pain. *The Pan African medical journal*, *17 Suppl 1*(Suppl 1), 5.

https://doi.org/10.11694/pamj.supp.2014.17.1.29 50

- Mostagi, F. Q., Dias, J. M., Pereira, L. M., Obara, K., Mazuquin, B. F., Silva, M. F.,Silva, M. A., de Campos, R. R., Barreto, M. S., Nogueira, J. F., Lima, T. B., Carregaro, R. L., & Cardoso, J. R. (2015). Pilates versus general exercise effectiveness on pain and functionality in non-specific chronic low back pain subjects. *Journal of bodywork and movement therapies*, 19(4), 636–645. https://doi.org/10.1016/j.jbmt.2014.11.009
- Unsgaard-Tøndel, M., Fladmark, A. M., Salvesen, Ø., & Vasseljen, O. (2010). Motor control exercises, sling exercises, and general exercises for patients with chronic low back pain: a randomized controlled trial with 1-year follow-up. *Physical therapy*, 90(10), 1426– 1440. https://doi.org/10.2522/ptj.20090421
- Araque-Martínez, M. Á., Ruiz-Montero, P. J., & Artés-Rodríguez, E. M. (2021). Effects of a multicomponent physical exercise program on fitness, self-esteem, anxiety and depres.

Datos de los/as autores/as y traductor/a:

Swathi Saina Senthil Purushothaman Shazia Neelam Vinosh Kumar Purushothaman Sivakumar Chinnusamy Tilak Francis T G swathithamada@gmail.com senthilp101010@gmail.com shzkhan73@gmail.com vinoshmpt@yahoo.com dseivv@gmail.com tilakfrancis@gmail.com

Autor/a Autor/a Autor/a Autor/a Autor/a Autor/a – Traductor/a