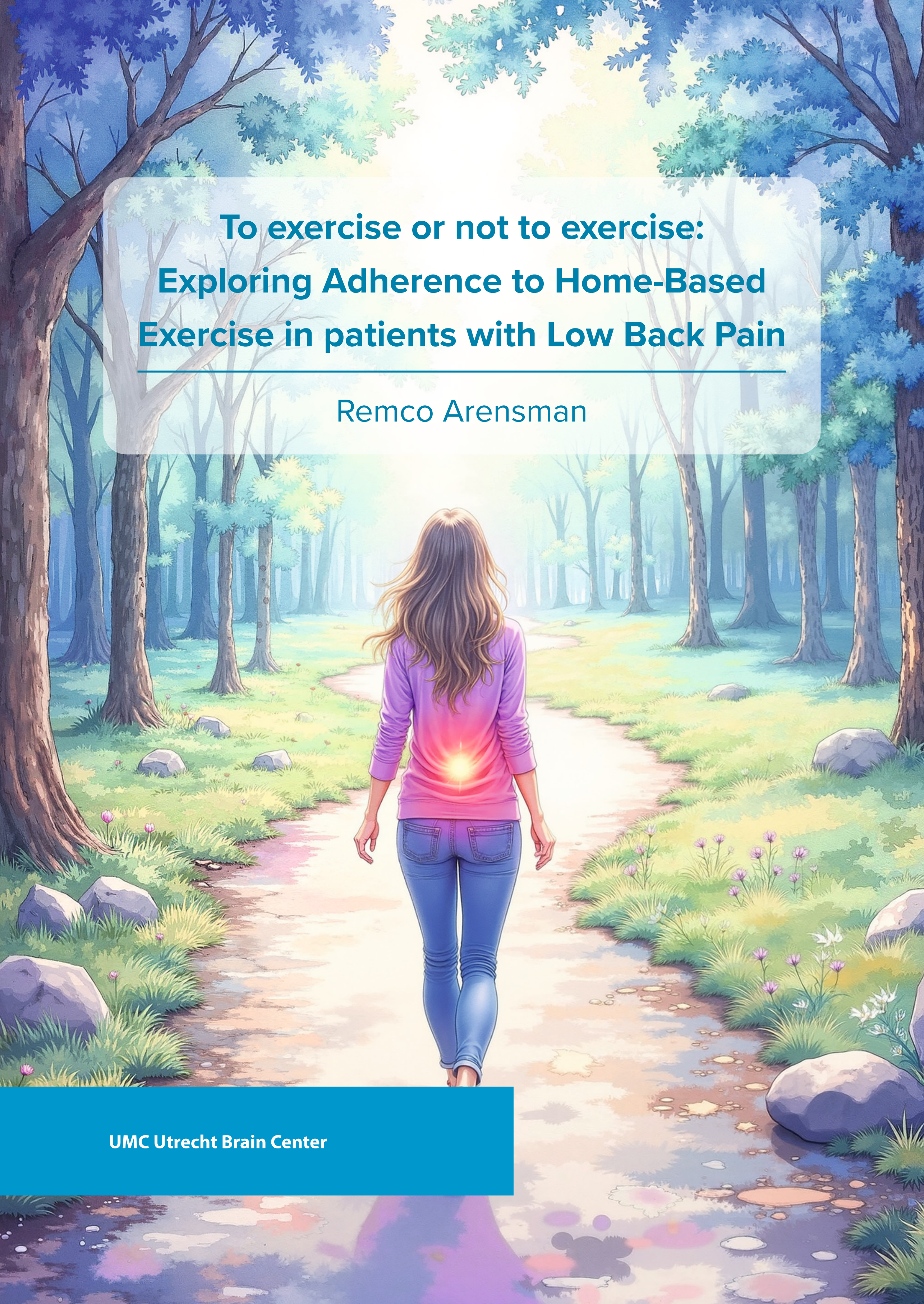


To exercise or not to exercise: Exploring Adherence to Home-Based Exercise in patients with Low Back Pain

Remco Arensman

UMC Utrecht Brain Center

To exercise or not to exercise: Exploring Adherence to Home-Based Exercise in patients with Low Back Pain

Remco Arensman

To exercise or not to exercise: Exploring Adherence to Home-Based Exercise in patients with Low Back Pain.

Utrecht University, Utrecht, The Netherlands

ISBN: 978-94-6506-432-1

DOI: https://doi.org/10.33540/2478

Provided by thesis specialist Ridderprint, ridderprint.nl

Printing: Ridderprint

Cover illustration: Remco Arensman

Layout and design: Bart Roelofs, persoonlijkproefschrift.nl

The research presented in this thesis was conducted at the Center for Physical Therapy Research and Innovation in Primary Care (AWF), a structural collaboration between the Julius Health Care Centers (Utrecht, The Netherlands), the Department of Rehabilitation, Physiotherapy Science & Sport (UMC Utrecht Brain Center, University Medical Center Utrecht, Utrecht, The Netherlands), the Research Group Innovation of Human Movement Care (Expertise Center Healthy Urban Living, HU University of Applied Sciences, Utrecht, The Netherlands), and the Research Group Empowering Healthy Behaviour (Department of Health Innovations and Technology, Fontys University of Applied Sciences, Eindhoven, The Netherlands).

To exercise or not to exercise: Exploring Adherence to Home-Based Exercise in patients with Low Back Pain

Bewegen of niet bewegen: Verkenning van therapietrouw aan thuisoefeningen bij patiënten met lage rugpijn

(met een samenvatting in het Nederlands)

Proefschrift

ter verkrijging van de graad van doctor aan de
Universiteit Utrecht
op gezag van de
rector magnificus, prof. dr. H.R.B.M. Kummeling,
ingevolge het besluit van het College voor Promoties
in het openbaar te verdedigen op

donderdag 14 november 2024 des ochtends te 10.15 uur

door

Remco Martijn Arensman

geboren op 30 mei 1986
te Woerden

Promotoren:
Prof. dr. C. Veenhof
Prof. dr. R.W.J.G. Ostelo

Copromotoren:
Dr. M.F. Pisters
Dr. C.J.J. Kloek

Beoordelingscommissie:
Prof. dr. Ir. C.E.M.J. van Dijk
Prof. dr. L.W. van Rhijn (voorzitter)
Dr. J.B. Staal
Prof. dr. J.M.A. Visser-Meilij
Prof. dr. D.L.M. Zwart MD

This thesis was funded by the Taskforce for Applied Research SIA (RAAK.PRO02.063), part of the Dutch Research Council (NWO).

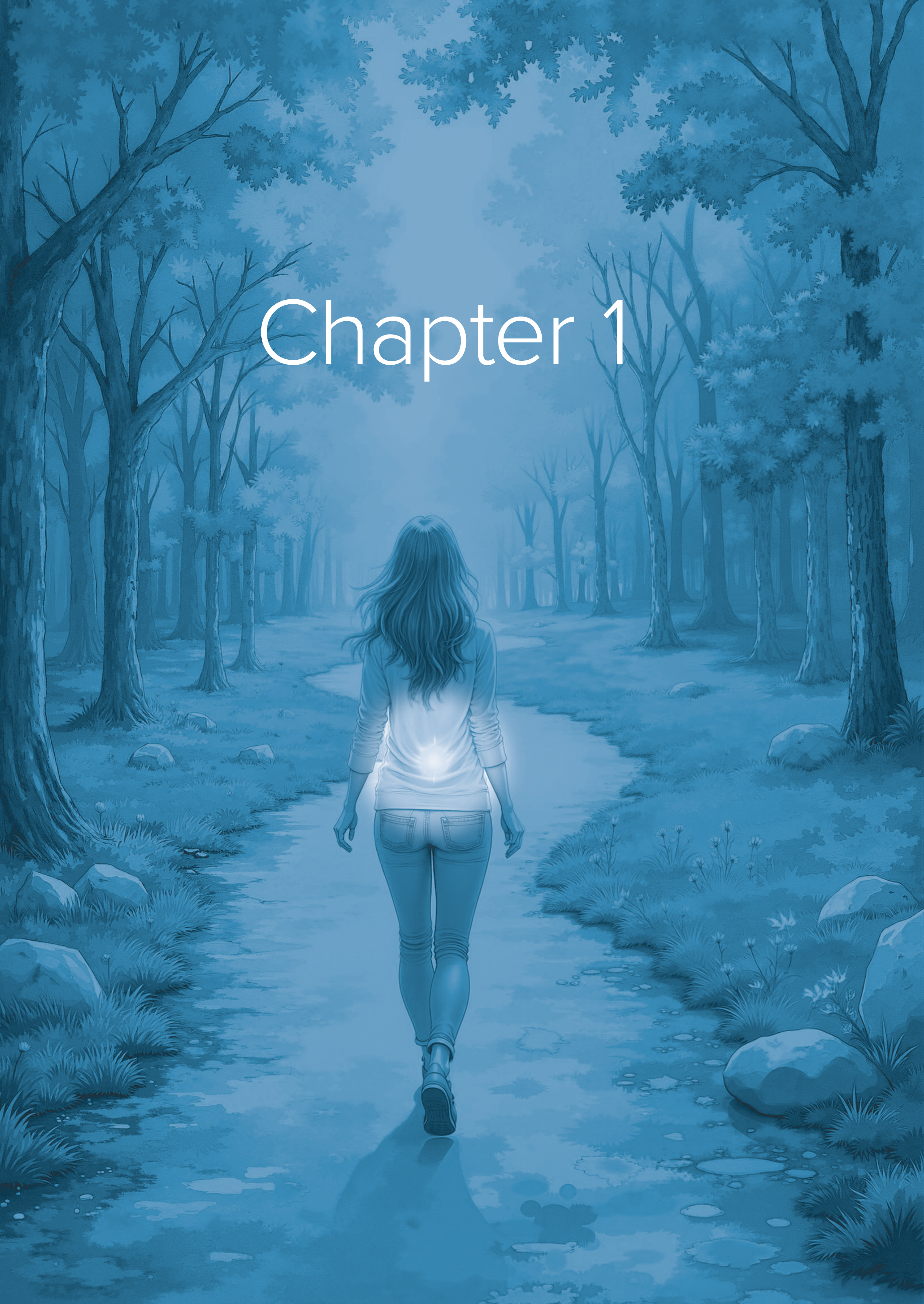
The printing of this thesis was financially supported by the Scientific College Physical Therapy (WCF) of the Royal Dutch Society for Physical Therapy (KNGF) and the Center for Physical Therapy Research and Innovation in Primary Care (AWF) of the Julius Health Care Centers.

“Science isn’t about why, it’s about why not!”

— J.K. Simmons (Portal 2) —

TABLE OF CONTENTS

Chapter 1



General introduction

INTRODUCTION

Physiotherapy is pivotal in managing musculoskeletal (MSK) conditions (1). Central to the management of MSK conditions is the biopsychosocial model, which highlights the complex relations between biological, psychological, and social factors in shaping the health and well-being of individuals with MSK pain (2). To translate the biopsychosocial model to clinical practice, clinical guidelines provide best practice recommendations for the assessment and treatment of MSK conditions, emphasizing the importance of patient education, self-management support, and interventions focused on physical activity and exercise (3). This evidence-based approach promotes active lifestyles and physical activity, offering short and long-term pain relief. It integrates components like manual therapy, patient education, and exercise therapy, typically provided by physiotherapists (3,4).

Exercise therapy in MSK conditions

Exercise therapy is “the systematic performance or execution of planned physical movements or activities intended to enable the patient or client to remediate or prevent impairments of body functions and structures, enhance activities and participation, reduce risk, optimize overall health, and enhance fitness and well-being“ (5). Exercise therapy is effective in managing musculoskeletal pain, demonstrating medium to large pain reduction effects and functional improvements compared to no exercise or other control (6). However, the effects vary between different MSK conditions, and optimal content and mode of delivery of exercise therapy remains inconclusive (7). Exercise therapy can be recommended as either supervised exercise by a physiotherapist, home-based exercise (HBE), or a combination of both. In supervised exercise, patients perform exercises at the physiotherapist’s clinic, where the therapist provides instruction, guidance, and coaching. To maintain endurance performance, healthy adults should have at least two exercise sessions per week, while maintaining strength requires one session, or two for older individuals (8). For enhanced endurance and strength, an additional exercise session is necessary to achieve the minimum effective dose (9,10). However, supervised exercises three or more times a week can be costly and time-consuming. To address these challenges, HBE supplements in-clinic sessions, allowing patients to continue exercising at home (11). This not only increases treatment dose, but also reduces the financial burden on the healthcare system by decreasing the need for supervised sessions over the course of treatment and it affords patients the flexibility to exercise according to their own schedules. Given these advantages, it is no surprise that many studies investigated the effectiveness of HBE interventions on reducing pain and disability in musculoskeletal conditions (12–17).

Exercise for low back pain

The most prevalent musculoskeletal condition is low back pain (LBP) and it affects a substantial proportion of the adult population worldwide (18). LBP leads to significant disability, economic burden, and reduced quality of life (19,20). A key treatment for LBP is exercise therapy, including supervised exercises and HBE, provided by physiotherapists to boost physical function, alleviate pain, facilitate recovery, and enhance self-management (21). HBE consists of targeted exercises prescribed by physiotherapists for home completion to enhance body functions such as joint mobility, muscle strength, or stability (22). Given the benefit of HBE in LBP management and its research interest, it's surprising that a recent review shows that only 32% of supervised exercise trials for LBP included some form of HBE (23). Moreover, just 45% of these HBE trials reported on patient adherence to the exercise recommendations (23). While there is no existing research specifically examining the consequences of non-adherence to HBE, it is anticipated that these effects might mirror those of non-adherence to medication, potentially leading to substantial economic strain on the healthcare system (24). Regardless of the economic implications, the effectiveness of an exercise intervention is intrinsically linked to the patient's adherence to the recommended exercise regimen.

Adherence to HBE recommendations and its measurement

Adherence is usually conceptualized as a behavior and defined as “the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider” by the World Health Organization (25). Applied to patient adherence to HBE recommendations, adherence would be defined as “the extent to which a person's behavior corresponds with agreed HBE recommendations from a health care provider”. In this context, the HBE recommendations include frequency (i.e. number of exercise sessions per day or week); intensity (i.e. number of repetitions per exercise session); and quality of performance of the HBE program (how well did the patient perform the exercises compared to the instructions). Despite a clear definition, measuring adherence to HBE recommendations remains a challenge. Various methods for measuring HBE adherence are described in the literature, including diaries, questionnaires, logs, visual scales, tally counters, and single-item questions (23,26–28). However, standardized, valid, and reliable tools to measure adherence are lacking, leading to difficulties in quantifying adherence and understanding its role in treatment outcomes. For instance, to accurately gauge the effectiveness of interventions that include HBE, it is essential to have a reliable method for assessing patients' adherence to these exercises. Consequently, the development of such a measurement tool is crucial for accurately evaluating the effectiveness of HBE-based interventions, investigating the relationship between adherence to HBE and clinical outcomes , and improving strategies for enhancing adherence in patients with LBP.

Strategies to improve adherence

Strategies to improve patients' adherence include physiotherapist support, limiting the exercise regimen to two to four key exercises, enhancing patient self-motivation and self-efficacy (29), improving physiotherapist communication skills (30), and using behavioral change techniques (31). However, while evidence on these strategies' short-term effectiveness is mixed, they appear ineffective for long-term adherence (32). Digital health technologies, designed to aid clinicians and patients, offer a potential solution (33,34). The use of digital health technologies such as apps or web-based platforms during treatment has shown promising results. For example, studies found that online apps with personalized exercises, video guides, and exercise reminders enhance HBE adherence, exercise quality, and therapist-patient interactions (35,36). For example, an app developed to provide patients with the HBE recommendations from their physiotherapist on their smartphone combined with remote support resulted in higher adherence compared to paper handouts alone (35). Smartphone apps can aid in patient self-management and adherence to HBE by incorporating persuasive design elements (33,36–38). Persuasive design seeks to motivate users towards a desired behavior, either short-term or continuously (39). Persuasively designed apps use personalized feedback based on performance, reward systems, and reminders to engage patients actively (33,40). Incorporating self-management tips from credible sources like physiotherapists, other patients, or public figures can further motivate patients to follow the app's guidance (33,41). Another advantage of the app lies in its constant availability, unlike the limited number and duration of face-to-face sessions with a physiotherapist. In a study investigating an app to support treatment of patients with osteoarthritis combined with face-to-face physiotherapy, patients indicated it improved treatment adherence and continuity between physiotherapist sessions (42,43). Despite the apparent advantages of the integration of the app in usual care, the acceptability, satisfaction, and performance of such technologies from the patient's perspective are not well-understood and require further investigation.

Development of e-Exercise LBP

The e-Exercise LBP intervention was designed to enhance both the effectiveness and patient adherence to physiotherapy for patients with LBP. The intervention was developed through a multiphase, iterative process based on the Center for eHealth Research (CeHRes) Roadmap principles (44). This intervention adapts the existing e-Exercise program for patients with hip/knee osteoarthritis (e-Exercise OA), improving physical function, pain, tiredness, quality of life, and self-efficacy (42,45,46). Patients' positive responses and high engagement with e-Exercise OA's online component, coupled with physiotherapists' feedback, shaped the e-Exercise LBP's development (43,47). Additionally, persuasive design elements (personalization, motivation, triggers, and conditioning) were implemented in the design of the e-Exercise app to facilitate and support behavior change in patients, and increase adherence to exercise recommendations from the physiotherapist. In total, fourteen different behavioral change techniques (such as goal setting, self-monitoring, shaping knowledge, tailored feedback, and shaping knowledge) were included in the app. The first three steps of the CeHRes Roadmap, namely contextual inquiry, value specification, and design, were followed in the development of e-Exercise LBP (44). Subsequently, a multicenter feasibility study tested the prototype, confirming its potential in reducing disability and pain (48). Based on these results and end-user usability experiences, the e-Exercise LBP prototype was further refined in preparation for broader operationalization and evaluation.

e-Exercise LBP

The e-Exercise LBP intervention uses a stratified blended approach, merging an app with traditional face-to-face physiotherapy to enhance treatment adherence and effectiveness. Both the app and in-person treatments adhere to the LBP guidelines set by the Royal Dutch Society for Physiotherapy (49). To improve the effectiveness and efficiency of physiotherapy care, treatment is stratified based on the patient's risk of developing persistent LBP using the Keele STarT Back Screening Tool (50,51). The intervention's duration, session count, and content are customized for three risk groups from the tool: low, medium, and high (52). The app features an information module with 12 weekly self-management themes, including assignments related to the etiology of LBP, physical activity, patient experiences, pain management, and psychosocial factors related to LBP. The app also includes an exercise module with a HBE program tailored to the patient's prognostic risk profile, and a physical activity module containing a goal-oriented training program intended to help the patient maintain or improve their level of physical activity. App support duration varies by risk group for persistent complaints: three weeks for low risk, and twelve for medium and high risk (50). Patients can access the app content even after this period. The app's content varies based on the patient's risk level, with the physical activity module and graded activity functionality added for "medium" and "high risk" patients. The physiotherapist can monitor the patient's use of the app, discuss assignments with the patient, and modify the HBE recommendations when needed. This enables personalized care adjustments to maintain patient adherence and optimize intervention results. Post-program, the app sends reminders every other week for six months to encourage ongoing adherence to a physically active lifestyle as recommended by the physiotherapist.

Trajectories of adherence to HBE recommendations

While the e-Exercise LBP program supports adherence, individual variations are likely due to numerous factors related to both patients and therapists (29,53–57). Additionally, adherence is also likely to vary over time during the treatment period among patients with LBP, resulting in distinct trajectories of adherence. While studies have yet to explore common adherence trajectories for patients with LBP, other patient groups have shown such patterns (58). Different trajectories imply varied clinical needs, and identifying a patient's trajectory early can help clinicians tailor support and coaching to enhance adherence. Therefore, investigating the unique trajectories of adherence to HBE recommendations in patients with LBP has the potential to increase the effectiveness of interventions for this patient group.

Adherence and outcomes

Although it's often thought that adhering to HBE directly impacts clinical outcomes, the link between adherence and LBP recovery may be more intricate, meriting deeper exploration. Only in more recent years have higher quality measurement instruments been published, allowing for more detailed and longitudinal measurement of adherence to HBE recommendations (22,59). Accordingly, this thesis concludes by examining how adherence to HBE influences LBP recovery in patients receiving physiotherapy.

In summary, this thesis describes a comprehensive exploration of adherence to HBE programs during the treatment of LBP. A key focus is developing a new tool to measure HBE adherence, enabling the assessment of adherence and its impact on therapeutic results. The research examines patient views on digital tools supporting HBE in physiotherapy and evaluates the clinical effectiveness, cost-effectiveness, and impact on adherence rates of the e-Exercise LBP intervention for patients with LBP. Finally, the thesis aims to identify distinct trajectories of adherence to HBE recommendations and examine the associations between adherence and recovery from LBP. Through these analyses, the thesis aims to offer new insights to healthcare professionals, potentially enhancing LBP management with a deeper understanding of adherence to HBE and its links to recovery. The thesis focusses on adherence to HBE recommendations and is part of the e-Exercise LBP trial. For a more comprehensive evaluation of the (cost-)effectiveness of the e-Exercise LBP trial, interested readers are referred to the thesis "e-Exercise Low Back Pain: Stratified blended physiotherapy for patients with nonspecific low back pain" (60).

Outline of the thesis

Chapter 2 delves into the development and validation of the Exercise Adherence Scale (EXAS), an instrument specifically designed to measure adherence to HBE programs recommended by physiotherapists. This chapter provides a foundation for the subsequent investigations by establishing a reliable tool for quantifying adherence.

Chapter 3 presents a qualitative study to understand patient perspectives on the acceptability, satisfaction, and performance of an app designed to support home-based exercise. This study provides insights into the app's benefits from the users' perspective and how it impacts their adherence to exercise recommendations.

Chapter 4 describes the protocol for a cluster randomized controlled trial, investigating the effectiveness and cost-effectiveness of stratified blended physiotherapy in patients with LBP. The intervention combines face-to-face physiotherapy with an app to improve self-management skills and adherence to exercise recommendations.

Chapter 5 presents the results of a cluster randomized controlled trial investigating the 3-month effectiveness and cost-effectiveness of e-Exercise LBP (a stratified blended physiotherapy intervention) compared to usual care physiotherapy in patients with LBP.

In Chapter 6, the study uses a longitudinal analysis to identify distinct trajectories of adherence to HBE recommendations among people with LBP. Additionally, the study aims to identify whether baseline characteristics can predict trajectories of adherence to inform better patient management.

Chapter 7 explores the association between adherence to HBE recommendations and recovery from LBP. This study examines whether high adherence rates improve clinical outcomes in patients LBP.

Lastly, Chapter 8 presents the discussion on the findings and methodological considerations of chapters 2 through 7. Furthermore, the implications for clinical practice, society, education, and future research are described. The thesis ends with a summary in English and in Dutch.

REFERENCES

1. Fullen BM, Wittink H, De Groef A, Hoegh M, McVeigh JG, Martin D, et al. Musculoskeletal Pain: Current and Future Directions of Physical Therapy Practice. Arch Rehabil Res Clin Transl. 2023;5:100258.
2. Engel GL. The Need for a New Medical Model: A Challenge for Biomedicine. Science (1979). 1977;196(4286):129–36.
3. Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, et al. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: Systematic review. Br J Sports Med. 2020;54(2):79–86.
4. Guillon M, Rochaix L, Dupont JCK. Cost-effectiveness of interventions based on physical activity in the treatment of chronic conditions: A systematic literature review. Int J Technol Assess Health Care. 2018;34(5):481–97.
5. American Physical Therapy Association. APTA Guide to Physical Therapist Practice 4.0. 2023. https://guide.apta.org. Accessed 7 Nov 2023.
6. Babatunde OO, Jordan JL, Van der Windt DA, Hill JC, Foster NE, Protheroe J. Effective treatment options for musculoskeletal pain in primary care: A systematic overview of current evidence. PLoS One. 2017;12(6):e0178621-.
7. van Seben R, van der Valk I, Huis in 't Veld T, Rodenburg G. Substitutie van zorg: Fyio- en oefentherapie op de juiste plek. Rotterdam; 2020 Dec.
8. Spiering BA, Mujika I, Sharp MA, Foulis SA. Maintaining Physical Performance: The Minimal Dose of Exercise Needed to Preserve Endurance and Strength Over Time. J Strength Cond Res. 2021;35(5):1449–58.
9. Borde R, Hortobágyi T, Granacher U. Dose–Response Relationships of Resistance Training in Healthy Old Adults: A Systematic Review and Meta-Analysis. Sports Medicine. 2015;45(12):1693–720.
10. Androulakis-Korakakis P, Fisher JP, Steele J. The Minimum Effective Training Dose Required to Increase 1RM Strength in Resistance-Trained Men: A Systematic Review and Meta-Analysis. Sports Medicine. 2020;50(4):751–65.
11. Hayden JA, Van Tulder MW, Tomlinson G. Systematic Review: Strategies for Using Exercise Therapy To Improve Outcomes in Chronic Low Back Pain. Ann Intern Med. 2005;142(9):776–85.
12. Jakobsen MD, Sundstrup E, Brandt M, Jay K, Aagaard P, Andersen LL. Effect of workplace- versus home-based physical exercise on musculoskeletal pain among healthcare workers: A cluster randomized controlled trial. Scand J Work Environ Health. 2015;41(2):153–63.
13. Daly RM, Gianoudis J, Hall T, Mundell NL, Maddison R. Feasibility, usability, and enjoyment of a home-based exercise program delivered via an exercise app for musculoskeletal health in community-dwelling older adults: Short-term prospective pilot study. JMIR mhealth uhealth. 2021;9(1):e21094.
14. Rören A, Yagappa DM, Théry C, Lefèvre-Colau MM, Rannou F, Nguyen C. Remote telerehabilitation to maintain adherence to home-based exercise therapy in people with musculoskeletal disorders: A pilot study. Ann Phys Rehabil Med. 2023;66(5):101723.

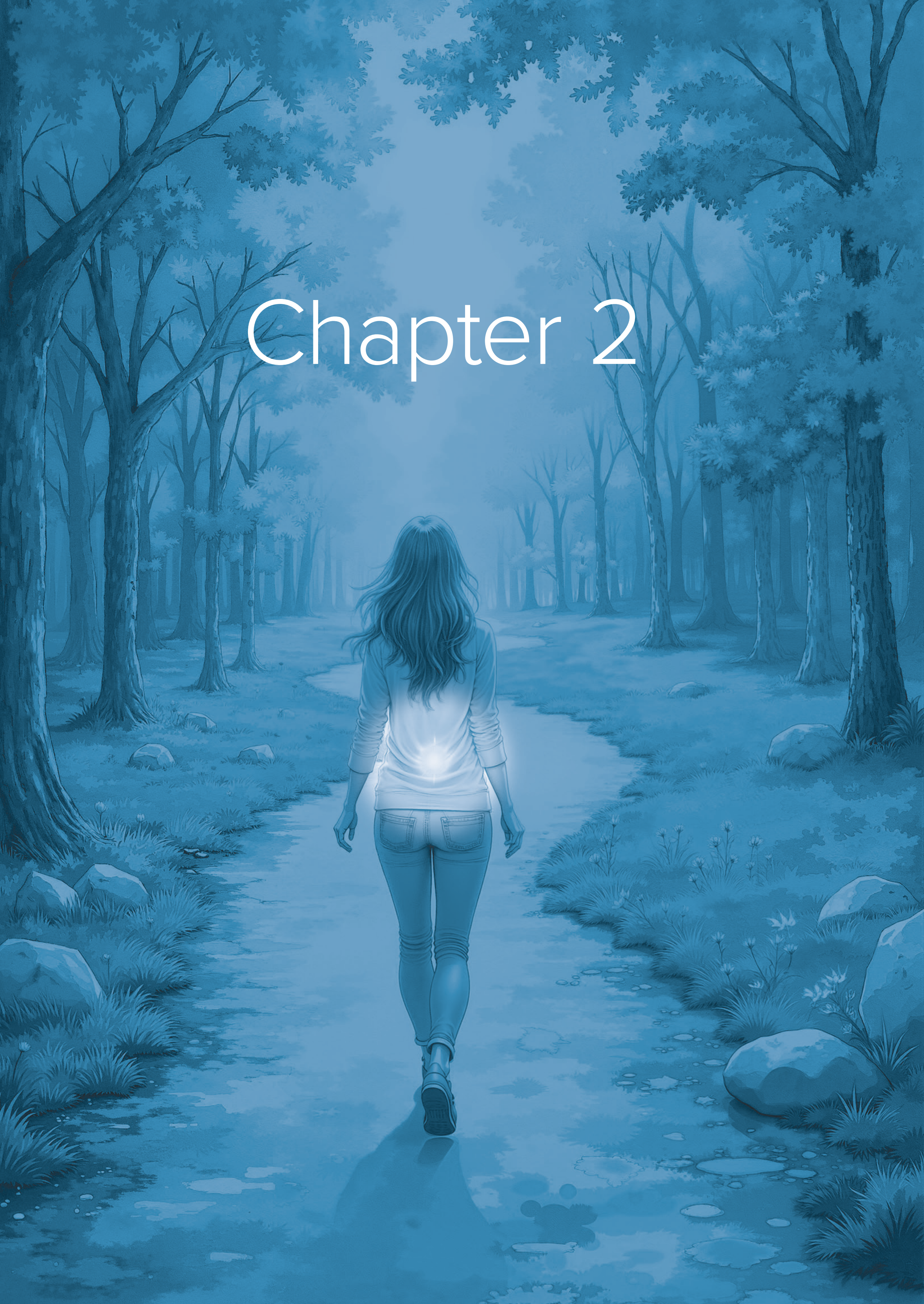
15. Macías-Hernández SI, Morones-Alba JD, Tapia-Ferrusco I, Vélez-Gutiérrez OB, Hernández-Diaz C, Nava-Bringas TI, et al. A home-based exercise program for temporomandibular joint osteoarthritis: Pain, functionality, and joint structure. J Korean Assoc Oral Maxillofac Surg. 2022;48(1):50–8.
16. Kuijlaars IAR, Sweerts L, Nijhuis-van der Sanden MWG, van Balen R, Staal JB, van Meeteren NLU, et al. Effectiveness of Supervised Home-Based Exercise Therapy Compared to a Control Intervention on Functions, Activities, and Participation in Older Patients After Hip Fracture: A Systematic Review and Meta-analysis. Arch Phys Med Rehabil. 2019;100:101–14.
17. Quentin C, Bagheri R, Ugbolue UC, Coudeyre E, Pélissier C, Descatha A, et al. Effect of home exercise training in patients with nonspecific low-back pain: A systematic review and meta-analysis. Int J Environ Res Public Health. 2021;18(16):8430.
18. James SL, Abate D, Abate KH, Abay SM, Abbafati C, Abbasi N, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2018;392(10159):1789–858.
19. Singh K, Andersson G, Watkins-Castillo SI. Low Back and Neck Pain. In: United States Bone and Joint Initiative: The Burden of Musculoskeletal Diseases in the United States (BMUS). Fourth Edition. Rosemont, IL: United States Bone and Joint Initiative.
20. Buchbinder R, van Tulder M, Öberg B, Costa LM, Woolf A, Schoene M, et al. Low back pain: a call for action. Lancet. 2018;391(10137):2384–8.
21. Foster NE, Anema JR, Cherkin D, Chou R, Cohen SP, Gross DP, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. Lancet. 2018;391(10137):2368–83.
22. Arensman RM, Geelen RH, Koppenaal T, Veenhof C, Pisters MF. Measuring exercise adherence in patients with low back pain: development, validity, and reliability of the EXercise Adherence Scale (EXAS). Physiother Theory Pract. 2022;38(7):928–37.
23. Lee GT, Himler P, Rhon DI, Young JL. Home Exercise Programs Are Infrequently Prescribed in Trials of Supervised Exercise for Individuals With Low Back Pain: A Scoping Review of 292 Randomized Controlled Trials. JOSPT. 2023;53(3):120–42.
24. Cutler RL, Fernandez-Llimos F, Frommer M, Benrimoj C, Garcia-Cardenas V. Economic impact of medication non-adherence by disease groups: A systematic review. BMJ Open. 2018;8(1).
25. Sabaté E. Adherence to long-term therapies: Evidence for action. Sabaté E, editor. European Journal of Cardiovascular Nursing. Geneva; 2003.
26. Bollen JC, Dean SG, Siegert RJ, Howe TE, Goodwin VA. A systematic review of measures of self-reported adherence to unsupervised home-based rehabilitation exercise programmes, and their psychometric properties. BMJ Open. 2014;4(6):e005044.
27. Frost R, Levati S, McClurg D, Brady M, Williams B. What Adherence Measures Should Be Used in Trials of Home-Based Rehabilitation Interventions? A Systematic Review of the Validity, Reliability, and Acceptability of Measures. Arch Phys Med Rehabil. 2017;98(6):1241-1256.e45.
28. McLean S, Holden MA, Potia T, Gee M, Mallett R, Bhanbhro S, et al. Quality and acceptability of measures of exercise adherence in musculoskeletal settings: A systematic review. Rheumatology. 2017;56(3):426–38.

29. Bachmann C, Oesch P, Bachmann S. Recommendations for Improving Adherence to Home-Based Exercise: A Systematic Review. Phys Medizin Rehabilitationsmedizin Kurortmedizin. 2018;28:20–31.
30. Lonsdale C, Hall AM, Murray A, Williams GC, McDonough SM, Ntoumanis N, et al. Communication Skills Training for Practitioners to Increase Patient Adherence to Home-Based Rehabilitation for Chronic Low Back Pain: Results of a Cluster Randomized Controlled Trial. Arch Phys Med Rehabil. 2017;98(9):1732-1743.e7.
31. Eisele A, Schagg D, Krämer LV, Bengel J, Göhner W. Behaviour change techniques applied in interventions to enhance physical activity adherence in patients with chronic musculoskeletal conditions: A systematic review and meta-analysis. Patient Educ Couns. 2019;102(1):25-36.
32. McLean SM, Burton M, Bradley L, Littlewood C. Interventions for enhancing adherence with physiotherapy: A systematic review. Man Ther. 2010;15(6):514–21.
33. Kelders SM, Kok RN, Ossebaard HC, Van Gemert-Pijnen JE. Persuasive System Design Does Matter: a Systematic Review of Adherence to Web-based Interventions. J Med Internet Res. 2012;14(6):e152.
34. Wentzel J, Van der Vaart R, Bohlmeijer ET, Van Gemert-Pijnen JEWC. Mixing online and face-to-face therapy: How to benefit from blended care in mental health care. JMIR Ment Health. 2016;3(1):e9.
35. Lambert TE, Harvey L a., Avdalis C, Chen LW, Jeyalingam S, Pratt C a., et al. An app with remote support achieves better adherence to home exercise programs than paper handouts in people with musculoskeletal conditions: A randomised trial. J Physiother. 2017;63(3):161–7.
36. Bennell KL, Marshall CJ, Dobson F, Kasza J, Lonsdale C, Hinman RS. Does a Web-Based Exercise Programming System Improve Home Exercise Adherence for People With Musculoskeletal Conditions? Am J Phys Med Rehabil. 2019;98(10):850–8.
37. Lustria MLA, Cortese J, Noar SM, Glueckauf RL. Computer-tailored health interventions delivered over the web: Review and analysis of key components. Patient Educ Couns. 2009;74(2):156–73.
38. Fogg BJ. Persuasive Technology: Using computers to change what we think and do. Morgan Kaufmann Publishers; 2003.
39. McGowan A, Sittig S, Bourrie D, Benton R, Iyengar S. The Intersection of Persuasive System Design and Personalization in Mobile Health: Statistical Evaluation. JMIR Mhealth Uhealth. 2022;10(9):e40576.
40. Saleem M, Kühne L, De Santis KK, Christianson L, Brand T, Busse H. Understanding Engagement Strategies in Digital Interventions for Mental Health Promotion: Scoping Review. JMIR Ment Health. 2021;8(12):e30000.
41. Oinas-Kukkonen H, Harjumaa M. Persuasive Systems Design: Key Issues, Process Model, and System Features. Communications of the Association for Information Systems. 2009;24(1):485–500.
42. Bossen D, Kloek C, Snippe HW, Dekker J, de Bakker D, Veenhof C. A Blended Intervention for Patients With Knee and Hip Osteoarthritis in the Physical Therapy Practice: Development and a Pilot Study. JMIR Res Protoc. 2016;5(1):e32.

43. de Vries HJ, Kloek CJJ, de Bakker DH, Dekker J, Bossen D, Veenhof C. Determinants of Adherence to the Online Component of a Blended Intervention for Patients with Hip and/or Knee Osteoarthritis: A Mixed Methods Study Embedded in the e-Exercise Trial. Telemed e-Health. 2017;23(12):1002–10.
44. van Gemert-Pijnen JE, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A Holistic Framework to Improve the Uptake and Impact of eHealth Technologies. J Med Internet Res. 2011;13(4):e111.
45. Kloek CJJ, Bossen D, Spreeuwenberg PM, Dekker J, de Bakker DH, Veenhof C. Effectiveness of a Blended Physical Therapist Intervention in People With Hip Osteoarthritis, Knee Osteoarthritis, or Both: A Cluster-Randomized Controlled Trial. Phys Ther. 2018;98(7):560–70.
46. Kloek CJJ, Van Dongen JM, De Bakker DH, Bossen D, Dekker J, Veenhof C. Cost-effectiveness of a blended physiotherapy intervention compared to usual physiotherapy in patients with hip and/or knee osteoarthritis: a cluster randomized controlled trial. BMC Public Health. 2018;18(1):1082.
47. Kloek CJJ, Bossen D, de Vries HJ, de Bakker DH, Veenhof C, Dekker J. Physiotherapists' experiences with a blended osteoarthritis intervention: a mixed methods study. Physiother Theory Pract. 2020;36(5):572–9.
48. Kloek CJJ, van Tilburg ML, Staal JB, Veenhof C, Bossen D. Development and proof of concept of a blended physiotherapeutic intervention for patients with non-specific low back pain. Physiotherapy. 2019;105(4):483–91.
49. Swart NM, Apeldoorn AT, Conijn D, Meerhoff GA, Ostello RWJG. KNGF-richtlijn lage rugpijn en lumbosacraal radiculair syndroom. KNGF-richtlijn Lage rugpijn en Lumbosacraal radiculair syndroom. 2021.
50. Hill JC, Whitehurst DGT, Lewis M, Bryan S, Dunn KM, Foster NE, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): A randomised controlled trial. Lancet. 2011;378(9802):1560–71.
51. Hill JC, Dunn KM, Lewis M, Mullis R, Main CJ, Foster NE, et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. Arthritis Rheum. 2008;59(5):632–41.
52. Koppenaal T, Arensman RM, Van Dongen JM, Ostelo RWJG, Veenhof C, Kloek CJJ, et al. Effectiveness and cost-effectiveness of stratified blended physiotherapy in patients with non-specific low back pain: Study protocol of a cluster randomized controlled trial. BMC Musculoskelet Disord. 2020;21(1):1–13.
53. Picha KJ, Howell DM. A model to increase rehabilitation adherence to home exercise programmes in patients with varying levels of self-efficacy. Musculoskeletal Care. 2018;16(1):233–7.
54. Essery R, Geraghty AWA, Kirby S, Yardley L. Predictors of adherence to home-based physical therapies: a systematic review. Disabil Rehabil. 2017;39(6):519–34.
55. Shahidi Id B, Padwal Id J, Lee E, Xu R, Northway S, Taitanoid L, et al. Factors impacting adherence to an exercise-based physical therapy program for individuals with low back pain. PLoS One. 2022;17(10):e0276326.

56. Medina-Mirapeix F, Escolar-Reina P, Gascón-Cánovas JJ, Montilla-Herrador J, Jimeno-Serrano FJ, Collins SM. Predictive factors of adherence to frequency and duration components in home exercise programs for neck and low back pain: an observational study. BMC Musculoskelet Disord. 2009;10(1):155.
57. Areerak K, Waongenngarm P, Janwantanakul P. Factors associated with exercise adherence to prevent or treat neck and low back pain: A systematic review. Musculoskelet Sci Pract. 2021;52:102333.
58. Nicolson PJA, Hinman RS, Kasza J, Bennell KL. Trajectories of adherence to home-based exercise programs among people with knee osteoarthritis. Osteoarthr Cartil. 2018;26(4):513–21.
59. Newman-Beinart NA, Norton S, Dowling D, Gavriloff D, Vari C, Weinman JA, et al. The development and initial psychometric evaluation of a measure assessing adherence to prescribed exercise: the Exercise Adherence Rating Scale (EARS). Physiotherapy. 2017;103(2):180–5.
60. Koppenaal T. e-Exercise Low Back Pain Stratified blended physiotherapy for patients with nonspecific low back pain [dissertation]. [Utrecht]: Utrecht University; 2023.

Chapter 2



Measuring exercise adherence in patients with low back pain: development, validity, and reliability of the EXercise Adherence Scale (EXAS)

Remco M. Arensman
Rianne H. Geelen
Tjarco Koppenaal
Cindy Veenhof
Martijn F. Pisters

Published in Physiotherapy Theory and Practice 2022:38(7):928-937

ABSTRACT

Objectives: To develop an instrument to measure adherence to frequency, intensity, and quality of performance of home-based exercise (HBE) programs recommended by a physical therapist and to evaluate its construct validity and reliability in patients with low back pain.

Methods: The Exercise Adherence Scale (EXAS) was developed following a literature search, an expert panel review, and a pilot test. The construct validity of the EXAS was determined based on data from 27 participants through an investigation of the convergent validity between adherence, lack of time to exercise, and lack of motivation to exercise. Associations between adherence, pain, and disability were determined to test divergent validity. The reliability of the EXAS quality of performance score was assessed using video recordings from 50 participants performing four exercises.

Results: Correlations between the EXAS and lack of time to exercise, lack of motivation to exercise, pain, and disability were rho = 0.47, rho = 0.48, rho = 0.005, and rho = 0.24, respectively. The intrarater reliability of the quality of performance score was Kappa quadratic weights (Kqw) = 0.87 (95%-CI 0.83–0.92). The interrater reliability was Kqw = 0.36 (95%-CI 0.27–0.45).

Conclusions: The EXAS demonstrates acceptable construct validity for the measurement of adherence to HBE programs. Additionally, the EXAS shows excellent intrarater reliability and poor interrater reliability for the quality of performance score and is the first instrument to measure adherence to frequency, intensity, and quality of performance of HBE programs. The EXAS allows researchers and clinicians to better investigate the effects of adherence to HBE programs on the outcomes of interventions and treatments.

BACKGROUND

Low back pain (LBP) is a major health problem affecting an estimated 576,989,000 (95% confidence interval: 518,940,400 to 637,177,900) people globally in 2017 (1). LBP has been the leading cause of disability in patients with musculoskeletal disorders since 1990, and its global prevalence has continued to increase (1). From 2012 to 2014, the total aggregate medical costs for spine-related problems were an estimated 315.4 USD billion in the United States of America alone (2). The impact of LBP on patient functioning and the economic burden on society call for effective treatments (3).

Previous research has shown that exercise therapy is effective in reducing pain intensity and disability in patients with LBP and is cost-effective when combined with stratified care based on risk prognosis (4,5). These exercise therapy interventions often require patients to adhere to a homebased exercise (HBE) program. Adherence to an HBE program is defined as the extent to which a person's exercise behavior corresponds with agreed recommendations by a health-care professional (6). These recommendations pertain to frequency (i.e. number of exercise sessions per day or week); intensity (i.e. number of repetitions per exercise session); and quality of performance of the HBE program. Furthermore, in this study, an HBE program is defined as a specific exercise or set of specific exercises recommended by a health-care professional to be completed at home to improve impairments in body functions (e.g. joint mobility, muscle strength, or joint stability). Although HBE programs have been shown to be effective, adherence in patients with LBP varies from approximately 70% to 90% and declines significantly over time (7,8). Additionally, adherence is difficult to assess due to the high rate of socially desirable answers provided by patients using diaries to record adherence, as well as the lack of a clinimetrically tested, standardized measure of exercise adherence (9–12). As a result, the treatment effects of HBE programs on LBP can be underestimated due to poor adherence rates in both research and clinical practice. To better investigate the effects of patient adherence to HBE programs on treatment outcomes, researchers require a reliable and valid measure of adherence (9,10). Additionally, a reliable and valid measure of adherence will allow clinicians to optimize patient adherence to HBE programs and improve treatment outcomes by tailoring treatments to individual patients. For example, strategies to increase self-efficacy, guidance, or exercise attention can be employed to improve low adherence to HBE programs (13,14).

Current measures of adherence to HBE programs employ a variety of strategies to measure adherence behavior (9,10,15). Bollen et al. (2014) found 29 questionnaires, 29 diaries, two visual analog scales, and a tally counter (9). Most of these instruments had been used in only one study and lacked clinimetric testing, emphasizing the absence of a reliable, valid, and standardized means to measure adherence behavior (9). Moreover, the existing instruments focus mainly on adherence to frequency and intensity recommendations of HBE programs (15). However, based on findings in patients with osteoarthritis treated by a physical therapist, quality of performance is an important factor in the treatment effects of HBE programs (16). Patients may perform exercises in the exact frequency and intensity recommended by their physical therapist, but if the quality of performance is lacking, the intended effect of the exercise (e.g. muscle strengthening) is far less likely to be achieved. Poor quality of performance of exercises can be especially problematic when trying to assess the effectiveness of HBE programs for the treatment of patients with LBP in both clinical practice and research environments.

Unfortunately, there is currently no instrument that can measure adherence to frequency, intensity, and quality of performance recommendations of HBE programs (9,10,15). Therefore, the aims of the current study are to develop an instrument to measure adherence to frequency, intensity, and quality of performance of HBE programs recommended by a health-care professional and to evaluate its construct validity and reliability.

METHODS

Development

This study was performed in primary care physical therapy practices in the Netherlands. In developing the Exercise Adherence Scale (EXAS), the goal was to create an instrument to be used during face-to-face treatment sessions by a physical therapist or other healthcare professionals to record HBE recommendations and patient-reported adherence to HBE recommendations. Furthermore, an observational component for assessing patients' quality of performance of HBEs was to be included. The resulting instrument measures patient adherence to HBE recommendations from a physical therapist on intensity, frequency, and quality of performance.

The instrument was developed using a three-step process consisting of a literature search to create items, a face and content validity check by an expert panel, and a pilot test involving a small sample of patients. In the first step, the literature was searched for studies reporting on adherence to HBE programs, and the tools used to quantify adherence were extracted where possible. The studies found used primarily patient diaries or short questionnaires aimed at quantifying adherence to intensity and frequency recommendations of HBE programs, such as the Sport Injury Rehabilitation Adherence Scale (17). None of the studies found reported on the quality of performance. Based on these findings, the authors created a first draft of the EXAS with a quality of performance component. In the second step, an expert panel comprising researchers from the fields of health-related measurement instrument creation, LBP, and adherence was created.

The expert panel provided feedback on the relevance and wording of the EXAS and suggested additions where needed in a two-round iterative process, thereby further refining the instrument. In the last step, five physical therapists pilot-tested the EXAS in patients with LBP to ensure that the questions were comprehensible and unambiguous. Based on feedback from the physical therapists and their patients, the final version of the EXAS was produced.

The final version of the EXAS is an interview-based instrument with an observational component, completed by the physical therapist together with the patient during each of the patient's visits (Supplemental File). During the patient's first treatment session, the physical therapist records the recommendations for the HBE program (i.e. type of exercises, frequency, and intensity) and shares them with the patient. During the patient's follow-up visits, the physical therapist uses the EXAS to record the frequency and intensity of HBE performance as reported by the patient in a standardized format. Additionally, the physical therapist asks the patient to perform the exercises and rates the quality of performance on a 5-point scale (i.e. poor, moderate, reasonable, good, and excellent). The EXAS contains a qualitative description for the "poor," "reasonable," and "excellent" categories to facilitate the rating process (Table 1). Based on the experiences of the physical therapists in the pilot test, completing the EXAS requires approximately five minutes.

The EXAS score for the HBE program is calculated in three steps. In step one, the ratio between the frequency and intensity of HBE performance reported by the patient and the corresponding recommendations from the physical therapist is calculated for each exercise and multiplied by 100 to determine the adherence rate [1]. If the patient-reported performance of frequency and intensity exceeds therapist recommendations, an adherence rate of 100% is scored instead.

Adherence rate

$$= \frac{\text{Number of days} * \text{number of times per day} * \text{sets} * \text{repetitions reported by the patient}}{\text{Number of days} * \text{number of times per day} * \text{sets} * \text{repetitions recommended by the therapist)}} * 100 \ [1]$$

In step two, the quality of performance score is used to calculate the adherence score for the individual exercise. To obtain the adherence score, the adherence rate for the individual exercise is multiplied by the quality of performance score for the individual exercise [2].

$$\text{Adherence score} = \text{Adherence rate} * \text{quality of performance score} \ [2]$$

The quality of performance score depends on the physical therapist's rating of the patient's quality of performance of each exercise. Currently, there is no theoretical basis for the impact of the quality of performance on the effectiveness of adherence to HBE recommendations. Therefore, the authors used their clinical experience and experience with instrument development to determine the magnitude of the impact of the quality of performance. In this study, each point on the quality of performance scale reflects 20% effectiveness (Table 1).

Table 1 Quality of performance score matrix.

Excellent	**Good**	**Reasonable**	**Moderate**	**Poor**
Score 1	Score 0.8	Score 0.6	Score 0.4	Score 0.2
All parts of the home-based exercise are performed perfectly according to the recommendations by the therapist. There is no room for improvement. It is certain the desired effect of the exercise has been achieved.		Most parts of the exercise are performed well according to the recommendations by the therapist. Important parts of the exercise can be improved. The desired effect of the exercise is likely to have been achieved.		The majority or all of the parts of the exercise are not performed according to the recommendations by the therapist. It is very unlikely that the desired effect of the exercise has been achieved.

In the third and final step, the EXAS score is obtained by calculating the mean of the adherence scores for all individual exercises in the HBE program [3].

$$EXAS\ score = \frac{Adherence\ score\ exercise\ 1 + \cdots + Adherence\ score\ exercise\ n}{\text{n}} \quad [3]$$

In the clinimetric study, the construct validity and reliability of the EXAS were investigated. Intrarater reliability was assessed only for the quality of the performance rating scale of the EXAS. For both the construct validity and reliability assessments of the EXAS, the physical therapists using the instrument were provided information on the theoretical background of adherence to HBE programs, in addition to receiving training in scoring the EXAS and incorporating the EXAS in clinical practice. Training involved completing the EXAS using data from a test patient and discussing the process with one of the researchers (RA or RG).

Construct validity

Construct validity refers to the extent to which scores obtained with a given measurement instrument relate to scores obtained with other instruments in a manner that is consistent with theoretically derived hypotheses, assuming the measurement instrument validly measures the construct of interest (18). Currently, there is no gold standard for the measurement of adherence to HBE recommendations. Therefore, construct validity was determined by testing convergent and divergent validity using four theoretical hypotheses. Convergent validity is the degree to which a measure correlates with other measures to which it is similar (19). Discriminant (divergent) validity is the degree to which a measure does not correlate with (diverges from) measures that are dissimilar (19).

The factor “Barriers” has been found to be the strongest indicator of nonadherence to HBE programs in Dutch patients with LBP (20). Lack of time to exercise and lack of motivation to exercise were among the barriers reported most frequently by patients who did not adhere to HBE recommendations and were chosen for hypothesis testing of convergent validity.

Essery, Geraghty, Kirby, and Yardley (2017) reviewed the literature on predictors of adherence to home-based physical therapies and found results for highly varied samples (21). They found that associations between adherence and a variety of possible predictors of adherence ranged mostly from no association to approximately r = 0.50. Therefore, the associations between perceived barriers and adherence were expected to be moderate (r = 0.30 to r = 0.50).

Pain and disability were reported as factors by both adherent and nonadherent patients. Therefore, both pain and disability were expected to be unrelated to adherence to HBE recommendations and were chosen to test hypotheses of divergent validity (20). Consequently, the correlations between adherence to HBE recommendations, pain, and disability were expected to be low (r = 0.00 to r = 0.30).

The resulting hypotheses to be tested were as follows: 1) The association between lack of time to exercise and the EXAS is between r = 0.30 and r = 0.50; 2) The association between lack of motivation to exercise and the EXAS is between r = 0.30 and r = 0.50; 3) The association between pain and the EXAS is between r = 0.00 and r = 0.30; and 4) The association between disability and the EXAS is between r = 0.00 and r = 0.30.

Participants and setting

For the validity study, 16 physical therapy primary care practices with 42 physical therapists participated and agreed to recruit patients with LBP according to the following inclusion criteria: the first visit to a physical therapist for the current episode of LBP as the primary complaint, current episode of LBP lasting more than four weeks at the first visit to a physical therapist, between the ages of 20 and 65, and having sufficient command of the Dutch language to read and understand questionnaires and spoken or written instructions. Patients were excluded if they had previously been diagnosed with lumbar radiculopathy, spinal osteoarthritis, or other conditions as the cause of their LBP or if they were unable to perform exercises due to physical or mental issues.

Measurements

Adherence to HBE. Recommendations were measured with the newly developed EXAS. The EXAS score was calculated using the previously stated assumption of 20% effectiveness for each point on the quality of performance scale.

Barriers. The barriers “lack of time to exercise” and “lack of motivation to exercise” were measured using single-item Likert scales based on the barriers subscale used by Sluijs, Kok, and van der Zee (1993) (20). Lack of time to exercise was reported on a 5-point scale ranging from 5 (“always”) to 1 (“never”). Lack of motivation to exercise was measured on a 4-point scale ranging from 1 (“very motivated”) to 4 (“not motivated”).

Pain. Pain was measured with the Numeric Rating Scale for pain (NRS Pain) (22–24). Patients were asked to rate the intensity of their current pain on an 11-point numeric scale ranging from 0 (“no pain”) to 10 (“worst pain imaginable”).

Disability. Disability was measured with the Dutch language version of the Quebec Back Pain Disability Scale (QBPDS) (25). The QBPDS quantifies disability caused by LBP in daily activities. The questionnaire consists of 20 items, and the total score ranges from 0 (no disability) to 100 (completely restricted). Moderate evidence for positive reliability and validity of the Dutch-language version of the QBPDS has been reported in a review by Speksnijder et al. (2016) (26).

Demographics. The following personal and demographic characteristics of the participants were measured: age (in years), gender, height (in centimeters), weight (in kilograms), level of education (i.e. elementary school, high school, vocational school, college, or university), and duration of symptoms (up to 3 months, 3 to 6 months, 6 to 12 months, or more than 12 months).

Procedures to test validity

All patients with LBP who visited the participating physical therapy practices and agreed to participate were screened for eligibility using the inclusion and exclusion criteria. Written informed consent was obtained from the participants prior to the start of the study. The patients received the usual care, and the physical therapists used the EXAS to record HBE recommendations. Additionally, measurements of pain, disability, barriers, and patient characteristics were completed. One week after the HBE program was recommended to the patient, the physical therapist completed the EXAS together with the patient during a follow-up visit.

Reliability

Reliability is defined as “the extent to which scores for patients who have not changed are the same for repeated measurement under several conditions: for example, . . . by different persons on the same occasion (interrater) or by the same persons (i.e. raters or responders) on different occasions (intrarater)” (18). The EXAS is designed to be used by a physical therapist who both recommends the HBE program to the patient and rates the quality of performance during the patient’s follow-up visit. However, in clinical practice, it is not uncommon for patients to have more than one physical therapist during their treatment period. For this reason, both intrarater reliability and interrater reliability of the EXAS quality of performance were assessed.

Participants and setting

For the reliability study, two researchers included a convenience sample of healthy adults aged 18–65 years with sufficient command of the Dutch language to read and understand written or spoken instructions. Potential participants were excluded if they were unable to perform exercises due to physical or mental issues or if they experienced pain or discomfort when performing exercises. Recruitment took place at Fontys University of Applied Sciences in the Netherlands.

MEASUREMENTS

Quality of performance of the exercises by the participants was rated using the scoring matrix of the EXAS (Table 1). The following personal and demographic characteristics of the participants were measured: age (in years); gender; height (in centimeters); weight (in kilograms); and level of education (i.e. elementary school, high school, vocational school, college, or university).

Procedures to test reliability

All participants provided written informed consent prior to the start of the study. Subsequently, personal and demographic data were collected. Four different exercises commonly recommended by physical therapists in HBE programs for LBP were selected for reliability testing by a panel of physical therapists specialized in treating patients with LBP. The selected exercises were the squat, the deadlift using a broomstick, the lunge, and the bridge. For each exercise, participants were asked to watch an instructional video showing an actor performing the exercise; additional written instructions were also available. Participant performance of the exercise was recorded using two high-definition video cameras (JVC Everio GZ-HM300, JVC, Yokohama, Japan) capturing video at 30 fps and set up at a distance of 3 meters from the front and from the left side. The process was repeated until the participant had completed all four exercises and recordings were successfully collected. Subsequently, two physical therapists were asked to view the video recordings and rate the quality of performance of the exercises by the participants. The physical therapists both had 10 or more years of experience treating patients with LBP, but they worked in different settings. The first physical therapist worked in a health-care center, and the second physical therapist worked in a primary care physical therapy practice. After one week, the first physical therapist repeated the process to complete data collection.

Data analysis

A priori, a sample size of 50 participants for both the validity and the reliability testing was used in accordance with the recommendations made for a good rating by the COSMIN initiative (27). All analyses were performed using IBM SPSS Statistics for Windows, Version 23.0 (Armonk, NY: IBM Corp). All data were anonymized before analysis.

Personal and demographic characteristics

Descriptive statistics were applied to describe the samples for the validity and reliability studies. For continuous data, means and standard deviations were calculated. For categorical data, percentages were calculated instead.

Validity

Validity was assessed using Spearman’s rho for the correlations, as all comparator data were collected using ordinal scales. As no gold standard exists for the measurement of adherence to HBE recommendations, it was decided a priori that at least three of the four predetermined hypotheses would need to be accepted to confirm the validity of the EXAS.

Reliability

Intrarater and interrater reliability were assessed using Cohen’s kappa with quadratic weights (28). Additionally, the 95% confidence interval was calculated. Results were interpreted using the guidelines proposed by Cicchetti and Sparrow (1981) (29). These guidelines state that kappa scores: below 0.40 are poor; between 0.40 and 0.59 are fair; between 0.60 and 0.74 are good; and between 0.75 and 1.00 are excellent.

RESULTS

Patient characteristics

For the validity study, 30 patients with LBP were included. Before data collection was completed, three patients withdrew without providing a reason. Therefore, validity was determined based on data from 27 patients. Missing values on all variables varied between 0% and 7%. In cases of missing data, pairwise exclusion was performed. At the time of testing, the mean age of the patients was 39.2 (± 11.1) years. Thirteen patients had been suffering from LBP for a period of less than 3 months, one subject for 3 to 6 months, and 13 subjects for more than 6 months. Further demographic data of the participants, adherence rates, and the EXAS score can be found in Table 2. In total, 50 participants performing four different exercises were recorded for the reliability study, resulting in 200 observations. The average age of the participants in the reliability study was 25.6 (±7.37) but ranged from 18 to 55 years (Table 3).

Table 2 Patient characteristics of the validity study of the exercise adherence scale.

	n	%	Mean (SD)	Range
Total sample	27			
Age, in years	27		39.5 (11.3)	21–59
Male	16	59.3		
Female	11	40.7		
Height (cm)	27	100	174 (10.1)	160–197
Weight (kg)	27	100	79.8 (16.2)	58–112
Education				
Elementary school	1	3.7		
High school	6	22.2		
Vocational school	18	66.6		
College or university	2	7.4		
Duration of symptoms				
0 to 3 months	13	48.1		
3 to 6 months	1	3.7		
More than 6 months	13	48.1		
Adherence rate*	27	100	67.4 (27.2)	16–100
EXAS score	27	100	57.1 (25.9)	12.8–100

n: number of participants in sample; SD: Standard Deviation; cm: centimeters; kg: kilograms; *: Adherence rate is calculated as the percentage of patient-reported adherence to therapist home-based exercises recommendations; EXAS: Exercise Adherence Scale

Table 3 Patient characteristics of the reliability study of the exercise adherence scale quality of performance score.

	n	%	Mean (SD)	Range
Total sample	50			
Age, in years	50	100	25.6 (7.37)	18–55
Male	31	62		
Female	19	38		
Height (cm)	50	100	177.1 (11.3)	151–200
Weight (kg)	50	100	73.3 (11.6)	50.4–106.1
Education				
Vocational school	1	2		
College or university	49	98		
EXAS Quality of performance	200*		4†	1–5

n: number of participants in sample; SD: Standard Deviation; cm: centimeters; kg: kilograms; EXAS: Exercise Adherence Scale; *: quality of performance scores from the first assessment only; †: Mode reported instead of mean.

Table 4 Associations between the exercise adherence scale and lack of time to exercise, lack of motivation to exercise, pain, and the Quebec back pain disability scale.

	Lack of time to exercise	Lack of motivation to exercise	Pain	QBPDS
n	27	27	27	26
EXAS	0.47*	0.48**	0.24	0.005

QBPDS: Quebec Back Pain Disability Scale; n: number of participants in sample; EXAS: Exercise Adherence Scale; *: p < 0.05; **: p < 0.001; Spearman's rho was used for all associations

Validity

For convergent validity, the association between lack of time to exercise and the EXAS was rho = 0.47 (p = .013), and the association between lack of motivation to exercise and the EXAS was rho = 0.48 (p = .011) (Table 4). For divergent validity, the association between pain and the EXAS was rho = 0.24 (p = .22), and the association between disability and the EXAS was rho = 0.005 (p = .98).

Reliability

For intrarater reliability, Cohen's kappa using quadratic weights was Kqw = 0.87 (95%-CI 0.83–0.92), p < .001, with a total of 200 observations of four exercises performed by 50 healthy subjects. In 200 observations, disagreement between repeated ratings of the same video by the same therapist occurred in 41 ratings. Out of these 41 ratings, only one differed by 2 points, and in all other cases, the difference was 1 point. Interrater reliability was much lower with Kqw = 0.36 (95%-CI 0.27–0.45), $p < .001$. The raters disagreed on the score in 142 cases, 77 ratings differed by 1 point, 53 ratings differed by 2 points, and the remaining 12 cases differed by 3 points.

DISCUSSION

The aims of the current study were to develop an instrument to measure adherence to frequency, intensity, and quality of performance of HBE programs recommended by a health-care professional and to evaluate its construct validity and intrarater reliability, resulting in the development of the EXAS. The instrument contains HBE recommendations from the health-care professional, patient-reported adherence to intensity and frequency of the HBE recommendations, and an observational component. This approach is in line with recommendations from Peek, Carey, Mackenzie, and Sanson-Fisher (2019) who suggested that adding an observational component to the assessment of adherence might more accurately reflect a patient's efforts to follow HBE recommendations from a physical therapist (30). For the validity of the EXAS, the strength of the correlations between the EXAS, time to exercise, and motivation to exercise were moderate and confirmed the initial hypotheses. It was hypothesized that the associations would be moderate at best due to the large variety of factors related to adherence to HBE programs and the consistently moderate associations found in the literature (20,30).

Divergent validity hypotheses were also all moderate as expected a priori. Both pain and disability were not significantly associated with the EXAS. It can be reasoned that pain and disability prevent patients from exercising or reduce adherence to HBE programs, which can potentially increase pain and disability. However, the opposite may also be true. Patients experiencing more pain and disability might be more motivated to exercise to reduce their symptoms. This ambiguity is reflected in the lack of association between pain and disability and the EXAS. A possible explanation for this can be found in the different strategies patients use to cope with pain and disability (31). Indeed, two of the most-reported strategies to cope with pain by patients with chronic LBP are praying and hoping (i.e. passive strategy) and increased behavioral activity (i.e. active strategy).

The intrarater reliability of the quality of performance component of the EXAS is excellent ($r = 0.87$, 95% CI 0.83–0.92). With this score, the reliability estimate exceeds the standard threshold of 0.70 for use as a between-groups comparison measure (19). This result is very similar to the intrarater reliability results found in a study using a 10-point rating scale (32). Of the six physical therapists rating patient quality of performance using this 10-point scale, four scored between 0.82 and 0.88, with the remaining two scoring 0.72 and 0.74, respectively. The primary difference between this study and the current study is the scale on which quality of the performance was rated. In the study by Hermet et al. (2018), a 10-point rating scale was used (32), whereas, in the current study, a 5-point ordinal scale with additional explanation was used to provide a more standardized means of interpreting the different ratings.

The results for interrater reliability of the EXAS quality of performance are poor. This finding is almost identical to the results of Hermet et al. (2018) (32), who found an interrater reliability of 0.34 (95%-CI 0.07–0.48) for primary care physical therapists rating strength exercises. They proposed that different backgrounds and expectations between physical therapists might be the cause of low interrater reliability, as higher reliability scores were found in trained physical therapists. The large number of disagreements between ratings by untrained therapists in the current study appears to support this hypothesis when compared with the much lower number of disagreements between repeated ratings by the same therapist. As a result, clinicians and researchers using the EXAS to assess adherence to HBE programs should consider training or instructing healthcare professionals in the scoring of quality of performance to increase interrater reliability.

During the data collection phase of the current study, a new measure of adherence was published (33). The Exercise Adherence Rating Scale (EARS) is a 6-item questionnaire aimed at measuring adherence behavior and exploring reasons for nonadherence. The full instrument consists of three sections: Prescribed Exercise Questionnaire (Section A), Exercise Adherence Rating Scale (EARS) (Section B), and What helps or hinders doing your exercises? (Section C) (33). Notably, the questions on frequency and intensity from Section A are similar to but less detailed than the frequency and intensity parts of the EXAS. Quality of performance is entirely absent from the EARS, whereas the EXAS collects no information on reasons for adherence behavior. When used complementarily, the EXAS and EARS provide detailed and extensive information on adherence to frequency, intensity, and quality of performance recommendations from a health-care professional, as well as on reasons for the adherence behavior reported by the patient.

Strengths and limitations

The first strength of this study is that it is the first to develop an instrument to measure adherence to frequency, intensity, and quality of performance of HBE recommendations in patients with LBP (15). During the development phase of the instrument, patients, physical therapists, and experts were involved, in accordance with the advice from Terwee et al. (2007) (34). In addition to development, the clinimetric properties of the instrument were also assessed. Using a measure with known validity and reliability provides a better understanding and interpretation of the findings when assessing adherence. As a result, clinicians are better able to tailor their treatments to individual patients. Researchers can use the EXAS to assess the effectiveness of HBE interventions and statistically control for adherence of the study participants, possibly reducing the underestimation of treatment effects. A second strength of this study is the high number of 200 observations used for the reliability testing of the EXAS. Furthermore, video recordings were used to rate the quality of performance, which eliminated the impact of possible variations in the performance of exercises by patients or differences in the rater's point of view between measurements. This increases confidence in the findings for intrarater and interrater reliability.

The current study also has several limitations. The first limitation is that the participants recruited for the reliability study were healthy subjects. Healthy subjects perform better during functional movement tasks when compared to patients with chronic LBP (35). However, the reliability of the scoring system for the quality of exercise performance depends on the agreement between different ratings made by the same rater. The underlying causes for better or worse performance by the patient are not relevant. In daily practice, a physical therapist will select exercises for an HBE program and tailor the difficulty of these exercises to correspond with the patient's level of ability, thereby eliminating any differences in performance with a healthy subject.

The second limitation is the low number of only four different exercises used for the reliability study. As a physical therapist can select from a vast list of possible exercises when designing an HBE program, using all of these exercises would have been impractical. Therefore, an expert panel selected four exercises commonly recommended to patients with LBP to be used in the study.

The third limitation is the potential patient bias when reporting adherence to frequency and intensity recommendations. However, the impact of overreporting of adherence by patients is most likely mitigated by adding the quality of performance score to the assessment of adherence. Quality of performance is likely to be low in nonadherent patients, resulting in a lower EXAS score and a more realistic approximation of actual adherence. However, more research is required to confirm this hypothesis.

Another limitation is the lack of reliability testing of the frequency and intensity aspects of the EXAS. Although the validity of the EXAS and the reliability of the quality of performance assessment were investigated in the current study, additional research is needed to determine the clinimetric properties of the EXAS in patients with LBP.

The last limitation is the relatively small sample size for the validity study of the EXAS. A sample size of 50 or greater is recommended by the COSMIN checklist for a "good" rating, but practical reasons prevented the achievement of this goal (27). Although 42 physical therapists agreed to recruit patients with LBP for the study, many of them did not manage to do so during the inclusion period of the study. Nevertheless, given the homogeneity of the patients in the validity study, it appears unlikely that including more patients would have yielded different results.

Adherence to HBE programs remains a complex and multi-dimensional construct. Although the EXAS appears to be a valid and reliable instrument, it is still inferior to direct observation. The EXAS shares this disadvantage with every measure of adherence, as all current measurement instruments for adherence to HBE recommendations rely on the patient's memory, perception, and honesty. Despite this limitation, the EXAS is the only instrument incorporating the quality of exercise performance in the assessment of adherence. Additionally, the EXAS score is an interesting theoretical construct that may allow for new ways to study which determinants of an HBE program are most important for the patient. For instance, an important question to answer in future research will be whether the quality of performance of exercises contributes to treatment effects or whether attention should be focused on adherence to frequency and intensity recommendations alone. Although a focus on the quality of performance of exercises could potentially deter patients from exercising at home, the added attention to detail could also improve a patient's feeling of being supported by their therapist, increase self-efficacy, and increase the perceived importance of exercising at home as part of their treatment leading to increased adherence. In daily practice, primary care physical therapists and other clinicians often rely on their training and experience to tailor treatment to respond to the individual needs of patients with LBP to achieve the best outcomes. Indeed, tailoring interventions to the patient has been found to increase patient outcomes and enhance treatment effects (36). However, for HBE programs, it remains unclear whether the specific exercises selected by the physical therapist, the quality of performance of the exercises by the patient, or the increase in physical activity from doing exercises are responsible for the effects found. The EXAS score allows researchers to investigate whether clinicians should focus on correct performance of exercises, on adherence to frequency and intensity, or on both.

Conclusion

The EXAS demonstrates acceptable construct validity for the measurement of adherence to HBE programs. Additionally, the EXAS shows excellent intrarater reliability and poor interrater reliability for the quality of performance score and is the first instrument to measure adherence to frequency, intensity, and quality of performance of HBE programs. The EXAS allows researchers and clinicians to better investigate the effects of adherence to HBE programs on the outcomes of interventions and treatments.

Acknowledgments

The authors would like to thank Thom Habets and Floor Vluggen for their assistance with data collection and Erik-Jan Haan for his assistance as a rater for reliability testing.

Conflicts of interest

None declared.

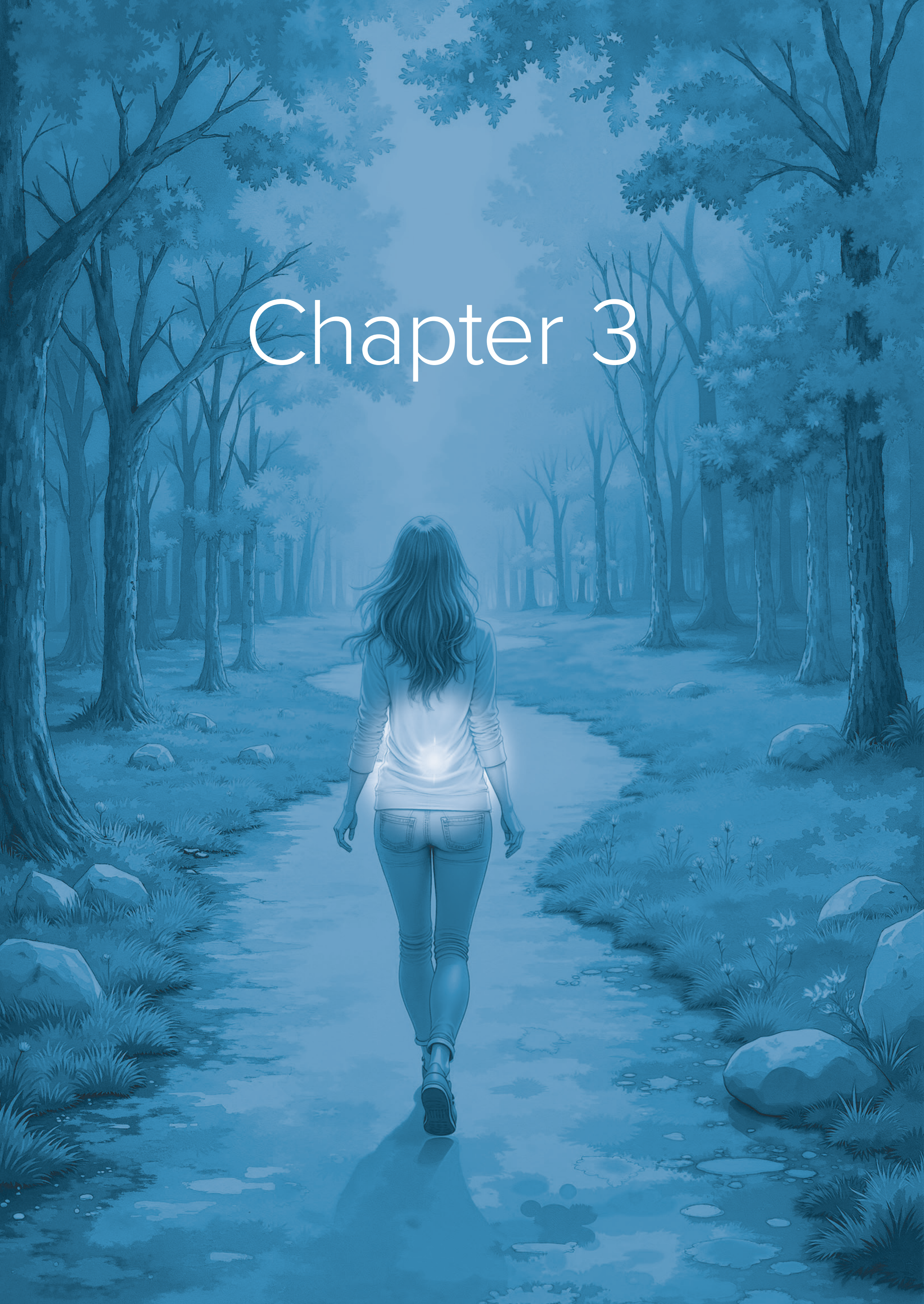
REFERENCES

1. James SL, Abate D, Abate KH, Abay SM, Abbafati C, Abbasi N, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2018;392(10159):1789–858.
2. United States Bone and Joint Initiative. The Burden of Musculoskeletal Diseases in the United States: Prevalence, Societal and Economic Cost. 4th ed. Rosemont, IL: United States Bone and Joint Initiative; 2018. Available from: www.boneandjointburden.org
3. Buchbinder R, van Tulder M, Öberg B, Costa LM, Woolf A, Schoene M, et al. Low back pain: a call for action. Lancet. 2018;391(10137):2384–8.
4. Gordon R, Bloxham S. A Systematic Review of the Effects of Exercise and Physical Activity on Non-Specific Chronic Low Back Pain. Healthcare. 2016;4(2):22.
5. Hill JC, Whitehurst DGT, Lewis M, Bryan S, Dunn KM, Foster NE, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. Lancet. 2011;378:1560–71.
6. Sabaté E. Adherence to long-term therapies: Evidence for action. Sabaté E, editor. European Journal of Cardiovascular Nursing. Geneva; 2003.
7. Hammer C, Degerfeldt L, Denison E. Mechanical diagnosis and therapy in back pain: Compliance and social cognitive theory. Adv Physiother. 2007;9(4):190–7.
8. Kolt GS, McEvoy JF. Adherence to rehabilitation in patients with low back pain. Man Ther. 2003;8(2):110–6.
9. Bollen JC, Dean SG, Siegert RJ, Howe TE, Goodwin VA. A systematic review of measures of self-reported adherence to unsupervised home-based rehabilitation exercise programmes, and their psychometric properties. BMJ Open. 2014;4(6):e005044.
10. Frost R, Levati S, McClurg D, Brady M, Williams B. What Adherence Measures Should Be Used in Trials of Home-Based Rehabilitation Interventions? A Systematic Review of the Validity, Reliability, and Acceptability of Measures. Arch Phys Med Rehabil. 2017;98(6):1241-1256.e45.
11. McLean S, Holden MA, Potia T, Gee M, Mallett R, Bhanbhro S, et al. Quality and acceptability of measures of exercise adherence in musculoskeletal settings: A systematic review. Rheumatology. 2017;56(3):426–38.
12. Stone AA, Shiffman S, Schwartz JE, Broderick JE, Hufford MR. Patient compliance with paper and electronic diaries. Control Clin Trials. 2003;24(2):182–99.
13. Bachmann C, Oesch P, Bachmann S. Recommendations for Improving Adherence to Home-Based Exercise: A Systematic Review. Phys Medizin Rehabilitationsmedizin Kurortmedizin. 2018;28:20–31.
14. Picha KJ, Howell DM. A model to increase rehabilitation adherence to home exercise programmes in patients with varying levels of self-efficacy. Musculoskeletal Care. 2018;16(1):233–7.
15. Uzawa H, Davis S. Outcome measures for adherence to home exercises among patients with chronic low back pain: a systematic review. J Phys Ther Sci. 2018;30(4):649–53.

16. Pisters MF, Veenhof C, Schellevis FG, Twisk JWR, Dekker J, De Bakker DH. Exercise adherence improving long-term patient outcome in patients with osteoarthritis of the hip and/or knee. Arthritis Care Res. 2010;62(8):1087–94.
17. Brewer BW, Van Raalte JL, Petitpas AJ, Sklar JH, Pohlman MH, Krushell RJ, et al. Preliminary psychometric evaluation of a measure of adherence to clinic-based sport injury rehabilitation. Physical Therapy in Sport. 2000;1(3):68–74.
18. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol. 2010;63(7):737–45.
19. Frost MH, Reeve BB, Liepa AM, Stauffer JW, Hays RD, Sloan JA. What is sufficient evidence for the reliability and validity of patient-reported outcome measures? Value in Health. 2007;10(SUPPL. 2):94–105.
20. Sluijs EM, Kok GJ, van der Zee J. Correlates of Exercise Compliance in Physical Therapy. Phys Ther. 1993 Nov 1;73(11):771–82.
21. Essery R, Geraghty AWAA, Kirby S, Yardley L. Predictors of adherence to home-based physical therapies: a systematic review. Disabil Rehabil. 2017;39(6):519–34.
22. Chiarotto A, Terwee CB, Ostelo RW. Choosing the right outcome measurement instruments for patients with low back pain. Best Pract Res Clin Rheumatol. 2016;30(6):1003–20.
23. Chiarotto A, Boers M, Deyo RA, Buchbinder R, Corbin TP, Costa LOP, et al. Core outcome measurement instruments for clinical trials in nonspecific low back pain. Pain. 2018;159(3):481–95.
24. Downie WW, Leatham PA, Rhind VM, Wright V, Branco JA, Anderson JA. Studies with pain rating scales. Annal of the Rheumatic Diseases. 1978;37(4):378–81.
25. Schoppink LEM, van Tulder MW, Koes BW, Beurskens SAJHM, de Bie RA. Reliability and validity of the Dutch adaptation of the Quebec Back Pain Disability Scale. Phys Ther. 1996;76(3):268–75.
26. Speksnijder CM, Koppenaal T, Knottnerus JA, Spigt M, Staal JB, Terwee CB. Measurement Properties of the Quebec Back Pain Disability Scale in Patients With Nonspecific Low Back Pain: Systematic Review. Phys Ther. 2016;96(11):1816–31.
27. Terwee CB, Mokkink LB, Knol DL, Ostelo RWJG, Bouter LM, De Vet HCW. Rating the methodological quality in systematic reviews of studies on measurement properties: A scoring system for the COSMIN checklist. Qual Life Res. 2012;21(4):651–7.
28. Kottner J, Audige L, Brorson S, Donner A, Gajewski BJ, Hroóbjartsson A, et al. Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. Int J Nurs Stud. 2011;48(6):661–71.
29. Cicchetti D V, Sparrow SA. Developing criteria for establishing interrater reliability of specific items: applications to assessment of adaptive behavior. Am J Ment Defic. 1981;86(2):127–37.
30. Peek K, Carey M, Mackenzie L, Sanson-Fisher R. Patient adherence to an exercise program for chronic low back pain measured by patient-report, physiotherapist-perception and observational data. Physiother Theory Pract. 2019;35(12):1304–13.
31. Cabak A, Dąbrowska-Zimakowska A, Truszczyńska A, Rogala P, Laprus K, Tomaszewski W. Strategies for Coping with Chronic Lower Back Pain in Patients with Long Physiotherapy Wait Time. Med Sci Monit. 2015;21:3913–20.

32. Hermet A, Roren A, Lefevre-Colau MM, Gautier A, Linieres J, Poiraudeau S, et al. Agreement among physiotherapists in assessing patient performance of exercises for low-back pain. BMC Musculoskelet Disord. 2018;19(265).
33. Newman-Beinart NA, Norton S, Dowling D, Gavriloff D, Vari C, Weinman JA, et al. The development and initial psychometric evaluation of a measure assessing adherence to prescribed exercise: the Exercise Adherence Rating Scale (EARS). Physiotherapy. 2017;103(2):180–5.
34. Terwee CB, Bot SDM, de Boer MR, van der Windt DAWM, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol. 2007;60(1):34–42.
35. Ko MJ, Noh KH, Kang MH, Oh JS. Differences in performance on the functional movement screen between chronic low back pain patients and healthy control subjects. J Phys Ther Sci. 2016;28(7):2094–6.
36. Foster NE, Mullis R, Hill JC, Lewis M, Whitehurst DGT, Doyle C, et al. Effect of stratified care for low back pain in family practice (IMPaCT back): A prospective population-based sequential comparison. Ann Fam Med. 2014;12(2):102–11.

Chapter 3



Patient perspectives on using a smartphone application to support home-based exercise during physical therapy treatment: a qualitative study.

Remco M. Arensman
Corelien J.J. Kloek
Martijn F. Pisters
Tjarco Koppenaal
Raymond J.W.G. Ostelo
Cindy Veenhof

Published in Journal of Medical Internet Research: Human Factors 2022;9(3):e35316

ABSTRACT

Background: Home-based exercise is an important part of physical therapy treatment for patients with low back pain. However, treatment effectiveness depends heavily on patient adherence to home-based exercise recommendations. Smartphone applications designed to support home-based exercise have the potential to support adherence to exercise recommendations and possibly improve treatment effects. A better understanding of patient perspectives regarding the use of smartphone applications to support home-based exercise during physical therapy treatment can assist physical therapists with optimal use and implementation of these applications in clinical practice.

Objective: The aim of this study is to investigate patient perspectives on the acceptability, satisfaction, and performance of a smartphone application to support home-based exercise following recommendations from a physical therapist.

Methods: Using a interpretivist phenomenology approach, nine patients (four males and five females, aged 20–71 years) with non-specific low back pain recruited from two primary care physical therapy practices were interviewed within two weeks after treatment ended. An interview guide was used for the interviews to ensure that different aspects of the patient's perspective were discussed. The Physitrack® smartphone application was used to support home-based exercise as part of treatment for all patients. Data were analyzed using the "Framework Method" to assist with interpretation of the data.

Results: Data analysis revealed 11 categories distributed among the three themes "acceptability," "satisfaction," and "performance." Patients were willing to accept the application as part of treatment when it is easy to use, when it benefits the patient, and when the physical therapist instructs the patient in its use. Satisfaction with the app is determined by users' perceived support from the application when exercising at home and the perceived increase in adherence. The video and text instructions, reminder functions, and self-monitor functions are considered most important for performance during treatment. The patients did not view the Physitrack® app as a replacement for the physical therapist and relied on their therapist for instruction and support when needed.

Conclusions: Patients who used an app to support home-based exercise as part of treatment are accepting of the app when it is easy to use, when it benefits the patient, and when the therapist instructs the patient in its use. Physical therapists using an app to support home-based exercise can use the findings from this study to effectively support their patients when exercising at home during treatment.

INTRODUCTION

The effectiveness of exercise therapy in the treatment of musculoskeletal disorders has been studied extensively, and exercise therapy remains an important part of treatment in clinical practice (1). However, treatment is not limited to supervised exercise. Home-based exercise (HBE) programs allow patients to exercise at home between visits to the clinic. Unfortunately, the effectiveness of HBE relies heavily on patient adherence, which has been shown to be low (2–5).

Different factors contribute to patient adherence to HBE, including several factors that can be easily influenced by a physical therapist (6,7). For example, a physical therapist can not only provide support and positive feedback, but also follow up on exercise recommendations during future visits to reinforce patient adherence. Additionally, practitioners can increase patient adherence to HBE by recommending a feasible maximum of 2-4 exercises, supporting and improving self-efficacy, and supporting patients to incorporate exercise into their daily life (6). These strategies aim to improve or reinforce patient adherence to the frequency, intensity, and quality of their performance of exercise recommendations. However, increasing adherence to HBE remains challenging even when employing different strategies.

Smartphone apps have the potential to provide new solutions to support adherence to exercise recommendations. Exercise apps using personalized exercise programs, video instructions, and reminders to exercise can increase adherence by providing performance guidance and remote support, and improving physical therapist–patient interactions regarding HBE (8,9). Furthermore, apps supporting health behaviors provide health benefits and additional support in the patient's own home environment (10,11). Research has shown that patients with nonspecific low back pain (LBP) are mainly worried that despite the benefits of new technologies (eg, reminders and remote support), their use leads to less personalized care (12). However, patients also expect these technologies to support HBE by increasing performance and adherence to exercise recommendations (12). To our knowledge, and based on our review of the literature, no qualitative studies are available on patients who used an app to support HBE alongside physical therapy, highlighting an important gap in the literature.

With the increasing availability of apps to support physical therapy treatment, a better understanding of patient perspectives on using these apps during physical therapy can assist physical therapists to effectively tailor the use of these apps for their patients and consequently improve treatment efficacy. Therefore, the aim of this study was to investigate patient perspectives on the acceptability, satisfaction, and performance of an app to support HBE following recommendations from a physical therapist.

METHODS

Design

This study was performed using qualitative methods associated with phenomenology and an interpretivist approach. Data were collected by interviewing a sample of patients with LBP who used Physitrack (Physitrack Limited) during treatment in a primary care physical therapy practice.

Ethics Approval

The Medical Research Ethics Committee of the University Medical Center Utrecht ruled that the Medical Research Involving Human Subjects Act does not apply to this study (protocol number 17-034/C). This study complies with the Declaration of Helsinki, and the standards for reporting qualitative research were followed in reporting this work (13).

Study Procedures and Recruitment

All patients were recruited from January to April 2018 from 2 participating primary care physical therapy practices in the Netherlands. For each participating practice, a physical therapist specializing in the treatment of spinal pain volunteered to recruit patients. Both physical therapists had 2 years of experience working with Physitrack. Physitrack allows physical therapists to create and share personalized exercise programs with patients through the Physitrack app, email, or paper handouts (see Figures 1 and 2 for examples). The app allows patients to set reminders to perform their exercises, track their adherence, rate pain scores during the exercises, and send direct messages to their physical therapists. To be eligible for participation, a patient had to have been treated by one of the participating physical therapists, their treatment had to have ended less than 2 weeks prior to participation in the study, and the physical therapist had to have sent the patient HBE recommendations using the Physitrack app during treatment. Patients were excluded if they had insufficient command of the Dutch language for casual conversation. Patients interested in the study were contacted by a researcher (RA) and were provided with information about the study and procedures. An appointment for the interview was made with interested patients, and written informed consent was obtained prior to the interview. A purposive sampling method was chosen to include a heterogeneous sample based on age and gender. Additionally, the participants were asked to complete the Systems Usability Scale (SUS) to provide an objective measure of usability for Physitrack (14). The SUS consists of 10 items rated on a 5-point scale ranging from strongly agree to strongly disagree. The SUS score ranges from 0 to 100, and usability of the app is acceptable for ratings of 70 or higher (15). The goal was to recruit similar numbers of males and females with a high variation in age until saturation of the data was achieved. Data saturation was reached when new data repeated previous data without adding new information, and saturation was checked during data analysis in an iterative process (16).

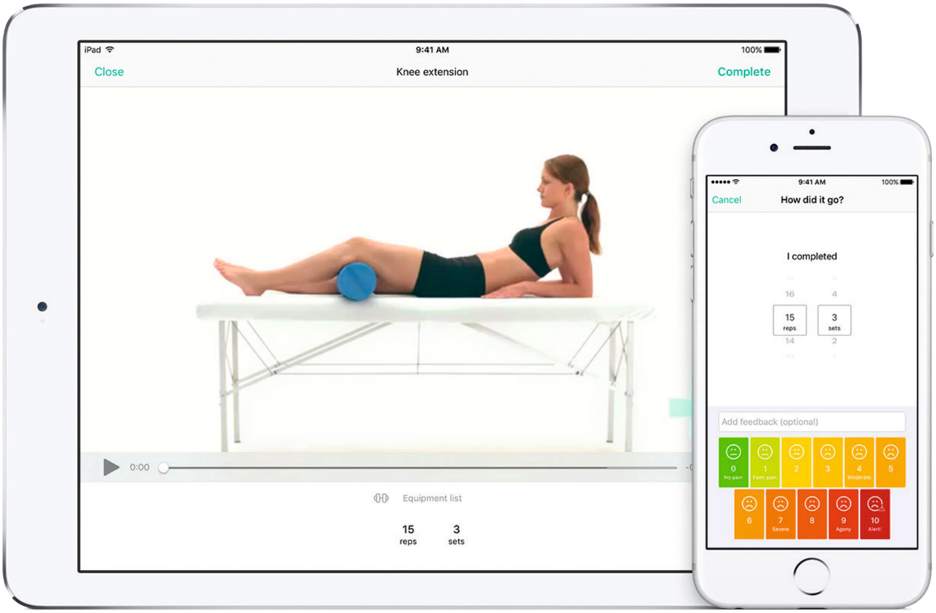


Figure 1 Examples of the Physitrack app used on a tablet and a smartphone.

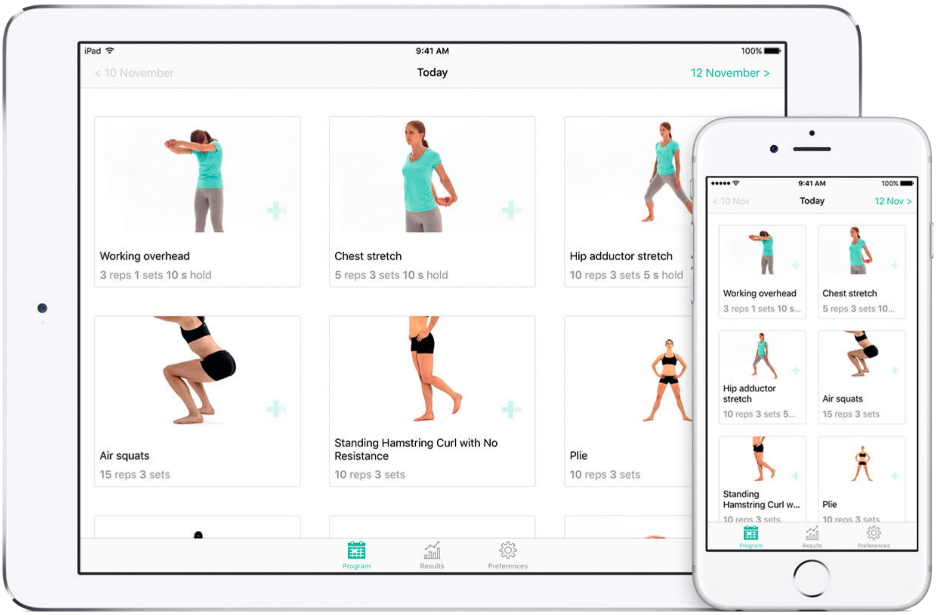


Figure 2 Examples of a home-based exercise program in the Physitrack app viewed on a tablet and a smartphone.

To guide the interviews, an interview guide based on the conceptual framework for testing electronic adherence monitoring devices was used (17). The conceptual framework contains an objective dimension and a subjective dimension. Because the focus of this study was on patients' perceptions, only the subjective dimension and the components performance, satisfaction, and acceptability were used (17). A first draft of the interview guide was created and refined using feedback from an expert meeting consisting of 15 researchers from the Physiotherapy Science research group at Utrecht University. Additionally, 5 physical therapists from the Leidsche Rijn Julius Healthcare centers were consulted to further refine and improve the interview guide. All researchers and physical therapists involved in this stage had experience working with mobile health (mHealth) apps in clinical practice, developing mHealth apps for other patient groups (e.g., patients after stroke, patients with osteoarthritis, and those with musculoskeletal complaints), or both.

Interviewer

All interviews were performed by a trained research assistant with a background in physical therapy and prior experience conducting interviews. The interviewer received an additional 2-hour training in qualitative interviewing techniques, and 2 pilot interviews were performed, recorded, and discussed with a researcher (RA) to ensure the thoroughness of the interviews. During data collection, the interviewer discussed each completed interview with the same researcher to ensure consistency between interviews.

Interviews

The interviews were conducted in a private room in the practice where the participant had received treatment. The research assistant audio recorded and transcribed each interview verbatim. A researcher (RA) checked the transcription for accuracy using the interview recording, after which a written summary of the interview was sent to the participant for a member check. The participant was asked to read the summary and provide additional information or corrections when the summary did not properly reflect their perspectives. None of the participants requested changes to their interview during the member check.

Data analysis

The transcripts were anonymized and subsequently analyzed using the "Framework Method" (18). This approach consists of 7 stages, namely transcription, familiarization with the interviews, coding, development of a working analytical framework, application of the analytical framework, charting of data into the framework matrix, and interpretation of the data. The goal was to describe the common experiences and perspectives of the participants. Stages 1 and 2 were completed during data collection.

An "inductive coding" approach was chosen for stage 3, the coding stage, and Microsoft Excel 2016 was used to aid with the analysis. Coding was performed by extracting meaningful quotes from the transcripts to an Excel datasheet, adding a short descriptive code to the quote, grouping related or similar quotes, and repeating the process until the entire transcript was coded. The first 3 interviews were independently coded by 2 researchers (RA and CK) (19). After an interview was coded, the researchers compared results and discussed differences in coding until they reached a consensus, and they labeled the codes with a short descriptive name. If the researchers could not reach a consensus, a third researcher (MP) was consulted. The remaining interviews were coded by 2 researchers (RA and CK) working together. During the coding process, the researchers continuously refined and adjusted the codes to best fit the data.

In stage 4, paper prints of the codes and their associated quotes from the first 3 interviews were used to allow a hands-on approach for the creation of categories and an initial analytical framework. Categories were formed by grouping codes that appeared to be related until all codes were assigned to a category. The categories were then grouped under themes based on the topics from the interview guide. To reduce bias introduced by the personal perspectives of a single researcher, the researchers (RA and CK) worked together to construct the framework and discussed each new category and its place within the framework until they reached a consensus. The analytical framework was continuously developed in an iterative process. Categories were merged, split, or relabeled, and codes were assigned to different categories in an attempt to best fit the data until all interviews were analyzed. After each iteration, the members of the research team (RA, CK, MP, TK, RO, and CV) discussed the new framework matrix and used the input from the discussion for the next iteration. The final framework matrix contained all categories with the summarized data from each interview and was used to interpret the data, completing stages 6 and 7 of the analysis.

RESULTS

Participant Characteristics

Once data saturation was reached after 9 interviews, recruitment ended. The characteristics of the patients included in the study can be found in Table 1.

Table 1 Participant characteristics.

Participant number	Gender	Age (years)	SUS[a] score (0-100)
1	Male	42	70
2	Female	29	82.5
3	Male	39	90

Table 1 *Continued.*

Participant number	Gender	Age (years)	SUS[a] score (0-100)
4	Female	33	90
5	Female	38	92.5
6	Female	45	97.5
7	Female	52	77.5
8	Male	71	85
9	Male	20	92.5

[a]SUS-score = Systems Usability Scale.

Data analysis revealed 11 categories distributed among the 3 themes "acceptability," "satisfaction," and "performance." "Acceptability" describes what was required for participants to accept the app as part of their treatment. The categories grouped under "satisfaction" describe the perceived benefits of using the app during treatment. The theme "performance" contains a single category with the same name and describes the most important app functions according to the participants, as well as suggestions to improve the performance of the app.

Acceptability

Usability

The app was easy to use, according to the participants. The app was simple in design, which made it very accessible.

I think it just has to be simple, without too many bells and whistles, and for me, it worked like that.

[Participant #3]

Availability

The availability of the exercises on the patients' smartphones was perceived as an advantage because using a smartphone was already integrated into their daily lives. None of the participants experienced the requirement to own a smartphone in order to use Physitrack as a problem.

It's just very easy. You carry your phone with you every day anyway, so when you forget something, you can just open the app and find it; very easy.

[Participant #7]

Willingness to Use the App

Participants were unaware that Physitrack existed before starting treatment, but all were willing to try the app to see if it would be useful for them. The perceived benefit from using the app during treatment determined its continued use for the participants.

I didn't have any expectations, and I went pretty open-minded into it. I thought that if it adds anything, it's great, but if it doesn't, I can just remove it from my phone.

[Participant #2]

Although patients were open-minded, perceived privacy issues were a concern for participant #1.

After reinstalling the app on my phone, I had to look through my old e-mails to find the login code, and it's, of course, strange that if anyone else gets his hands on that e-mail, they can see all my exercises and my private information.

[Participant #1]

Importance of instruction

Participants found it essential to be taught how to use the app and told which functions of the app are important for them. The interviewees saw the physical therapist as the person responsible for properly instructing patients in the use of the app.

I only used the videos because the physical therapist showed me, but I didn't look for any other options. I think that if you want to use all the functions of the app, the physical therapist has to explain them or provide a manual or something.

[Participant #4]

Patients rarely mentioned experiencing problems when using the app, suggesting that instructions by the physical therapist were sufficient to use the app in daily life. The only issues mentioned were setting the reminder for the exercises and not receiving the reminders.

After checking, I found that reminders were turned off, which is odd since I turned the reminders on and then didn't get any.

[Participant #1]

Satisfaction

Being reminded

The reminder messages for the app's exercises helped almost all participants to exercise more often or more regularly than they expected to without using the app.

In my busy life, the reminders motivated me to take some time to get it done.

[Participant #4]

Only participant #6 found the reminders useless, as they would come at inconvenient moments, even though the participant chose the time for the reminders.

Nine out of ten times when I set a reminder, I don't get to doing it anyway, so I just turned them off after a while.

[Participant #6]

Feeling supported

Being able to review the exercise recommendations at home and having something to fall back on were positive experiences and gave the patients the feeling that the app was supporting them.

After listening to the therapist, I would come home and still have questions or forgot what the therapist said. Then, I had something to fall back on, and that was very pleasant.

[Participant #8]

Satisfaction with own adherence

Participants were delighted with their adherence to the exercise recommendations and felt that the app helped them exercise as often as recommended and correct their performance.

The app helped with exercising. Not because I forgot them, … but I could check which exercises I had to do and how often.

[Participant #5]

Thanks to the app, I could see what exactly it was I was supposed to do … That definitely increased how often I exercised.

[Participant #9]

Although the app supported the patients with exercising, usage of the app generally declined quickly when exercises remained the same or when complaints were resolved.

The first time, I watched all the videos and memorized them. After that, I think I read the instructions for the exercises once or twice, but mostly used the app for the reminders.

[Participant #5]

I used the app only when new exercises were added because I already knew the others.

[Participant #6]

Supporting treatment

Patients considered the use of the app to record problems, adherence, or pain scores or the use of the chat function to ask a quick question as contributing to the quality of the treatment. The physical therapist had access to information recorded by the patient between therapy sessions and could use it to personalize treatment for the patient. Participants saw the app as something to combine with the expertise of the physical therapist rather than a replacement. The physical therapist used the face-to-face treatments to adjust and personalize the HBE program, and the participants used the app to bring the support from their physical therapist into their own homes.

First, we practiced the exercises together, then I received the app, and the next week the therapist asked me how it went. If I had any problems, I could discuss them with him so he could change the exercise program for me.

[Participant #7]

The app is good progress, but it's not yet a replacement of the physical therapist.

[Participant #8]

Quality of exercise performance

Patients felt that the app helped to improve their performance of the recommended exercises and perceived the app as a tool to maintain the quality of performance expected from them by the physical therapist. The visual examples of the app's exercises appeared to increase self-efficacy and might have increased adherence.

There was one exercise I had trouble doing right, so if I didn't have the video, I probably wouldn't have remembered how to do it and probably wouldn't have done it at all.

[Participant #3]

I wouldn't say it improves how you do it if you already did it well. But it does make sure you don't do it worse. It helps to keep the quality high.

[Participant #9]

Self-monitoring
Not all patients mentioned recording pain or adherence to exercises in Physitrack. However, patients who did record these metrics used the information to monitor their progress or demonstrate to the physical therapist that they had followed the exercise recommendations.

I felt that my back was very painful this week, but actually my pain score after doing the exercises is decreasing. That is, for me, a reminder I'm going in the right direction, and I find that very reassuring.

[Participant #2]

Performance
According to the patients, the most appreciated or essential functions of Physitrack were the video and text instructions and the reminder function. Recording and monitoring their own progress and the chat function were mentioned less often but were still considered important by several patients.

Something that should stay in the app is this overview with all the videos and the names of the exercises and how often I'm supposed to do them. Together with the reminder, I think those are important.

[Participant #5]

The patients also suggested several improvements for the app, including connecting the app with the calendar on users' mobile phones, such that follow-up visits could be automatically entered into the calendar. Other suggestions included repeated reminders when exercise performance was not recorded in the app, the option to connect the exercise videos to the television, and a loop or timer in the videos so that the patient could exercise along with the video.

DISCUSSION

Principal findings
The aim of this study was to investigate patient perspectives regarding an app to support HBE recommended by a primary care physical therapist. Qualitative data analysis revealed 11 categories describing the 3 themes of "acceptability," "satisfaction," and "performance."

The "acceptability" theme contains the subthemes of usability, availability, willingness to use the app, and importance of instruction, and it describes what the patients perceived as essential to accept the app as part of treatment. Participants commented on how easy or difficult it was to use the app in their daily lives. Patients' acceptance and continued use of the app as part of treatment appear to be based mainly on the perceived benefit. When a patient did not perceive or no longer saw any benefit from using the app, use declined quickly. The participants unanimously agreed that Physitrack was easily integrated into their daily routine. Although none of the participants had previously used Physitrack or a similar app during physical therapy, the app was accepted by all participants. Unfortunately, the quick and easy acceptance of a new mHealth app is not always reliable and depends on several different factors such as “perceived usefulness,” “social influence,” and “attitude”(20,21).

The acceptance of Physitrack in this study was possibly realized by the combination of the physical therapist introducing the app as part of treatment and the ease of use of the app. Even when a participant no longer found the app useful, it was very easy for them to stop using the app. As a result, there was no downside for the participant to try the app, as they could decide on its usefulness and continued use later on.

The participants felt that more instructions from their physical therapist were needed for optimal use of the app. The participants viewed the app as part of treatment and therefore relied on the physical therapist to provide guidance and support. Similarly, when participants experienced a problem using the app, they relied on the physical therapist for assistance. This finding underlines the importance of instructions, personal contact, and support from a physical therapist during treatment when using apps such as Physitrack (22). It appears that part of the success of the integration of Physitrack into treatment relies on patient-therapist interaction. This is further supported by previous findings that the diagnosis of the patient does not seem to significantly impact the acceptance of mHealth apps during treatment(20).

“Satisfaction” describes the perceived benefit of using the app during treatment and how the app supports treatment and adherence. Having easy access to the exercise recommendations from the physical therapist through their own smartphone made it easy for patients to not only exercise as often as recommended, but also maintain proper form during the exercises. The push messages sent by the app as a reminder to perform the exercises, the option to set the reminder at a preferred time, and the video instructions of the exercises all contributed to patients’ confidence when exercising at home.

In a previous study, participants had no experience with digital technologies to support exercise adherence but were asked about their expectations regarding new technologies (12). The patients were not very enthusiastic about the idea of reminder messages on their smartphones and expected them to be too intrusive. It is possible that in practice, it is important for a patient to use a new technology as part of treatment for some time before deciding on its added value. The participants in this study mentioned using this strategy to determine the usefulness of the app for themselves. Therefore, physical therapists should support patients with the shift toward the use of mHealth apps during treatment to allow patients to experience the benefits these new developments bring.

The last theme, “performance,” describes which functions of the app are most important according to the patients and how the performance of the app could be improved in the future. The video and text instructions, the reminders, and the option to self-monitor adherence were considered to be the most important functions of the app. Suggestions for future improvements were mainly aimed at making it even easier to use the app at home.

The findings of this study are similar to the results from studies on other mHealth or eHealth apps (23,24). For instance, Svendsen et al reviewed the qualitative literature on digital interventions for the self-management of LBP (23). After analyzing the included studies, 4 major themes were found: information technology (IT) usability and accessibility, quality and amount of content, tailoring and personalization, and motivation and support. A different review found that health status, usability, convenience and accessibility, perceived utility, and motivation were the main themes describing the barriers to and facilitators of engagement with remote measurement technology for health management (24).

Although the terminology describing the themes differs between studies, the content of the themes is broadly similar. For instance, “reminders and notifications,” “accessible at all hours and locations,” “easily accessible with low effort,” and “high user friendliness” were found to be facilitators for IT usability and accessibility in the study by Svendsen et al, whereas the themes “usability” and “convenience and accessibility” from the study by Simblett et al have similar facilitators (23,24). In this study, the use of reminders, easy integration in daily life, and the high usability of the app contributed to its acceptability, corresponding with the findings from the previous studies. The high agreement between previous studies and this study, despite the different types of apps used by patients with different health problems, suggests that these findings can most likely be generalized between apps and health problems. This study adds to the findings that patients view the interaction between patients and physical therapists as vital when using an app as part of treatment. This suggests that Physitrack is well suited to support treatment but not to replace a physical therapist.

LIMITATIONS AND TRUSTWORTHINESS

To put these results into perspective, several issues must be discussed. First, none of the included participants scored the usability of Physitrack lower than 70 (i.e., acceptable) on the SUS. A possible explanation is that the physical therapists treating potential participants for the study only used Physitrack with patients they expected to benefit from the app. Patients who might have found the app unusable or who would not be able to use the app effectively might not have been offered the app as part of treatment.

A second limitation of the study was that the participants were relatively young, with just one exception. Older patients might not be able to use an app as effectively as younger participants. Similar to the first limitation, the physical therapists might not have offered the app to patients they expected would have no or little benefit from it. In addition to age, a patient might not have been suitable for treatment using an app for other reasons. Using an instrument, such as the "Dutch Blended Physiotherapy Checklist," can assist physical therapists with deciding when to and when not to use an app such as Physitrack (25).

The last limitation is that the generalizability of the results in this study might be limited because of the specific app used and the inclusion of only patients with LBP in the study. However, the advantages of Physitrack mentioned by the patients relate mainly to features of the app and the patient-therapist interaction. Patients did not mention the cause of their complaints as having an impact on their acceptance of the app or how they used the app. Combined with the previously mentioned findings that barriers and facilitators related to the acceptance of mHealth apps do not seem to be impacted by a specific diagnosis, the results of this study can most likely be safely generalized to patients with other musculoskeletal disorders (20,23,24).

To increase the trustworthiness of data collection, prior to interviewing participants, the interviewer practiced the interviews and use of the interview guide with volunteers not participating in the study. The feedback from the volunteers helped to improve the thoroughness and consistency of the interviews. During data collection, a member check was performed by providing participants with a written summary of the interview and the opportunity to request changes or additions to their interviews to ensure its completeness. Furthermore, the use of the "Framework Method" methodology provided a transparent and rigorous method for data analysis (18).

Implications

Physitrack appears to be a useful tool to complement physical therapists' face-to-face treatment of patients with LBP. Although other mHealth solutions have displayed beneficial effects for patients with LBP and other musculoskeletal complaints, further research is required to investigate whether adherence to HBE interventions improves when using these apps during treatment (26–28). Knowledge of the added value from Physitrack and similar apps to support HBE and the results of this study can support the implementation of these apps in clinical practice. The apparent importance of the physical therapist–patient interaction found in this study should be investigated further. Additional information on physical therapists' perspectives regarding working with mHealth apps to support HBE and the effects of the physical therapist–patient relation on treatment results might lead to more effective treatments in the future. Although explorative research regarding the usability and acceptability of an app to support HBE by physical therapists is available, research involving physical therapists, patients, and their interactions when using smartphone apps to support HBE is still lacking and should be further investigated (29).

Conclusion

Patients who used Physitrack accepted the app as part of treatment when it was easy for them to use, when it benefited their needs, and when the therapist instructed them in its use. Satisfaction is determined by the perceived support from the app when exercising at home and the perceived increase in adherence. Patients considered the video and text instructions, reminder functions, and self-monitor functions to be the most important aspects for the performance of the app during treatment. Physical therapists using Physitrack and similar apps to support HBE can use the findings from this study to effectively support their patients when exercising at home during treatment.

Acknowledgments

We would like to thank Bram Kuijpers for his assistance with data collection. This study was co-funded by the Taskforce for Applied Research SIA (RAAK.PRO02.063), part of the Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek [NWO]). The funders played no role in the design, conduct, or reporting of this study.

Conflicts of Interest

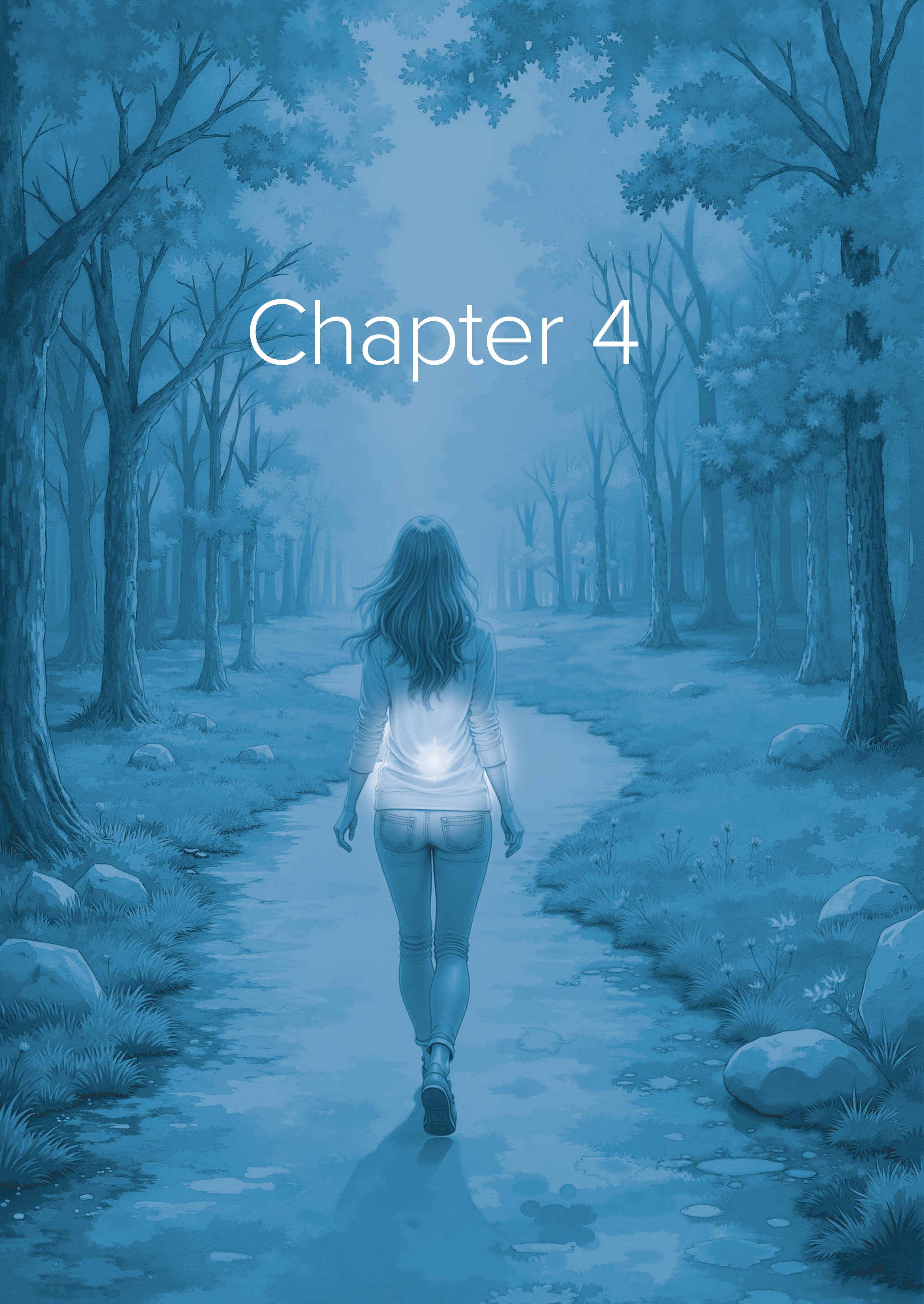
None declared.

REFERENCES

1. Pedersen BK, Saltin B. Exercise as medicine - Evidence for prescribing exercise as therapy in 26 different chronic diseases. Scand J Med Sci Sports. 2015;25:1–72.
2. Nicolson PJA, Hinman RS, Wrigley T V., Stratford PW, Bennell KL. Self-Reported Home Exercise Adherence: A Validity and Reliability Study Using Concealed Accelerometers. JOPST. 2018;48(12):943–50.
3. Nicolson PJA, Hinman RS, Kasza J, Bennell KL. Trajectories of adherence to home-based exercise programs among people with knee osteoarthritis. Osteoarthr Cartil. 2018;26(4):513–21.
4. Essery R, Geraghty AWAA, Kirby S, Yardley L. Predictors of adherence to home-based physical therapies: a systematic review. Disabil Rehabil. 2017;39(6):519–34.
5. Bassett S. The assessment of patient adherence to physiotherapy rehabilitation. New Zealand journal of physiotherapy. 2003;31(2):60–6.
6. Bachmann C, Oesch P, Bachmann S. Recommendations for Improving Adherence to Home-Based Exercise: A Systematic Review. Phys Medizin Rehabilitationsmedizin Kurortmedizin. 2018;28:20–31.
7. Sluijs EM, Kok GJ, van der Zee J. Correlates of Exercise Compliance in Physical Therapy. Phys Ther. 1993;73(11):771–82.
8. Lambert TE, Harvey L a., Avdalis C, Chen LW, Jeyalingam S, Pratt C a., et al. An app with remote support achieves better adherence to home exercise programs than paper handouts in people with musculoskeletal conditions: A randomised trial. J Physiother. 2017;63(3):161–7.
9. Bennell KL, Marshall CJ, Dobson F, Kasza J, Lonsdale C, Hinman RS. Does a Web-Based Exercise Programming System Improve Home Exercise Adherence for People with Musculoskeletal Conditions?: A Randomized Controlled Trial. Am J Phys Med Rehabil. 2019;98(10):850–8.
10. Beatty L, Lambert S. A systematic review of internet-based self-help therapeutic interventions to improve distress and disease-control among adults with chronic health conditions. Clin Psychol Rev. 2013;33(4):609–22.
11. Zhao J, Freeman B, Li M. Can mobile phone apps influence people's health behavior change? An evidence review. J Med Internet Res. 2016;18(11):e287.
12. Palazzo C, Klinger E, Dorner V, Kadri A, Thierry O, Boumenir Y, et al. Barriers to home-based exercise program adherence with chronic low back pain: Patient expectations regarding new technologies. Ann Phys Rehabil Med. 2016;59(2):107–13.
13. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: A synthesis of recommendations. Academic Medicine. 2014;89(9):1245–51.
14. Brooke J. SUS - A quick and dirty usability scale. In: Jordan P, Thomas B, Weerdmeester B, McClelland I, editors. Usability evaluation in industry. London: Taylor&Francis Ltd; 1996. p. 189–94.
15. Bangor A, Kortum PT, Miller JT. An Empirical Evaluation of the System Usability Scale. Int J Hum Comput Interact. 2008;24(6):574–94.

16. Saunders B, Sim J, Kingstone T, Baker S, Waterfield J, Bartlam B, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. Qual Quant. 2018;52(4):1893–907.
17. de Bleser L, de Geest S, Vincke B, Ruppar T, Vanhaecke J, Dobbels F. How to Test Electronic Adherence Monitoring Devices for Use in Daily Life. Comput Inform Nurs. 2011;29(9):489–95.
18. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol. 2013;13(1):1–8.
19. Given L. Open coding. In: Given L, editor. The SAGE Encyclopedia of Qualitative Research Methods. SAGE Publications, Inc.; 2008. p. 582–582.
20. Harst L, Lantzsch H, Scheibe M. Theories predicting end-user acceptance of telemedicine use: Systematic review. J Med Internet Res. 2019;21(5).
21. Kontos E, Blake KD, Chou WYS, Prestin A. Predictors of ehealth usage: Insights on the digital divide from the health information national trends survey 2012. J Med Internet Res. 2014;16(7):1–16.
22. Talboom-Kamp EPWA, Verdijk NA, Kasteleyn MJ, Numans ME, Chavannes NH. From chronic disease management to person-centered eHealth; a review on the necessity for blended care. Clinical eHealth. 2018;1(1):3–7.
23. Svendsen MJ, Wood KW, Kyle J, Cooper K, Rasmussen CDN, Sandal LF, et al. Barriers and facilitators to patient uptake and utilisation of digital interventions for the self-management of low back pain: a systematic review of qualitative studies. BMJ Open. 2020;10(12):e038800.
24. Simblett S, Greer B, Matcham F, Curtis H, Polhemus A, Ferrão J, et al. Barriers to and facilitators of engagement with remote measurement technology for managing health: Systematic review and content analysis of findings. J Med Internet Res. 2018;20(7): e10480.
25. Kloek CJJ, Janssen J, Veenhof C. Development of a Checklist to Assist Physiotherapists in Determination of Patients' Suitability for a Blended Treatment. Telemed e-Health. 2020;26(8):1051–65.
26. Du S, Liu W, Cai S. The efficacy of e-health in the self-management of chronic low back pain: A meta analysis. Int J Nurs Stud. 2020;106:103507.
27. Schäfer AGM, Zalpour C, Von Piekartz H, Hall TM, Paelke V. The efficacy of electronic health-supported home exercise interventions for patients with osteoarthritis of the knee: Systematic review. J Med Internet Res. 2018;20(4).
28. Sandal LF, Bach K, Øverås CK, Svendsen MJ, Dalager T, Jensen JSD, et al. Effectiveness of App-Delivered, Tailored Self-management Support for Adults With Lower Back Pain–Related Disability: A selfBACK Randomized Clinical Trial. JAMA Intern Med. 2021;181(10):1288–96.
29. Baschung Pfister P, Tobler-Ammann B, Knols RH, de Bruin ED, de Bie RA. Usability and Acceptance of an Interactive Tablet-Based Exercise Application: A Mixed Methods Study. Front Digit Health. 2020;2:578281.

Chapter 4



Effectiveness and cost-effectiveness of stratified blended physiotherapy in patients with non- specific low back pain: study protocol of a cluster randomized controlled trial

Tjarco Koppenaal
Remco M. Arensman
Johanna M. van Dongen
Raymond W.J.G. Ostelo
Cindy Veenhof
Corelien J.J. Kloek
Martijn F. Pisters

Published in BMC Musculoskeletal Disorders 2020;21(1):265

ABSTRACT

Background: Patient education, advice on returning to normal activities and (home-based) exercise therapy are established treatment options for patients with non-specific low back pain (LBP). However, the effectiveness of physiotherapy interventions on physical functioning and prevention of recurrent events largely depends on patient self-management, adherence to prescribed (home-based) exercises and recommended physical activity behaviour. Therefore we have developed e-Exercise LBP, a blended intervention in which a smartphone application is integrated within face-to-face care. E-Exercise LBP aims to improve patient self-management skills and adherence to exercise and physical activity recommendations and consequently improve the effectiveness of physiotherapy on patients' physical functioning. The aim of this study is to investigate the short- (3 months) and long-term (12 and 24 months) effectiveness on physical functioning and cost-effectiveness of e-Exercise LBP in comparison to usual primary care physiotherapy in patients with LBP.

Methods: This paper presents the protocol of a prospective, multicentre cluster randomized controlled trial. In total 208 patients with LBP pain were treated with either e-Exercise LBP or usual care physiotherapy. E-Exercise LBP is stratified based on the risk for developing persistent LBP. Physiotherapists are able to monitor and evaluate treatment progress between face-to-face sessions using patient input from the smartphone application in order to optimize physiotherapy care. The smartphone application contains video-supported self-management information, video-supported exercises and a goal-oriented physical activity module. The primary outcome is physical functioning at 12-months follow-up. Secondary outcomes include pain intensity, physical activity, adherence to prescribed (home-based) exercises and recommended physical activity behaviour, self-efficacy, patient activation and health-related quality of life. All measurements will be performed at baseline, 3, 12 and 24 months after inclusion. An economic evaluation will be performed from the societal and the healthcare perspective and will assess cost-effectiveness of e-Exercise LBP compared to usual physiotherapy at 12 and 24 months.

Discussion: A multi-phase development and implementation process using the Center for eHealth Research Roadmap for the participatory development of eHealth was used for development and evaluation. The findings will provide evidence on the effectiveness of blended care for patients with LBP and help to enhance future implementation of blended physiotherapy.

Trial Registration: ISRCTN, ISRCTN94074203. Registered 20 July 2018 – Retrospectively registered.

Keywords: E-health; Non-specific low back pain; Physiotherapy; Telemedicine

BACKGROUND

Low back pain (LBP) is the most common cause of disability in western society (1). LBP causes a significant economic burden and is responsible for high direct healthcare costs as well as high indirect costs due to time lost from work (2). LBP can be caused by a specific pathology or trauma; however, in more than 90% of cases an underlying disease is absent (3,4). The clinical course of this so-called 'non-specific LBP' varies; some people recover within a couple of days or weeks, and other people experience persistent disabling symptoms leading to chronic LBP (2,5,6). Both national and international clinical LBP guidelines endorse patient education, advice on returning to normal activities and the prescription of home-exercises and/or supervised exercise therapy (7–10).

However, the effectiveness of physiotherapy in patients with LBP does not solely depend on providing the most adequate physiotherapy interventions. It also highly depends on patients' adherence to prescribed (home) exercises and recommended physical activity behaviour (11,12). Earlier research showed that 45–70% of patients do not adhere to prescribed exercises and physical activity recommendations (13–15), whereas adherent patients with LBP who continue a physically active lifestyle have a reduced risk of recurrent LBP (16). Therefore, supporting self- management and adherence in patients with LBP is expected to be essential for the effectiveness of physiotherapy interventions on patients' physical functioning and prevention of recurrent events.

Online applications, such as websites and apps, provide new solutions to support patients' ability to manage their physical functioning in their home environment, and are promising to support self-management and adherence to prescribed (home) exercises between face-to- face sessions (17–20). Consequently, the integration of online applications into healthcare, so- called blended care (21), is expected to have several advantages for patients with LBP. Firstly, a blended intervention can stimulate self-management and exercise adherence to prescribed (home) exercises and recommended physical activity behaviour in patients with LBP by its 24/7 online support and persuasive design (20,22–24). Secondly, the use of online applications enables monitoring and coaching of the patients' individual health behaviour and provides the physiotherapist with information to optimize and tailor face-to-face care to the patients' individual needs (22,23,25–27).

Despite all these benefits, matching the appropriate blended treatment for the individual patient is reported as a challenge (28). To resolve this challenge within traditional face-to-face guidance, stratification tools have gained more attention in the last decade. Within a stratified-care approach, the treatment is matched upon the patients' risk of developing persistent LBP, for example determined with the Keele STarT Back Screening Tool (29). Research showed that such an approach results in improved physical functioning and satisfaction with care among patients with LBP while reducing costs of healthcare in both physiotherapy (30) and primary care settings (31,32). Whereas the STarT Back Screening Tool can be used for matching the appropriate content of the face-to-face care to the individual patient, this tool also might have the same potential for matching the right digital content to the individual patient. Up until now, no other groups have used a stratification tool for personalization of blended physiotherapy as a whole.

Recently, the authors' research group developed e-Exercise LBP, a blended and stratified intervention, in co-creation with patients, physiotherapists and experts (33). E-Exercise LBP consists of face-to-face physiotherapy treatment, in which eCoaching is integrated using a smartphone application. E-Exercise LBP aims to improve patients' physical functioning by offering a blended stratified-care approach, and consequently influencing patients' self- management skills and adherence to exercise and physical activity recommendations in a positive way. At the long-term, e-Exercise LBP could result in an improved handling of recurrent LBP and direct and indirect costs. This blended care intervention is an adapted version of previously developed and evaluated blended physiotherapy programs (34,35). A pilot study using a prototype of the e-Exercise LBP intervention in 41 patients with LBP demonstrated feasibility and proof-of-concept on functional disability and pain (33). Based on the results of the pilot study and end-user (patients and physiotherapist) usability experiences, the e-Exercise LBP program was further improved in preparation for the current study.

This study aims to investigate the short- (3 months) and long-term (12 and 24 months) effectiveness on physical functioning and cost-effectiveness of e-Exercise LBP, a primary care based personalized stratified blended care intervention, in comparison to usual primary care physiotherapy in patients with non-specific LBP.

METHOD/DESIGN

Study design

A prospective, multicentre cluster randomized controlled trial (RCT) will be conducted. The study has been approved by the Medical Research Ethics Committee of the University Medical Center Utrecht, the Netherlands (ISRCTN 94074203) for all centre sites. Within primary care, e-Exercise LBP will be compared to usual physiotherapy care. A flow diagram of the study protocol is shown in Figure 1.

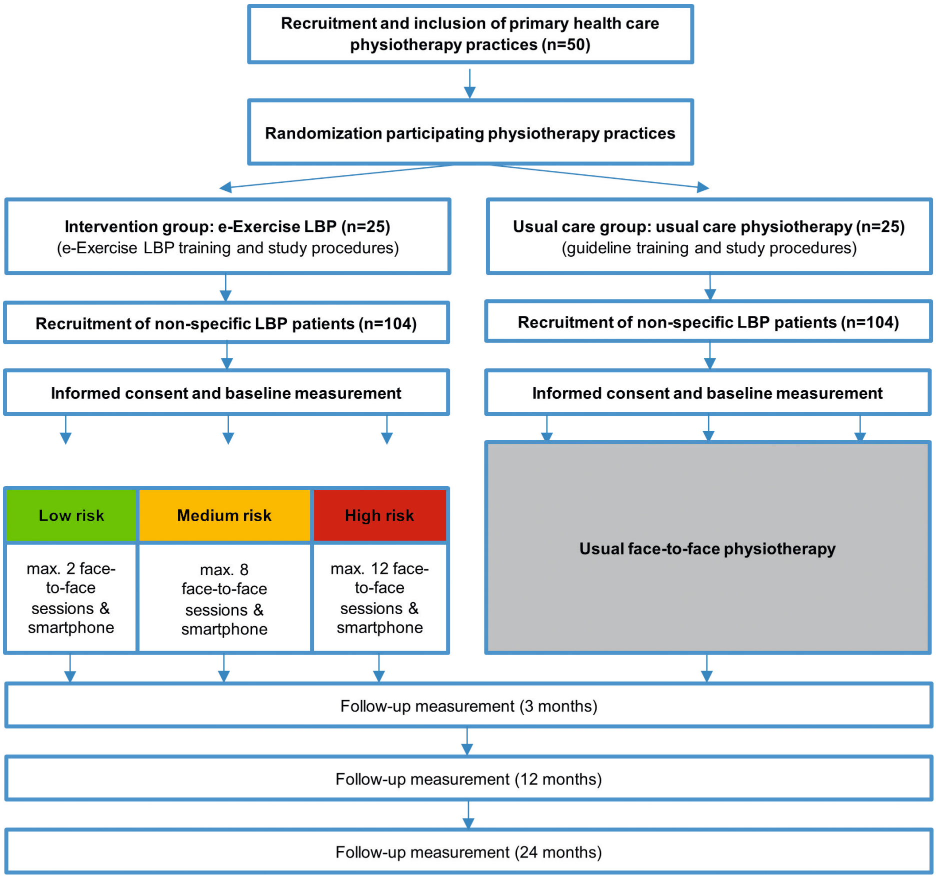


Figure 1 RCT Study procedures

Participants

Primary care physiotherapy practices

Primary care physiotherapy practices will be invited by letter to participate in the study. Contact details of potential participating practices will be obtained from the professional network of the authors and a previous e- Exercise study (35). Additionally, a recruitment advertisement will be placed in the online newsletter of The Royal Dutch Association for Physiotherapy (KNGF). Primary care physiotherapy practices are eligible to participate if at least five patients with non-specific LBP consult the practice for physiotherapy treatment each month. Each participating physiotherapy practice will be asked to enroll at least two physiotherapists in order to ensure continuity of care. All primary care physiotherapists, regardless of professional experience and education or specialization (e.g. manual therapist) are eligible to participate.

Patients

All patients with LBP who visit a participating physiotherapy practice will be invited to participate in the study.

Eligibility criteria of patients include: (i) being a patient requesting physiotherapy treatment for LBP, defined as pain in the lumbosacral region (sometimes associated with radiating pain to the buttock or leg) (10,36), (ii) age 18 years or older, (iii) possessing a smartphone or tablet with access to the internet, (iv) mastery of the Dutch language.

Exclusion criteria include: (i) a specific cause of LBP determined through medical imaging or a medical doctor (e.g. osteoporotic fractures, spinal nerve compromise, malignancy, ankylosing spondylitis, canal stenosis, or severe spondylolisthesis), (ii) serious comorbidities (e.g., malignancy, stroke), (iii) current pregnancy, because of the prevalence of pelvic girdle pain as a specific form of LBP.

Study procedure

Physiotherapy practices that are willing to participate in the study will be screened on eligibility by a researcher (TK or RA). Cluster randomization will be performed at the level of the participating physiotherapy practices. Each practice will be randomly assigned to the intervention (e- Exercise LBP) or the usual care group by an independent researcher using an a priori created computer-generated random sequence table. Physiotherapists in the intervention group will receive two 4-h training sessions about e-Exercise LBP and the study procedures. In the usual care group, physiotherapists will receive one 4-h training session in current best evidence practice according to the guideline LBP of the Royal Dutch Association for Physiotherapy (KNGF) (10) and the study procedures.

Physiotherapists, or their colleagues who will handle the initial registration of the patient, will orally inform potentially eligible patients about the study. Interested patients will receive the patient information letter by e-mail and will be contacted by one of the researchers (TK or RA) by phone prior to the first physiotherapy appointment. When a patient is willing to participate, a face-to-face appointment with one of the researchers (TK or RA) will be scheduled to screen in- and exclusion criteria and to provide written informed consent. After signing informed consent, the patient’s physiotherapist will be informed about the patient’s participation.

During the study period, both patient groups can still receive care from any other healthcare professional.

Interventions

E-exercise LBP

A multi-phase development process based on the Center for eHealth Research (CeHRes) Roadmap (37) was used for development of the e-Exercise LBP intervention (33). The e-Exercise LBP intervention integrates eCoaching using a smartphone application within face-to-face physiotherapy. The content is based on recommendations from national and international guidelines (7,8,10), and preferences and needs of patients and physiotherapists (33). The principles of stratified care are used to personalize e-Exercise LBP to individual needs (30,31).

Smartphone application The smartphone application consists of three modules (Table 1): (i) An information module containing 12 weekly self-management themes (text and video), including assignments, about the aetiology of LBP, physical activity, patient experiences, pain management, and psychosocial factors related to LBP. (ii) An exercise module including a home-based video-instructed exercise program per prognostic risk profile. The selection, frequency and repetitions can be adjusted by the physiotherapist to address the patient's specific functional limitations. (iii) A physical activity module containing a goal-oriented training program consisting of three sessions a week, to maintain or improve the level of physical activity for a self-chosen type of activity (e.g., cycling or walking). The training program starts with a 3-day baseline test, and can be optionally supported by graded activity functionality with tailored feedback, which was previously studied in two osteoarthritis studies (35,38).

In patients having a "low risk" for developing persistent LBP the smartphone application will offer support for 3 weeks. In "medium" – and "high risk" patients the support will be 12 weeks. Afterwards the content of the smartphone application will remain available for the patients. In "low risk" patients the smartphone application will only contain the information – and exercise modules. In "medium – and high risk" patients the physical activity module will be added. The results of the baseline test of the physical activity module will be used by the physiotherapist and patient to set a goal to reach within 11 weeks. The graded activity functionality can be switched on in "medium risk" patients who avoid physical activity because of LBP. For "high risk" patients the graded activity functionality will always be activated. Print screens of the smartphone application are given in Appendix 1.

Table 1 Overview e-Exercise LBP intervention

	Low risk profile	Medium risk profile	High risk profile
Smartphone application			
Duration	3 weeks	12 weeks	12 weeks
Information module	Knowledge-based platform with several LBP self-management information themes (directly available)	12 weekly self-management themes, including assignments	12 weekly self-management themes, including assignments, pain education and psychosocial risk factors
Exercise module	3-4 home-based exercises tailored to the patient's specific functional limitations	3-4 home-based exercises tailored to the patient's specific functional limitations	3-4 home-based exercises tailored to the patient's specific functional limitations
Physical activity module	Physical activity recommendations in accordance with the KNGF guideline LBP	A 3-day baseline test to determine current level of physical activity. An 11-week, 3 times per week, goal-oriented training program to maintain or improve the level of physical activity. In patients avoiding physical activity due to LBP a graded activity functionality can be activated	A 3-day baseline test to determine current level of physical activity. An 11-week, 3 times per week, goal-oriented training program to maintain or improve the level of physical activity using a graded activity approach
Face-to-face care			
Sessions	2 sessions	Max. 8 sessions	Max. 12 sessions
Content	Reassurance, information about LBP, instruction on self-management options, and the importance of adequate physical activity behaviour	Content similar as low risk and additionally: The physiotherapist can consider to provide evidence-based interventions (e.g. passive or active joint mobilization) as recommended by KNGF guideline LBP	Content similar as medium risk and additionally: The physiotherapist will address patient's specific psychosocial risk factors using a cognitive-behavioural approach and pain education will be given

Table 1 *Continued.*

	Low risk profile	Medium risk profile	High risk profile
Integration face-to-face care – smartphone application			
First session	Provide information about LBP and instruction on home-based exercises addressing patient's specific functional limitations using the smartphone application	Provide information about LBP, instruction on home-based exercises addressing patient's specific functional limitations, and instruction on 3-day baseline test using the smartphone application	Provide information about LBP, instruction on home-based exercises addressing patient's specific functional limitations, and instruction on 3-day baseline test using the smartphone application
Middle sessions		Evaluation of progress with smartphone application and optimizing face-to-face care	Evaluation of progress with smartphone application and optimizing face-to-face care
Final session	Evaluate the progress with smartphone application and give recommendations to prevent recurrent episodes of LBP and maintain or improve the physical activity level	Evaluate the progress with smartphone application and give recommendations to prevent recurrent episodes of LBP and maintain or improve the physical activity level	Evaluate the progress with smartphone application and give recommendations to prevent recurrent episodes of LBP and maintain or improve the physical activity level

LBP = low back pain, KNGF = Royal Dutch Association for Physiotherapy, Max. = Maximum

Face-to-face care During the first face-to-face session, the physiotherapist will tailor the e- Exercise LBP intervention to the patients' identified risk for developing persistent LBP (i.e. low, medium or high), using the Keele STarT Back Screening Tool (29,39,40) (Figure 1, Table 1). Patients are asked to schedule their exercises and physical activities in the smartphone application, after which the smartphone application will sent automatic pop-up reminders accordingly. Physiotherapists will be able to monitor patients' use of the smartphone application, monitor evaluated assignments, and select other types of exercises. With this information, the physiotherapist will be able to evaluate the progress and beliefs of the patients between face-to-face sessions, optimize the content of the smartphone application to patients' individual needs, and tailor face-to-face care.

Physiotherapists are recommended to provide two face-to-face physiotherapy sessions to patients labelled as "low risk", 8 sessions for patients labelled as "medium risk", and

12 sessions for patients labelled as “high risk”. The objective of face-to-face care is to reassure the patient, provide information about LBP, instruct on self-management options, and underline the importance of adequate physical activity behaviour in accordance with the guideline LBP of the Royal Dutch Association for Physiotherapy (KNGF) (10). Additionally, in medium- and high risk patients, the physiotherapist can consider to provide evidence-based interventions (e.g., passive or active joint mobilization) as recommended by the guideline LBP of the Royal Dutch Association for Physiotherapy (KNGF) (10). In high risk patients, the physiotherapist will address patient specific psychosocial risk factors using a cognitive behavioural therapy approach, and pain education will be given (41,42). However, with respect to the physiotherapists’ clinical competences, physiotherapists are allowed to deviate from the e-Exercise protocol.

After completing e-Exercise LBP, the patient will receive fortnightly reminders from the smartphone application for up to 6 months to continue a physically active lifestyle.

Usual care

Patients in the usual care group will receive face-to-face usual care following the recommendations of the guideline LBP of the Royal Dutch Association for Physiotherapy (KNGF) (10). Although eCoaching applications are not recommended in the guideline, physiotherapists from the usual care group are instructed to treat people without using any eCoaching applications. According to the guideline, the physiotherapy treatment includes information, exercises, and recommendations regarding physical activity. Practical content considerations will be made by the physiotherapists themselves with respect to their clinical expertise. The number of sessions will differ per patient.

Measurements

Four time points (baseline, 3, 12 and 24 months) will be used for data collection of the primary and secondary outcomes using an online questionnaire. Baseline measurement will be conducted face-to-face and follow-up measurements preferably through online communication, e.g., Skype or FaceTime. When follow-up measurements through online communication are not possible, follow-up measurements will be conducted face-to-face. At all four time points participants will receive an accelerometer (Activ8) for the objective measurement of physical activity. Participants will be instructed to wear the Activ8 for five consecutive weeks at baseline and eight consecutive days at all following time points, except during sleeping, showering, bathing or swimming. For the economic evaluation, patients will be asked to complete eight retrospective 3-monthly online cost questionnaires. All of these questionnaires will have a 3-month recall period to cover the full duration of follow-up (i.e., 24 months). No financial incentives to complete questionnaires or to wear accelerometers will be offered. Table 2 gives a summary of all outcome measures and time points.

Primary outcome measure

The primary outcome measure is physical functioning and is derived from the internationally accepted "Core Outcome Set" (COS) for research into patients with non-specific LBP. The other recommended outcomes are included as secondary parameters, i.e., pain intensity, health-related quality of life, psychological functioning and pain interference (43–45) (Table 2). All selected measurement instruments in the current study are determined to be valid and reliable in previous research.

Physical functioning due to pain in LBP patients is assessed by the Oswestry Disability Index (ODI), version 2.1a (44–46).

Secondary outcome measures

Pain intensity is measured with an 11-point Numeric Rating Scale (NRS) for the average LBP intensity in the last week (44,45,47).

Physical activity is objectively measured using a 3-axial accelerometer, the Activ8 (ACTIV8, Valkenswaard, The Netherlands) (48). The Activ8 is a valid instrument to detect sedentary behaviour (combination of lying and sitting), standing, walking, running, and cycling. Additionally, MET-values are given. The Activ8 measures with 12.5 Hz, an epoch of 1 s a sample interval of 5 s. Every 5 min a summary is stored of the different postures and MET-values (49). In addition, participants are requested to fill out a short activity diary about unusual activities and reasons for device removal.

Patient self-reported adherence to prescribed home exercises is measured by the Exercise Adherence Rating Scale (EARS). Besides that, the EARS measures the exercise prescription and the reasons for (non-)adherence (50).

Physiotherapist based assessment of adherence to prescribed home exercises is measured by the Exercise Adherence Scale (EXAS). The EXAS is an interview-based questionnaire which is used by the physiotherapist during face-to-face care to determine both the qualitative performance of the recommended home exercises and the agreement between recommended home exercises and patient reported adherence (51).

Adherence to the smartphone application is measured in the experimental group only by means of quantitative data about usage (e.g., completed modules). The data is automatically stored on the backend of the smartphone application.

Fear avoidance beliefs about physical activity and work is measured using the Fear-Avoidance Beliefs Questionnaire (FABQ). The FABQ assesses the fear of movement/(re) injury and consists of items related to physical activity and work (52).

Pain catastrophizing is measured by the Pain Catastrophizing Scale (PCS) The PCS is a self-report measurement tool that provided a valid index of catastrophizing in clinical and non-clinical populations (53,54).

Self-efficacy, i.e., the patients beliefs in their efficacy to influence events that affect their lives (55), is measured using the General Self-efficacy Scale (GSE Scale) (56–58).

Patient activation is assessed by the Dutch version of the short form Patient Activation Measure (PAM 13-Dutch) (59,60). The Pam 13-Dutch assesses patient (or consumer) self-reported knowledge, skills and confidence for self-management of one's health or chronic condition.

The number of recurrent LBP episodes is measured by the number of self-reported LBP episodes during the follow-up period. A recurrent LBP episode is defined as return of LBP with a minimum duration of 24h after a period of at least 4 weeks without pain (61).

Other measures

Patient characteristics, i.e., age, gender, educational level, profession, employment status, and medical history related to LBP over the past 2 years, are measured using an online questionnaire. Besides that, relevant clinical variables such as duration of current complaints, Body Mass Index, past surgeries, risk of developing persistent LBP, the presence of central sensitivity, and possible comorbidities are collected.

Content and number of physiotherapy sessions are measured trough registration forms, developed by the researchers. The registration forms collect information on the number and content of face-to-face sessions, adherence to face-to-face sessions and deviations from the study protocol and are completed by the physiotherapists.

Table 2 Schedule of enrolment, interventions, and assessments.

	STUDY PERIOD									
	Enrolment	**Allocation**	**Post-allocation**							**Close-out**
TIMEPOINT	**0m**	**0m**	**3m**	**6m**	**9m**	**12m**	**15m**	**18m**	**21m**	**24m**
ENROLMENT:										
Eligibility screening	X									
Informed consent	X									
Allocation		X								
INTERVENTIONS:										
e-Exercise LBP		←	→							
Usual care		←	→							
ASSESSMENTS:										
Patient characteristics										
Age		X								
Gender		X								
BMI		X								
Educational level, profession and employment status		X								
Medical history related to LBP, past surgeries and co-morbidities		X								
Duration of LBP complaints		X								
Risk of developing persistent LBP		X								
Central sensitivity		X								
Primary outcome measure										
Physical functioning (ODI)		X	X			X				X

Table 2 *Continued.*

	STUDY PERIOD									
	Enrolment	**Allocation**	**Post-allocation**							**Close-out**
TIMEPOINT	**0m**	**0m**	**3m**	**6m**	**9m**	**12m**	**15m**	**18m**	**21m**	**24m**
Secondary outcome measures										
Pain intensity (11-point NRS)		X	X			X				X
Physical activity (Activ8)		X	X			X				X
Patient self-reported Adherence to prescribed exercises (EARS)			X			X				X
PT assessed adherence to prescribed exercises (EXAS)		←	→							
Adherence to the smartphone application (backend application)		←	—	—	—	—	—	—	—	→
Fear avoidance beliefs (FABQ)		X	X			X				X
Pain catastrophizing (PCS)		X	X			X				X
Self-efficacy (GSE Scale)		X	X			X				X
Patient activation (PAM 13-Dutch)		X	X			X				X
Number of recurrent LBP episodes (Questionnaire)			X			X				X
Economic evaluation										
Health related quality of life (EQ-5D-5L)		X	X			X				X
LBP related costs (Cost questionnaire)		X	X	X	X	X	X	X	X	X
Other measures										
Content and number of PT sessions (Registration form)		←	→							

⟷ Indicator for a period; duration of the period is not limited to length of the indicator and dependent on duration of interventions and use of smartphone application LBP = low back pain, BMI = Body Mass Index, ODI = Oswestry Disability Index, NRS = Numeric Rating Scale, EARS = Exercise Adherence Rating Scale, PT = Physiotherapist, EXAS = Exercise Adherence Scale, FABQ = Fear-Avoidance Beliefs Questionnaire, PCS = Pain Catastrophizing Scale, GSE scale = General Self-efficacy Scale, PAM = Patient Activation Measure, EQ-5D-5L = EuroQol 5D Sample size calculation

The required sample size was calculated according to the recommendations of Campbell et al. (2010) for cluster randomized trials (62,63), taking into account repeated measures of the primary outcome measure physical functioning on the ODI during follow-up (64). An intracluster correlation coefficient of 0.05 was used (65,66). Additionally, to detect a clinical relevant difference between groups at 12 months following baseline, a difference of > 6 points in physical functioning on the ODI (67,68) and a standard deviation of 14.5 (69) were used in the sample size calculation. For the repeated measures of physical functioning on the ODI a correlation of 0.5 is estimated between baseline and follow-up measurements until 12 months follow-up (64). Based on these assumptions (using a power of 80% and α =0.05) and average cluster size of 5, in total 165 patients are needed. With an expected dropout rate of 20% a total of 207 participating patients (104 patients per arm) are needed.

Statistical analysis

Descriptive statistics (e.g., means and proportions) will be used to explore baseline comparability. To investigate selective attrition, general characteristics and primary baseline variables of dropouts and non-dropouts will be compared All analyses will be performed according to the ‘intention-to-treat’ principle. Missing data for all outcomes and cost measures will be imputed using ‘Multivariate Imputation by Chained Equations’ under the assumption that data are missing at random given baseline confounders. For all analysis, a two-tailed significance level of $p < 0.05$ is considered to be statistically significant. All analyses will be carried out using IBM SPSS Statistics version 24.0 (Amork, New York, USA).

Effectiveness

The primary purpose of this study is to estimate the effectiveness of e-Exercise LBP for improving physical functioning compared to usual primary care physiotherapy in patients with LBP. The primary analysis time point for the study will be 12 months following baseline, however 3- and 24-month changes will also be evaluated. To evaluate the overall effectiveness of e-Exercise LBP, differences in change scores per group and time period will be estimated on primary and secondary outcomes using linear mixed models (LMM) with random effects to control for correlation within patients and physiotherapists (70,71). The three- level hierarchy will exist of repeated measurements (level 1), nested within patients (level 2), nested within physiotherapists (level 3). Analysis will be controlled for baseline variables that have been shown to be related to physical functioning, e.g., age, gender, pain severity scores, duration of pain (72–74).

In addition, a per-protocol analysis that only includes patients of the intervention group which were adherent to the smartphone application and the entire usual care group will be performed. Patients will be considered to be adherent to the smartphone application if they used the application for at least 2/3rd of the duration (i.e., 2 out of 3 week for the "low-risk" profile and 8 out of 12 weeks for the "medium- and high-risk" profile) (35,75). Per-protocol analyses will be performed using LMM with the same 3-level structure, and will be controlled for the same variables as the primary analysis.

Economic evaluation

An economic evaluation will be performed from the societal and the healthcare perspective and will assess the cost-effectiveness of e-Exercise LBP compared to usual physiotherapy at 12 and 24 months.

Identification, measurement and valuation of costs When the societal perspective is applied intervention, healthcare, informal care, unpaid productivity, and paid productivity costs will be included. When the healthcare perspective is applied, only costs accruing to the formal Dutch healthcare sector will be included. The costs of e-Exercise LBP will be estimated using a bottom-up micro-costing approach (76). Information on the patients' other kinds of resource use will be collected using eight 3-monthly retrospective cost questionnaires with 3-month recall periods. Healthcare utilization, unpaid productivity, and informal care will be valued in accordance with the "Dutch Manual of Costing" (77). Paid productivity losses comprise of absenteeism (i.e., sickness absence) and presenteeism (i.e., reduced productivity while at work). Absenteeism was measured using a modified version of the IMTA Productivity Cost Questionnaire (iPCQ). Absenteeism will be valued in accordance with the "Friction Cost Approach" (FCA), using gender-specific price weights (78,79). Presenteeism will be measured using the "World Health Organization – Work Performance Questionnaire" as well as the "Productivity and Disease Questionnaire", and valued using gender-specific price weights as well (78–81).

Measurement and valuation of health-related quality of life The patients' health states will be measured using the EuroQol-5D-5L (EQ-5D-5L) (82–85). This questionnaire comprises of five health dimensions, i.e., mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Per health dimension, patients are asked to indicate their severity level. Health states will be converted into utility values using the Dutch tariff (86) and Quality Adjusted Life Years (QALYs) will be estimated using linear interpolation between measurement points.

Statistical analyses Missing cost and effect data will be imputed using 'Multivariate Imputation by Chained Equations' and the results will be pooled using Rubin's rules (87). Cost differences (ΔC) and effect differences (ΔE) will be estimated using LMM, and will be corrected for the same baseline variables as the effectiveness analysis. To account for the highly skewed nature of cost data, bias-corrected and accelerated bootstrapping with 5000 replications will be used to estimate 95% confidence intervals around the cost differences (ΔC). Incremental cost-effectiveness ratios cost (ICERs) will be calculated by dividing the difference in costs by the difference in effects (ΔC/ΔE). Uncertainty surrounding the ICERs will be graphically illustrated by plotting bootstrapped cost-effect pairs on cost-effectiveness planes and by estimating cost-effectiveness acceptability curves. To test the robustness of the study results, several sensitivity analyses will be performed (88).

Timeline

Recruitment of physiotherapy practices began in January 2018. The trial started in July 2018. Until January 2020 patients are able to enroll in the study. The follow-up will last until January 2022. Analysis of short-term effectiveness will start in March 2020, analysis of 12-month (cost)effectiveness will start in January 2021.

DISCUSSION

This paper describes the design and methods of the e-Exercise LBP trial. The aim of the presented study is to investigate the short-term as well as the long-term effectiveness and cost-effectiveness of e-Exercise LBP compared to usual physiotherapy in patients with LBP. E-Exercise LBP is a stratified blended care intervention in which an eCoaching smartphone application is integrated into primary care face-to-face physiotherapy.

A major strength of this study is that the e-Exercise LBP trial is part of a multi-phase development and implementation process which was based on the Center for eHealth Research (CeHRes) Roadmap (37). This holistic framework provides guidance during the participatory development of eHealth in order to enhance future implementation. As part of the development of the e-Exercise LBP intervention, needs and values of end-users and various stakeholders (e.g., physiotherapists, developers) were used to develop the first prototype (33). Next, the prototype was tested on feasibility in a pilot study (33). Based on experiences of patients and physiotherapists several important adaptations were made to the prototype of the e-Exercise LBP intervention. A first important adaptation is the development of a smartphone application, which was based on the web-based application used in the prototype. Secondly, the content of the smartphone application was stratified to match the stratification of face-to-face care for patients at low, medium or high risk for developing persistent LBP. As a result, the content of the smartphone application for low-risk patients was provided immediately instead of spread out over 12 weeks. The graded activity functionality was made mandatory for patients with a high risk for developing persistent LBP. On top of that, each information theme was enriched with an assignment in order to stimulate self-reflection. Overall, we believe that the improved smartphone application with various options for physiotherapists to personalize the content of the application, might help to improve patients' level of physical functioning in patients with LBP.

Besides further development of the e-Exercise LBP intervention, several important methodological considerations were made with respect to the study design of the e-Exercise LBP trial. A first consideration was the use of a cluster-randomized controlled design to avoid contamination between the e-Exercise LBP intervention and usual physiotherapy care at the level of the participating physiotherapist. Cluster-randomization at the level of the participating physiotherapy practices ensures that each participating physiotherapist working in the same physiotherapy practice delivers the same intervention (89). The influence of clustering will be corrected using LMM in the statistical analysis.

Since the e-Exercise LBP intervention aims to improve physical functioning, this outcome measurement was selected as primary outcome measurement. Intervention duration will last up to 3 months, but a 12-month evaluation will provide insight in the effectiveness of e-Exercise LBP on the long-term. However, with respect to the cost-effectiveness, it is hypothesized that patients who followed e-Exercise LBP are able to manage recurrent complaints independently, resulting in reduced healthcare usage or sickness absence. Since a 12-month follow-up might be too short to study this hypothesis, we added a 24-month follow-up focusing on the management of recurrent complaints.

Because the study design is well-considered, several potential operational issues are taken into account. An important operational issue is the physiotherapists' training in the e-Exercise LBP intervention. From previous studies we learned that implementing a blended intervention into daily routine is a complex process that changes existing routines (28). Therefore, training of the participating physiotherapists in the e-Exercise LBP intervention has been expanded from a 4-h training session to two 4-h training sessions. Additionally, Siilo, a secure messenger for healthcare professionals to communicate and share information, will be used during the study to be able to provide direct assistance to participating physiotherapists. And finally, instruction videos were created to support physiotherapists in using the e-Exercise LBP intervention. Another important operational issue is the possible increased risk of drop- outs during this study due to the 24-month follow-up period and the 11 questionnaires that have to be completed during this period. To minimize this risk, a researcher (TK or RA) will conduct the follow-up assessments at 3, 12 and 24 months in person, i.e., by phone, Skype or face-to-face. A final operational issue is the belief that e-Exercise LBP will not provide a solution for all patients having LBP, nor for all physiotherapists treating patients with LBP. Therefore, selection bias could occur, e.g., participants or physiotherapists having low digital literacy skills, or have a more negative attitude towards technology in general, are less likely to be included in this study.

However, with respect to our digitalized society it is expected that the majority of patients with LBP can benefit from the e-Exercise LBP intervention. The results of this study will help to understand whether blended physiotherapy for patients with LBP can be implemented on this basis.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12891-020-3174-z.

Additional file 1. Print screens of the smartphone application.

Abbreviations

CeHRes: Center for eHealth Research; COS: Core Outcome Set; EARS: Exercise Adherence Rating Scale; EQ-5D-5 L: EuroQol 5D; EXAS: Exercise Adherence Scale; FABQ: Fear-Avoidance Beliefs Questionnaire; FCA: Friction Cost Approach; GSE scale: General Self-efficacy Scale; ICERs: Incremental Cost-Effectiveness Ratios; iPCQ: IMTA Productivity Cost Questionnaire; KNGF: Royal Dutch Association for Physiotherapy; LBP: Low Back Pain; LMM: Linear Mixed Models; NRS: Numeric Rating Scale; ODI: Oswestry Disability Index; PAM: Patient Activation Measure; PCS: Pain Catastrophizing Scale; QALY's: Quality Adjusted Life Years; RCT: Randomized Controlled Trial

Acknowledgements

Not applicable.

Authors' contributions

All authors (TK, RA, JD, RO, CV, CK, and MP) made substantial contributions to the design of this study AND have drafted the work or substantively revised it. Furthermore, all authors (TK, RA, JD, RO, CV, CK, and MP) have approved the submitted version (and any substantially modified version that involves the author's contribution to the study). Finally, all authors (TK, RA, JD, RO, CV, CK, and MP) agree both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

Funding

This study is co-funded by the Taskforce for Applied Research SIA (RAAK.-PRO02.063), part of the Dutch Research Council (NWO). The external grant body undertook peer-review during the funding process. The Taskforce for Applied Research SIA had no role

in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Availability of data and materials

Not applicable as this is a protocol for a study.

Ethics approval and consent to participate

This study has been reviewed and approved by the Medical Research Ethics Committee of the University Medical Center Utrecht, the Netherlands (ISRCTN 94074203) for all centre sites and will be conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

REFERENCES

1. James SL, Abate D, Abate KH, Abay SM, Abbafati C, Abbasi N, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2018;392(10159):1789–858.
2. Hartvigsen J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, et al. What low back pain is and why we need to pay attention. Lancet. 2018;391(10137):2356–67.
3. Koes BW, Tulder MW van, Thomas S. Diagnosis and treatment of low back pain. BMJ. 2006;332(7555):1430.
4. Maher C, Underwood M, Buchbinder R. Non-specific low back pain. Lancet. 2017;389(10070):736–47.
5. Chou R, Shekelle P. Will This Patient Develop Persistent Disabling Low Back Pain? JAMA. 2010;303(13):1295–302.
6. Hayden JA, Dunn KM, van der Windt DA, Shaw WS. What is the prognosis of back pain? Best Pract Res Clin Rheumatol. 2010;24(2):167–79.
7. Wong JJ, Côté P, Sutton DA, Randhawa K, Yu H, Varatharajan S, et al. Clinical practice guidelines for the noninvasive management of low back pain: A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. Eur J Pain. 2017;21(2):201–16.
8. Foster NE, Anema JR, Cherkin D, Chou R, Cohen SP, Gross DP, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. Lancet. 2018;391(10137):2368–83.
9. Oliveira CB, Maher CG, Pinto RZ, Traeger AC, Lin CWC, Chenot JF, et al. Clinical practice guidelines for the management of non-specific low back pain in primary care: an updated overview. Eur Spine J. 2018;27(11):2791–803.
10. Staal JB, Hendriks EJM, Heijmans M, Kiers H, Rutten A M L-BG, van Tulder MW, et al. KNGF richtlijn Lage rugpijn. KNGF-richtlijn Lage rugpijn. 2013;V-07/2013:13.
11. Mannion AF, Helbling D, Pulkovski N, Sprott H. Spinal segmental stabilisation exercises for chronic low back pain: programme adherence and its influence on clinical outcome. Eur Spine J. 2009;18(12):1881–91.
12. van Gool CH, Penninx BWJH, Kempen GIJM, Rejeski WJ, Miller GD, van Eijk JThM, et al. Effects of exercise adherence on physical function among overweight older adults with knee osteoarthritis. Arthritis Care Res. 2005;53(1):24–32.
13. Sluijs EM, Kok GJ, van der Zee J. Correlates of Exercise Compliance in Physical Therapy. Phys Ther. 1993 Nov 1;73(11):771–82.
14. Friedrich M, Gittler G, Halberstadt Y, Cermak T, Heiller I. Combined exercise and motivation program: effect on the compliance and level of disability of patients with chronic low back pain: a randomized controlled trial. Arch Phys Med Rehabil. 1998;79(5):475–8.
15. Sabaté E. Adherence to long-term therapies: Evidence for action. Sabaté E, editor. Eur J Cardiovasc Nurs. Geneva; 2003.
16. Choi BKL, Verbeek JH, Tam WW san, Jiang JY. Exercises for prevention of recurrences of low-back pain. Cochrane Database Syst Rev. 2010;(1):CD006555.

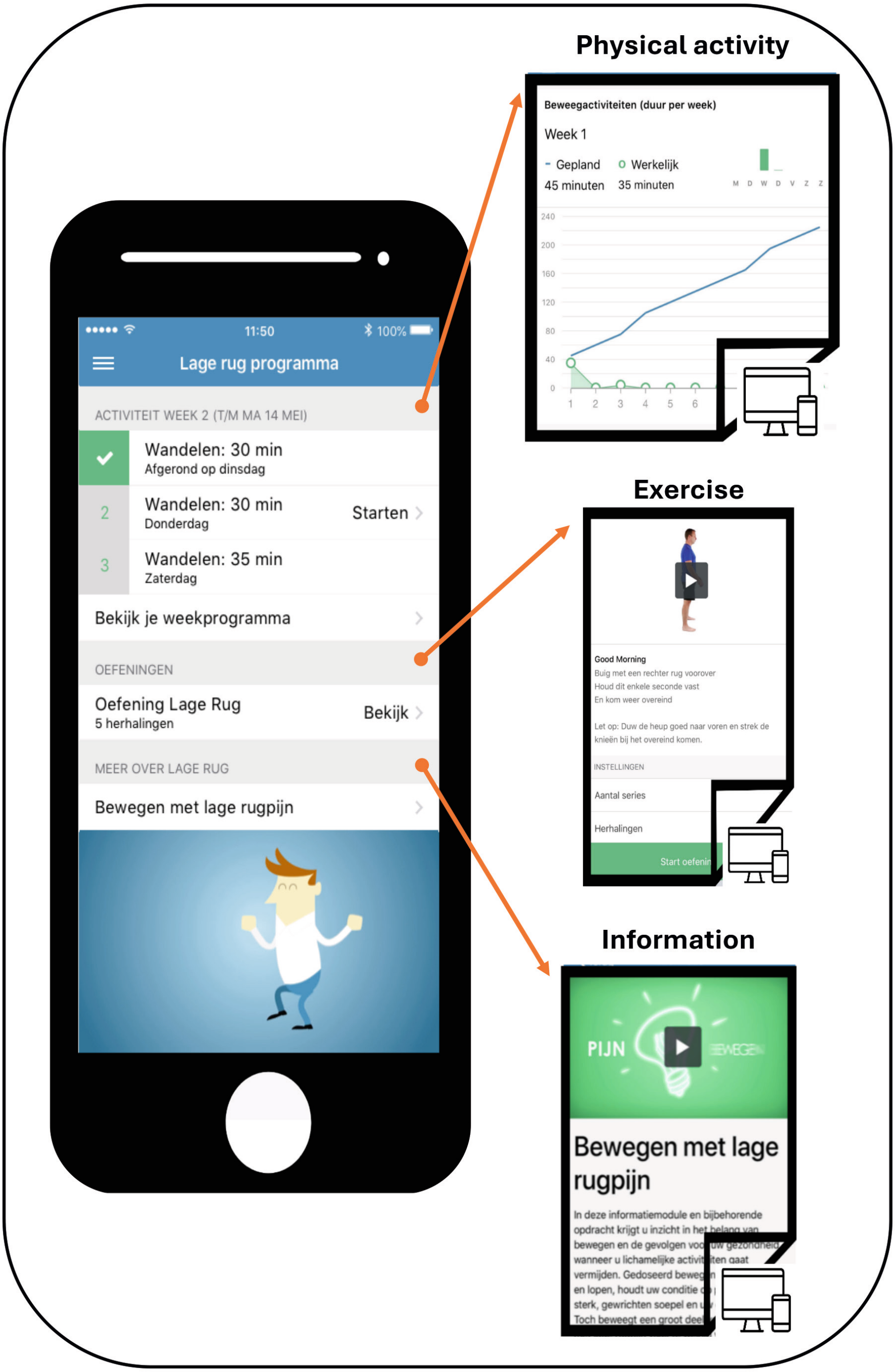
17. Nicholl BI, Sandal LF, Stochkendahl MJ, McCallum M, Suresh N, Vasseljen O, et al. Digital Support Interventions for the Self-Management of Low Back Pain: A Systematic Review. J Med Internet Res. 2017;19(5):e179.
18. Lambert TE, Harvey L a., Avdalis C, Chen LW, Jeyalingam S, Pratt C a., et al. An app with remote support achieves better adherence to home exercise programs than paper handouts in people with musculoskeletal conditions: A randomised trial. J Physiother. 2017 Jul;63(3):161–7.
19. Machado GC, Pinheiro MB, Lee H, Ahmed OH, Hendrick P, Williams C, et al. Smartphone apps for the self-management of low back pain: A systematic review. Best Pract Res Clin Rheumatol. 2016;30(6):1098–109.
20. Bennell KL, Marshall CJ, Dobson F, Kasza J, Lonsdale C, Hinman RS. Does a Web-Based Exercise Programming System Improve Home Exercise Adherence for People with Musculoskeletal Conditions?: A Randomized Controlled Trial. Am J Phys Med Rehabil. 2019;98(10):850–8.
21. Wentzel J, Van der Vaart R, Bohlmeijer ET, Van Gemert-Pijnen JEWC. Mixing online and face-to-face therapy: How to benefit from blended care in mental health care. JMIR Ment Health. 2016;3(1):e9.
22. Lustria MLA, Cortese J, Noar SM, Glueckauf RL. Computer-tailored health interventions delivered over the web: Review and analysis of key components. Patient Educ Couns. 2009;74(2):156–73.
23. Noar SM, Benac CN, Harris MS. Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. Psychol Bull. 2007;133(4):673–93.
24. Kelders SM, Kok RN, Ossebaard HC, Van Gemert-Pijnen JE. Persuasive System Design Does Matter: a Systematic Review of Adherence to Web-based Interventions. J Med Internet Res. 2012;14(6):e152.
25. Linn AJ, Vervloet M, van Dijk L, Smit EG, Van Weert JC. Effects of eHealth Interventions on Medication Adherence: A Systematic Review of the Literature. J Med Internet Res. 2011;13(4):e103.
26. Wantland DJ, Portillo CJ, Holzemer WL, Slaughter R, McGhee EM. The Effectiveness of Web-Based vs. Non-Web-Based Interventions: A Meta-Analysis of Behavioral Change Outcomes. J Med Internet Res. 2004;6(4):e40.
27. Whitehead M. The Concept of Physical Literacy. Eur J Phys Edu. 2001;6(2):127–38.
28. Kloek CJJ, Bossen D, de Vries HJ, de Bakker DH, Veenhof C, Dekker J. Physiotherapists' experiences with a blended osteoarthritis intervention: a mixed methods study. Physiother Theory Pract. 2020;36(5):572–9.
29. Hill JC, Dunn KM, Lewis M, Mullis R, Main CJ, Foster NE, et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. Arthritis Rheum. 2008;59(5):632–41.
30. Hill JC, Whitehurst DGT, Lewis M, Bryan S, Dunn KM, Foster NE, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): A randomised controlled trial. Lancet. 2011;378(9802):1560–71.
31. Foster NE, Mullis R, Hill JC, Lewis M, Whitehurst DGT, Doyle C, et al. Effect of stratified care for low back pain in family practice (IMPaCT back): A prospective population-based sequential comparison. Ann Fam Med. 2014;12(2):102–11.

32. Whitehurst DGT, Bryan S, Lewis M, Hill J, Hay EM. Exploring the cost–utility of stratified primary care management for low back pain compared with current best practice within risk-defined subgroups. Ann Rheum Dis. 2012;71(11):1796–802.
33. Kloek CJJ, van Tilburg ML, Staal JB, Veenhof C, Bossen D. Development and proof of concept of a blended physiotherapeutic intervention for patients with non-specific low back pain. 2019;105(4):483–91.
34. van Westrienen PE, Pisters MF, Toonders SA, Gerrits M, Veenhof C, de Wit NJ. Effectiveness of a Blended Multidisciplinary Intervention for Patients with Moderate Medically Unexplained Physical Symptoms (PARASOL): Protocol for a Cluster Randomized Clinical Trial. JMIR Res Protoc. 2018;7(5):e120.
35. Kloek CJJ, Bossen D, Spreeuwenberg PM, Dekker J, de Bakker DH, Veenhof C. Effectiveness of a Blended Physical Therapist Intervention in People With Hip Osteoarthritis, Knee Osteoarthritis, or Both: A Cluster-Randomized Controlled Trial. Phys Ther. 2018;98(7):560–70.
36. Hoy D, Bain C, Williams G, March L, Brooks P, Blyth F, et al. A Systematic Review of the Global Prevalence of Low Back Pain. Arthritis Rheum. 2012;64(6):2028–37.
37. van Gemert-Pijnen JE, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A Holistic Framework to Improve the Uptake and Impact of eHealth Technologies. J Med Intern Res. 2011;13(4):e111.
38. Bossen D, Veenhof C, Van Beek KE, Spreeuwenberg PM, Dekker J, De Bakker DH. Effectiveness of a Web-Based Physical Activity Intervention in Patients With Knee and/or Hip Osteoarthritis: Randomized Controlled Trial. J Med Internet Res. 2013;15(11):e257.
39. Hill JC, Dunn KM, Main CJ, Hay EM. Subgrouping low back pain: A comparison of the STarT Back Tool with the Örebro Musculoskeletal Pain Screening Questionnaire. Eur J Pain. 2010;14(1):83–9.
40. Bier JD, Ostelo RWJG, van Hooff ML, Koes BW, Verhagen AP. Validity and Reproducibility of the STarT Back Tool (Dutch Version) in Patients With Low Back Pain in Primary Care Settings. Phys Ther. 2017;97(5):561–70.
41. Nijs J, Paul van Wilgen C, Van Oosterwijck J, van Ittersum M, Meeus M. How to explain central sensitization to patients with 'unexplained' chronic musculoskeletal pain: Practice guidelines. Man Ther. 2011;16(5):413–8.
42. Brunner E, De Herdt A, Minguet P, Baldew SS, Probst M. Can cognitive behavioural therapy based strategies be integrated into physiotherapy for the prevention of chronic low back pain? A systematic review. Disabil Rehabil. 2013;35(1):1–10.
43. Chiarotto A, Deyo RA, Terwee CB, Boers M, Buchbinder R, Corbin TP, et al. Core outcome domains for clinical trials in non-specific low back pain. Eur Spine J. 2015;24(6):1127–42.
44. Chiarotto A, Terwee CB, Ostelo RW. Choosing the right outcome measurement instruments for patients with low back pain. Best Pract Res Clin Rheumatol. 2016;30(6):1003–20.
45. Chiarotto A, Boers M, Deyo RA, Buchbinder R, Corbin TP, Costa LOP, et al. Core outcome measurement instruments for clinical trials in nonspecific low back pain. Pain. 2018;159(3):481–95.
46. Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine (Phila Pa 1976). 2000;25(22):2940–52.

47. Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. The journal of pain : official journal of the American Pain Society. 2008;9(2):105–21.
48. Bussmann H. Validation of the Active8 Activity Monitor: detection of body postures and movements. Rotterdam; 2013. 49. Activ8 Physical Activity Monitor. [cited 2019 Mar 18]. Available from: https://www.Active8all.com
50. Newman-Beinart NA, Norton S, Dowling D, Gavriloff D, Vari C, Weinman JA, et al. The development and initial psychometric evaluation of a measure assessing adherence to prescribed exercise: the Exercise Adherence Rating Scale (EARS). Physiotherapy. 2017;103(2):180–5.
51. Arensman RM, Geelen RH, Koppenaal T, Veenhof C, Pisters MF. Measuring exercise adherence in patients with low back pain: development, validity, and reliability of the EXercise Adherence Scale (EXAS). Physiother Theory Pract. 2022;38(7):928–37.
52. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain. 1993;52(2):157–68.
53. van Damme S. Catastroferen over pijn: pain Catastrophizing scale-Dutch version (PCS-DV). Gent, Belgium: Universiteit Gent; 2002.
54. Sullivan MJL, Bishop SR, Pivik J. The Pain Catastrophizing Scale: Development and validation. Psychol Assess. 1995;7(4):524–32.
55. Bandura A. Self-efficacy. In: Ramachaudran VS, editor. Encyclopedia of human behavior. New York: Academic Press; 1994. p. 71–81.
56. Schwarzer R, Jerusalem M. Causal and Control Beliefs. In: Measures in Health Psychology: A User's Portfolio. 1995. p. 35–7.
57. Teeuw B, Schwarzer R, Jerusalem M. Dutch Adaptation of the General Self-Efficacy Scale. 1994. Available from: https://userpage.fu-berlin.de/~health/dutch.htm
58. Scholz U, Doña BG, Sud S, Schwarzer R. Is General Self-Efficacy a Universal Construct? Psychometric findings from 25 countries. Eur J Psychol Assess. 2002;18(3):242–51.
59. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and Testing of a Short Form of the Patient Activation Measure. Health Serv Res. 2005;40(6p1):1918–30.
60. Rademakers J, Nijman J, van der Hoek L, Heijmans M, Rijken M. Measuring patient activation in The Netherlands: translation and validation of the American short form Patient Activation Measure (PAM13). BMC Pub Health. 2012;12(1):577.
61. Vet H De, Heymans MW, Dunn KM, Pope D. Episodes of Low Back Pain: A Proposal for Uniform Definitions to Be Used in Episodes of Low Back Pain A Proposal for Uniform Definitions to Be Used in Research. Spine. 2002;27(21):2409–16.
62. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012;345:e5661–e5661.
63. Sedgwick P. Cluster randomised controlled trials: sample size calculations. BMJ. 2013;346:f2839–f2839.
64. Vickers AJ. How many repeated measures in repeated measures designs? Statistical issues for comparative trials. BMC Med Res Methodol. 2003;3(1):22.

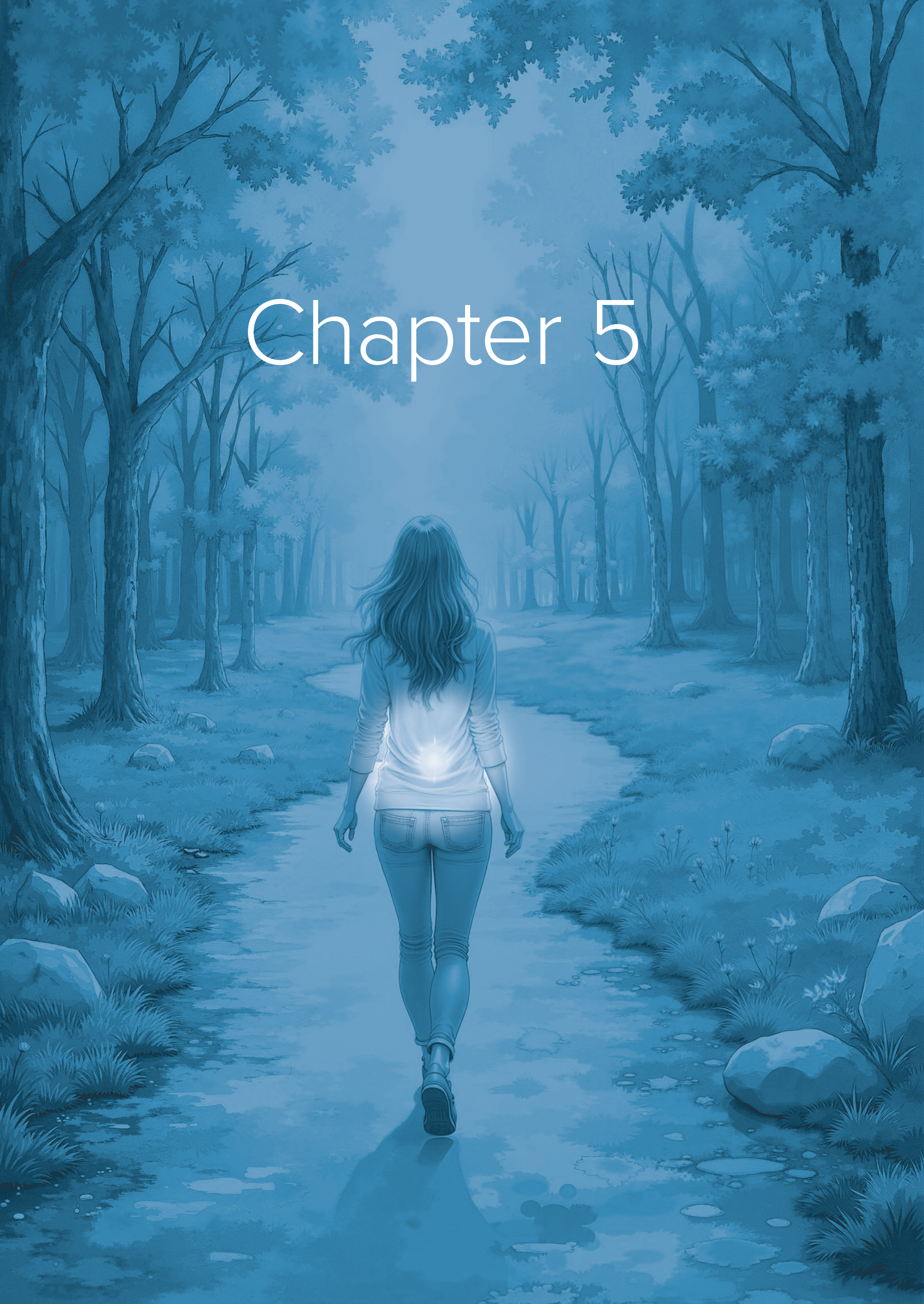
65. Eccles M, Grimshaw J, Steen N, Parkin D, Purves I, McColl E, et al. The design and analysis of a randomized controlled trial to evaluate computerized decision support in primary care: the COGENT study. Fam Pract. 2000;17(2):180–6.
66. Thomas R. Cluster randomized trial of a guideline-based open access urological investigation service. Fam Pract. 2003;20(6):646–54.
67. Fritz JM, Irrgang JJ. A Comparison of a Modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. Phys Ther. 2001;81(2):776–88.
68. Resnik L, Dobrzykowski E. Guide to outcomes measurement for patients with low back pain syndromes. J Orthop Sports Phys Ther. 2003;33(6):307–18.
69. Apeldoorn AT, Ostelo RW, van Helvoirt H, Fritz JM, Knol DL, van Tulder MW, et al. A Randomized Controlled Trial on the Effectiveness of a Classification-Based System for Subacute and Chronic Low Back Pain. Spine. 2012;37(16):1347–56.
70. Raudenbush S, Bryk A. Hierarchical linear models: applications and data analysis methods (advanced quantitative techniques in the social sciences). 2nd edition. Newbury Park: Sage Publications; 2001.
71. Goldstein H. Multilevel Statistical Models. Hoboken, New Jersey: Wiley; 1987.
72. Dunnl KM, Jordan KP, Croft PR. Contributions of prognostic factors for poor outcome in primary care low back pain patients. Eur J Pain. 2011;15(3):313–9.
73. Hayden JA, Chou R, Hogg-Johnson S, Bombardier C. Systematic reviews of low back pain prognosis had variable methods and results—guidance for future prognosis reviews. J Clin Epidemiol. 2009;62(8):781-796.e1.
74. Grotle M, Foster NE, Dunn KM, Croft P. Are prognostic indicators for poor outcome different for acute and chronic low back pain consulters in primary care? Pain. 2010;151(3):790–7.
75. de Vries HermanJ, Kloek CJJ, de Bakker DH, Dekker J, Bossen D, Veenhof C. Determinants of Adherence to the Online Component of a Blended Intervention for Patients with Hip and/or Knee Osteoarthritis: A Mixed Methods Study Embedded in the e-Exercise Trial. Telemedi J E Health. 2017;23(12):1002–10.
76. Frick KD. Microcosting Quantity Data Collection Methods. Med Care. 2009;47(7_Supplement_1):S76–81.
77. Kanters TA, Bouwmans CAM, van der Linden N, Tan SS, Hakkaart-van Roijen L. Update of the Dutch manual for costing studies in health care. PLoS One. 2017;12(11):e0187477.
78. Hakkaart-van Roijen L, van der Linden N, Bouwmans CAM, Kanters T, Tan SS. Kostenhandleiding: Methodologie van kostenonderzoek en referentieprijzen voor economische evaluaties in de gezondheidszorg. Diemen: CVZ; 2015. 1–120 p.
79. Koopmanschap MA, Rutten FFH, van Ineveld BM, van Roijen L. The friction cost method for measuring indirect costs of disease. J Health Econ. 1995;14(2):171–89.
80. Kessler RC, Ames M, Hymel PA, Loeppke R, McKenas DK, Richling DE, et al. Using the World Health Organization Health and Work Performance Questionnaire (HPQ) to Evaluate the Indirect Workplace Costs of Illness. J Occup Environ Med. 2004;46(6):S23–37.
81. Kessler RC, Barber C, Beck A, Berglund P, Cleary PD, McKenas D, et al. The World Health Organization Health and Work Performance Questionnaire (HPQ). J Occup Environ Med. 2003;45(2):156–74.
82. EuroQol Group. EuroQol - a new facility for the measurement of health-related quality of life. Health Policy (New York). 1990;16(3):199–208.

83. Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011;20(10):1727–36.
84. Janssen MF, Pickard AS, Golicki D, Gudex C, Niewada M, Scalone L, et al. Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: a multi-country study. Qual Life Res. 2013;22(7):1717–27.
85. Soer R, Reneman MF, Speijer BLGN, Coppes MH, Vroomen PCAJ. Clinimetric properties of the EuroQol-5D in patients with chronic low back pain. Spine J. 2012;12(11):1035–9.
86. M. Versteegh M, M. Vermeulen K, M. A. A. Evers S, de Wit GA, Prenger R, A. Stolk E. Dutch Tariff for the Five-Level Version of EQ-5D. Value Health. 2016;19(4):343–52.
87. Rubin D. Multiple imputation for nonresponse in surveys. New York: Wiley; 1987.
88. Drummond MF. Methods for the economic evaluation of health care programmes. 4th edition. Oxford: Oxford University Press; 2015.
89. Brierley G, Brabyn S, Torgerson D, Watson J. Bias in recruitment to cluster randomized trials: a review of recent publications. J Eval Clin Pract. 2012;18(4):878–86.



Appendix 1. Print screens of the smartphone application

Chapter 5



The 3-Month Effectiveness of a Stratified Blended Physiotherapy Intervention in Patients With Nonspecific Low Back Pain: Cluster Randomized Controlled Trial

Tjarco Koppenaal
Martijn F. Pisters
Corelien J.J. Kloek
Remco M. Arensman
Raymond W.J.G. Ostelo
Cindy Veenhof

Published in Journal of Medical Internet Research 2022;24(2):e31675

ABSTRACT

Background: Patient education, home-based exercise therapy, and advice on returning to normal activities are established physiotherapeutic treatment options for patients with nonspecific low back pain (LBP). However, the effectiveness of physiotherapy interventions on health-related outcomes largely depends on patient self-management and adherence to exercise and physical activity recommendations. e-Exercise LBP is a recently developed stratified blended care intervention comprising a smartphone app integrated with face-to-face physiotherapy treatment. Following the promising effects of web-based applications on patients' self-management skills and adherence to exercise and physical activity recommendations, it is hypothesized that e-Exercise LBP will improve patients' physical functioning.

Objective: This study aims to investigate the short-term (3 months) effectiveness of stratified blended physiotherapy (e-Exercise LBP) on physical functioning in comparison with face-to-face physiotherapy in patients with nonspecific LBP.

Methods: The study design was a multicenter cluster randomized controlled trial with intention-to-treat analysis. Patients with nonspecific LBP aged ^{3}18 years were asked to participate in the study. The patients were treated with either stratified blended physiotherapy or face-to-face physiotherapy. Both interventions were conducted according to the Dutch physiotherapy guidelines for nonspecific LBP. Blended physiotherapy was stratified according to the patients' risk of developing persistent LBP using the Keele STarT Back Screening Tool. The primary outcome was physical functioning (Oswestry Disability Index, range 0-100). Secondary outcomes included pain intensity, fear-avoidance beliefs, and self-reported adherence. Measurements were taken at baseline and at the 3-month follow-up.

Results: Both the stratified blended physiotherapy group (104/208, 50%) and the face-to-face physiotherapy group (104/208, 50%) had improved clinically relevant and statistically significant physical functioning; however, there was no statistically significant or clinically relevant between-group difference (mean difference −1.96, 95% CI −4.47 to 0.55). For the secondary outcomes, stratified blended physiotherapy showed statistically significant between-group differences in fear-avoidance beliefs and self-reported adherence. In patients with a high risk of developing persistent LBP (13/208, 6.3%), stratified blended physiotherapy showed statistically significant between-group differences in physical functioning (mean difference −16.39, 95% CI −27.98 to −4.79) and several secondary outcomes.

Conclusions: The stratified blended physiotherapy intervention e-Exercise LBP is not more effective than face-to-face physiotherapy in patients with nonspecific LBP in improving physical functioning in the short term. For both stratified blended physiotherapy and face-to-face physiotherapy, within-group improvements were clinically relevant. To be able to decide whether e-Exercise LBP should be implemented in daily physiotherapy practice, future research should focus on the long-term cost-effectiveness and determine which patients benefit most from stratified blended physiotherapy.

Trial Registration: ISRCTN Registry 94074203; https://doi.org/10.1186/ISRCTN94074203

International Registered Report Identifier (IRRID): RR2-https://doi.org/10.1186/s12891-020-3174-z

(J Med Internet Res 2022;24(2):e31675) doi: 10.2196/31675

Keywords: eHealth; nonspecific low back pain; physiotherapy; blended care; mobile phone

5

INTRODUCTION

Low back pain (LBP)–related disability and the related socioeconomic burden remain high despite the many treatment options and health care resources available for LBP (1). LBP can be caused by a specific pathology or trauma; however, in >90% of cases, an underlying disease is absent (2). The clinical course of this so-called *nonspecific LBP* varies and, as expected, is often less favorable; some patients recover within a couple of days or weeks, and other patients experience persistent disabling symptoms leading to chronic LBP. Up to 65% of primary care patients with LBP still experience pain 1 year after onset (3,4).

Clinical practice guidelines recommend a patient-centered approach for the management of LBP (5,6). This approach identifies patients with an increased likelihood of delayed recovery at an early stage and stratifies the treatment accordingly (6–8). An example of a tool for identifying individuals at risk of delayed recovery is the Keele STarT Back Screening Tool (9,10). In general, in patients who have a low risk for delayed recovery, early management comprises advice, reassurance, and education about the nonspecific nature of their LBP and encouragement to stay active. For individuals at medium risk for developing persistent LBP, personalized and supervised exercise therapy should be considered. For the high-risk group, this exercise therapy can be supported by a graded activity approach or cognitive behavioral components (8,11). In addition to a patient-centered and stratified approach, patients' adherence to prescribed (home-based) exercises and recommended physical activity behavior is crucial for the effectiveness of care (12). Earlier research showed that 45% to 70% of patients do not adhere to prescribed exercises and physical activity recommendations, whereas adherent patients with LBP have a reduced risk of recurrent LBP (13,14).

Within the treatment of patients with LBP, blended care is a promising new and understudied field (15). Blended care refers to the integration of web-based and offline components within the treatment process and requires that both components contribute equally to the treatment process (16,17). The integration of web-based components, such as websites and apps, provides new solutions to monitor and coach patients' individual health behaviors and support the optimization of face-to-face care tailored to the patients' individual needs (18–20). Thereafter, web-based components can be an effective means of stimulating adherence to prescribed exercises at home between face-to-face sessions and possibly increase self-management of LBP (21,22). Until now, evidence on patient-centered and stratified care has not been integrated into blended care. Therefore, we recently developed e-Exercise LBP, a stratified blended intervention in which a smartphone app is integrated within face-to-face physiotherapy treatment, and established its feasibility and proof of concept for the treatment of functional disability and pain (23). e-Exercise LBP is an adapted version of previously developed and evaluated blended physiotherapy programs (24,25). Following the promising effects of web-based applications for patients' self-management skills and adherence to exercise and physical activity recommendations, it is hypothesized that e-Exercise LBP will improve patients' physical functioning. However, the effectiveness of e-Exercise LBP in comparison with primary care physiotherapy still needs to be determined. The primary aim of this study is to investigate the short-term (3 months) effectiveness of stratified blended physiotherapy (e-Exercise LBP) on physical functioning in comparison with face-to-face physiotherapy in patients with nonspecific LBP.

METHODS

Design and Ethical Considerations

The e-Exercise LBP study was a prospective multicenter cluster randomized controlled trial. The study protocol was approved by the medical research ethics committee of the University Medical Center Utrecht, the Netherlands (18-085/D), and registered at the onset of patient enrollment (ISRCTN 94074203). From January 2018 to June 2018, 122 physiotherapists working in 58 primary care physiotherapy practices were recruited and randomized to either stratified blended physiotherapy (e-Exercise LBP) or face-to-face physiotherapy. Details of the design and methods of the study have been published previously (26). This study is reported according to the CONSORT (Consolidated Standards of Reporting Trials) statement for cluster randomized trials (Multimedia Appendix 1).

Recruitment

Setting and Randomization

Physiotherapists were recruited by an invitational letter sent to the professional network of the authors and physiotherapists who participated in a previous e-Exercise study (24). In addition, an advertisement was placed in the web-based newsletter of the Royal Dutch Society for Physiotherapy. Physiotherapy practices could participate with ≥ 1 physiotherapist, regardless of professional experience and education or specialization (eg, manual therapy). Physiotherapists were cluster randomized at the level of practice to avoid contamination. Treatment allocation was concealed and performed by an independent researcher using a computer-generated, a priori created, random sequence table and in a 1:1 allocation ratio. Physiotherapists and patients were not blinded to the group allocation.

The physiotherapists in the stratified blended physiotherapy group received two 4-hour training sessions on e-Exercise LBP and the study procedures. In the face-to-face physiotherapy group, physiotherapists received a 4-hour training session in current best practices according to the LBP guidelines of the Royal Dutch Society for Physiotherapy (11) and the study procedures.

Patients

Patients with LBP who contacted a participating physiotherapy practice were orally informed about the study and invited to participate. Interested patients received a patient information letter by email and an informative phone call by one of the researchers (TK or RMA) before the first appointment. When a patient was willing to participate after the phone call, a face-to-face appointment was scheduled (by TK or RMA) to obtain written informed consent and verify eligibility. The eligibility criteria were as follows: (1) being a patient requesting physiotherapy treatment for nonspecific LBP, defined as pain in the lumbosacral region (sometimes associated with radiating pain to the buttock or leg) (11); (2) aged ≥18 years; (3) possessing a smartphone or tablet (iOS or Android operating system) with access to the internet; and (4) mastery of the Dutch language. The exclusion criteria were as follows: (1) a specific cause of LBP determined through medical imaging or a medical physician, (2) serious comorbidities (e.g., malignancy or stroke), and (3) current pregnancy because of the prevalence of pelvic girdle pain as a specific form of LBP.

Intervention

Experimental: Stratified Blended Physiotherapy (e-Exercise LBP)

Patients allocated to the stratified blended physiotherapy group received blended physiotherapy, comprising a smartphone app integrated within face-to-face physiotherapy treatment (23,26). Both the contents of the smartphone app and the face-to-face physiotherapy treatment are based on the recommendations of the LBP guidelines of the Royal Dutch Society for Physiotherapy (11). The duration and content of the stratified blended physiotherapy intervention were based on the patients' risk for developing persistent LBP (low, medium, or high) using the Keele STarT Back Screening Tool (9,10). The smartphone app contains video-supported self-management information, video-supported exercises, and a goal-oriented physical activity module. Both the contents of face-to-face care and the smartphone app were tailored by the physiotherapists to the patients' individual needs and progress (Table 1). Although physiotherapists were recommended to treat according to the stratified blended physiotherapy protocol, they were free to deviate from the protocol with respect to their clinical competence. Print screens of the smartphone app are provided in Multimedia Appendix 2.

Table 1 Overview of the stratified blended physiotherapy intervention (e-Exercise low back pain [LBP]).

Mode of delivery	Low-risk profile	Medium-risk profile	High-risk profile
Smartphone app			
Duration	3 weeks	12 weeks	12 weeks
Information module	Knowledge-based platform with several LBP self-management information themes (directly available)	12 weekly self-management themes, including assignments	12 weekly self-management themes, including assignments, pain education, and psychosocial risk factors
Exercise module	3-4 home-based exercises tailored to the patient's specific functional limitations	3-4 home-based exercises tailored to the patient's specific functional limitations	3-4 home-based exercises tailored to the patient's specific functional limitations
Physical activity module	Physical activity recommendations in accordance with the LBP guidelines of the Royal Dutch Association for Physiotherapy	A 3-day baseline test to determine the current level of physical activity; an 11-week, 3 times per week, goal-oriented training program to maintain or improve the level of physical activity; in patients avoiding physical activity due to LBP, a graded activity functionality can be activated	A 3-day baseline test to determine the current level of physical activity; an 11-week, 3 times per week, goal-oriented training program to maintain or improve the level of physical activity using a graded activity approach
Face-to-face care			
Sessions	2 sessions	Maximum of 8 sessions	Maximum of 12 sessions
Content	Reassurance, information about LBP, instruction on self-management options, and the importance of adequate physical activity behavior	Content similar as low risk, and in addition, the physiotherapist can consider providing evidence-based interventions (e.g. passive or active joint mobilization) as recommended by guideline LBP of the Royal Dutch Association for Physiotherapy	Content similar to medium risk, and in addition, the physiotherapist will address the patient's specific psychosocial risk factors using a cognitive-behavioral approach, and pain education will be given

Table 1 *Continued.*

Mode of delivery	Low-risk profile	Medium-risk profile	High-risk profile
Integration face-to-face care and smartphone app			
First session	Provide information about LBP and instruction on home-based exercises addressing patient's specific functional limitations using the smartphone app	Provide information about LBP, instruction on home-based exercises addressing patient's specific functional limitations, and instruction on 3-day baseline test using the smartphone app	Provide information about LBP, instructions on home-based exercises addressing patient's specific functional limitations, and instruction on 3-day baseline test using the smartphone app
Middle sessions	N/A[a]	Evaluation of progress with the smartphone app and optimizing face-to-face care	Evaluation of progress with smartphone app and optimizing face-to-face care
Final session	Evaluate the progress with the smartphone app and give recommendations to prevent recurrent episodes of LBP and maintain or improve the physical activity level	Evaluate the progress with smartphone app and give recommendations to prevent recurrent episodes of LBP and maintain or improve the physical activity level	Evaluate the progress with smartphone app and give recommendations to prevent recurrent episodes of LBP and maintain or improve the physical activity level

[a]N/A: not applicable.

Control: Face-to-face Physiotherapy

Patients in the face-to-face physiotherapy group received only face-to-face care following the recommendations of the LBP guidelines of the Royal Dutch Society for Physiotherapy (11). The guideline distinguishes between three different patient profiles based on the clinical course of recovery (i.e., normal recovery, abnormal recovery without predominant psychosocial factors, and abnormal recovery with predominant psychosocial factors) but does not use a specific tool to stratify care a priori. The content of face-to-face physiotherapy was the same as the stratified blended care intervention (i.e., information, exercises, and recommendations regarding physical activity). However, no recommendations or restrictions were provided with regard to the number of face-to-face sessions. Although web-based applications, such as websites and apps, are not recommended in the guidelines, physiotherapists were instructed to treat people without using any web-based applications to assure contrast between both groups. Practical content considerations were made by the physiotherapists themselves with respect to their clinical expertise.

Measurements

Patients received a web-based questionnaire and an accelerometer at baseline and after 3 months of follow-up. Baseline measurements were conducted face to face and follow-up measurements through web-based communication (e.g., FaceTime) or face to face when requested. No financial incentives were offered to complete the measurements. In the case of an unfilled questionnaire, patients were reminded after 7 and 14 days.

Outcome Measures

Primary Outcome

Physical functioning because of pain was assessed using the Oswestry Disability Index (ODI; version 2.1a) (27,28). The ODI was derived from the internationally accepted core outcome set for research into patients with nonspecific LBP (28). A higher score (0-100) indicates increased functional disability.

Secondary Outcomes

Pain intensity was measured using an 11-point numeric rating scale for the average LBP intensity in the last week (0=no pain and 10=worst possible pain) (28,29).

Physical activity was objectively measured using Activ8 (2M Engineering) (30). Patients were instructed to wear the Activ8 for 5 consecutive weeks starting at baseline and 8 consecutive days at the 3-month follow-up, except during sleeping, showering, bathing, or swimming. For the purpose of this study, only the first 7 days at both the baseline and 3-month follow-up were used. Accelerometer data were eligible if patients had worn the meter for at least 3 days for ≥10 hours a day (31). For each patient, the mean time spent in moderate to vigorous physical activity (all activities >3.0 metabolic equivalents (32)) in minutes per day was computed by summation and divided by the number of eligible wearing days.

Fear-avoidance beliefs about physical activity and work were measured using the Fear-Avoidance Beliefs Questionnaire (33). A higher score (range 0-96) indicates stronger fear and avoidance beliefs about how physical activity and work negatively affect LBP.

Pain catastrophizing was measured using the Pain Catastrophizing Scale (34). A higher score (range 0-55) indicates a higher level of catastrophizing.

Self-efficacy was measured using the General Self-Efficacy Scale (35,36). A higher score (range 10-40) indicates greater or stronger perceived self-efficacy.

Self-management ability was assessed using the Dutch version of the short form Patient Activation Measure (37). A higher score (range 0-100) indicates a higher level of self-management.

Health-related quality of life was measured using the EuroQol-5D-5L (38). A higher score (range 0-100) indicates a higher health-related quality of life.

Patient self-reported adherence to prescribed home exercises was measured using the Exercise Adherence Rating Scale (39). A higher score (range 0-24) indicates better adherence.

Other Measures

Physiotherapists were asked to complete a registration form about the number of face-to-face sessions and report the applied treatment modalities per session. Patient characteristics and relevant clinical variables were assessed as part of the baseline questionnaire.

Data Analysis

Overview

Descriptive statistics were used to explore baseline comparability and describe patients' general characteristics, the number of face-to-face physiotherapy sessions, and the treatment modalities. To investigate selective attrition, general characteristics and primary baseline variables of dropouts and nondropouts were compared. All analyses were performed according to the intention-to-treat principle. Missing value analyses were performed by assuming the missing at random assumption. Multiple imputation was applied using multivariate imputation by chained equations with predictive mean matching for missing data in all outcomes. A total of 36 imputed data sets were generated, corresponding to the highest missing value percentage (40). For all analyses, a 2-tailed significance level of $P<.05$ was considered statistically significant.

Analyses of Effectiveness

Linear mixed models (LMMs) with random effects to control for correlation within patients and physiotherapy practices (41) were used to determine the short-term effectiveness of stratified blended physiotherapy compared with face-to-face physiotherapy on primary and secondary outcome measures. Regression coefficients with 95% CIs signifying the differences between stratified blended physiotherapy and face-to-face physiotherapy were estimated. Analyses were adjusted for predefined confounders (e.g., age, gender, and duration of pain (42–44)) that changed the between-group estimate by ≥10%. In addition, analyses were also adjusted for variables with a substantial difference at baseline that changed the regression coefficient for the between-group estimate by ≥10%. Potential interaction terms were explored. In the case of a statistically significant interaction term, stratified LMM analyses, controlling for the same variables as the primary analysis, were performed for the effect modifier.

Sample Size

The power calculation was based on the recommendations of Campbell et al (45) for cluster randomized trials and performed for the physical functioning primary outcome at the primary end point of the e-Exercise LBP study (i.e., 12-month follow-up). In addition, repeated measures of the primary outcome during follow-up were taken into account (46). An intraclass correlation coefficient of 0.05 was assumed. In addition, to detect a clinically relevant difference between groups at the 12-month follow-up, a difference of >6 points in physical functioning (ODI) (47,48), and an SD of 14.5 (49) were used in the sample size calculation. For the repeated measures of physical functioning, a correlation of 0.5 was estimated between baseline and follow-up measurements until the 12-month follow-up (46). On the basis of these assumptions (power 80%; α=.05) and an average cluster size of 5, a total of 165 patients were needed. With an expected dropout rate of 20%, a total of 208 participating patients (n=104 per arm) were needed.

RESULTS

Flow of Participants, Therapists, and Centers Through the Study

From June 2018 to December 2019, 434 eligible patients with LBP were asked to participate in 58 physiotherapy practices. In 22 physiotherapy practices allocated to stratified blended physiotherapy and 20 practices allocated to face-to-face physiotherapy, 47.9% (208/434) patients were included (Figure 1).

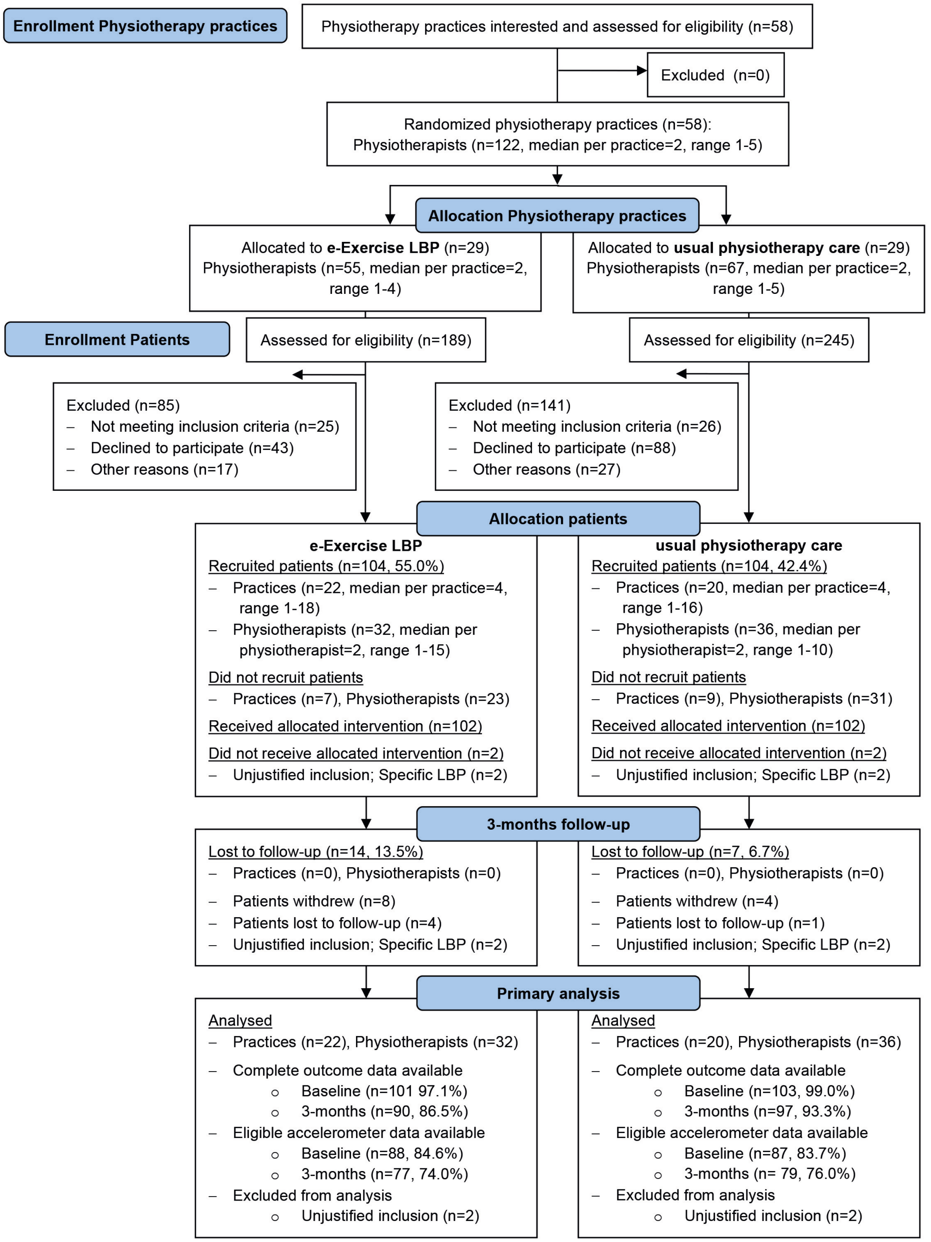


Figure 1 Flow Diagram of the e-Exercise LBP study

Baseline characteristics of the patients are presented in Table 2. The stratified blended physiotherapy group comprised more men, more patients with a low level of education, and more patients with a duration of LBP >12 months. No other relevant differences in characteristics were seen between groups. At baseline, complete data on outcome measures were available from 97.1% (101/104) of the patients in the stratified blended physiotherapy group and 99% (103/104) of the patients in the face-to-face physiotherapy group, and eligible accelerometer data were available from 84.6% (88/104) and 83.7% (87/104), respectively. Of the 208 patients, 4 (1.9%) ineligible patients (n=2, 50% in the stratified blended physiotherapy group and 2, 50% in the face-to-face physiotherapy group) were unjustified included, did not receive the allocated intervention and were therefore excluded from all analyses.

At the 3-month follow-up, complete data on outcome measures were available from 86.5% (90/104) of the patients in the stratified blended physiotherapy group and 93.3% (97/104) of the patients in the face-to-face physiotherapy group, and eligible accelerometer data were available from 74% (77/104) and 76% (79/104) of these patients, respectively.

Table 2 Baseline demographic and clinical characteristics for patients from the stratified blended physiotherapy group and face-to-face physiotherapy group (n=208).

Characteristics	Baseline	
	Stratified blended physiotherapy (n=104)	Face-to-face physiotherapy (n=104)
Gender (female), n (%)	45 (43.3)	57 (54.8)
Age (years), mean (SD)	48.10 (15.08)	47.26 (13.58)
BMI (kg/m^2), mean (SD)	25.78 (3.79)	26.31 (5.11)
Presence of comorbidities (yes), n (%)	38 (36.5)	28 (26.9)
Past LBP[a] surgery, n (%)		
None	100 (96.2)	101 (97.1)
Lumbar fusion	0 (0.0)	1 (1.0)
Lumbar discectomy	4 (3.9)	2 (1.9)
Central sensitization (score 0-100), mean (SD)	30.88 (13.38)	30.17 (12.19)
Educational level, n (%)		
Low	22 (21.2)	13 (12.5)
Middle	33 (31.7)	36 (34.6)
High	49 (47.1)	55 (52.9)
Duration of LBP complaints, n (%)		
0 to 6 weeks	37 (35.6)	49 (47.1)
6 to 12 weeks	11 (10.6)	19 (18.3)
12 weeks to 12 months	9 (8.7)	9 (8.7)
> 12 months	47 (45.2)	27 (26)

Table 2 *Continued.*

Characteristics	Baseline	
	Stratified blended physiotherapy (n=104)	Face-to-face physiotherapy (n=104)
Physical functioning (score 0-100), mean (SD)	19.37 (15.64)	20.38 (13.99)
Pain intensity (average score 7 days 0-10), mean (SD)	5.61 (1.99)	5.36 (2.01)
Physical activity (MVPA[b] minutes/day), mean (SD)	80.34 (36.75)	74.82 (40.94)
Health-related quality of life (score 0-100), mean (SD)	67.90 (18.08)	69.75 (17.63)
Fear-avoidance beliefs (score 0-96), mean (SD)	27.86 (16.03)	25.08 (16.18)
Pain catastrophizing (score 0-52), mean (SD)	11.06 (9.30)	10.21 (8.75)
Self-efficacy (score 10-40) mean (SD)	32.13 (4.36)	33.12 (3.62)
Patient activation (score 0-100), mean (SD)	62.48 (12.38)	64.75 (12.68)

[a]LBP: low back pain.
[b]MVPA: moderate to vigorous physical activity.

Number and Treatment Modalities of Physiotherapy Sessions

In total, 189 physiotherapist registration forms were returned (n=95, 50.3% stratified blended physiotherapy and n=94, 49.7% in face-to-face physiotherapy). Table 3 shows the number and treatment modalities of the face-to-face physiotherapy sessions. Patients in the stratified blended physiotherapy group received an average of 4.81 (SD 2.94) face-to-face sessions. For the low-, medium-, and high-risk groups, the average number of sessions was 3.77 (SD 2.54), 5.65 (SD 2.65), and 7.67 (SD 3.54), respectively. Patients in the face-to-face physiotherapy group received an average of 4.94 (SD 2.26) face-to-face sessions. The average number of sessions for the low-, medium-, and high-risk groups was 4.88 (SD 2.02), 5.09 (SD 2.51), and 4.33 (SD 4.16), respectively.

In general, education was the main treatment modality during the face-to-face sessions in both treatment groups. No remarkable differences in treatment modalities were found between the 2 groups or between the different risk groups of developing persistent LBP.

Table 3 Number and treatment modalities of face-to-face physiotherapy sessions for patients from the stratified blended physiotherapy group and face-to-face physiotherapy group.

Category	Stratified blended physiotherapy (risk of developing persistent LBP[a])				Face-to-face physiotherapy (risk of developing persistent LBP)			
	Low (n = 52)	Medium (n = 34)	High (n = 9)	Total (n = 95)	Low (n = 57)	Medium (n = 34)	High (n = 3)	Total (n = 94)
Number of sessions, mean (SD)	3.77 (2.54)	5.65 (2.65)	7.67 (3.54)	4.81 (2.94)	4.88 (2.02)	5.09 (2.51)	4.33 (4.16)	4.94 (2.26)
Treatment modalities, n (%)b								
Education	42 (81)	24 (71)	6 (67)	72 (76)	43 (75)	25 (74)	2 (67)	70 (74)
Strength exercises	9 (17)	3 (9)	1 (11)	13 (14)	7 (12)	6 (18)	0 (0)	13 (14)
Stability exercises	14 (27)	5 (15)	4 (44)	23 (24)	14 (25)	11 (32)	0 (0)	25 (27)
Endurance training	1 (2)	0 (0)	0 (0)	1 (1)	3 (5)	0 (0)	0 (0)	3 (3)
Functional exercises	3 (6)	0 (0)	0 (0)	3 (3)	4 (7)	0 (0)	0 (0)	4 (4)
Active mobilization	15 (29)	10 (29)	2 (22)	27 (28)	22 (39)	11 (32)	2 (67)	35 (37)
Passive mobilization	12 (23)	16 (47)	3 (33)	31 (33)	15 (26)	9 (26)	1 (33)	25 (27)
Massage	4 (8)	8 (24)	2 (22)	14 (15)	9 (16)	5 (15)	0 (0)	14 (15)

[a]LBP: low back pain

[b]Amount (%) of patients who received the treatment modality as part of the face-to-face physiotherapy session for ≥ 60% of the total number of face-to-face physiotherapy sessions

Is Stratified Blended Physiotherapy Effective Compared With Face-to-face Physiotherapy?

In the mixed model analyses, log likelihood ratios of naive models and models that included a random intercept for both physiotherapy practice and physiotherapist were similar. Therefore, physiotherapy practice or physiotherapist was not included as a level in the LMM analyses. At 3 months, LMM analyses showed no clinically relevant or statistically significant between-group difference in the primary outcome of physical functioning (mean difference [MD] −1.96, 95% CI −4.47 to 0.55). For the secondary outcomes, a statistically significant between-group difference was found in favor of stratified blended physiotherapy for fear-avoidance beliefs (MD −4.29, 95% CI −7.22 to −1.37) and patients' self-reported adherence to prescribed home exercises (MD 0.73, 95% CI 0.06-1.39). Within-group analyses showed clinically relevant and statistically significant improvements in physical functioning (MD −11.48, 95% CI −15.06 to −7.91), average pain intensity (MD −2.38, 95% CI −3.00 to −1.76), and fear-avoidance beliefs (MD −5.14, 95% CI −9.22 to −1.06) in the stratified blended physiotherapy group. In the face-to-face physiotherapy group, clinically relevant and statistically significant improvements in physical functioning (MD −11.22, 95% CI −14.64 to −7.80) and average pain intensity (MD −2.51, 95% CI −3.11 to −1.90) were found (Table 4). As indicated by a statistically significant interaction term, the patients' risk of developing persistent LBP was an effect modifier of the between-group differences on the primary outcome of physical functioning. In patients with a high risk of developing persistent LBP, the stratified analysis showed a statistically significant between-group difference in favor of stratified blended physiotherapy on physical functioning (MD–16.39, 95% CI –27.98 to –4.79), average pain intensity (MD–3.43, 95% CI –6.55 to –0.31), and fear-avoidance beliefs (MD–14.51, 95% CI –28.21 to –0.81). In patients with a medium risk of developing persistent LBP, a statistically significant between-group difference was found in favor of stratified blended physiotherapy on fear-avoidance beliefs (MD –5.93, 95% CI –11.45 to –0.40). In patients with a low risk of developing persistent LBP, no statistically significant between-group differences were found (Table 5).

Table 4 Unadjusted and Adjusted Primary and Secondary Outcome Measures: Improvements and Differences Within and Between Groups (N=208).

Stratified blended physiotherapy (n=102)				Face-to-face physiotherapy (n=102)				Between group differences[a]			
Measurements, mean (SD)		Unadjusted within-group differences		Measurements, mean (SD)		Unadjusted within-group differences		Unadjusted		Adjusted[b]	
Baseline	3 months	Mean (95% CI)	*P* value	Baseline	3 months	Mean (95% CI)	*P* value	Mean (95% CI)	*P* value	Mean (95% CI)	*P* value
Physical functioning (range 0-100)											
19.39 (15.56)	7.91 (9.64)	-11.48 (-15.06 to -7.91)	<.001	20.20 (13.90)	8.97 (10.75)	-11.22 (-14.64 to -7.80)	<.001	-0.83 (-3.43 to 1.77	.53	-1.98 (-4.49 to 0.53)	.12
Pain intensity (average score 7 days; range 0-10)											
5.67 (1.94)	3.29 (2.42)	-2.38 (-3.00 to -1.75)	<.001	5.40 (2.00)	2.90 (2.36)	-2.51 (-3.11 to -1.90)	<.001	0.31 (-0.35 to 0.98)	.36	0.08 (-0.57 to 0.74)	.80
Physical activity (MVPA[c] min/day)											
81.97 (38.52)	78.58 (44.45)	-3.37 (-15.63 to 8.88)	.59	75.70 (41.89)	71.24 (40.34)	-4.42 (-16.91 to 8.07)	.49	3.49 (-8.38 to 15.36)	.56	3.62 (-8.27 to 15.51)	.55
Fear-avoidance beliefs (range 0-96)											
27.92 (16.01)	22.77 (13.38)	-5.14 (-9.25 to -1.04)	.01	25.51 (16.24)	24.82 (16.92)	-0.70 (-5.26 to 3.87)	.77	-3.73 (-6.63 to -0.82	.01	-4.29 (-7.22 to -1.37)	<.001
Pain catastrophizing (range 0-52)											
11.02 (9.30)	8.97 (8.05)	-2.04 (-4.50 to 0.43)	.11	10.33 (8.76)	9.16 (9.84)	-1.17 (-3.74 to 1.40)	.37	-0.63 (-2.58 to 1.32)	.53	-0.96 (-2.95 to 1.02)	.34

Table 4 *Continued.*

Stratified blended physiotherapy (n=102)				Face-to-face physiotherapy (n=102)				Between group differences[a]			
Measurements, mean (SD)		Unadjusted within-group differences		Measurements, mean (SD)		Unadjusted within-group differences		Unadjusted		Adjusted[b]	
Baseline	3 months	Mean (95% CI)	*P* value	Baseline	3 months	Mean (95% CI)	*P* value	Mean (95% CI)	*P* value	Mean (95% CI)	*P* value
Self-efficacy (range 10-40)											
32.05 (4.38)	32.02 (4.27)	-0.03 (-1.24 to 1.19)	.97	33.12 (3.63)	32.58 (3.99)	-0.54 (-1.59 to 0.52)	.32	0.12 (-0.82 to 1.06)	.81	0.14 (-0.82 to 1.10)	.77
Health-related quality of life (range 0-100)											
67.70 (18.09)	71.44 (20.07)	3.73 (-1.68 to 9.14)	.18	69.75 (12.65)	72.57 (21.06)	2.82 (-2.56 to 8.20)	.31	-0.65 (-6.38 to 5.08)	.82	0.95 (-4.80 to 6.69)	.75
Patient activation (range 0-100)											
62.43 (12.37)	62.45 (11.89)	0.02 (-3.42 to 3.46)	.99	64.72 (12.65)	64.39 (12.71)	-0.33 (-3.84 to 3.18)	.85	-0.83 (-3.94 to 2.27)	.60	-0.79 (-3.95 to 2.36)	.62
Adherence to prescribed home exercises (range 0-24)[d]											
N/A[e]		N/A	N/A	N/A	11.18 (2.17)	N/A	N/A	0.78 (0.13 to 1.44)	.02	0.73 (0.06 to 1.39)	.03

[a]Difference between baseline and 3 months in stratified blended physiotherapy versus face-to-face physiotherapy.
[b]Adjusted for baseline and duration of low back complaints (<12 vs >12 weeks).
[c]MVPA: moderate to vigorous physical activity.
[d]Patient self-reported adherence to prescribed home exercises could only be measured after the treatment period.
[e]N/A: not applicable.

Table 5 Adjusted Primary and Secondary Outcome Measures: Improvements and Differences Between Groups stratified for the risk of developing persistent low back pain (LBP; N=204).

Outcome measure	Risk of developing persistent LBP					
	Low risk (n = 120)		Medium risk (n = 71)		High risk (n = 13)	
	Between-group difference, mean (95% CI)[a]	*P* value	Between-group difference, mean (95% CI)[a]	*P* value	Between-group difference, mean (95% CI)[a]	*P* value
Physical functioning (range 0-100)	-0.82 (-2.92 to 1.27)	.44	-3.48 (-8.99 to 2.03)	.22	-16.39 (-27.98 to -4.79)	.01
Pain Intensity (average score 7 days; range 0-10)	0.30 (-0.52 to 1.13)	.47	0.01 (-1.08 to 1.11)	.98	-3.43 (-6.55 to -0.31)	.03
Physical activity (MVPA[b] minutes/day)	3.80 (-12.05 to 19.65)	.64	1.08 (-16.70 to 18.86)	.91	39.50 (-1.24 to 80.24)	.06
Fear avoidance beliefs (range 0-96)	-2.70 (-6.22 to 0.82)	.13	-5.93 (-11.45 to -0.40)	.04	-14.51 (-28.21 to -0.81)	.04
Pain catastrophizing (range 0-52)	0.28 (-2.03 to 2.59)	.81	-2.66 (-5.73 to 0.41)	.09	-14.47 (-31.89 to 2.94)	.10
Self-efficacy (range 10-40)	-0.58 (-1.76 to 0.60)	.33	0.85 (-0.92 to 2.62)	.35	1.50 (-4.02 to 7.02)	.60
Health related quality of life (range 0-100)	1.26 (-7.15 to 9.68)	.77	0.84 (-6.47 to 8.15)	.82	15.84 (-3.92 to 35.61)	.12
Patient activation (range 0-100)	-2.22 (-6.38 to 1.93)	.29	1.85 (-3.27 to 6.97)	.48	7.49 (-1.35 to 16.34)	.10
Adherence to prescribed home exercises (range 0-24)	0.82 (-0.01 to 1.65)	.05	0.86 (-0.35 to 2.08)	.16	-1.19 (-3.37 to 0.99)	.28

LBP = Low Back Pain
MVPA = Moderate to Vigorous Physical Activity
Difference between baseline and 3-months in Stratified blended physiotherapy vs. Face-to-face physiotherapy per risk group and adjusted for baseline and duration of LBP complaints (<12 weeks vs. >12 weeks)

DISCUSSION

Principal Findings

This study evaluated the short-term (3 months) effectiveness of the stratified blended physiotherapy intervention e-Exercise LBP on physical functioning in comparison with face-to-face physiotherapy in patients with nonspecific LBP. In contrast to our expectations, the study results showed no statistically significant between-group difference in physical functioning and most of the secondary outcome measures. Only fear-avoidance beliefs and patient self-reported adherence to prescribed home exercises improved significantly in patients who were allocated to stratified blended physiotherapy. When looking at the different prognostic risk groups in patients with a high risk of developing persistent LBP, a statistically significant between-group difference in favor of stratified blended physiotherapy on physical functioning, average pain intensity, and fear-avoidance beliefs was found; however, these results come with some uncertainty.

Interpretation of the Findings

The results of this study complement the findings from previous systematic reviews of randomized controlled trials that showed that in the short term, web-based applications could reduce LBP-related pain and disability; however, when compared with other interventions, the results are inconclusive (15,22,50). A possible explanation for these inconclusive findings is the considerable heterogeneity in the studied characteristics and comparators, which hampers a clear comparison. For example, in our study, we integrated a web-based application within face-to-face guidance and compared it with face-to-face physiotherapy. Previous studies in this research area have focused predominantly on web-based applications as a stand-alone intervention without the face-to-face guidance of a health care professional (15,22,50). Only a few studies have investigated web-based applications as an adjunct to face-to-face guidance, and the results regarding the added value of these combined interventions have been inconclusive (15,51). Similar to our study, Sandal et al (51) investigated a smartphone app as an adjunct to face-to-face guidance. The app was tailored using artificial intelligence and did not influence face-to-face guidance. In this study, the reported between-group difference was statistically significant in favor of the combined intervention when compared with face-to-face guidance alone; however, the difference was small and of uncertain clinical significance.

Another example of heterogeneity in research on web-based applications is the large variation in delivery modes and duration. Similar to e-Exercise LBP, most web-based applications tailored the content of the intervention using patient characteristics and focused on self-management support, home-based exercise, and physical activity prescription (15,22,50). However, the e-Exercise LBP app provided this content in weekly information modules and daily reminders to exercise and physical activity recommendations during a 3- or 12-week duration (26); the duration in other studies ranged from 3 weeks to 1 year. In addition, the delivery modes showed large variation; that is, from no specific recommendations to multiple web- or telephone-based coaching sessions (15,22,51).

Thus, looking at the different characteristics of web-based applications, such as the role of the health care professional within the intervention and the delivery mode and duration, future research needs to focus on the comparison of web-based applications with different characteristics to obtain a better understanding of which elements work the best.

In our study, the short-term within-group improvements in physical functioning and average pain intensity of stratified blended physiotherapy were comparable with face-to-face physiotherapy, both of which were statistically significant and clinically meaningful. Patients in the stratified blended physiotherapy group improved on average 11.48 (95% CI−15.06 to −7.91) points (59.5%) in physical functioning, and patients in the face-to-face physiotherapy group improved by an average of 11.22 (95% CI −14.64 to −7.80) points (56%). For average pain intensity, these improvements were 2.38 (95% CI −3.00 to −1.76) points (42.8%) and 2.51 (95% CI −3.11 to −1.90) points (46.9%), respectively. As physical functioning and average pain intensity decreased by >30%, the improvements in both groups were considered clinically meaningful (52). At the moment, e-Exercise LBP cannot be considered an alternative to face-to-face physiotherapy as this study was conducted as a superiority trial. To be able to value the true potential of e-Exercise LBP, the meaningful within-group improvements must be considered from the perspective of the additional effort and costs needed to implement such an intervention in daily physiotherapy practice. Future cost-effectiveness analyses will provide more insight into the long-term economic benefits of stratified blended physiotherapy. On the other hand, given the additional effort and costs, the potential of e-Exercise LBP needs to be considered from the perspective of future health care. It is expected that technology will be increasingly integrated into care for patients who are suitable to use it. Future studies need to determine which patients benefit most from a stratified blended physiotherapy approach.

The e-Exercise LBP intervention significantly increased patients' self-reported adherence to prescribed home exercises, as hypothesized. In addition, it resulted in a significant reduction of fear-avoidance beliefs when compared with face-to-face physiotherapy. The between-group difference in patients' self-reported adherence to prescribed home exercises was 3.3% points in favor of the e-Exercise LBP intervention. For fear-avoidance beliefs, the between-group difference was −4.6% points in favor of the e-Exercise LBP intervention. Although there are no established cutoffs for the minimum clinically important between-group differences in these outcomes, we consider the between-group differences as small. The difference in adherence might be explained by the benefits of integrating a smartphone app. The 24/7 availability of the app and functionality to remind the patient to perform scheduled exercises might have stimulated the patients to adhere to their prescribed home exercises in a better way than in the face-to-face physiotherapy group (18,53). Further research on the long-term clinical relevance of adherence to home exercises as prescribed in e-Exercise LBP is ongoing.

The reduction of fear-avoidance beliefs complements evidence from a systematic review and meta-analysis that concluded that patient education provides reassurance for patients with acute or subacute LBP (54). In our study, this reduction in the stratified blended physiotherapy group might be explained by the information module of the smartphone app. As the information module provides the patient with self-management information about LBP, the patient can reread the advice and reassurance given in the face-to-face sessions by the physiotherapist about their LBP at all times. As a result, the harmless and nonspecific nature of LBP is possibly remembered in a better way (55). Long-term results should indicate whether this reduction in fear-avoidance beliefs also influences physical functioning, the handling of recurrent complaints, and costs a patient incurs because of LBP.

Several explanations are possible to clarify why the additional benefits of stratified blended physiotherapy were not found. A first explanation is that the added value of a stratified approach in itself must be critically evaluated. Although clinical practice guidelines have adopted and advocated a stratified care approach for several years to improve patient outcomes, the added value of this approach is, at present, unclear. On the basis of previous recommendations, we decided to use the Keele STarT Back Screening Tool to create a matched web-based application (10). Our results show that, after specific training, treatment intensity (i.e., the number of face-to-face sessions) in the e-Exercise LBP group was in line with the patient's risk profile, which was not the case in our control group. However, this difference in treatment intensity did not lead to relevant between-group differences. This seems to be in line with more recent studies evaluating the stratified approach according to the Keele STarT Back Screening Tool. The results from these studies are not convincing regarding the added value of such a stratified approach (56,57). Future research should focus on determining whether this concerns the added value of the tool itself or the added value of a stratified care approach in general.

In addition, stratified blended physiotherapy might not be suitable for every patient. Earlier research has shown that it is difficult to determine what works best for each individual patient (22,50). In our study, we did not take into account the patient's suitability for blended care to determine the optimal personalized blended treatment (58). As a result, patients might have received stratified blended physiotherapy without being suitable for it; for example, a lack of motivation or digital literacy skills. Consequently, this could have resulted in the suboptimal effectiveness of our stratified blended physiotherapy intervention when compared with face-to-face physiotherapy. For future studies on blended care, it is recommended to use patients' suitability for blended care as inclusion criteria or criteria to match treatment. The Dutch Blended Physiotherapy Checklist (58) could be a useful aid in this process.

A third explanation might be the relatively high proportion of patients with a low risk of developing persistent LBP in this study. For this group, earlier research has shown that providing advice as a single intervention is likely to reassure the patient with LBP but does not result in different management of pain and disability in the short term (54,59). In addition, for this group, a stratified approach is beneficial from an economic perspective rather than in terms of clinical outcomes, as many of these patients recover completely within 2 to 3 weeks but nevertheless receive unnecessary treatment (57,60,61).

A final explanation is the timing of our follow-up measurement at 3 months only. Given the favorable course of LBP (62) and the rationale that stratified blended physiotherapy will stimulate patients' self-management and adherence (21,22), patients in the stratified blended physiotherapy group might recover faster, which is not captured by a single follow-up measurement at 3 months. Therefore, for future studies that aim to investigate postintervention effectiveness, it is recommended to measure the clinical outcomes immediately after the intervention is completed and to monitor the time to recovery.

Strengths and Limitations

This study had several important strengths. It is the next step in a multiphase development and implementation process based on the Center for eHealth Research Roadmap (63). After developing a prototype and testing its feasibility in a pilot study (23), this study determined the short-term effectiveness of the final stratified blended physiotherapy protocol and showed its potential compared with face-to-face physiotherapy. The pragmatic, multicenter, cluster randomized controlled trial design allowed for the evaluation of stratified, blended physiotherapy in comparison with face-to-face physiotherapy in a real-world situation. The baseline characteristics of both treatment groups and the distribution of the different prognostic risk groups of developing persistent LBP reflect the characteristics of patients with LBP normally being treated in primary care physiotherapy (60), which enhances the generalizability of our results. The use of measurement instruments recommended in the core outcome set for research into patients with nonspecific LBP (28) and a low dropout rate (10.1%) guaranteed the internal validity of the results.

Nevertheless, this study also had a few limitations. First, the results seem to suggest that patients' risk of developing persistent LBP could be an effect modifier of the between-group differences on the primary outcome. Especially in the highest risk group, consistent between-group differences were seen in both the primary and secondary outcomes, supporting the rationale for stratified blended physiotherapy. As it was not the primary aim of this study, the sample size calculation did not take interaction into account, the numbers were small, and therefore, the results should be interpreted with caution. Second, as we conducted a pragmatic study, the experiences of physiotherapists in either using web-based applications or treating patients with nonspecific LBP were not considered inclusion criteria for physiotherapy practices. However, given both the complexity of blended care (17) and the complexity of treating patients with nonspecific LBP (4), it can be expected that more experienced physiotherapists are able to deliver better treatment than less experienced physiotherapists. Therefore, experience might have influenced our analysis. Finally, 4 included patients were excluded from the analysis after being diagnosed with specific LBP. As this number is low and occurred equally in both treatment groups (2 in each group), we expect that this has not influenced the results (64).

CONCLUSIONS

The stratified blended physiotherapy intervention e-Exercise LBP is not more effective than face-to-face physiotherapy in patients with nonspecific LBP in improving physical functioning in the short term. For both stratified blended physiotherapy and face-to-face physiotherapy, within-group improvements were clinically relevant. To be able to decide whether e-Exercise LBP should be implemented in daily physiotherapy practice, future research should focus on the long-term cost-effectiveness and determine which patients benefit most from stratified blended physiotherapy.

Acknowledgments

This study was cofunded by the Taskforce for Applied Research SIA (RAAK.PRO02.063), part of the Dutch Research Council. The funder had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript. The authors are grateful for the invaluable help provided by Loes Kolenberg in the analysis of the physical activity data.

Authors' Contributions

TK participated in the development of the design of the study, conducted the study, performed the statistical analyses, and drafted and revised the manuscript. MFP was the principal investigator, developed the design of the study, and participated in the writing and revision of the manuscript. CJJK participated in the development of the design of the study and participated in the writing and revision of the manuscript. RMA participated in the design of the study, conducted the study, and participated in revising the manuscript. RWJGO supervised the project, advised the design of the study and statistical analysis, and participated in revising the manuscript. CV supervised the project, advised the design of the study and statistical analysis, and participated in revising the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

REFERENCES

1. GBD 2017 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2018;392(10159):1789–858.
2. Koes BW, Tulder MW van, Thomas S. Diagnosis and treatment of low back pain. BMJ. 2006;332(7555):1430.
3. Itz CJ, Geurts JW, van Kleef M, Nelemans P. Clinical course of non-specific low back pain: A systematic review of prospective cohort studies set in primary care. Eur J Pain. 2013;17(1):5–15.
4. Hartvigsen J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, et al. What low back pain is and why we need to pay attention. Lancet. 2018;391(10137):2356–67.
5. Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, et al. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: Systematic review. Br J Sports Med. 2020;54(2):79–86.
6. Foster NE, Anema JR, Cherkin D, Chou R, Cohen SP, Gross DP, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. Lancet. 2018;391(10137):2368–83.
7. Maher C, Underwood M, Buchbinder R. Non-specific low back pain. Lancet. 2017;389(10070):736–47.
8. Wong JJ, Côté P, Sutton DA, Randhawa K, Yu H, Varatharajan S, et al. Clinical practice guidelines for the noninvasive management of low back pain: A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. Eur J Pain. 2017;21(2):201–16.
9. Hill JC, Whitehurst DGT, Lewis M, Bryan S, Dunn KM, Foster NE, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): A randomised controlled trial. Lancet. 2011;378(9802):1560–71.
10. Hill JC, Dunn KM, Lewis M, Mullis R, Main CJ, Foster NE, et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. Arthritis Rheum. 2008;59(5):632–41.
11. Staal JB, Hendriks EJM, Heijmans M, Kiers H, Lutgers-Boomsma AM, Rutten G, et al. KNGF-richtlijn Lage rugpijn. 2017.
12. Friedrich M, Gittler G, Halberstadt Y, Cermak T, Heiller I. Combined exercise and motivation program: effect on the compliance and level of disability of patients with chronic low back pain: a randomized controlled trial. Arch Phys Med Rehabil. 1998;79(5):475–8.
13. van Gool CH, Penninx BWJH, Kempen GIJM, Rejeski WJ, Miller GD, van Eijk JThM, et al. Effects of exercise adherence on physical function among overweight older adults with knee osteoarthritis. Arthritis Care Res. 2005;53(1):24–32.
14. Mannion AF, Helbling D, Pulkovski N, Sprott H. Spinal segmental stabilisation exercises for chronic low back pain: programme adherence and its influence on clinical outcome. Eur Spine J. 2009;18(12):1881–91.

15. Dario AB, Moreti Cabral A, Almeida L, Ferreira ML, Refshauge K, Simic M, et al. Effectiveness of telehealth-based interventions in the management of non-specific low back pain: a systematic review with meta-analysis. Spine J. 2017;17(9):1342–51.
16. van der Vaart R, Witting M, Riper H, Kooistra L, Bohlmeijer ET, van Gemert-Pijnen LJ. Blending online therapy into regular face-to-face therapy for depression: content, ratio and preconditions according to patients and therapists using a Delphi study. BMC Psychiatry. 2014;14(1):355.
17. Wentzel J, Van der Vaart R, Bohlmeijer ET, Van Gemert-Pijnen JEWC. Mixing online and face-to-face therapy: How to benefit from blended care in mental health care. JMIR Ment Health. 2016;3(1):e9.
18. Lustria MLA, Cortese J, Noar SM, Glueckauf RL. Computer-tailored health interventions delivered over the web: Review and analysis of key components. Patient Educ Couns. 2009;74(2):156–73.
19. Noar SM, Benac CN, Harris MS. Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. Psychol Bull. 2007;133(4):673–93.
20. Wantland DJ, Portillo CJ, Holzemer WL, Slaughter R, McGhee EM. The Effectiveness of Web-Based vs. Non-Web-Based Interventions: A Meta-Analysis of Behavioral Change Outcomes. J Med Internet Res. 2004;6(4):e40.
21. Bennell KL, Marshall CJ, Dobson F, Kasza J, Lonsdale C, Hinman RS. Does a Web-Based Exercise Programming System Improve Home Exercise Adherence for People with Musculoskeletal Conditions?: A Randomized Controlled Trial. Am J Phys Med Rehabil. 2019;98(10):850–8.
22. Nicholl BI, Sandal LF, Stochkendahl MJ, McCallum M, Suresh N, Vasseljen O, et al. Digital Support Interventions for the Self-Management of Low Back Pain: A Systematic Review. J Med Internet Res. 2017;19(5):e179.
23. Kloek CJJ, van Tilburg ML, Staal JB, Veenhof C, Bossen D. Development and proof of concept of a blended physiotherapeutic intervention for patients with non-specific low back pain. Physiotherapy. 2019;105(4):483–91.
24. Kloek CJJ, Bossen D, Spreeuwenberg PM, Dekker J, de Bakker DH, Veenhof C. Effectiveness of a Blended Physical Therapist Intervention in People With Hip Osteoarthritis, Knee Osteoarthritis, or Both: A Cluster-Randomized Controlled Trial. Phys Ther. 2018;98(7):560–70.
25. Kloek CJJ, Van Dongen JM, De Bakker DH, Bossen D, Dekker J, Veenhof C. Cost-effectiveness of a blended physiotherapy intervention compared to usual physiotherapy in patients with hip and/or knee osteoarthritis: a cluster randomized controlled trial. BMC Public Health. 2018;18(1):1082.
26. Koppenaal T, Arensman RM, Van Dongen JM, Ostelo RWJG, Veenhof C, Kloek CJJ, et al. Effectiveness and cost-effectiveness of stratified blended physiotherapy in patients with non-specific low back pain: Study protocol of a cluster randomized controlled trial. BMC Musculoskelet Disord. 2020;21(1):265.
27. Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine. 2000;25(22):2940–52.
28. Chiarotto A, Terwee CB, Ostelo RW. Choosing the right outcome measurement instruments for patients with low back pain. Best Pract Res Clin Rheumatol. 2016;30(6):1003–20.

29. Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain. 2008;9(2):105–21.
30. Horemans H, Kooijmans H, van den Berg-Emons R, Bussmann H. The Activ8 activity monitor: Validation of posture and movement classification. J Rehabil Assist Technol Eng. 2020;7:205566831989053.
31. Quante M, Kaplan ER, Rueschman M, Cailler M, Buxton OM, Redline S. Practical considerations in using accelerometers to assess physical activity, sedentary behavior, and sleep. Sleep Health. 2015;1(4):275–84.
32. Ainsworth BE, Haskell WL, Herrmann SD, Meckes N, Bassett DR, Tudor-Locke C, et al. 2011 compendium of physical activities: A second update of codes and MET values. Med Sci Sports Exerc. 2011;43(8):1575–81.
33. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain. 1993;52(2):157–68.
34. Sullivan MJL, Bishop SR, Pivik J. The Pain Catastrophizing Scale: Development and validation. Psychol Assess. 1995;7(4):524–32.
35. Teeuw B, Schwarzer R, Jerusalem M. Dutch Adaptation of the General Self-Efficacy Scale. 1994. Available from: https://userpage.fu-berlin.de/~health/dutch.htm
36. Scholz U, Doña BG, Sud S, Schwarzer R. Is General Self-Efficacy a Universal Construct? Psychometric findings from 25 countries. Eur J Psychol Assess. 2002;18(3):242–51.
37. Rademakers J, Nijman J, van der Hoek L, Heijmans M, Rijken M. Measuring patient activation in The Netherlands: translation and validation of the American short form Patient Activation Measure (PAM13). BMC Public Health. 2012;12(1):577.
38. Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011;20(10):1727–36.
39. Newman-Beinart NA, Norton S, Dowling D, Gavriloff D, Vari C, Weinman JA, et al. The development and initial psychometric evaluation of a measure assessing adherence to prescribed exercise: the Exercise Adherence Rating Scale (EARS). Physiotherapy. 2017;103(2):180–5.
40. Sullivan TR, Salter AB, Ryan P, Lee KJ. Bias and Precision of the “Multiple Imputation, Then Deletion” Method for Dealing With Missing Outcome Data. Am J Epidemiol. 2015;182(6):528–34.
41. Goldstein H. Multilevel Statistical Models. Hoboken, New Jersey: Wiley; 1987.
42. Dunnl KM, Jordan KP, Croft PR. Contributions of prognostic factors for poor outcome in primary care low back pain patients. Eur J Pain. 2011;15(3):313–9.
43. Hayden JA, Chou R, Hogg-Johnson S, Bombardier C. Systematic reviews of low back pain prognosis had variable methods and results—guidance for future prognosis reviews. J Clin Epidemiol. 2009;62(8):781-796.e1.
44. Grotle M, Foster NE, Dunn KM, Croft P. Are prognostic indicators for poor outcome different for acute and chronic low back pain consulters in primary care? Pain. 2010;151(3):790–7.
45. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012;345(sep04 1):e5661–e5661.

46. Vickers AJ. How many repeated measures in repeated measures designs? Statistical issues for comparative trials. BMC Med Res Methodol. 2003;3(1):22.
47. Fritz JM, Irrgang JJ. A Comparison of a Modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. Phys Ther. 2001;81(2):776–88.
48. Resnik L, Dobrzykowski E. Guide to outcomes measurement for patients with low back pain syndromes. J Orthop Sports Phys Ther. 2003;33(6):307–18.
49. Apeldoorn AT, Ostelo RW, van Helvoirt H, Fritz JM, Knol DL, van Tulder MW, et al. A Randomized Controlled Trial on the Effectiveness of a Classification-Based System for Subacute and Chronic Low Back Pain. Spine. 2012;37(16):1347–56.
50. Du S, Liu W, Cai S. The efficacy of e-health in the self-management of chronic low back pain: A meta analysis. Int J Nurs Stud. 2020;106:103507.
51. Sandal LF, Bach K, Øverås CK, Svendsen MJ, Dalager T, Stejnicher Drongstrup Jensen J, et al. Effectiveness of app-delivered, tailored self-management support for adults with lower back pain-related disability: A selfBACK randomized clinical trial. JAMA Intern Med. 2021 Oct 1;181(10):1288–96.
52. Ostelo RWJG, Deyo RA, Stratford P, Waddell G, Croft P, Von Korff M, et al. Interpreting Change Scores for Pain and Functional Status in Low Back Pain: Towards International Consensus Regarding Minimal Important Change. Spine. 2008;33(1):90–4.
53. Kelders SM, Kok RN, Ossebaard HC, Van Gemert-Pijnen JE. Persuasive System Design Does Matter: a Systematic Review of Adherence to Web-based Interventions. J Medical Internet Res. 2012;14(6):e152.
54. Traeger AC, Hübscher M, Henschke N, Moseley GL, Lee H, McAuley JH. Effect of Primary Care–Based Education on Reassurance in Patients With Acute Low Back Pain: Systematic Review and Meta-analysis. JAMA Intern Med. 2015;175(5):733–43.
55. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. Ann Behav Med. 2013;46(1):81–95.
56. Cherkin D, Balderson B, Wellman R, Hsu C, Sherman KJ, Evers SC, et al. Effect of Low Back Pain Risk-Stratification Strategy on Patient Outcomes and Care Processes: the MATCH Randomized Trial in Primary Care. J Gen Intern Med. 2018;33(8):1324–36.
57. Delitto A, Patterson CG, Stevans JM, Freburger JK, Khoja SS, Schneider MJ, et al. Stratified care to prevent chronic low back pain in high-risk patients: The TARGET trial. A multi-site pragmatic cluster randomized trial. EClinicalMedicine. 2021;34:100795.
58. Kloek CJJ, Janssen J, Veenhof C. Development of a Checklist to Assist Physiotherapists in Determination of Patients' Suitability for a Blended Treatment. Telemed e-Health. 2020;26(8):1051–65.
59. Jones CMP, Shaheed CA, Ferreira GE, Kharel P, Christine Lin CW, Maher CG. Advice and education provide small short-term improvements in pain and disability in people with non-specific spinal pain: a systematic review. J Physiother. 2021;67(4):263–70.
60. Bier JD, Sandee-Geurts JJW, Ostelo RWJG, Koes BW, Verhagen AP. Can primary care for back and/or neck pain in the Netherlands benefit from stratification for risk groups according to the STarT Back Tool classification? Arch Phys Med Rehabil. 2018;99(1):65–71.

61. Deyo RA, Mirza SK, Turner JA, Martin BI. Overtreating Chronic Back Pain: Time to Back Off? J Am Board Fam Med [Internet]. 2009;22(1):62–8.
62. Williams CM, Maher CG, Latimer J, McLachlan AJ, Hancock MJ, Day RO, et al. Efficacy of paracetamol for acute low-back pain: a double-blind, randomised controlled trial. Lancet. 2014;384(9954):1586–96.
63. van Gemert-Pijnen JE, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A Holistic Framework to Improve the Uptake and Impact of eHealth Technologies. J Med Intern Res. 2011;13(4):e111.
64. Fergusson D, Aaron SD, Guyatt G, Hébert P. Post-randomisation exclusions: the intention to treat principle and excluding patients from analysis. BMJ. 2002;325(7365):652.

Abbreviations

CONSORT: Consolidated Standards of Reporting Trials

LBP: low back pain LMM: linear mixed model MD: mean difference

LMM: linear mixed model

MD: mean difference

ODI: Oswestry Disability Index

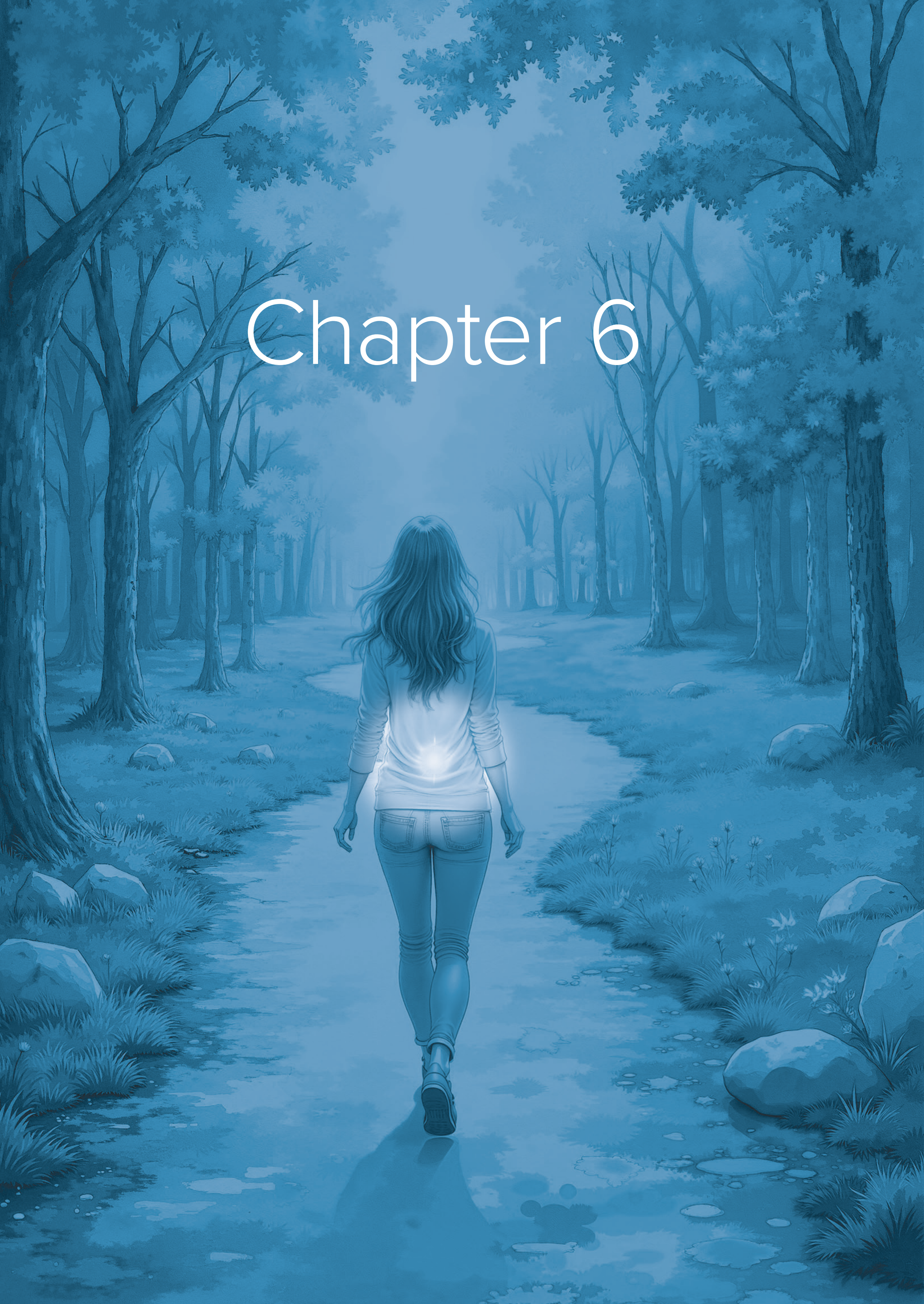
Multimedia Appendix 1

CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth; version 1.6) checklist.

Multimedia Appendix 2

Print screens of the smartphone app.

Chapter 6



Trajectories of Adherence to Home-Based Exercise Recommendations Among People With Low Back Pain: A Longitudinal Analysis

Remco M. Arensman
Martijn W. Heymans
Corelien J.J. Kloek
Raymond J.W.G. Ostelo
Cindy Veenhof
Tjarco Koppenaal
Martijn F. Pisters

Published in Physical Therapy 2023;103(12):1-9

ABSTRACT

Objective. This study aimed to examine the presence of distinct trajectories of adherence to home-based exercise recommendations among people with low back pain (LBP). This study also aimed to identify differences in baseline characteristics among groups.

Methods. This study was a secondary analysis of a prospective, multicenter cluster randomized controlled trial investigating the cost-effectiveness of a stratified blended physical therapist intervention compared to usual care physical therapy in patients with LBP. The intervention group received usual care with integrated support via a smartphone app. A total of 208 patients were recruited from 58 primary care physical therapist practices. Baseline data included patient characteristics, physical functioning, pain intensity, physical activity, fear avoidance, pain catastrophizing, self-efficacy, self-management ability, and health-related quality of life. The Exercise Adherence Scale (score range = 0–100) was used to measure adherence during each treatment session. Latent class growth analysis was used to estimate trajectories of adherence.

Results. Adherence data were available from 173 out of 208 patients (83%). Data were collected during an average of 5.1 (standard deviation [SD] = 2.5) treatment sessions, with total treatment duration of 51 (SD = 41.7) days. Three trajectory classes were identified: “declining adherence” (12%), “stable adherence” (45%), and “increasing adherence” (43%). No differences in baseline characteristic were found between groups.

Conclusion. Three adherence trajectories to exercise recommendations were identified in patients with LBP. However, baseline characteristics cannot identify a patient’s trajectory group.

Impact. Despite the presence of distinct trajectories of adherence in patients with LBP, physical therapists should not attempt to place a patient in a trajectory group at the start of treatment. Instead, adherence should be closely monitored as treatment progresses and supported when required as part of an ongoing process.

Keywords: Adherence, Home-Based Exercise, Low Back Pain, Physical Therapists, Trajectories

INTRODUCTION

The impact of low back pain (LBP) on society and health care and its related cost is well established (1). For decades, exercise has been studied as a potential treatment for LBP, and as a result, exercise (e.g., strength training or mobility exercises) is part of the core recommendations for the treatment of LBP in many clinical guidelines (2–5). However, the heterogeneity of effects found between different studies, caused by factors such as differences in interventions, methodologies, and follow-up durations, makes it difficult to determine which exercise intervention is most effective for individual patients. Despite this, pooled data from 27 trials involving 3514 participants showed that exercise therapy reduces pain and functional limitations compared with non-exercise treatment in patients with persistent LBP (6). Furthermore, many interventions incorporate home-based exercise (HBE) to increase treatment effectiveness or as a solution to alleviate the burden of LBP on the public health system (7). However, the effectiveness of exercise interventions largely depends on adherence, and without supervision from a clinician, patient adherence to HBE recommendations is often low, reducing treatment effectiveness (8–10).

The World Health Organization defined adherence as "the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" (11). Adherence to HBE recommendations would then be defined as "the extent to which a person's behavior corresponds with agreed HBE recommendations from a health care provider." Research has shown that adherence to exercise recommendations from a physical therapist is a complicated and multi- factorial construct, with factors such as social support, guidance by the therapist, the number of exercises, self-motivation, self-efficacy, and psychological aspects influencing individual patients' adherence (10).

To increase patient adherence to HBE recommendations, interventions targeting patient adherence were developed and showed varying levels of effectiveness. For instance, a trial investigating the effects of practitioner communication skills training on patients' adherence to HBE recommendations in patients with chronic LBP found that adherence declined over time and the intervention appeared to only slow the rate of decline (12). In another study, using a smartphone application to support adherence to HBE recommendations increased self-reported adherence compared to usual care after 3 months (13). Unfortunately, the complexity of adherence to HBE recommendations makes it a challenging construct to measure resulting in a large number of different measurement instruments (14,15). Although many instruments aimed at measuring adherence to HBE recommendations are available, there is a lack of validated instruments making adherence difficult to study (14). To fill this gap, the recently developed Exercise Adherence Scale (EXAS) was designed to measure adherence to frequency, intensity, and quality of performance recommendations for HBE (16). The EXAS allows for the measurement of adherence during the treatment process, providing more detailed information on the patient's self- reported adherence.

With the large number of both patient- and therapist-related factors influencing patient adherence, it is likely that adherence varies significantly between individuals and over time. Furthermore, the trajectory of adherence over time during the treatment period is likely to vary among patients with LBP.

Although, to date, no studies have examined the presence of common trajectories of adherence to HBE recommendations in patients with LBP, evidence for distinct trajectories of adherence has been found in patients with osteoarthritis of the knee and/or hip, and in older adults with cognitive impairment rehabilitating at home after hip fractures (17,18). Although both the nature of rehabilitation and the health of the patients are not comparable to those of patients with LBP, these studies showed that trajectories of adherence are present in different groups of patients. Each distinct trajectory has different clinical implications, and early identification of group membership of a patient can assist clinicians to determine which patients benefit from interventions designed to boost adherence and at what timepoint during treatment. Furthermore, identification of factors associated with the trajectory of adherence of patients with LBP can assist in the development of interventions to boost patient adherence. Therefore, investigating the unique trajectories of adherence to HBE recommendations from a physical therapist in patients with LBP has the potential to increase the effectiveness of interventions for this patient group.

Therefore, the aim of this study was to investigate the presence and proportion of groups of patients with distinct trajectories of adherence to HBE recommendations among people with LBP and to identify differences in baseline characteristics between groups.

METHODS

Study design

This study was a secondary analysis of a prospective, multicenter cluster randomized controlled trial investigating the cost-effectiveness of a stratified blended physical therapist intervention compared to usual care in patients with LBP. The detailed study protocol of the parent trial has been published previously (19). The Guidelines for Reporting on Latent Trajectory Studies checklist was used to aid in the reporting of this study (20).

One hundred and twenty-two physical therapists (median 12; interquartile range 19.5 years of experience) from 58 primary care physical therapist practices in the Netherlands participated in the study and recruited patients from July 2018 to December 2019. Practices were cluster-randomized to either the intervention group or usual care group. The patients included in the parent trial were treated as a single cohort of patients with LBP and treatment group allocation was included in the analyses as a baseline characteristic. The study was approved by the Medical Research Ethics Committee of the University Medical Center Utrecht, the Netherlands (ISRCTN 94074203).

Participants

Patients with LBP were recruited through the participating physical therapists. Prior to participating, written informed consent was obtained from all patients, and eligibility was checked by the researchers (R.A. or T.K.). A patient was eligible for participation when (1) the patient requested physical therapist treatment for LBP (pain in the lumbosacral region sometimes associated with radiating pain to the buttock or leg) (21,22), (2) aged 18 years or older, (3) in possession of a smartphone or tablet with internet access, (4) B1-level proficiency in the Dutch language (23). Patients were excluded when patients had: (1) a specific cause of LBP determined through medical imaging or diagnosed by a medical doctor (including pelvic girdle pain caused by current pregnancy), or (2) serious comorbidities. When inclusion for the trial ended, a total of 208 patients enrolled in the study.

Treatment

All patients received treatment based on the clinical guideline for LBP from The Royal Dutch Society for Physiotherapy (22). The guideline recommends giving information and advice about the nature and diagnosis of LBP, the course and prognosis of LBP, and inhibiting and facilitating factors. Furthermore, the guideline recommends providing personalized exercise therapy, and behavior-oriented and hands-on treatments for specific patients. Patients in the intervention group received stratified blended physical therapy, consisting of usual care face-to-face physical therapy with integrated support from a smartphone application (e-Exercise LBP) (13,24). The content of the e-Exercise LBP app was also based on the clinical guideline for LBP from The Royal Dutch Society for Physiotherapy (22). The content of the e-Exercise application was tailored to the needs of the patient by the physical therapist and contained texts and videos with self-management information, the HBE exercises recommended by the physical therapist, and a mod- ule to support the patient's physical activity. Each patient received treatment exclusively from the same physical therapist, maintaining consistent therapeutic interactions between patients and their respective physical therapists throughout the study duration. The evaluation of the effectiveness of the e-Exercise LBP intervention in patients with LBP showed no significant between-group differences after 3 months for almost all outcomes (25). Only fear-avoidance beliefs and self- reported adherence to prescribed HBE showed a statistically significant difference between the intervention and control groups. To account for the possible effect of the intervention on adherence during physical therapist treatment, treatment group allocation was included as a baseline characteristic for data analyses.

Outcomes

All outcomes were measured at baseline only, except for adherence to HBE recommendations. Adherence to HBE recommendations was measured using the EXAS during patients' visits at the clinic and recorded on a case report form by the physical therapist (16). During the first treatment session, the exercises and recommended frequency and intensity were recorded, and at the start of the following treatment session, the patient reported adherence to the recommendations. The physical therapist recorded patient-reported adherence using the EXAS and rated the quality of performance of the exercises on a 5-point scale (poor, moderate, reasonable, good, excellent). Adherence was then calculated as a percentage, and the resulting percentage was modified by the quality of performance rating. The EXAS score was then obtained by calculating the mean modified adherence percentage for all exercises, resulting in an EXAS score for every treatment session after the first session. The EXAS score ranges from 100 (perfect adherence) to 0 (no adherence). After the last treatment session, the therapist recorded the total number of treatment sessions.

For the comparison between groups with distinct trajectories of adherence, patients completed questionnaires on patient characteristics, physical functioning, pain intensity, fear avoidance, pain catastrophizing, self-efficacy, self- management ability, and health-related quality of life at the start of the study.

Physical functioning was measured using the Oswestry Disability Index (ODI), version 2.1a (26,27). The score on the ODI ranges from 0 to 100 with a higher score indicating increased functional disability. The ODI is part of the "Core Outcome Set" for research involving patients with nonspecific LBP (28).

Pain intensity was measured with an 11-point Numeric Pain Rating Scale for the average pain intensity in the past 7 days or since the onset of the pain if pain duration was less than 7 days (27,29). Pain scores range from 0 to 10 (0 = no pain; 10 = worst pain imaginable).

Fear avoidance beliefs were assessed using the Fear- Avoidance Beliefs Questionnaire (FABQ) (30). The FABQ score ranges from 0 to 96, and a higher score indicates stronger fear and avoidance beliefs regarding how physical activity affects LBP.

Pain catastrophizing was measured with the Pain Catastrophizing Scale (PCS) (31). The PCS score ranges from 0 to 52, and a higher score on the PCS corresponds to a higher level of pain catastrophizing.

Self-efficacy was measured using the General Self-Efficacy Scale (32,33). The score ranges from 10 to 40, and a higher score corresponds to higher self-efficacy.

Self-management ability was rated using the Dutch language version of the short form Patient Activation Measure (PAM 13-Dutch) (34). A higher score (range = 0–100) corresponds to a higher level of self-management.

Health-related quality of life was measured using the EuroQol-5D-5L (35). A higher score (range 0–1) corresponds with higher health-related quality of life.

Data analysis

Data preparation and calculation of descriptive statistics were performed using SPSS 27 (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0, Armonk, NY) and R (R foundation, Vienna, Austria). Subsequent analyses were performed using R. For a longitudinal analysis of the data, at least 2 EXAS scores are required. The first EXAS score can be calculated after treatment session 2, based on patient adherence to HBE recommendations from the physical therapist given during the first session. Similarly, the second EXAS score can be calculated after the third treatment and so on. Therefore, data from patients with fewer than 2 EXAS scores were excluded. Missing values analyses were performed to evaluate if observed variables were correlated with variables with missing data. Relationships between baseline variables and missingness of adherence variables were found; therefore, further analyses of the data were performed by assuming data were missing at random. Multivariate imputation by chained equations was used to impute missing data in R using the mice package (36,37). One imputed dataset was created for every percent of cases with missing data for a total of 52 imputed datasets. To model latent class growth analysis (LCGA) trajectories using the imputed datasets, adherence LCGA trajectories were estimated in each separate imputed dataset. Second, all imputed datasets were used to create an "overall mean adherence trajectory." This trajectory was obtained by pooling the mean adherence values at each follow-up moment over all patients and all imputed datasets. Then, the imputed dataset with the smallest mean difference from the overall mean adherence trajectory was selected and used for further analyses.

To assess the presence of subgroups of patients with distinct trajectories of adherence, LCGA was performed using the lcmm package in R (38). Trajectories were estimated for linear models and models with a quadratic term for time. Model fit was tested for solutions with 1, 2, 3, and 4 classes. To find the optimal model the maximum log-likelihood ratio, Akaike Information Criterion, Bayesian Information Criterion, and entropy values of the different models were compared (39). When less than 5% of the sample was assigned to a class, the model with k-1 classes was chosen instead to maintain the clinical usefulness of the final model. To test for differences in baseline characteristics between participants based on class membership from the LCGA, chi-square tests were used for categorical variables. The Kruskal–Wallis test was used for continuous variables due to the non-normal distribution of the data.

Role of the Funding Source

The funder played no role in the design, conduct, or reporting of this study.

RESULTS

Data on adherence and received treatment during the study were available for 191 of the 208 participants. The unavailability of adherence data for a patient was caused by physical therapists not using the case report form properly during treatment or not returning the case report form to the researchers after the treatment ended. Eighteen patients received fewer than 3 treatments, leaving data from 173 participants avail- able for analysis.

Data on patient adherence were collected during 5.1 (SD 2.5) treatment sessions and total treatment duration lasted for 51 (SD 41.7) days. Baseline characteristics of included patients can be found in Table 1. Results from the LCGA are limited to 11 treatment sessions (10 timepoints), because only 1 patient received more than 11 treatment sessions.

Table 1 Baseline demographic and clinical characteristics for all patientsa

Patient characteristics	n = 173
Sex (female), *n* (%)	88 (50.9)
Age (y), median (IQR)	48 (24.3)
Height (cm), median (IQR)	175 (12)
Weight (kg), median (IQR)	80 (20)
BMI (kg/m^2), median (IQR)	25.5 (4.7)
Educational level, n (%)	
Low	30 (17.3)
Middle	60 (34.7)
High	83 (48.0)
Central sensitization (score = 0-100), median (IQR)	27 (18)

Table 1 *Continued.*

Patient characteristics	n = 173
Duration of current LBP episode, *n* (%)	
0-6 wk	72 (41.6)
6-12 wk	26 (15.0)
12 wk to 12 mo	15 (8.7)
> 12 mo	60 (34.7)
Physical functioning (score 0-100), median (IQR)	18 (20)
Pain intensity (average score = 7 d, 0-10), median (IQR)	6 (3.0)
Fear-avoidance beliefs (score 0-96), median (IQR)	23 (18)
Pain catastrophizing (score 0-52), median (IQR)	8 (11)
Self-efficacy (score 10-40), median (IQR)	33 (5)
Self-management ability (score 0-100), median (IQR)	63.1 (19.3)
Health-related quality of life (score 0-1), median (IQR)	0.9 (0.2)
Intervention group, *n* (%)	87 (50.3)

[A]BMI = body mass index; IQR = interquartile range; LBP = low back pain

Figure 1 shows the plotted overall mean values for the EXAS-score at each timepoint (thick gray line), plots for all individual imputed datasets (thin gray lines), and the plot for dataset #24 with the smallest mean deviation from the mean of all datasets (black line).

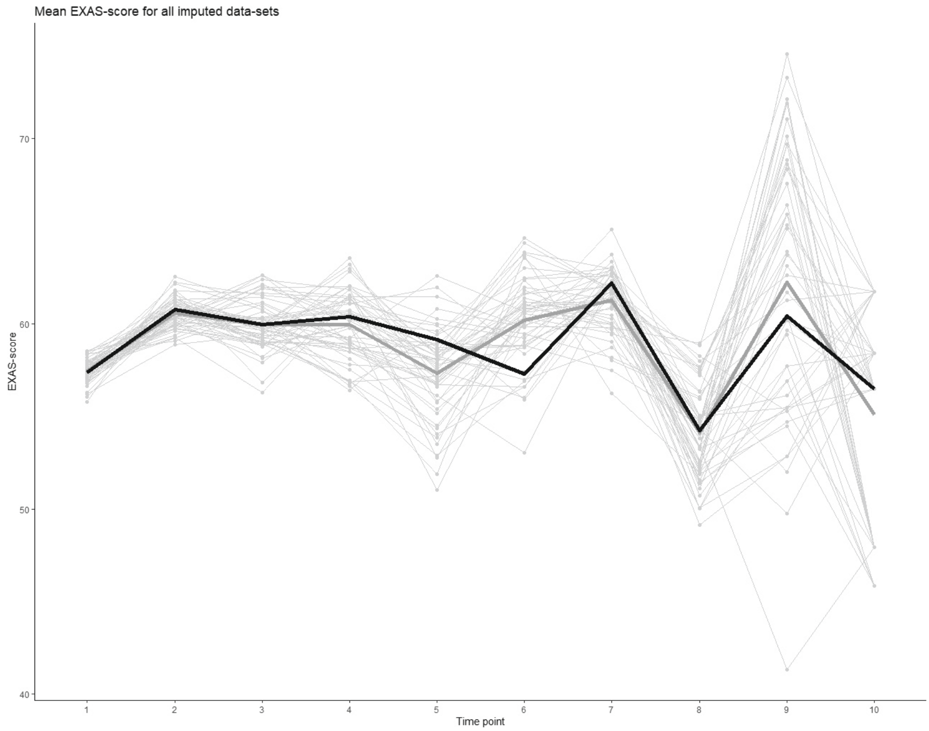


Figure 1 Overall mean adherence trajectory estimated from 52 imputed datasets (thick grey), mean adherence trajectory estimated from each of the 52 imputed datasets separately (thin grey) and mean adherence trajectory of the imputed dataset (#24) with the smallest mean deviation from the overall mean adherence trajectory (black).

Models with 1 to 4 classes were estimated using LCGA. The addition of a quadratic term for time did not increase the fit of the linear models. The 4-class solution showed optimal performance based on the maximum log-likelihood criterion, with a value of −3115.1, while the 2-class and 3-class models yielded lower log-likelihood scores of −3126.3 and − 3119.1, respectively. Similarly, the Akaike Information Criterion favored the 4-class solution with a value of 6254.2, compared to the 2-class (6264.7) and 3-class (6256.3) models.

Conversely, the Bayesian Information Criterion favored the 2- class model with a lower value of 6283.6, in contrast to the 3-class (6284.6) and 4-class (6292.0) models. Furthermore, the entropy measure indicated a better fit for the 2-class model (0.61) compared to the 3-class (0.49) and 4-class (0.54) models. However, the 2-class model displayed 2 nearly parallel trajectories (Fig. 2), suggesting limited clinical significance and within the 4-class model, the fourth class contained less than 5% (4.6%) of the patient population. Therefore, the k-1 model (model 3) was chosen instead (Fig. 3).

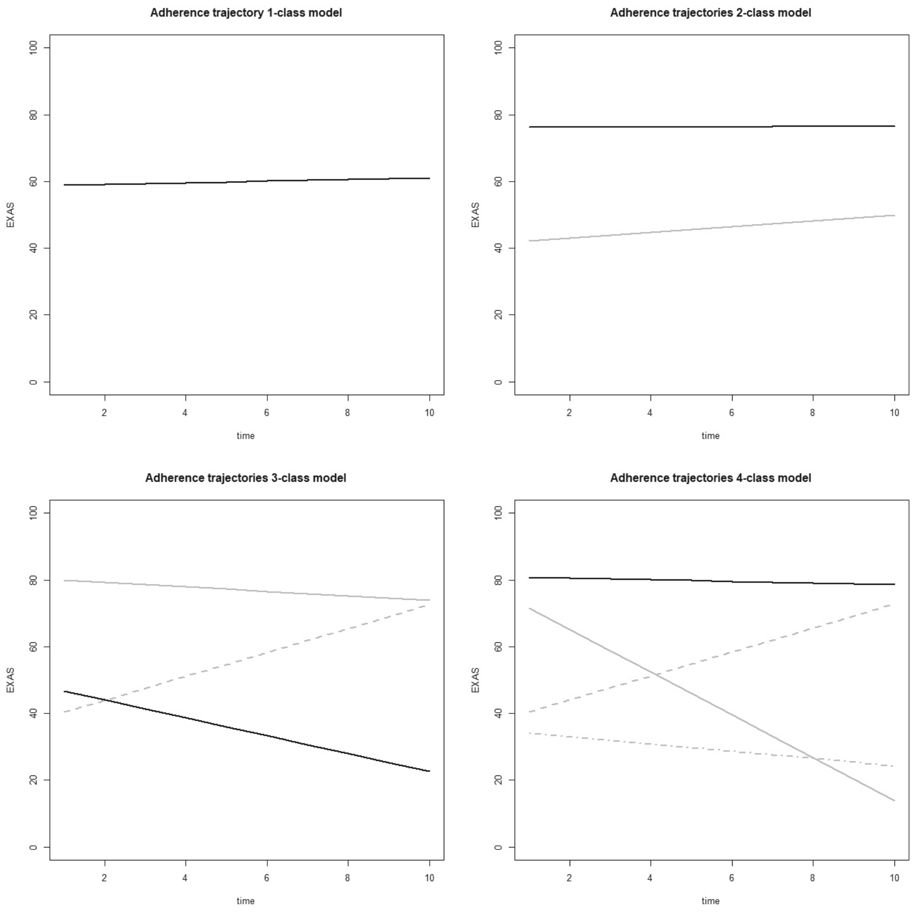


Figure 2 Predicted trajectories of adherence over time based on class assignment for the 1-class (black), 2-class (grey), 3-class (grey/dash), and 4-class (grey/dot-dash) trajectory models.

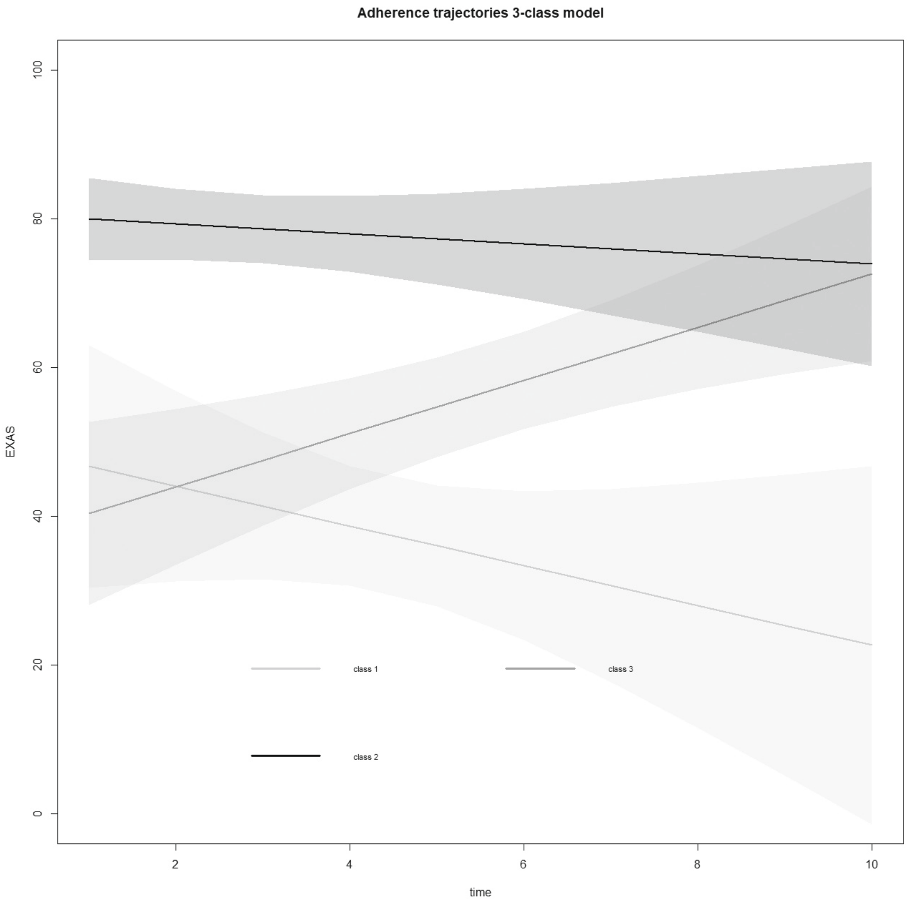


Figure 3 Estimated trajectories for the 3-class trajectory model with 95% CI.

Baseline characteristics of the patient groups for each trajectory class are shown in Table 2. Approximately 12% of participants belong to the "declining adherence" class, 45% to the "stable adherence" class, and 43% to the "increasing adherence" class. No differences were found between the 3 patient groups based on baseline characteristics (Table 3). Additionally, no differences in the proportion of patients from the treatment group in the parent trial were observed between the trajectory classes.

Table 2 Comparison between identified trajectory classes based on baseline characteristics[a]

Patient Characteristics	Class 1 Low Declining Adherence (n=21)	Class 2 High Stable Adherence (n=78)	Class 3 Low Increasing Adherence (n=74)	P Between Groups
Age (y), median (IQR)	45 (17.8)	47.7 (25.5)	49.1 (21.2)	.78
Height (cm), median (IQR)	173 (10)	175 (12.8)	174.5 (14)	.83
Weight (kg), median (IQR)	80 (12)	77.5 (22.8)	79 (22)	.68
BMI (kg/m^2), median (IQR)	25.1 (5.4)	24.9 (4.7)	26 (4.9)	.32
Central sensitization (score = 0-100), median (IQR)	31 (25)	26 (15.8)	29 (18)	.29
Physical functioning (score = 0-100), median (IQR)	22 (26)	18 (16)	18 (20)	.84
Pain intensity (average score = 7 d, 0-10), median (IQR)	6 (3)	6 (3)	6 (3)	.49
Fear-avoidance beliefs (score = 0-96), median (IQR)	25 (23)	20.5 (18)	24.5 (17)	.20
Pain catastrophizing (score = 0-52), median (IQR)	12 (9.0)	8 (10)	8.5 (13.5)	.51
Self-efficacy (score = 10-40), median (IQR)	32 (5)	34 (5.8)	32 (5.8)	.79
Self-management ability (score = 0-100), median (IQR)	63.1 (14.6)	63.1 (16.9)	63.1 (19.3)	.78
Health-related quality of life (score = 0-1), median (IQR)	0.85 (0.2)	0.89 (0.2)	0.89 (0.2)	.46
Sex (female), *n* (%)	10 (47.6)	43 (55.1)	35 (47.3)	.60[b]
Educational level, *n* (%)				.78[b]
Low	5 (23.8)	15 (19.2)	10 (13.5)	
Middle	7 (33.3)	25 (32.1)	28 (37.8)	
High	9 (42.9)	38 (48.7)	36 (48.6)	
Duration of current LBP episode, *n* (%)				.62[b]
0-6 wk	9 (42.9)	29 (37.2)	34 (45.9)	
6-12 wk	4 (19.0)	13 (16.7)	9 (12.2)	
12 wk to 12 mo	1 (4.8)	5 (6.4)	9 (12.2)	
> 12 mo	7 (33.3)	31 (39.7)	22 (29.7)	
Intervention group, *n* (%)	12 (57.1)	41 (52.6)	34 (45.9)	.57[b]

[a]% = percentage of the total sample; BMI = body mass index; IQR = interquartile range; LBP = low back pain; [b]P from chi-square test.

DISCUSSION

The current study aimed to investigate the presence of groups of patients with distinct trajectories of adherence to HBE recommendations among people with LBP and to identify differences in baseline characteristics between groups. Three groups with distinct trajectories were identified. The "low declining adherence" group started with moderate adherence and declined to almost no adherence over the course of treatment. The "low increasing adherence" group started at around the same level of moderate adherence as the "low declining adherence" group, but adherence increased over time to almost 80 points on the EXAS. The "high stable adherence" group started with the highest adherence, and adherence declined slowly to approximately the same level as the "low increasing adherence" group at the end of the trajectory. None of the baseline characteristics showed statistically significant differences between the identified trajectory classes, including treatment group allocation in the intervention study. It is noteworthy that the width of the confidence intervals of the trajectories increases sharply as the number of treatments increases. This is because the number of patients still receiving treatment declines quickly after 6 treatment sessions reducing the precision of estimated trajectories past this point. To our knowledge, the current study is the first to measure adherence trajectories to HBE recommendations in patients with LBP during treatment by a physical therapist, making direct comparison of our results with similar studies in patients with LBP difficult. However, trajectories of adherence were previously investigated in patients with osteoarthritis of the knee and/or hip (17). The authors found 3 distinct trajectories of adherence over time, similar to the current study. A major difference with the current study, however, is the development of the identified trajectories over time. In patients with osteoarthritis of the knee and/or hip, the trajectories either declined gradually or rapidly, or adherence was low for the entire trajectory. This contrasts with the trajectories found in the current study, which started either around the 40-point mark or at the 80-point mark with a gradual change over time and only the trajectory for the smallest group (12.1% of the participants) showed a large decrease in adherence over time. The patients belonging to the other groups reported either increasing adherence or very slowly decreasing adherence over the course of treatment, with both groups ending up at roughly the same level of adherence after 10 treatment sessions. A possible explanation for this difference between the trajectories of adherence found in both studies is the time period over which the measurements were taken. In our study, all treatments ended within 12 weeks and measurements were only taken while the patient was still being treated by their therapist, whereas in the other study results were included from studies where treatment lasted from 12 weeks to 6 months and adherence was measured for 36 to 78 weeks. As a result, patients in our study most likely had far more opportunities to receive support from their therapist during the period in which adherence was measured, leading to higher adherence numbers. Furthermore, the longer time period during which measurements were taken in the study with patients with osteoarthritis of the hip and/or knee allows for more time for adherence to decline, resulting in a higher likelihood of decreasing adherence over time. Another explanation is the difference in measurement instruments used to measure adherence between the studies. The EXAS used in the current study provides a more accurate measurement of adherence than the recall over several weeks used in the other study.

In patients with osteoarthritis of the knee and/or hip, differences between the identified groups were found for pain, function, and self-efficacy. This is in line with studies investigating factors associated with adherence but is in stark contrast to the findings from the current study (8). Despite the fact that baseline characteristics were selected for the comparison based on existing literature (8,10), none of the baseline characteristics measured were significantly different between the trajectory groups in our study. There are several possible explanations for the differences between factors related to adherence found in the literature and the findings of the current study. The first and most straightforward explanation is that patient adherence to HBE recommendations during treatment is determined by patient characteristics that were not measured and therefore no differences between groups could be found. However, the baseline characteristics chosen for baseline comparison between groups were carefully selected based on existing literature and have consistently been shown to be related to adherence. This makes it unlikely that a single patient characteristic explaining the different trajectories was missed and left out of the analysis.

Another explanation is that adherence to HBE recommendations during treatment is mainly determined by factors outside of the patient, such as environmental factors, social factors, intervention-related factors, or therapist-related fac- tors. Indeed, a number of the factors related to adherence reported in the literature are external factors not directly related to the patient (8,10). For instance, a recent pilot study showed very high adherence when patients received external support in the form of telemonitoring and regular check-ups from their physical therapist (40). However, this would mean that external factors are far more important than patient factors for patient adherence during treatment. Although possible, it seems unlikely that patients have little influence on their own adherence to HBE recommendations during physical therapist treatment. A more plausible explanation is that adherence to HBE recommendations is not determined by baseline patient characteristics alone, but also by the change in these characteristics over time as treatment progresses and interactions between patients, their environments, and their physical therapists. For example, a physical therapist can incorporate strategies to support or increase self-efficacy in patients with low self-efficacy at the start of treatment in an attempt to increase adherence during treatment. For future research, it would be interesting to combine repeated measurements of baseline characteristics with measurement of adherence. Combined with investigating the patient-therapist interactions during treatment sessions and their effects on patient adherence, this can help to further understand patient adherence.

Strengths and limitations

Our study has a number of strengths. The application of multiple imputation by chained equations for missing data helped to reduce bias introduced by missing data. Since a large number of cases had at least 1 missing data point due to illegible reporting by the therapist, no reporting by the therapist or other problems not related to the patient, performing a complete case analysis would have significantly reduced the number of cases available for the analysis. Imputing missing data allowed optimal use of the available data and therefore provide more robust results. Another strength of the study is the use of the EXAS for the measurement of adherence during every treatment session. The detailed information on patient adherence provided by the EXAS allowed the use of LCGA to determine different groups of patients with distinct adherence trajectories.

Limitations of the study should also be discussed. The first limitation is the introduction of missing data through the way data on adherence was collected. To keep the added workload for the physical therapists participating in the study low, we chose a method that allowed the physical therapists to write down the data on a form they could keep on their desk. Although this methodology requires little effort from the therapist, it introduced more room for errors in reporting (illegible handwriting, forgetting to complete part of the form, etc.) than for example digital reporting through a web–based application. Although imputation was used to minimize the effects of missing data on the results, the best way to handle missing data is to prevent it. A second limitation is that there are currently no existing rules or conventions for the pooling of estimates from LCGA on imputed datasets. Imputation of missing data and analysis of the imputed data generally consists of 3 steps (37). First, a number of different datasets with imputed data are created. Then, the parameters of interest are estimated from each imputed dataset. The last step is the pooling of the parameter estimates and estimating the variance of the pooled estimate. Although the mice package from R provides the tools to pool estimates for linear models, these tools are not available for LCGA in the mice package. Although manually pooling and estimating the parameters of interest would have been possible, similar procedures for the Kruskal-Wallis test used to compare baseline characteristics of the identified trajectory groups do not exist. Instead, we decided to calculate the average of all variables with imputed data over all imputed datasets and find the dataset with the smallest mean deviation from the overall mean to perform the analyses on. This allows the use of imputation to maximize the data available for analysis at the cost of precision of the estimated parameters and estimated variance. The last limitation of the study is the higher proportion of patients with a duration of the current episode of LBP of less than 12 weeks is greater than the proportion of patients with a longer duration of LBP at the start of the study. This difference in proportions might make it difficult to generalize the current findings to patients with chronic LBP. However, the proportions of patients with a duration of the current episode of more than 12 weeks are roughly similar between all 3 trajectory classes at 38.1, 46.1, and 41.9%, respectively. Furthermore, these proportions are again roughly similar to the proportion of 43.4% of patients with a duration of the current episode of more than 12 weeks in the entire sample. Therefore, it appears that the results from the current study can be reasonably well generalized to patients with LBP of all durations.

Although no differences between baseline characteristics of the identified trajectory groups were found, the results show that there is no single trajectory of adherence for all patients and that it might not be possible to distinguish different subgroups based on baseline characteristics alone. Therefore, when planning patient treatment, clinicians should not attempt to determine adherence of their patients at the start of treatment and base interventions on that assessment. Instead, monitoring adherence during treatment using an instrument such as the EXAS and intervening when adherence is too low appears to be the optimal strategy.

Future research should incorporate the patient–therapist interaction, the patient's social environment, and patient characteristics when studying patient adherence to better under- stand how patient adherence can be supported during physical therapist treatment. Another important next step in the research on patient adherence in patients with LBP is to study the association between trajectories of adherence to HBE and clinical outcomes to assess the effects of adherence on clinical outcomes.

Conclusion

Three different trajectories of adherence to HBE recommendations were identified in patients with LBP. No differences in baseline characteristics were found between the 3 trajectory groups; therefore, physical therapists should not attempt to place a patient in a trajectory group at the start of treatment. Instead, adherence should be closely monitored as treatment progresses and supported when required.

Author Contributions

Concept/idea/research design: R. Arensman, C.J.J. Kloek, R.W.J.G. Ostelo, C. Veenhof, T. Koppenaal, M.F. Pisters Writing: R. Arensman, M.W. Heymans, C.J.J. Kloek

Data collection: R. Arensman, T. Koppenaal

Data analysis: R. Arensman, M.W. Heymans, M.F. Pisters

Project management: R. Arensman, C.J.J. Kloek, T. Koppenaal, M.F. Pisters

Fund procurement: M.F. Pisters, C. Veenhof

Providing facilities/equipment: C. Veenhof, M.F. Pisters

Providing institutional liaisons: C. Veenhof, M.F. Pisters

Consultation (including review of manuscript before submitting): R. Arensman, M.W. Heymans, C.J.J. Kloek, R.W.J.G. Ostelo, C. Veenhof, T. Koppenaal, M.F. Pisters

Acknowledgments
The authors thank Sophie Konings for her assistance with data collection.

Ethics Approval
This study was approved by the Medical Research Ethics Committee of the University Medical Center Utrecht, the Netherlands (ISRCTN 94074203).

Funding
This study was cofunded by the Taskforce for Applied Research SIA (RAAK-PRO02.063), part of the Dutch Research Council (NWO).

Data Availability
The datasets generated, analyzed, or both during the current study will be available from the corresponding author on reasonable request on the completion of the study.

Disclosures
The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.

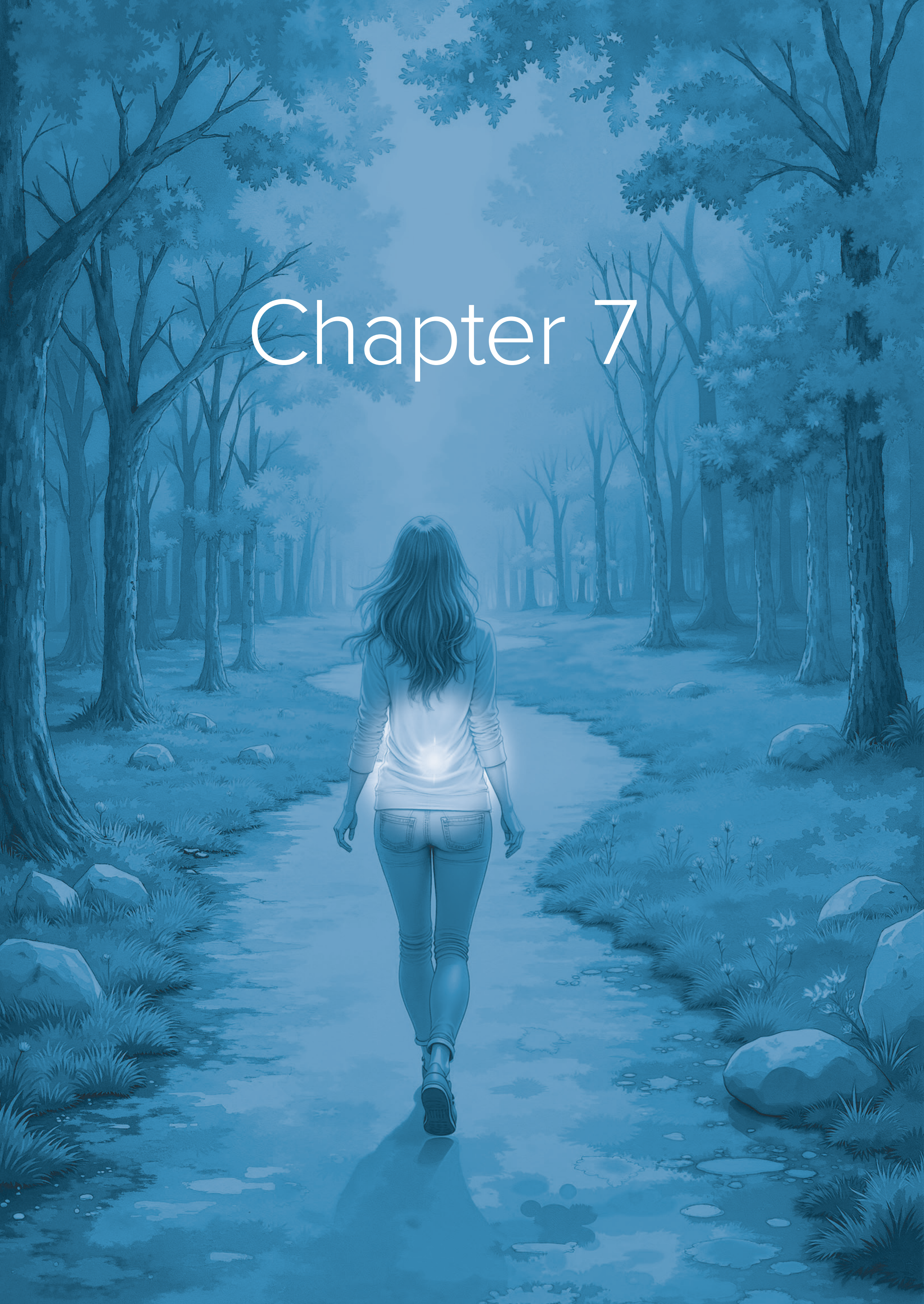
REFERENCES

1. Hartvigsen J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, et al. What low back pain is and why we need to pay attention. ancet. 2018;391(10137):2356–67.
2. Oliveira CB, Maher CG, Pinto RZ, Traeger AC, Lin CWC, Chenot JF, et al. Clinical practice guidelines for the management of non-specific low back pain in primary care: an updated overview. Eur Spine J. 2018;27(11):2791–803.
3. Wong JJ, Côté P, Sutton DA, Randhawa K, Yu H, Varatharajan S, et al. Clinical practice guidelines for the noninvasive management of low back pain: A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. Eur J Pain. 2017;21(2):201–16.
4. Almeida M, Saragiotto B, Richards B, Maher CG. Primary care management of non-specific low back pain: Key messages from recent clinical guidelines. Med J Aust. 2018;208(6):272–5.
5. Wang R, Weng LM, Peng MS, Wang XQ. Exercise for low back pain: A bibliometric analysis of global research from 1980 to 2018. J Rehabil Med. 2020;52(4).
6. Hayden JA, Wilson MN, Stewart S, Cartwright JL, Smith AO, Riley RD, et al. Exercise treatment effect modifiers in persistent low back pain: An individual participant data meta-analysis of 3514 participants from 27 randomised controlled trials. Br J Sports Med. 2020;54(21):1277–8.
7. Quentin C, Bagheri R, Ugbolue UC, Coudeyre E, Pélissier C, Descatha A, et al. Effect of home exercise training in patients with nonspecific low-back pain: A systematic review and meta-analysis. Vol. 18, International Journal of Environmental Research and Public Health. MDPI AG; 2021.
8. Essery R, Geraghty AWAA, Kirby S, Yardley L. Predictors of adherence to home-based physical therapies: a systematic review. Disabil Rehabil. 2017;39(6):519–34.
9. Nicolson PJA, Hinman RS, Wrigley T v., Stratford PW, Bennell KL. Self-Reported Home Exercise Adherence: A Validity and Reliability Study Using Concealed Accelerometers. J Orthop Sports Phys Ther. 2018;48(12):943–50.
10. Bachmann C, Oesch P, Bachmann S. Recommendations for Improving Adherence to Home-Based Exercise: A Systematic Review. Phys Medizin Rehabilitationsmedizin Kurortmedizin. 2018;28(01):20–31.
11. World Health Organization. Adherence to long-term therapies: Evidence for action. Geneva; 2003.
12. Lonsdale C, Hall AM, Murray A, Williams GC, McDonough SM, Ntoumanis N, et al. Communication Skills Training for Practitioners to Increase Patient Adherence to Home-Based Rehabilitation for Chronic Low Back Pain: Results of a Cluster Randomized Controlled Trial. Arch Phys Med Rehabil. 2017;98(9):1732-1743.e7.
13. Koppenaal T, Pisters MF, Kloek CJJ, Arensman RM, Ostelo RWJG, Veenhof C. The 3-Month Effectiveness of a Stratified Blended Physiotherapy Intervention in Patients With Nonspecific Low Back Pain: Cluster Randomized Controlled Trial. J Med Internet Res. 2022;24(2).

14. Bollen JC, Dean SG, Siegert RJ, Howe TE, Goodwin VA. A systematic review of measures of self-reported adherence to unsupervised home-based rehabilitation exercise programmes, and their psychometric properties. BMJ Open. 2014;4(6).
15. Frost R, Levati S, McClurg D, Brady M, Williams B. What Adherence Measures Should Be Used in Trials of Home-Based Rehabilitation Interventions? A Systematic Review of the Validity, Reliability, and Acceptability of Measures. Arch Phys Med Rehabil. 2017;98(6):1241-1256.e45.
16. Arensman RM, Geelen RH, Koppenaal T, Veenhof C, Pisters MF. Measuring exercise adherence in patients with low back pain: development, validity, and reliability of the EXercise Adherence Scale (EXAS). Physiother Theory Pract. 2022;38(7):928–37.
17. Nicolson PJA, Hinman RS, Kasza J, Bennell KL. Trajectories of adherence to home-based exercise programs among people with knee osteoarthritis. Osteoarthr Cartil. 2018;26(4):513–21.
18. Kuo WY, Chen MC, Lin YC, Yan SF, Lotus Shyu YI. Trajectory of adherence to home rehabilitation among older adults with hip fractures and cognitive impairment. Geriatr Nurs. 2021;42:1569-1576
19. Koppenaal T, Arensman RM, Van Dongen JM, Ostelo RWJG, Veenhof C, Kloek CJJ, et al. Effectiveness and cost-effectiveness of stratified blended physiotherapy in patients with non-specific low back pain: Study protocol of a cluster randomized controlled trial. BMC Musculoskelet Disord. 2020;21(1):265.
20. van de Schoot R, Sijbrandij M, Winter SD, Depaoli S, Vermunt JK. The GRoLTS-Checklist: Guidelines for Reporting on Latent Trajectory Studies. Struct Equ Modeling. 2017;24(3):451–67.
21. Hoy D, Bain C, Williams G, March L, Brooks P, Blyth F, et al. A Systematic Review of the Global Prevalence of Low Back Pain. Arthritis Rheum. 2012;64(6):2028–37.
22. Staal JB, Hendriks EJM, Heijmans M, Kiers H, Lutgers-Boomsma AM, Rutten G, et al. KNGF-richtlijn Lage rugpijn. 2017.
23. Global scale - Table 1 (CEFR 3.3): Common Reference levels. Accessed 2022 10 Feb. Available from: https://www.coe.int/en/web/common-european-framework-reference-languages/table-1-cefr-3.3-common-reference-levels-global-scale
24. Kloek CJJ, van Tilburg ML, Staal JB, Veenhof C, Bossen D. Development and proof of concept of a blended physiotherapeutic intervention for patients with non-specific low back pain. Physiotherapy. 2019;105(4):483–91.
25. Koppenaal T, Pisters MF, Kloek CJJ, Arensman RM, et al. The 3-Month Effectiveness of a Stratified Blended Physiotherapy Intervention in Patients With Nonspecific Low Back Pain: Cluster Randomized Controlled Trial. J Med Internet Res. 2022; 24(2):e31675.
26. Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine. 2000;25(22):2940–52.
27. Chiarotto A, Terwee CB, Ostelo RW. Choosing the right outcome measurement instruments for patients with low back pain. Best Pract Res Clin Rheumatol. 2016;30(6):1003–20.
28. Chiarotto A, Boers M, Deyo RA, Buchbinder R, Corbin TP, Costa LOP, et al. Core outcome measurement instruments for clinical trials in nonspecific low back pain. Pain. 2018;159(3):481–95.

29. Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain. 2008;9(2):105–21.
30. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain. 1993;52(2):157–68.
31. Sullivan MJL, Bishop SR, Pivik J. The Pain Catastrophizing Scale: Development and validation. Psychol Assess. 1995;7(4):524–32.
32. Teeuw B, Schwarzer R, Jerusalem M. Dutch Adaptation of the General Self-Efficacy Scale. 1994. Available from: https://userpage.fu-berlin.de/~health/dutch.htm
33. Scholz U, Doña BG, Sud S, Schwarzer R. Is General Self-Efficacy a Universal Construct? Psychometric findings from 25 countries. Eur J Psychol Assess. 2002;18(3):242–51.
34. Rademakers J, Nijman J, van der Hoek L, Heijmans M, Rijken M. Measuring patient activation in The Netherlands: translation and validation of the American short form Patient Activation Measure (PAM13). BMC Public Health. 2012;12(1):577.
35. Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011;20(10):1727–36.
36. van Buuren S, Groothuis-Oudshoorn K. mice : Multivariate imputation by chained equations in R. J Stat Softw. 2011;45(3).
37. van Buuren S. Flexible Imputation of Missing Data. 2nd edition. Boca Raton, FL: CRC Press; 2018.
38. Proust-Lima C, Philipps V, Liquet B. Estimation of Extended Mixed Models Using Latent Classes and Latent Processes: The R Package lcmm. J Stat Softw. 2017;78(2):1-56
39. Nylund KL, Asparouhov T, Muthén BO. Deciding on the number of classes in latent class analysis and growth mixture modeling: A Monte Carlo simulation study. Structural Equation Modeling. 2007;14(4):535–569.
40. Krkoska P, Vlazna D, Sladeckova M, Minarikova J, Barusova T, Batalik L, et al. Adherence and Effect of Home-Based Rehabilitation with Telemonitoring Support in Patients with Chronic Non-Specific Low Back Pain: A Pilot Study. 2023;20(1504).

Chapter 7



Exploring the association between adherence to home-based exercise recommendations and recovery of nonspecific low back pain: a prospective cohort study.

Remco M. Arensman
Martijn F. Pisters
Corelien J.J. Kloek
Tjarco Koppenaal
Cindy Veenhof
Raymond J.W.G. Ostelo

Under review

ABSTRACT

Background: Adherence to home-based exercise (HBE) recommendations is critical in physical therapy for patients with low back pain (LBP). However, limited research has explored its connection with clinical outcomes. This study examined how adherence to HBE relates to changes in physical function, pain intensity, and recovery from LBP in patients undergoing physiotherapy treatment.

Methods: Data from a multicenter cluster randomized controlled trial in the Netherlands involving patients with LBP from 58 primary care physiotherapy practices were used. Adherence to HBE was assessed with the Exercise Adherence Scale (EXAS) at each treatment session. Previously identified adherence trajectories served as a longitudinal measure of adherence and included the classes "declining adherence" (12% of participants), "stable adherence" (45%), and "increasing adherence" (43%). The main outcomes included disability (Oswestry Disability Index), pain (Numeric Pain Rating Scale), and recovery (pain-free for > 4 weeks), which were measured at baseline and three months posttreatment. Linear and binomial logistic regression analyses adjusted for confounders were used to examine adherence–outcome relationships.

Results: In the parent trial, 208 participants were included. EXAS scores were available for 173 participants, collected over a median of 4.0 treatment sessions (IQR 3.0 to 6.0). Forty-five (28.5%) patients considered themselves to have recovered after a median of 4 sessions (IQR 3 to 6). The median improvements in the Oswestry Disability Index and Numeric Pain Rating Scale were 8 (IQR 1 to 20) and 2 (IQR 0.5 to 4), respectively. The mean EXAS scores varied among patient classes: "declining adherence" (46.0, SD 19.4), "stable adherence" (81.0, SD 12.4), and "increasing adherence" (39.9, SD 25.3), with an overall mean of 59.2 (SD 25.3). No associations between adherence and changes in physical functioning or pain were found in the regression analyses.

Conclusions: No association between adherence to HBE recommendations and changes in clinical outcomes in patients with LBP was found. These findings suggest that the relationship between adherence to HBE recommendations and treatment outcomes may be more complex than initially assumed. Further research using detailed longitudinal data combined with qualitative methods to investigate patient motivation and beliefs may lead to a deeper understanding of the relationship between adherence and clinical outcomes in patients with LBP.

Keywords: Exercise, Home-based exercise, adherence, low back pain, disability.

INTRODUCTION

Exercise therapy is often a primary choice physical therapy treatment for patients with persistent nonspecific low back pain (LBP) (1). It has also been shown to reduce pain and disability in patients with acute LBP (1). Incorporating home-based exercise (HBE) into treatment plans can help alleviate the burden of LBP on the public health system. HBE, often recommended as a combination of strength and other exercises such as relaxation or postural exercises, has been shown to be effective in mitigating pain and disability in patients with LBP (2). However, adherence to exercise recommendations is frequently low, with nonadherence rates reaching up to 70% in patients with LBP, which may substantially reduce the effectiveness of these interventions (3–5).

Studying patient adherence is a complex and challenging task because it is influenced by numerous external factors, such as financial constraints and healthcare accessibility, as well as patient-related factors, such as motivation and self-efficacy (6,7). Although external factors are beyond physiotherapist control, patient- and treatment-related factors can be effectively targeted through specific interventions (7). Several factors have been linked to adherence, including physiotherapist guidance, the quantity of prescribed exercises, self-motivation, self-efficacy, past adherence behavior, initial physical or aerobic activity levels, focus during exercise, increased pain during exercise, and significant levels of helplessness, depression, or anxiety (7,8). Additionally, adherence is not a static concept; it can vary over time. Distinct adherence trajectories have been observed in patients with LBP and osteoarthritis, indicating that adherence changes over time and that there are patient subgroups with similar patterns of adherence change (9,10).

While there is evidence available identifying factors linked to adherence to HBE in patients with LBP (6,11–13) and interventions aimed at enhancing adherence have been studied (14), the majority of adherence measurement tools either lack comprehensive psychometric testing or are too simplistic (15,16). Only in recent years have researchers developed and more rigorously tested novel measurement instruments, facilitating more detailed and long-term tracking of adherence to HBE recommendations in studies (17,18).

In clinical practice, clinicians face the challenge of discerning whether to adjust their HBE recommendations due to ineffectiveness or whether they should provide additional support to their patients to enhance adherence when treatment effects fall short of expectations. Despite identifying different groups of patients with LBP and their distinct adherence trajectories over time as a potential solution, the fundamental assumption that adherence to HBE recommendations correlates with clinical outcomes remains insufficiently explored (10). Consequently, the aim of this study was to explore the associations between adherence to HBE recommendations and changes in clinical outcomes in patients with LBP.

METHODS

Study design

This study is a secondary cohort analysis using data from the e-Exercise LBP trial (19). The e-Exercise LBP trial was a multicenter cluster randomized controlled trial investigating the effectiveness of a stratified blended physiotherapy intervention in patients with LBP (20). Patients with LBP were recruited from 58 primary care physiotherapy practices in the Netherlands from January to June 2018. Patients received treatment from participating physiotherapists, and to avoid contamination between the intervention group and usual care group, physiotherapy practices were cluster-randomized to either the intervention group or usual care group. In the intervention group, physical therapy consisted of face-to-face physiotherapy treatment combined with support from an eHealth application on their smartphone (e-Exercise LBP) (20,21). Patients in the usual care group received care based on the guidelines for LBP from The Royal Dutch Society for Physiotherapy (22). The Medical Research Ethics Committee of the University Medical Center Utrecht, the Netherlands, approved the study (ISRCTN 94074203).

Participants

Patients were eligible for participation if they (1) requested physiotherapy treatment for LBP (pain in the lumbosacral region sometimes associated with radiating pain to the buttock or leg) (22,23), (2) were aged 18 years or older, (3) had a smartphone or tablet with internet access, and (4) had B1-level proficiency in the Dutch language(24). Patients were excluded if a specific cause of LBP was determined through medical imaging, if they were diagnosed by a medical doctor (including pelvic girdle pain caused by current pregnancy), or if they suffered from serious comorbidities. When inclusion for the trial ended, a total of 208 patients participated in the study.

Outcomes

The outcomes measured were physical functioning, pain intensity, and recovery from LBP. The Oswestry Disability Index (ODI) version 2.1a (25,26) was used to measure physical functioning. A higher ODI score (range 0-100) indicates increased physical disability. The ODI is included in the "Core Outcome Set" for research involving patients with nonspecific LBP (27). The ODI change score was calculated by subtracting the ODI baseline score from the ODI score after three months. Pain intensity was measured using the Numeric Pain Rating Scale (NPRS) and was reported by the patient as an average score over the last seven days (26,28). If a patient experienced pain for fewer than seven days, the average pain intensity since the onset of pain was used instead. Pain scores on the NPRS range from 0 (no pain) to 10 (worst pain imaginable). The NPRS change score was calculated by subtracting the NPRS score at baseline from the NPRS score after three months. Recovery from LBP was reported by the patient after three months. After three months, patients were asked about recurrent pain, and patients who reported being free from LBP for at least four consecutive weeks were considered to have recovered. All other patients were considered to have not recovered.

Exposures

The exposure of interest was adherence to HBE recommendations and was assessed by the physical therapist using the Exercise Adherence Scale (EXAS) during every physical therapy treatment session (18). The EXAS measures adherence to frequency, intensity, and quality of performance recommendations. First, the physical therapist instructed the patient in the performance of the exercises for at home and recorded the recommended frequency and intensity. At the start of the following treatment session, the patient reported adherence to the HBE recommendations, and the physical therapist rated the quality of performance of the exercises by the patient on a 5-point Likert scale (poor, moderate, reasonable, good, excellent) (18). For each exercise, adherence was then calculated by expressing patient-reported adherence as a percentage of physiotherapist recommendations for frequency and intensity, and the resulting percentage was modified by the quality of performance rating (18). The mean score for all exercises was calculated and resulted in an EXAS score for every treatment session following the first session where exercises were recommended. The EXAS score ranges from 100 (perfect adherence to HBE recommendations) to 0 (no adherence to HBE recommendations). After the last treatment session, the therapist recorded the number of treatment sessions. To obtain the overall mean EXAS score, all EXAS scores for the individual treatment sessions were averaged.

Trajectory classes of adherence in the cohort of patients in this study were established in a prior study by utilizing EXAS scores from individual treatment sessions (10). Three distinct adherence classes were identified: “declining adherence” (12% of participants), “stable adherence” (45% of participants), and “increasing adherence” (43% of participants). The trajectory classes served as a metric for changes in adherence over time.

Potential confounders

Patient characteristics (age, sex, height, weight, BMI, education level, and duration of LBP prior to the start of treatment) and factors known to be related to adherence (fear avoidance, pain catastrophizing, central sensitization, self-efficacy, self-management ability, and health-related quality of life) were recorded at the start of treatment.

Fear avoidance beliefs were measured using the Fear-Avoidance Beliefs Questionnaire (FABQ) (29). The FABQ score ranges from 0 to 96, with a higher score indicating stronger fear and avoidance beliefs regarding the effects of physical activity on LBP.

For the measurement of pain catastrophizing, the Pain Catastrophizing Scale (PCS) was used (30). The PCS score ranges from 0 to 52, with higher scores corresponding to higher levels of pain catastrophizing.

The Dutch Central Sensitization Inventory (CSI) was used to assess central sensitization (31). The CSI score ranges from 0 to 100, with higher scores corresponding to higher levels of central sensitization.

Self-efficacy was assessed with the General Self-Efficacy Scale (GSE Scale) (32,33). The GSE scale score ranges from 10 to 40, with higher scores corresponding to greater self-efficacy.

Self-management ability was measured using the Dutch language version of the short-form Patient Activation Measure (PAM 13-Dutch) (34). The PAM 13-Dutch score ranges from 0 to 100, and a higher score corresponds to higher levels of self-management.

Health-related quality of life was assessed with the EuroQol-5D-5L (35). A higher score (range 0-1) corresponds to higher health-related quality of life.

Treatment group allocation in the e-Exercise LBP parent trial (19) was the last potential confounder of interest.

Data analysis

Data preparation was performed using SPSS 27 (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp.). Descriptive statistics were used to report patient characteristics, utilizing means and standard deviations (SDs) for normally distributed data and medians with interquartile ranges (IQRs) for data that were not normally distributed. Subsequent analyses were performed using R (R Foundation, Vienna, Austria). For an EXAS score, a minimum of two treatment sessions are required, which excluded patients with only one treatment session from the analyses. Multivariate imputation by chained equations was used to impute missing data in R using the ‘mice’ package (36,37). In 52% of the cases, at least one measurement was missing, and an imputed dataset was generated for every percentage of cases with missing data, resulting in 52 imputed datasets. The analyses and computations of the pooled results were performed on all imputed datasets using the ‘miceafter’ extension package for ‘mice’.

Linear regression and binomial logistic regression were used to test the relationship between adherence and the outcomes. The changes in the ODI and NPRS between baseline and after three months and recovery from LBP were used as outcomes. The mean EXAS score over all treatment sessions and the previously determined trajectory of adherence classes were used as determinants of adherence. All three outcomes were modelled using both determinants of adherence separately and adjusted for confounding factors, resulting in two models per outcome. To explore potential confounders, the association between the outcome and adherence was estimated with and without the potential confounders in the model. When the estimate of the association changed by more than 10%, the variable was added to the final model as a confounder. Furthermore, treatment group allocation from the parent trial was always included in the final model to control for the influence of the e-Exercise LBP intervention on adherence and outcomes (19). For each regression model, the assumptions of linearity, homoscedasticity, independence and normality were checked and confirmed. Multicollinearity was assessed for the final models but was not found.

RESULTS

A total of 208 participants were included in the parent trial (19). EXAS scores and trajectory of adherence class allocation were available for 173 participants who received two or more treatment sessions. The data were collected during a median of 4.0 treatment sessions [IQR 3.0, 6.0]. Missing data were caused by incomplete case reports forms or the absence of case reports forms from the participating physical therapists, and loss to follow up (14 patients). Demographic characteristics of the included patients can be found in Table 1. After three months, forty-five (28.5%) patients considered themselves to have recovered from LBP after a median of 4 [IQR 3, 6] treatment sessions. The median changes in the ODI and NPRS were -8 [IQR -20, -1] and -2 [IQR -4, -0.5], respectively. The mean EXAS score for all patients was 59.2 (SD 25.3), with 46.0 (SD 19.4) for the "declining adherence" class, 81.0 (SD 12.4) for the "stable adherence" class, and 39.9 for the "increasing adherence" class (SD 25.3).

Table 1 Demographic characteristics of the participating patients with low back pain. (n=173)

Variable	Overall (n=173)	"Declining adherence" class (n=21)	"Stable adherence" class (n=78)	"Increasing adherence" class (n=74)
Age (years), median IQR]	47.7 [35.2, 59.5]	45.0 [39.0, 56.8]	47.7 [35.9, 61.4]	49.1 [34.7, 56.0]
Sex (female), n (%)	85 (49.1)	11 (52.4)	35 (44.9)	39 (52.7)
Height (cm), mean (SD)	175.5 (9.7)	175.0 (7.3)	176.1 (9.7)	175.1 (10.3)
Weight (kg), median [IQR]	80.0 [70.0, 90.0]	80.0 [73.0, 85.0]	77.5 [67.2, 90.0]	79.0 [71.0, 93.0]
BMI, median [IQR]	25.5 [23.4, 28.1]	25.1 [23.4, 28.7]	24.9 [23.0, 27.7]	26.0 [23.7, 28.6]
Education level, n (%)				
Low	30 (17.3)	5 (23.8)	15 (19.2)	10 (13.5)
Middle	60 (34.7)	7 (33.3)	25 (32.1)	28 (37.8)
High	83 (48.0)	9 (42.9)	38 (48.7)	36 (48.6)
Duration of LBP (weeks), n (%)				
0-6 weeks	72 (41.6)	9 (42.9)	29 (37.2)	34 (45.9)
6-12 weeks	26 (15.0)	4 (19.0)	13 (16.7)	9 (12.2)
12 weeks-12 months	15 (8.7)	1 (4.8)	5 (6.4)	9 (12.2)
>12 months	60 (34.7)	7 (33.3)	31 (39.7)	22 (29.7)
ODI, median [IQR]	18.0 [8.0, 28.0]	22.0 [8.0, 34.0]	18.0 [10.0, 26.0]	18.0 [8.0, 28.0]
ODI change, median [IQR]	-8.0 [-20.0, -1.0]	-10.0 [-29.0, -1.0]	-8.0 [-16.0, -2.0]	-8.0 [-20.0, 0.0]
NPRS, median [IQR]	6.0 [4.0, 7.0]	6.0 [4.0, 7.0]	6.0 [4.0, 7.0]	6.0 [4.0, 7.0]
NPRS change, median [IQR]	-2.0 [-4.0, -0.5]	-2.0 [-4.0, 0.0]	-2.0 [-5.0, -0.8]	-3.0 [-4.2, -1.0]
FABQ, median [IQR]	23.5 [15.0, 33.0]	25.0 [18.0, 41.0]	21.0 [13.0, 31.0]	24.5 [17.0, 34.5]
PCS, median [IQR]	8.5 [4.0, 15.0]	12.0 [6.0, 15.0]	8.0 [4.0, 14.0]	9.5 [3.8, 17.0]

Table 1 *Continued.*

Variable	Overall (n=173)	"Declining adherence" class (n=21)	"Stable adherence" class (n=78)	"Increasing adherence" class (n=74)
CSI, median [IQR]	27.0 [20.0, 38.0]	31.0 [20.0, 45.0]	26.0 [20.0, 36.0]	28.5 [20.0, 38.2]
GSE Scale, median [IQR]	33.0 [30.0, 35.8]	32.0 [30.0, 35.0]	34.0 [30.0, 36.0]	32.0 [30.0, 36.0]
PAM-13 Dutch, median [IQR]	63.1 [53.2, 72.5]	61.9 [52.7, 69.0]	63.1 [55.6, 72.5]	63.1 [53.2, 72.5]
EuroQol-5D-5L, median [IQR]	0.9 [0.8, 1.0]	0.9 [0.8, 1.0]	0.9 [0.8, 1.0]	0.9 [0.8, 1.0]
Number of treatment sessions, median [IQR]	4.0 [3.0, 6.0]	6.0 [4.0, 7.0]	4.5 [3.0, 6.0]	4.0 [3.0, 7.0]
EXAS, mean (SD)	59.2 (25.3)	46.0 (19.4)	81.0 (12.4)	39.9 (25.3)
Recovered from LBP, n (%)	45 (28.5)	4 (21.1)	18 (25.4)	23 (33.8)
Treatment (intervention), n (%)	87 (50.3)	12 (57.1)	41 (52.6)	34 (45.9)

IQR Interquartile range, SD standard deviation, BMI Body Mass Index, LBP Low back pain, ODI Oswestry Disability Index, NPRS Numeric Pain Rating Scale, FABQ Fear-Avoidance Beliefs Questionnaire, PCS Pain Catastrophizing Scale, CSI Central Sensitization Inventory, GSE General Self-Efficacy, PAM-13 Dutch Patient Activation Measure, EXAS Exercise Adherence Rating Scale

The results from the linear regression analyses and the binomial logistic regression analyses can be found in Table 2 and Table 3. The results from the analyses showed no associations between determinants of adherence and changes in physical functioning or changes in pain when adjusted for confounders and controlling for the e-Exercise LBP intervention.

Table 2 Unadjusted models and adjusted models testing the relationship between adherence and changes in pain and disability. (n=173)

		Unadjusted		Adjusted	
Model	n	Coefficient	95%-CI	Coefficient	95%-CI
ODI change~ EXAS		0.07	-0.01 - 0.15	0.08	-0.00 - 0.17
NPRS change ~ EXAS		-0.00	-0.02 - 0.02	-0.00	-0.02 - 0.02
ODI change ~ "stable adherence"*	78	5.21	-1.50 - 11.92	4.58	-3.09 - 10.60
ODI change ~ "increasing adherence"*	74	4.38	-2.38 - 11.13	3.71	-2.20 - 11.36
NPRS change ~ "stable adherence"*	78	-0.38	-1.75 - 0.99	-0.39	-2.00 - 0.68
NPRS change ~ "increasing adherence"*	74	-0.49	-1.87 - 0.88	-0.48	-1.76 - 0.98

95%-CI 95% Confidence Interval, ODI Oswestry Disability Index after 3 months, EXAS Exercise Adherence Scale, NPRS Numeric Pain Rating Scale after 3 months. * "declining adherence" (n=21) was used as the reference category. Models were adjusted for age, sex, body mass index, education level, Fear-Avoidance Beliefs Questionnaire score, Pain Catastrophizing Scale score, Central Sensitization Inventory score, General Self-Efficacy Scale score, Patient Activation Measure score, EuroQol-5D-5L score, and treatment group.

Table 3 Unadjusted models and adjusted models testing the relationship between adherence and recovery. (n=173)

		Unadjusted		Adjusted	
Model	n	OR	95%-CI	OR	95%-CI
Recovery ~ EXAS		1.01	1.00 - 1.02	1.02	1.00 - 1.03
Recovery ~ "stable adherence"*	78	0.78	0.23 - 2.68	0.82	0.23 - 3.00
Recovery ~ "increasing adherence"*	74	0.50	0.15 - 1.70	0.48	0.13 - 1.72

OR Odds Ratio, 95%-CI 95% confidence interval, Recovery patient reported recovery from low back pain, EXAS Exercise Adherence Scale. * "declining adherence" (n=21) was used as the reference category. Models were adjusted for age, sex, body mass index, education level, Fear-Avoidance Beliefs Questionnaire score, Pain Catastrophizing Scale score, Central Sensitization Inventory score, General Self-Efficacy Scale score, Patient Activation Measure score, EuroQol-5D-5L score, and treatment group.

DISCUSSION

This study is among the first to explore the relationship between adherence to HBE recommendations and changes in clinical outcomes in patients with LBP. The results indicate that, both before and after adjusting for confounders, there are no significant associations between adherence to HBE recommendations and clinical outcome changes in LBP patients. Similarly, there is no evident association between LBP recovery and adherence. Although comparable literature focusing specifically on LBP patients is lacking, a similar study has examined the relationship between adherence to an HBE program and clinical outcomes in patients with knee osteoarthritis (38). A significant distinction from our study is the cross-sectional design used in the study. Nevertheless, the findings in patients with knee osteoarthritis are very similar to the findings of the current study. Although difficult to generalize, these findings suggest that there is no apparent association between adherence to exercise recommendations and changes in pain or disability or recovery from LBP.

Nevertheless, prior to confirming a lack of association between adherence and clinical outcomes, it is important to consider potential factors or underlying reasons that might account for these nonsignificant results. The first is that the construct of adherence to HBE recommendations is much more complex than previously thought. Existing research on predictors of adherence to HBE or other forms of exercise in patients with LBP reveals that patient factors, treatment-related factors, therapist factors, environmental factors, and social factors can influence adherence (3,4,6,7,11,13,39–42). Further complicating the construct of adherence is that the influence of these factors on adherence behavior can differ significantly among patients. For example, reduced pain and disability from LBP as a result of HBE may encourage one patient to remain adherent, while another might discontinue exercising, believing it is unnecessary as their pain and limitations decrease. In contrast, increased pain may prompt one patient to cease exercising while stimulating another to exercise more. Unfortunately, because the outcomes were not measured during every physiotherapy session, this remains hypothetical. However, this could explain the large standard deviations of the mean EXAS scores for the different groups in the current study. Furthermore, although the regression models were adjusted for a number of factors (e.g., age, body mass index, education level, pain catastrophizing, self-efficacy, self-management), many factors could not be adjusted for.

A second explanation is that although adherence to frequency, intensity, and quality of performance recommendations are important indicators of adherence, the EXAS might not be optimal for their measurement. Despite improvements in existing measures of adherence, the accuracy of the EXAS score is limited by patient reporting bias (e.g., recall or patient honesty) and reporting errors by the physiotherapist. It appears that properly investigating the intricate connection between adherence to HBE recommendations and recovery from LBP calls for innovative research approaches. An initial step could involve gathering data on adherence and clinical outcomes during every treatment session and throughout the follow-up period, allowing comprehensive longitudinal analysis. Technological advances and innovations such as the TRAK© telerehabilitation tool (43) might lead to novel platforms to prescribe and support HBE and facilitate the measurement of adherence and clinical outcomes on a larger scale. By also integrating qualitative methods to explore patient motivations and beliefs, a more holistic understanding of adherence can be achieved. Emerging new insights might then contribute to the development of effective strategies for enhancing adherence in patients with LBP.

The last explanation is that the number of patients in some groups used in the regression models was relatively small, which reduces precision and might be the reason for the wide 95% confidence intervals (95% CIs). This is especially apparent for the models testing the relationship between adherence and recovery. Only 28.5% of participants considered themselves to have recovered from LBP after 3 months, which equates to 4 (21.1%) participants who recovered from the “declining adherence” trajectory class. The “increasing adherence” class had the highest percentage of recovered participants (33.8%) and had the largest effect (OR 0.48), with a wide 95% CI ranging from 0.13 to 1.72, indicating that a lack of precision might be the cause of the nonsignificant difference. This variability suggests an underlying trend that recovery is associated with the trajectory of the patient’s adherence class, although this finding was not statistically significant in this study. Therefore, while the current results do not establish a definitive statistical association, they do hint at a potential relationship that warrants further investigation in future studies with more participants to achieve narrower confidence intervals and more definitive conclusions.

This study has several important strengths. The data for this study were collected as part of a prospective, multicenter cluster randomized controlled trial, and the included patients reflected the characteristics of patients with LBP typically treated in primary care physical therapy practices in the Netherlands (19,44). Therefore, the results from this study can be generalized to the population of patients with LBP in the Netherlands. Another strength is the use of multiple imputation to handle missing data. With 52% of the participants having at least one missing data point, performing complete case analyses would have severely limited the statistical power and reduced the robustness of the findings.

There are some limitations to the current study. First, although the EXAS provides data on adherence to HBE recommendations for every treatment session separately, the other outcomes in the study were assessed only at the start and after three months. This design limits the possibilities for repeated measures analysis, resulting in less precise regression models. However, measuring all outcomes at every treatment session leads to considerable additional administrative burden on patients, therapists, and researchers. Short and high-quality measurement instruments, such as those from the Patient-Reported Outcomes Measurement Information System (PROMIS®), might help mitigate those downsides (45).

A second limitation is that data on patient adherence were collected by physical therapists. Although all participating physical therapists were trained for data collection, adherence data from 21 patients were lost and could not be used in the analyses. However, given the current results, it is unlikely that without lost data, the analyses would have produced different results.

Ultimately, while increasing adherence may seem to be an easy solution to improve treatment effects, the results from the current study, along with the complexity of the construct of adherence and its measurement, suggest a more intricate relationship that warrants further investigation.

CONCLUSIONS

This study explored the association between adherence to HBE recommendations and changes in clinical outcomes for patients with LBP. Contrary to expectations, no association was found between adherence measures and changes in clinical outcomes. These findings suggest that the relationship between adherence to HBE recommendations and treatment outcomes may be more complex than initially assumed. Further research using detailed longitudinal data combined with qualitative methods to investigate patient motivation and beliefs may lead to a deeper understanding of the relationship between adherence and clinical outcomes in patients with LBP.

Abbreviations

LBP: Low Back Pain; HBE: Home-based Exercise; ODI: Oswestry Disability Index; NPRS: Numeric Pain Rating Scale; EXAS: Exercise Adherence Scale; FABQ: Fear-Avoidance Beliefs Questionnaire; PCS: Pain Catastrophizing Scale; CSI: Central Sensitization Inventory; GSE Scale: General Self-Efficacy Scale; PAM: Patient Activation Measure; IQR: Interquartile range; SD: Standard Deviation; 95%-CI: 95% confidence interval.

DECLARATIONS

Ethics approval and consent to participate

This study was reviewed and approved by the Medical Research Ethics Committee of the University Medical Center Utrecht, the Netherlands (ISRCTN 94074203), for all participating sites and was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants prior to participation.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This study is cofunded by the Taskforce for Applied Research SIA (RAAK.-PRO02.063), part of the Dutch Research Council (NWO). The external grant body undertook peer review during the funding process. The Taskforce for Applied Research SIA had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Author contributions

All authors (RA, MP, CK, TK, CV, and RO) made substantial contributions to the design of this study AND drafted the work or substantively revised it. The data were collected by RA and TK. Data analysis was performed by RA and MP. Furthermore, all authors (RA, MP, CK, TK, CV, and RO) have approved the submitted version (and any substantially modified version that involves the author's contribution to the study). Finally, all authors (RA, MP, CK, TK, CV, and RO) agree both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even those in which the author was not personally involved, are appropriately investigated and resolved and that the resolution is documented in the literature.

Acknowledgements

Not applicable.

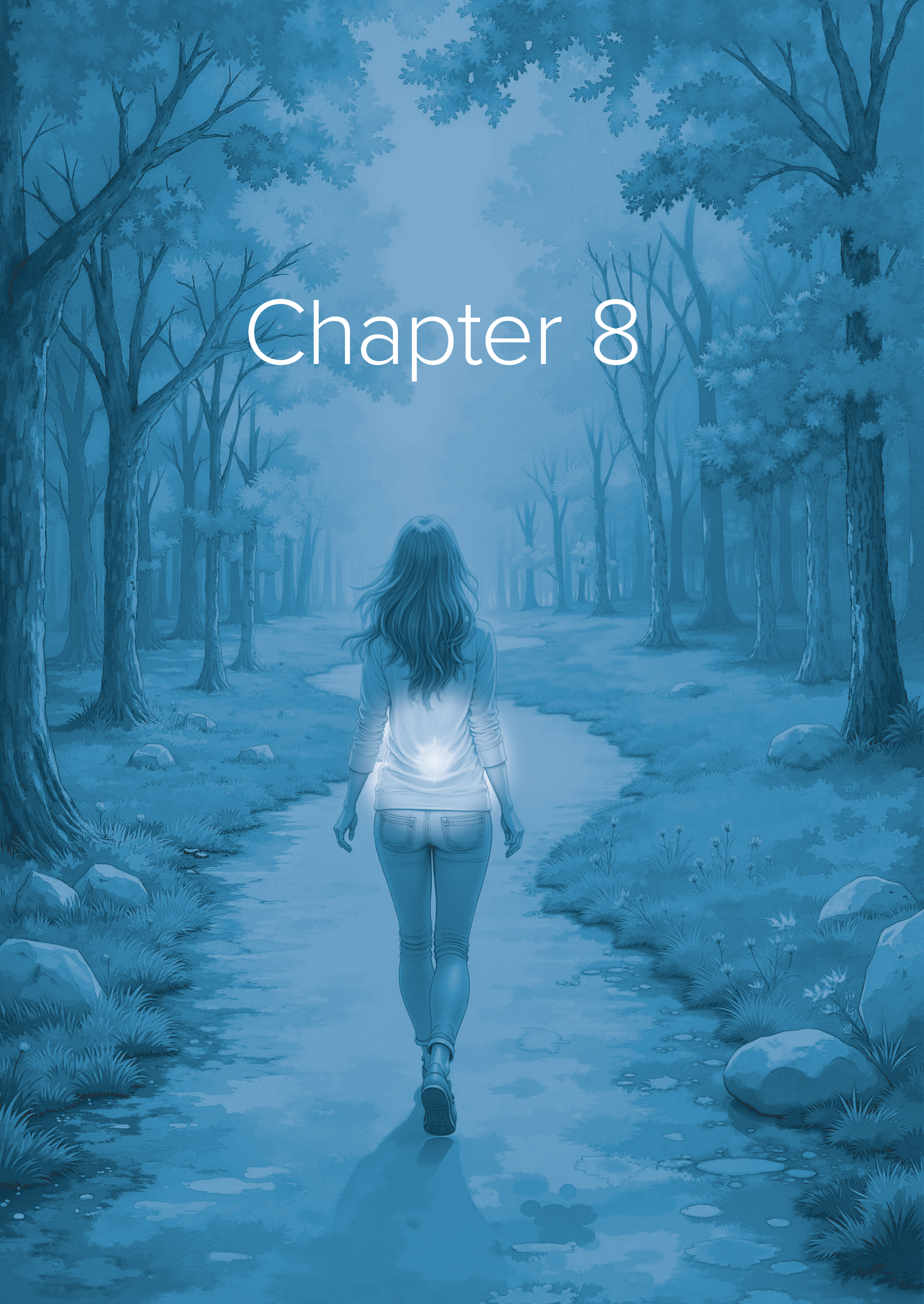
REFERENCES

1. Foster NE, Anema JR, Cherkin D, Chou R, Cohen SP, Gross DP, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. Lancet. 2018;391(10137):2368–83.
2. Quentin C, Bagheri R, Ugbolue UC, Coudeyre E, Pélissier C, Descatha A, et al. Effect of home exercise training in patients with nonspecific low-back pain: A systematic review and meta-analysis. Int J Environ Res Public Health. 2021;18(16):8430.
3. Beinart N a., Goodchild CE, Weinman J a., Ayis S, Godfrey EL. Individual and intervention-related factors associated with adherence to home exercise in chronic low back pain: A systematic review. Spine Journal. 2013;13(12):1940–50.
4. Essery R, Geraghty AWAA, Kirby S, Yardley L. Predictors of adherence to home-based physical therapies: a systematic review. Disabil Rehabil. 2017;39(6):519–34.
5. Nicolson PJA, Hinman RS, Wrigley T V., Stratford PW, Bennell KL. Self-Reported Home Exercise Adherence: A Validity and Reliability Study Using Concealed Accelerometers. J Orthop Sports Phys Ther. 2018;48(12):943–50.
6. Shahidi B, Padwal J, Lee E, Xu R, Northway S, Taitano L, et al. Factors impacting adherence to an exercise-based physical therapy program for individuals with low back pain. Reddy RSY, editor. PLoS One. 2022;17(10):e0276326.
7. Bachmann C, Oesch P, Bachmann S. Recommendations for Improving Adherence to Home-Based Exercise: A Systematic Review. Phys Medizin Rehabilitationsmedizin Kurortmedizin. 2018;28:20–31.
8. Palazzo C, Klinger E, Dorner V, Kadri A, Thierry O, Boumenir Y, et al. Barriers to home-based exercise program adherence with chronic low back pain: Patient expectations regarding new technologies. Ann Phys Rehabil Med. 2016;59(2):107–13.
9. Nicolson PJA, Hinman RS, Kasza J, Bennell KL. Trajectories of adherence to home-based exercise programs among people with knee osteoarthritis. Osteoarthr Cartil. 2018;26(4):513–21.
10. Arensman RM, Heymans MW, Kloek CJJ, Ostelo RJWG, Veenhof C, Koppenaal T, et al. Trajectories of Adherence to Home-Based Exercise Recommendations Among People With Low Back Pain: A Longitudinal Analysis. Phys Ther. 2023;103(12):1–9.
11. Areerak K, Waongenngarm P, Janwantanakul P. Factors associated with exercise adherence to prevent or treat neck and low back pain: A systematic review. Musculoskelet Sci Pract. 2021;52:102333.
12. Beinart NA, Goodchild CE, Weinman JA, Ayis S, Godfrey EL. Individual and intervention-related factors associated with adherence to home exercise in chronic low back pain: A systematic review. Spine J. 2013;13(12):1940–50.
13. Medina-Mirapeix F, Escolar-Reina P, Gascón-Cánovas JJ, Montilla-Herrador J, Jimeno-Serrano FJ, Collins SM. Predictive factors of adherence to frequency and duration components in home exercise programs for neck and low back pain: an observational study. BMC Musculoskelet Disord. 2009;10(1):155.

14. Jordan JL, Holden MA, Mason EEJ, Foster NE. Interventions to improve adherence to exercise for chronic musculoskeletal pain in adults. Cochrane Database Syst Rev. 2010;(1):CD005956.
15. Bollen JC, Dean SG, Siegert RJ, Howe TE, Goodwin VA. A systematic review of measures of self-reported adherence to unsupervised home-based rehabilitation exercise programmes, and their psychometric properties. BMJ Open. 2014;4(6).
16. Frost R, Levati S, McClurg D, Brady M, Williams B. What Adherence Measures Should Be Used in Trials of Home-Based Rehabilitation Interventions? A Systematic Review of the Validity, Reliability, and Acceptability of Measures. Arch Phys Med Rehabil. 2017;98(6):1241-1256.e45.
17. Newman-Beinart NA, Norton S, Dowling D, Gavriloff D, Vari C, Weinman JA, et al. The development and initial psychometric evaluation of a measure assessing adherence to prescribed exercise: the Exercise Adherence Rating Scale (EARS). Physiotherapy. 2017;103(2):180–5.
18. Arensman RM, Geelen RH, Koppenaal T, Veenhof C, Pisters MF. Measuring exercise adherence in patients with low back pain: development, validity, and reliability of the EXercise Adherence Scale (EXAS). Physiother Theory Pract. 2022;38(7):928–37.
19. Koppenaal T, Pisters MF, Kloek CJ, Arensman RM, Ostelo RW, Veenhof C. The 3-Month Effectiveness of a Stratified Blended Physiotherapy Intervention in Patients With Nonspecific Low Back Pain: Cluster Randomized Controlled Trial. J Med Internet Res. 2022;24(2):e31675.
20. Koppenaal T, Arensman RM, Van Dongen JM, Ostelo RWJG, Veenhof C, Kloek CJJ, et al. Effectiveness and cost-effectiveness of stratified blended physiotherapy in patients with non-specific low back pain: Study protocol of a cluster randomized controlled trial. BMC Musculoskelet Disord. 2020;21(1):265.
21. Kloek CJJ, van Tilburg ML, Staal JB, Veenhof C, Bossen D. Development and proof of concept of a blended physiotherapeutic intervention for patients with non-specific low back pain. Physiotherapy. 2019;105(4):483–91.
22. Staal JB, Hendriks EJM, Heijmans M, Kiers H, Lutgers-Boomsma AM, Rutten G, et al. KNGF-richtlijn Lage rugpijn. 2017.
23. Hoy D, Bain C, Williams G, March L, Brooks P, Blyth F, et al. A Systematic Review of the Global Prevalence of Low Back Pain. Arthritis Rheum. 2012;64(6):2028–37.
24. Global scale - Table 1 (CEFR 3.3): Common Reference levels. Accessed 2022 10 Feb. Available from: https://www.coe.int/en/web/common-european-framework-reference-languages/table-1-cefr-3.3-common-reference-levels-global-scale
25. Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine. 2000;25(22):2940–52.
26. Chiarotto A, Terwee CB, Ostelo RW. Choosing the right outcome measurement instruments for patients with low back pain. Best Pract Res Clin Rheumatol. 2016;30(6):1003–20.
27. Chiarotto A, Boers M, Deyo RA, Buchbinder R, Corbin TP, Costa LOP, et al. Core outcome measurement instruments for clinical trials in nonspecific low back pain. Pain. 2018;159(3):481–95.
28. Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain. 2008;9(2):105–21.

29. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain. 1993;52(2):157–68.
30. Sullivan MJL, Bishop SR, Pivik J. The Pain Catastrophizing Scale: Development and validation. Psychol Assess. 1995;7(4):524–32.
31. Kregel J, Vuijk PJ, Descheemaeker F, Keizer D, van der Noord R, Nijs J, et al. The Dutch Central Sensitization Inventory (CSI). Clin J Pain. 2016;32(7):624–30.
32. Teeuw B, Schwarzer R, Jerusalem M. Dutch Adaptation of the General Self-Efficacy Scale. 1994. Available from: https://userpage.fu-berlin.de/~health/dutch.htm
33. Scholz U, Doña BG, Sud S, Schwarzer R. Is General Self-Efficacy a Universal Construct? Psychometric findings from 25 countries. Eur J Psychol Assess. 2002;18(3):242–51.
34. Rademakers J, Nijman J, van der Hoek L, Heijmans M, Rijken M. Measuring patient activation in The Netherlands: translation and validation of the American short form Patient Activation Measure (PAM13). BMC Public Health. 2012;12(1):577.
35. Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011;20(10):1727–36.
36. van Buuren S, Groothuis-Oudshoorn K. mice : Multivariate imputation by chained equations in R. J Stat Softw. 2011;45(3).
37. van Buuren S. Flexible Imputation of Missing Data. 2nd edition. Boca Raton, FL: CRC; 2018.
38. de Santana GN, Dibai-Filho AV, da Silva Júnior JEF, da Silva ACB, de Jesus SFC, dos Santos PG, et al. Association between adherence to a home exercise program and central sensitization, pain intensity, and functionality in individuals with knee osteoarthritis. BMC Musculoskelet Disord. 2022;23:989.
39. Medina-Mirapeix F, Escolar-Reina P, Gascón-Cánovas J, Montilla-Herrador J, Collins S. Personal characteristics influencing patients' adherence to home exercise during chronic pain: A qualitative study. J Rehabil Med. 2009;41(5):347–52.
40. Peek K, Sanson-Fisher R, Mackenzie L, Carey M. Interventions to aid patient adherence to physiotherapist prescribed self-management strategies: a systematic review. Physiotherapy. 2016;102:127–35.
41. Saner J, Bergman EM, de Bie RA, Sieben JM. Low back pain patients' perspectives on long-term adherence to home-based exercise programmes in physiotherapy. Musculoskelet Sci Pract. 2018;38:77–82.
42. Palazzo C, Klinger E, Dorner V, Kadri A, Thierry O, Boumenir Y, et al. Barriers to home-based exercise program adherence with chronic low back pain: Patient expectations regarding new technologies. Ann Phys Rehabil Med. 2016;59(2):107–13.
43. TRAK HEALTH SOLUTIONS SL. TRAK. 2024. Accessed 2024 11 Feb. Available from: https://www.trakphysio.com/en/
44. Bier JD, Sandee-Geurts JJW, Ostelo RWJG, Koes BW, Verhagen AP. Can primary care for back and/or neck pain in the Netherlands benefit from stratification for risk groups according to the STarT Back Tool classification? Arch Phys Med Rehabil. 2018;99(1):65–71.
45. HealthMeasures. PROMIS® (Patient-Reported Outcomes Measurement Information System). 2023. Accessed 2024 4 Jan. Available from: https://www.healthmeasures.net/explore-measurement-systems/promis

Chapter 8



General discussion

DISCUSSION

In this thesis, we primarily explored the role of adherence to home-based exercise (HBE) programs in the treatment of low back pain (LBP), with a particular focus on the usage of an app to improve adherence and outcomes. Physiotherapists coached their patients on adherence to exercise behavior, utilizing the data provided by the patients through the platform. They used the app to deliver tailored information and HBE programs, as well as to monitor patient adherence. Furthermore, we detailed the development and validation of an instrument designed to measure adherence and examined patient views on utilizing a smartphone app to support HBE as part of their treatment. We also explored the relationship between adherence to HBE recommendations, variations in adherence throughout the treatment, and recovery from LBP. Additionally, we investigated the cost-effectiveness of a stratified blended physiotherapy intervention. In this comprehensive discussion section, we will examine our principal findings, consider methodological aspects, and discuss future implications for clinical practice and research, particularly concerning patient adherence to HBE recommendations. For an in-depth analysis and discussion of the cost-effectiveness of the e-Exercise LBP intervention in managing LBP, we direct interested readers to the dissertation by Koppenaal (1).

Key findings

Chapter 2 details the development and validation of the Exercise Adherence Scale (EXAS) for patients with LBP, which measures adherence to HBE programs regarding frequency, intensity, and quality of performance recommendations. It demonstrated good construct validity and excellent intra-rater reliability, thereby demonstrating its suitability for the study of adherence in the e-Exercise LBP trial. In chapter 3 we investigated patients' views on using a smartphone app to support HBE during physiotherapy for LBP, revealing that patients accepted and valued the app for its ease of use and support in exercise adherence, while also emphasizing the vital role of physiotherapists in guiding its optimal use. In chapter 6 we analyzed adherence patterns in patients with LBP, identifying three distinct trajectories: declining, stable, and increasing adherence. None of the baseline characteristics were associated with these trajectories, emphasizing the need for physiotherapists to continuously monitor and support adherence during treatment. Building on this, chapter 7 explores the link between adherence to HBE and clinical outcomes in patients with LBP, but we found no significant associations between adherence and changes in physical functioning or pain intensity, and recovery from LBP. This indicates a more complex relationship between HBE adherence and recovery from LBP than previously assumed. Regarding the stratified blended physiotherapy intervention, chapter 4 outlines a cluster randomized controlled trial protocol to evaluate the effectiveness and cost-effectiveness of the e-Exercise LBP intervention. E-Exercise

LBP is a blended approach combining a smartphone app with traditional face-to-face physiotherapy, aimed at enhancing adherence to HBE, self-management skills, and physical activity in patients with LBP. Finally, chapter 5 shows that while the e-Exercise LBP intervention did not surpass usual face-to-face physiotherapy in enhancing physical functioning overall, it was effective in reducing fear-avoidance beliefs and increasing self-reported adherence to HBE recommendations, particularly benefitting high-risk patients with persistent LBP.

Our approach to understanding adherence to HBE recommendations posits that adherence is essential for evaluating the effectiveness of new treatment strategies. This is because if participants do not adhere to the minimal required treatment dose for a given intervention, determining the intervention's success is impossible. We also presuppose that clinicians design HBE regimens based on exercise physiology and sports science principles to maximize treatment outcomes. Therefore, to effectively assess the optimal content of exercise interventions and their impact on clinical outcomes for patients with LBP in research and clinical practice, comprehending and accurately measuring patients' adherence behavior is a crucial first step. To this end, three main themes will be discussed. First, our findings warrant reconsidering our perspectives on the construct of adherence to HBE recommendations. Second, the measurement of adherence to HBE recommendations needs further refinement to improve the accuracy of data available for researchers and clinicians. Lastly, optimizations for the e-Exercise LBP program or novel interventions to improve adherence behavior of patients with LBP need to be identified to improve patient adherence in clinical practice.

Perspectives on adherence to HBE recommendations

Previous research on adherence to HBE recommendations in patients with LBP has identified several predictors of adherence. These include patient-related factors like self-efficacy and educational background, aspects specific to the treatment such as its type and setting, therapist-related elements including perceived support and coaching style, environmental factors like the distance to the practice and financial considerations, as well as social influences, for instance, support from peers (2–9).

Despite including a number of these factors in our analyses, we did not find any factors related to the membership of a trajectory adherence class (chapter 6). This was unexpected, given the apparent theoretical basis for the factors that were included. Furthermore, the existing literature on LBP indicates ambiguous or limited support for the effectiveness of exercise in diminishing pain and disability (10,11), yet studies also often report low adherence or provide no information on adherence to exercise interventions (11,12). Therefore, our initial assumption was that the disappointing effectiveness of exercise interventions could be explained by variable patient adherence and that the observed effectiveness of an intervention is directly influenced by adherence. In other words, adherent patients would show better clinical outcomes than non-adherent patients. However, our study did not reveal any associations between adherence to HBE and clinical outcomes in patients with LBP and we found that adherence to HBE recommendations varies greatly among patients and over time within the same patient (chapters 6 and 7). Interestingly, despite existing literature suggesting a more pronounced benefit of exercise interventions in patients with chronic LBP, our findings do not support this, even though patients with chronic LBP were well represented in our study (44% of our participants) (11). It appears that the relationship between adherence to exercise recommendations and recovery in patients with LBP is not as straightforward as we previously assumed and unknown factors combined with individual variation are important determinants of adherence. Therefore, before drawing definitive conclusions about the effectiveness of exercise interventions for the management of LBP, it is important to develop a nuanced understanding of adherence and its relationship with clinical outcomes.

Understanding exercise adherence through medication adherence models

Building upon this need for a more nuanced understanding of adherence, it is noteworthy that in the field of pharmacology, the complexity of adherence behavior has already been a significant focus of study for decades (13). This has led the World Health Organization to identify five domains of adherence to medicine (14). These domains include patient-related factors, medication-related factors, condition-related factors, healthcare system/healthcare provider-related factors, and socioeconomic factors. This model was subsequently expanded into an adaptable conceptual framework for understanding the factors contributing to medication adherence (figure 1) (14,15).

In applying this refined model to a diverse array of patient groups, the authors identified common factors. Across these groups, patient-related factors, particularly cognitive and psychological aspects like beliefs, perceptions, and concerns, were most commonly cited (15). Although no rationale was given for these common factors, the authors do provide insights in the rationales for each individual patient group. The common trend appears to be that patients weigh perceived benefits of the medication (symptomatic relief, prevention of symptoms/disease, prevention of disease progression) and their concerns (potential side effects, tolerability of side effects) in the decision to adhere to the prescribed regimen or not. These perceptions are in turn influenced by the healthcare provider through information and counselling, underscoring the importance of the role of the healthcare provider regarding patient adherence behavior.

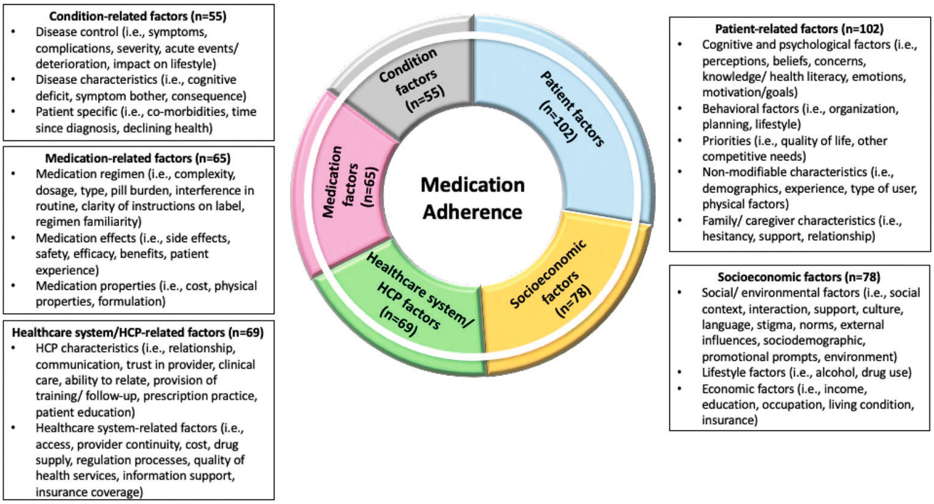


Figure 1 A conceptual model for factors contributing to medication adherence based on a systematic review of 102 conceptual frameworks. Abbreviations: healthcare provider (HCP). Source: Peh et al. (2021)

The Perceptions and Practicalities Approach (PaPA) similarly centers the patient related factors motivation and ability as core concepts of medication adherence (16). The model describes how motivation is influenced by perceptions and intentional processes, while ability is influenced by unintentional processes and practicalities. Internal or external triggers then prompt the intentional and unintentional processes, with opportunity doing the same for perceptions and practicalities. By addressing patients' perceptions regarding the treatment and supporting the patient with the practical considerations related to adhering to the treatment, this approach aims to support adherence by affecting its essential attributes. Therefore, the authors recommend that interventions aimed at improving medication adherence should not only have a strong theoretical basis, but also consider which patients benefit most from the intervention, consider perceptual and practical barriers to adherence, tailor the intervention to an individual's needs, and optimize the content, context, and channel of delivery (17). Building upon these recommendations, future research focusing on adherence to HBE recommendations should integrate these suggestions with the e-Exercise LBP design. Specifically, it should include evaluation of a patient's suitability for blended treatment (18), consider patient preferences in choosing the most suitable delivery method for the intervention's content, and continuous assessment of patient perceptions of the treatment.

From medication models to adherence to HBE

The common denominator between the models from pharmacology are the perceptions of the patient. Perceived susceptibility, severity, barriers, benefits, and concerns seem to be the core of patient motivation for adherence behavior. These perceptions reflect the constant weighing of the perceived necessity or expected costs and benefits of being adherent by the patient before deciding on their actual behavior. However, the impact of these components on adherence behaviors likely varies significantly among individuals, over time, and between treatments (19). For example, while reduced pain and disability following HBE might motivate one patient to continue their regimen, another patient might perceive the exercises as no longer necessary upon experiencing pain relief and opt to discontinue them. Similarly, increased pain could lead some patients to stop their HBE exercise program, while others might intensify their efforts in an attempt to increase the effectiveness of the HBE program.

Furthermore, external factors such as social support, available time for HBE, or real-life events are often impossible to predict by both the patient and therapist, yet significantly impact adherence. Circumstances like illness, caring for a sick family member, work-related events, and other similar occurrences can lead to temporary or more prolonged changes in a patient's adherence behavior. These unaccounted factors and the individual variation in perceived costs and benefits of adherence might explain the lack of association between adherence and changes in physical function, pain, or recovery from LBP as discussed in chapter 7. Lastly, the role of physiotherapists in influencing patient perceptions of their treatment, including its benefits and costs, cannot be overstated. For example, if physiotherapists fail to effectively communicate the importance of exercise in recovering from LBP (resulting in patients perceiving the benefits as minimal) or if they recommend an impractical HBE regimen (making perceived costs high), patients are less likely to exhibit the expected adherence behavior. Thus, it seems essential that the approach to encouraging adherence is personalized, taking into account each patient's unique perceptions, needs, and context. This requires physiotherapists to possess not only extensive knowledge on the clinical management of LBP, but also the communication skills necessary to adequately support their patients perceptions.

Measuring adherence behavior needs further refinement

The literature reveals that a diverse range of approaches is employed to measure adherence, including methods such as questionnaires, diaries, tally counters, and tracking the number of visits to the practice. However, many of these methods lack robust psychometric testing and/or suffer from poor conceptual foundations (20–22). The majority of these instruments are unidimensional, focusing solely on one aspect of adherence such as for example the number of completed exercise sessions, or they lack detail, measuring only frequency and intensity of patients' adherence behavior. A combination of different components for measuring adherence, such as therapist reporting, patient reporting, and observational components, might yield a more accurate reflection of the patient's adherence behavior (23).

To address this gap, we developed the EXAS (chapter 2), which collects information on adherence to frequency, intensity, and quality of performance recommendations. We assessed the construct validity and test-retest reliability of this new instrument (24). However, the EXAS shares some limitations common to other patient-reported measures of adherence, such as the potential for reporting bias (20) and the administrative burden. Although including quality of performance in the assessment of patient adherence is one of the strengths of the EXAS, it is also a limitation. There is currently no consensus on how to incorporate quality of performance in the measurement of adherence, so we had to determine this ourselves based on clinical experience and expert opinion. As a result, it is possible that the EXAS underestimates patient adherence. Another possible limitation could be the way the EXAS attributes therapist-determined factors of the HBE program, such as the number of exercises, recommended sets and repetitions, and exercise type, to the patient when assessing adherence behavior. For example, if a physiotherapist prescribes an impractically large number of exercises, resulting in the patient's inability to complete the HBE program as recommended, the EXAS may rate the patient's adherence as low, despite the patient's best efforts. Nevertheless, the EXAS is currently one of the best instruments available for the measurement of adherence to HBE, which is why we used it in conjunction with the Exercise Adherence Rating Scale (EARS) (25), a 3-month recall measure of adherence, to gain deeper insights into patient adherence during and after treatment (chapter 5).

For a more effective measurement of adherence and its impact on the management of patients with LBP, several amendments are advisable for the EXAS. Firstly, to reduce reporting bias, a revision of the EXAS wording is recommended, encouraging patients to report nonadherence rather than adherence. This change is supported by recent findings suggesting that reports of nonadherence tend to be more reliable than those of adherence (17).

Secondly, an additional component that enables the collection of data on reasons for non-adherence should be added to each EXAS measurement. This addition would facilitate a better understanding of the factors influencing each patient's adherence behavior and more effectively explain variations in adherence. It would also allow physiotherapists to determine perceived barriers negatively impacting patient adherence, enabling timely adjustments during treatment.

Thirdly, further research is needed to understand the best method for integrating the quality of exercise performance into adherence measurement. This includes evaluating whether modifying the EXAS is the most effective strategy or if developing a new measurement tool would be preferable.

Lastly, creating uniform standards for interpreting adherence measurements is paramount and represents a crucial next step. The current diversity in measurement tools, scales, and scores (20,21) makes it challenging to clearly define what constitutes high or low, or when adherence is sufficient. Specifically for the EXAS, setting a threshold for adherence leads to an arbitrary judgment value, which could result in two patients with only minor differences in their adherence scores being classified differently, one as adherent and the other not.

Improving adherence behavior of patients with LBP using e-Exercise LBP

Evaluating e-Exercise LBP in relation to adherence

During the development of the e-Exercise LBP intervention, one of our objectives was to create a tool that facilitates personalized care to support and maintain patient adherence during and after treatment (26). Drawing from experiences with e-Exercise Osteoarthritis, we integrated various behavioral change techniques (BCT's) and persuasive design elements into the intervention (27–29). For example, to support and enhance the understanding and execution of the HBE regimen, the app complements the physiotherapist's instructions and practical sessions with video and written instructions for the exercises. In doing so, we aimed to minimize patients' uncertainty and doubts about how to perform the exercises correctly. Additionally, the physiotherapist sets exercise goals together with the patient, and the app supports these goals through customizable reminders and feedback through push notifications and messages. The pilot test of the intervention with patients with LBP indicated positive results (27). Our expectations regarding the efficacy of the intervention for improving adherence behavior were further strengthened by a review showing that interventions that implemented BCT's showed significantly higher adherence in the treatment group in patients with musculoskeletal complaints (30). More specifically, implementing social support, goal setting, instruction of behavior, demonstration of behavior, and behavior practice/rehearsal were most supported by the evidence. Despite the careful development of the e-Exercise LBP intervention, we observed no to minor effects of the intervention on the outcomes (31). Based on our experiences, we identified potential improvements for the intervention.

Improvements for e-Exercise LBP

There are several areas where the e-Exercise LBP program could be further improved. Firstly, the training provided to physiotherapists should be expanded to include more comprehensive theory on adherence concepts, the importance of understanding patient perceptions regarding costs and benefits of adhering to HBE recommendations and enhanced communication skills (32). This knowledge is crucial for understanding and addressing the perceived and practical barriers that patients might face with adherence to HBE. Furthermore, the same skills and knowledge can be used by the physiotherapist to tailor not only treatment, but also the mode of delivery of the treatment to each individual patient's needs. Using the e-Exercise LBP app itself might not be the optimal solution for every patient. Some patients might prefer paper handouts of the information and exercises provided through the app or prefer using a website instead. To this end, another improvement could involve utilizing tools such as the Dutch Blended Physiotherapy Checklist (18) to screen patients for their suitability for blended care interventions, ensuring that each patient receives the most appropriate form of intervention. Another improvement would be to incorporate statistics on app use by the patient in the online dashboard of the physiotherapist to allow the therapist to coach the patient in its use. Similar to HBE, the effectiveness of the e-Exercise LBP app depends on patient adherence and improving use of the app by patients might be an opportunity for improvement.

Lastly, a consideration should be made regarding which patients are most likely to benefit from the intervention or specific parts of the intervention (17). In the current design of the e-Exercise LBP intervention, the content of the app is based on the patient's risk for chronic complaints (26), which means that adherent patients receive the same support as non-adherent patients. Reducing support through the app in adherent patients and increasing support for non-adherent patients could result in more effective use of resources.

Future directions

Research methodologies to study exercise adherence

To increase our understanding of adherence among patients with LBP, it is crucial to adopt research designs that can accommodate the wide range of individual differences among patients, as well as variations in the length, composition, and setting of treatments. The RCT design has received criticism as the golden standard for the design of intervention studies for physiotherapy (33). While RCTs are appropriate for identifying the average effects of treatments across populations, applying these results to individual cases in clinical practice is challenging, including for individuals who participated in the trial (33). An RCT provides the average effect of a treatment across a group, but this average does not guarantee the same level of effectiveness for each individual receiving the treatment. This suggests that if a RCT shows an effect size close to zero, the treatment being studied may be considered ineffective overall. Instead, it could also imply that the individuals who actually experienced benefits from the intervention might not have been adequately represented in the trial.

We will now explore two methodologies that could enhance physiotherapy research broadly and specifically improve our understanding of adherence in patients LBP. The first is the interrupted time series design (ITS) (34). The ITS design is a quasi-experimental approach used to measure outcomes at various points before, during, and after an intervention within a patient group. This approach enables a detailed comparison of changes in outcomes over time, allowing researchers to assess the effectiveness of an intervention by examining shifts in trends and levels of the outcomes of interest before and after its implementation. The ITS design is particularly well-suited for examining how healthcare interventions are implemented within specific settings. Furthermore, due to the collection of multiple different outcomes at multiple points prior to, during, and after implementation of a new intervention, this design also allows researchers to study temporal changes in (clinical) outcome and the associations between outcomes and their changes. For example, the ITS design would allow study of the relationship between changes in pain or disability over time and adherence trajectories over time. An advantage of the ITS design for use in physiotherapy research is its ability to utilize outcome measures from routine care in the analysis, significantly reducing the administrative and resource burdens associated with conducting such studies. The ITS design also has its limitations. For instance, the ITS design requires multiple measurements within each period to ensure reliability, typically three or more, leading to increased data collection efforts. Additionally, determining the adequate sample size remains a challenge, introducing uncertainty in the study's statistical power and conclusions. Analyzing data from an ITS study necessitates specialized statistical techniques, expertise, and software, which might not be readily accessible to all researchers. This requirement can pose significant challenges in effectively conducting and interpreting ITS analyses (34). Lastly, the analyses of data collected using the ITS design involves comparing group level trends and changes in outcomes, reducing its viability when individual change is of interest.

The second research design that might be more appropriate for physiotherapy research are the single case experimental designs (SCEDs), which are "the prospective, intensive, and experimental study of an individual who serves as his or her own control" (35). SCEDs, being experimental, generate quantitative data, distinguishing them significantly from case reports, which are qualitative in nature. This distinction highlights the strength of SCEDs in yielding specific, data-driven insights into how individual patients respond to various treatments, enabling a deeper understanding of the efficacy of therapeutic interventions. Furthermore, SCEDs enable the examination of how individual variability changes over time on different outcomes or factors, as well as the exploration of the relationships between these variations. Several types of SCEDs exist, such as the withdrawal/reversal design, changing criterion design, or multiple-baseline design), and are designed to determine a causal relationship between an intervention and clinical outcomes (36). The multiple-baseline design appears to be the most suited for physiotherapy research, due to its stronger internal validity, and its ability to adjust for unknown effect duration and carry-over times of treatments (36). This is especially important when a washout effect of the intervention is undesirable, for instance when studying interventions designed to reduce pain or disability in patients. Limitations of the design are that missing data can be problematic and attrition can threaten interpretation of the results. Furthermore, the multiple-baseline design requires three to five participants to start the study concurrently, which can be a logistical issue (36). Similarly to the ITS design, the proper use of research methods and statistical analysis can be challenging due to the unfamiliarity of researchers with these designs. However, using the Single-Case Reporting Guideline in Behavioral Interventions (SCRIBE) Checklist provides a way to standardize the design, analysis, and reporting of multiple-baseline design studies (37).

Technology to improve and support adherence in clinical practice

In addition to refining existing interventions and methodological approaches in research and clinical practice, new technological advances such as gamification or generative artificial intelligence (AI) might offer substantial benefits in improving adherence to HBE recommendations. Gamification, which is the incorporation of gaming elements in a non-gaming environment, has already shown promise in musculoskeletal rehabilitation and LBP by improving motivation and exercise adherence (38). Similarly, an AI-assisted interactive health promotion system has demonstrated effectiveness in managing neck/shoulder stiffness/pain and low back pain (39). However, the use of AI in healthcare is only a recent development and new ways to leverage its advantages are discovered daily (40). For instance, generative AI might assist patients with instant responses to any questions or concerns they might have by being able to chat with AI bots specifically trained on guidelines and other verified sources of information. Another possibility could be that patients can ask a generative AI to provide alternatives for exercises or receive real-time feedback and encouragement when exercising, such as using the TRAK© telerehabilitation tool (41). These possibilities indicate a future where generative AI and other technologies could significantly transform physiotherapy treatments and the support tools available for patients with LBP.

Clinical practice and education

Our findings underscore the challenges for clinicians in the support of adherence behavior of their patients. Despite technological advances and the willingness of patients to incorporate digital health applications into their treatment (42), physiotherapists are still seen as instrumental for the success of treatment by their patients. To effectively use these digital solutions physiotherapists require specific skills, such as technical skills (both for using the technologies, but also to support patients when they experience issues), communication skills (to gain a deeper understanding of patient perceptions and practicalities regarding their complaints, treatment, and adherence behavior), and coaching skills (to increase patient engagement and support adherence). Physiotherapy education should evolve to include training on these digital health interventions, emphasizing the development of communication skills to effectively convey the benefits and of HBE for their patients and assist patients with finding solutions for their practical barriers. Educators should also focus on fostering an understanding of behavior change techniques and the use of data-driven insights to support patient adherence. This approach not only prepares future physiotherapists to leverage technology in treatment but also equips them with the skills to address the multifaceted nature of patient adherence, and hopefully ultimately leading to improved outcomes in LBP treatment.

Conclusion

In this thesis we showed the multifaceted nature of adherence to HBE in the management of patients with LBP, underscoring the pivotal role of physiotherapists and the potential of digital tools in enhancing patient adherence and outcomes. Our exploration into the complexities of adherence, the development and refinement of measurement instruments, and the integration of technology into physiotherapy treatment offers valuable insights and directions for future research and clinical practice. As we move forward, a deeper understanding of patient adherence behaviors and embracing personalized, technology-supported interventions will be crucial in advancing the efficacy of treatment for patients with LBP.

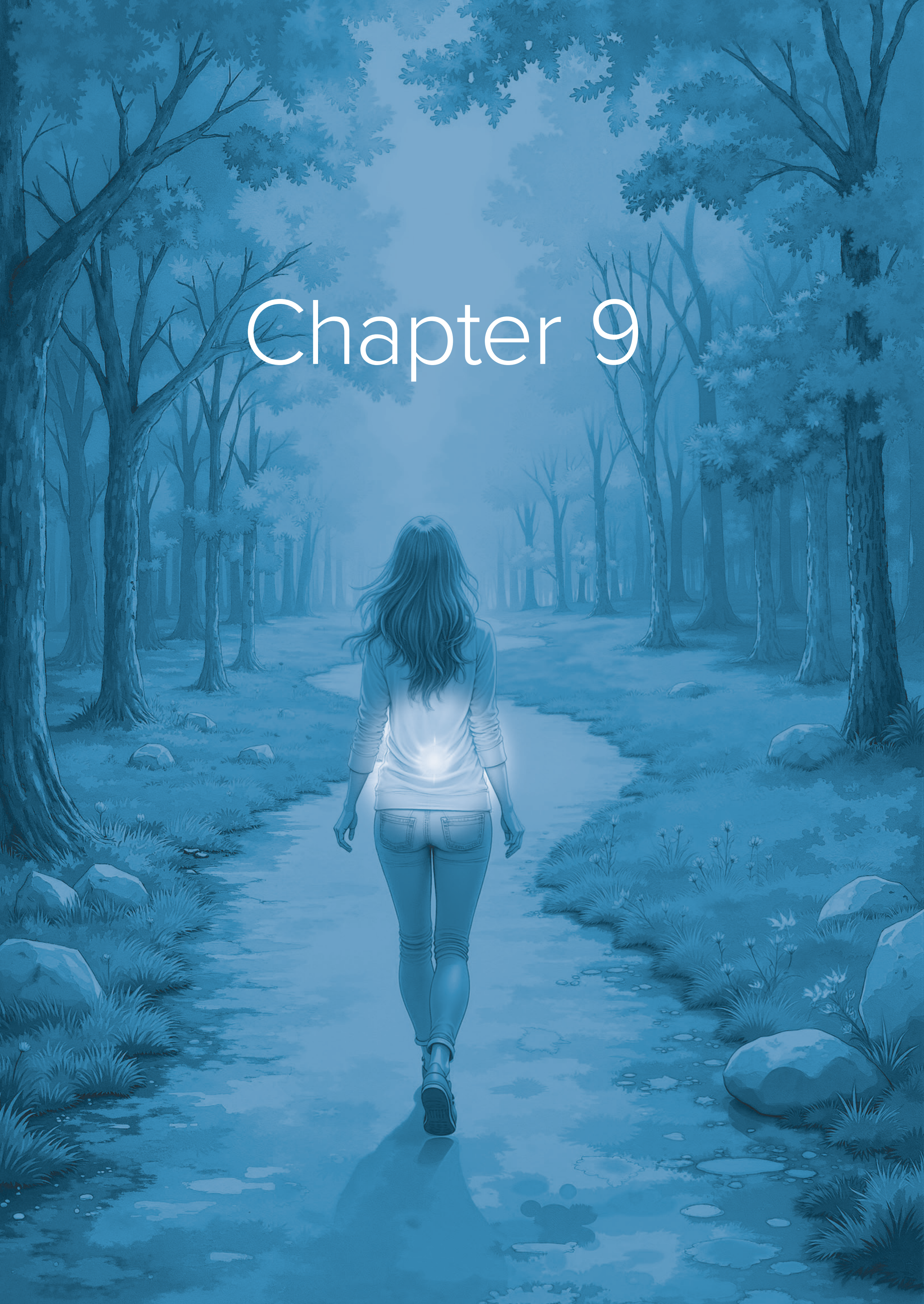
REFERENCES

1. Koppenaal T. e-Exercise Low Back Pain Stratified blended physiotherapy for patients with nonspecific low back pain [dissertation]. [Utrecht]: Utrecht University; 2023.
2. Jack K, McLean SM, Moffett JK, Gardiner E. Barriers to treatment adherence in physiotherapy outpatient clinics: A systematic review. Man Ther. 2010 Jun;15(3):220–8.
3. Bachmann C, Oesch P, Bachmann S. Recommendations for Improving Adherence to Home-Based Exercise: A Systematic Review. Phys Medizin Rehabilitationsmedizin Kurortmedizin. 2018;28:20–31.
4. Essery R, Geraghty AWAA, Kirby S, Yardley L. Predictors of adherence to home-based physical therapies: a systematic review. Disabil Rehabil. 2017;39(6):519–34.
5. Medina-Mirapeix F, Escolar-Reina P, Gascón-Cánovas J, Montilla-Herrador J, Collins S. Personal characteristics influencing patients' adherence to home exercise during chronic pain: A qualitative study. J Rehabil Med. 2009;41(5):347–52.
6. Areerak K, Waongenngarm P, Janwantanakul P. Factors associated with exercise adherence to prevent or treat neck and low back pain: A systematic review. Musculoskelet Sci Pract. 2021 Apr 1;52:102333.
7. Shahidi Id B, Padwal Id J, Lee E, Xu R, Northway S, Taitanoid L, et al. Factors impacting adherence to an exercise-based physical therapy program for individuals with low back pain. PLoS One. 2022;17(10):e0276326.
8. Saner J, Bergman EM, de Bie R, Sieben JM. Low back pain patients' perspectives on long-term adherence to home-based exercise programmes in physiotherapy. Musculoskelet Sci Pract. 2018;38:77–82.
9. Beinart NA, Goodchild CE, Weinman JA, Ayis S, Godfrey EL. Individual and intervention-related factors associated with adherence to home exercise in chronic low back pain: A systematic review. Spine J. 2013;13(12):1940–50.
10. Gianola S, Bargeri S, Del Castillo G, Corbetta D, Turolla A, Andreano A, et al. Effectiveness of treatments for acute and subacute mechanical non-specific low back pain: a systematic review with network meta-analysis. Br J Sports Med. 2022;56(1):40–51.
11. Hayden JA, Ellis J, Ogilvie R, Malmivaara A, van Tulder MW. Exercise therapy for chronic low back pain. Cochrane Database Syst Rev. 2021;2021(9).
12. van Koppen B, Zandwijk P, de Vries J, van Mameren H, de Bie R. Adherence to home-based exercises and/or activity advice in low back pain patients: a systematic review. Eur J Physiother. 2022;24(4):227–42.
13. Horne R. Adherence to Medication: A Review of Existing Research. In: Myers L, Midence K, editors. Adherence to Treatment in Medical Conditions. 1st Ed. CDC Press; 1998.
14. Sabaté E. Adherence to long-term therapies: Evidence for action. Sabaté E, editor. Eur J Cardiovasc Nurs. Geneva; 2003.
15. Peh KQE, Kwan YH, Goh H, Ramchandani H, Phang JK, Lim ZY, et al. An Adaptable Framework for Factors Contributing to Medication Adherence: Results from a Systematic Review of 102 Conceptual Frameworks. J Gen Intern Med. 2021;36(9):2784–95.

16. Horne R, Cooper V, Wileman V, Chan A. Supporting Adherence to Medicines for Long-Term Conditions: A Perceptions and Practicalities Approach Based on an Extended Common-Sense Model. Eur Psychol. 2019;24(1):82–96.
17. Stewart SJF, Moon Z, Horne R. Medication nonadherence: health impact, prevalence, correlates and interventions. Psychol Health. 2023;38(6):726–65.
18. Kloek CJJ, Janssen J, Veenhof C. Development of a Checklist to Assist Physiotherapists in Determination of Patients' Suitability for a Blended Treatment. Telemed e-Health. 2020;26(8):1051–65.
19. Horne R, Weinman J, Barber N, Elliott RA, Morgan M, Cribb A, et al. Concordance, adherence and compliance in medicine taking. Report for National Co-ordinating Centre for NHS Service Delivery and Organisation. 2005.
20. Bollen JC, Dean SG, Siegert RJ, Howe TE, Goodwin VA. A systematic review of measures of self-reported adherence to unsupervised home-based rehabilitation exercise programmes, and their psychometric properties. BMJ Open. 2014;4(6):e005044.
21. Frost R, Levati S, McClurg D, Brady M, Williams B. What Adherence Measures Should Be Used in Trials of Home-Based Rehabilitation Interventions? A Systematic Review of the Validity, Reliability, and Acceptability of Measures. Arch Phys Med Rehabil. 2017;98(6):1241-1256.e45.
22. McLean S, Holden MA, Potia T, Gee M, Mallett R, Bhanbhro S, et al. Quality and acceptability of measures of exercise adherence in musculoskeletal settings: A systematic review. Rheumatology. 2017;56(3):426–38.
23. Peek K, Carey M, Mackenzie L, Sanson-Fisher R. Patient adherence to an exercise program for chronic low back pain measured by patient-report, physiotherapist-perception and observational data. Physiother Theory Pract. 2019;35(12):1304–13.
24. Arensman RM, Geelen RH, Koppenaal T, Veenhof C, Pisters MF. Measuring exercise adherence in patients with low back pain: development, validity, and reliability of the EXercise Adherence Scale (EXAS). Physiother Theory Pract. 2022;38(7):928–37.
25. Newman-Beinart NA, Norton S, Dowling D, Gavriloff D, Vari C, Weinman JA, et al. The development and initial psychometric evaluation of a measure assessing adherence to prescribed exercise: the Exercise Adherence Rating Scale (EARS). Physiotherapy. 2017;103(2):180–5.
26. Koppenaal T, Arensman RM, Van Dongen JM, Ostelo RWJG, Veenhof C, Kloek CJJ, et al. Effectiveness and cost-effectiveness of stratified blended physiotherapy in patients with non-specific low back pain: Study protocol of a cluster randomized controlled trial. BMC Musculoskelet Disord. 2020;21(1):1–13.
27. Kloek CJJ, van Tilburg ML, Staal JB, Veenhof C, Bossen D. Development and proof of concept of a blended physiotherapeutic intervention for patients with non-specific low back pain. Physiotherapy. 2019;105(4):483–91.
28. Kloek CJJ, Bossen D, Spreeuwenberg PM, Dekker J, De Bakker DH, Veenhof C. Effectiveness of a Blended Physical Therapist Intervention in People With Hip Osteoarthritis, Knee Osteoarthritis, or Both: A Cluster-Randomized Controlled Trial. Phys Ther. 2018;98(7):560-70.

29. Asbjørnsen RA, Smedsrød ML, Nes LS, Wentzel J, Varsi C, Hjelmesæth J, et al. Persuasive system design principles and behavior change techniques to stimulate motivation and adherence in electronic health interventions to support weight loss maintenance: Scoping review. J Med Internet Res. 2019 Jun 1;21(6):e14265.
30. Wiley J, Meade LB, Bearne LM, Sweeney LH, Alageel SH, Godfrey EL. Behaviour change techniques associated with adherence to prescribed exercise in patients with persistent musculoskeletal pain: Systematic review. Br J Health Psychol. 2019;24:10–30.
31. Koppenaal T, Pisters MF, Kloek CJJ, Arensman RM, Ostelo RWJG, Veenhof C. The 3-Month Effectiveness of a Stratified Blended Physiotherapy Intervention in Patients With Nonspecific Low Back Pain: Cluster Randomized Controlled Trial. J Med Internet Res. 2022;24(2).
32. McLeod G, Morgan E, McMillan S, McCahon S, Sanna N. Why Are Patients Not Doing Their Prescribed Home-Based Exercises? An Updated Review of the Factors Affecting Adherence to Prescribed Home-Based Exercise in Patients With Chronic Low Back Pain. Home Health Care Manag Pract. 2023;35(2):114–22.
33. Deaton A, Cartwright N. Understanding and misunderstanding randomized controlled trials. Soc Sci Med. 2018 Aug 1;210:2–21.
34. Ewusie JE, Soobiah C, Blondal E, Beyene J, Thabane L, Hamid JS. Methods, applications and challenges in the analysis of interrupted time series data: A scoping review. J Multidiscip Healthc. 2020;13:411–23.
35. Tate RL, Perdices M. Research Note: Single-case experimental designs. J Physiother. 2020;66(3):202–6.
36. Nikles J, Evans K, Hams A, Sterling M. A systematic review of N-of-1 trials and single case experimental designs in physiotherapy for musculoskeletal conditions. Musculoskelet Sci Pract. 2022;62:102639.
37. Tate RL, Perdices M, Rosenkoetter U, Shadish W, Vohra S, Barlow DH, et al. The Single-Case Reporting Guideline in BEhavioural Interventions (SCRIBE) 2016 statement. Can J Occup Ther. 2016;83(3):184–95.
38. Alfieri FM, da Silva Dias C, de Oliveira NC, Battistella LR. Gamification in Musculoskeletal Rehabilitation. Curr Rev Musculoskelet Med. 2022;15(6):629–36.
39. Anan T, Kajiki S, Oka H, Fujii T, Kawamata K, Mori K, et al. Effects of an artificial intelligence-assisted health program on workers with neck/shoulder pain/stiffness and low back pain: Randomized controlled trial. JMIR Mhealth Uhealth. 2021;9(9):e27535.
40. Leveraging Generative CA, Yu P, Xu H, Hu X, Deng C. Leveraging Generative AI and Large Language Models: A Comprehensive Roadmap for Healthcare Integration. Healthc. 2023;11:2776.
41. TRAK HEALTH SOLUTIONS SL. TRAK [Internet]. 2024 [cited 2024 Feb 11]. Available from: https://www.trakphysio.com/en/
42. Arensman R, Kloek C, Pisters M, Koppenaal T, Ostelo R, Veenhof C. Patient perspectives on using a smartphone application to support home-based exercise during physical therapy treatment: a qualitative study. JMIR Hum Factors. 2022;9(3):e35316.

Chapter 9



Summary

Low back pain (LBP) is a musculoskeletal condition affecting a significant portion of the adult population globally, leading to substantial disability and economic burden. Clinical guidelines advocate the biopsychosocial model as the basis of LBP management and emphasize patient education, self-management, and interventions centered around physical activity and exercise to promote pain relief and physical well-being.

Exercise therapy has been shown to be effective for the management of LBP, but it's effectiveness varies considerably between patients. Exercise therapy can be delivered face-to-face in clinics, but this is associated with significant costs in time and resources. Therefore, face-to-face physiotherapy is often combined with home-based exercise (HBE) recommendations to increase treatment dosage without increasing treatment costs. However, the effectiveness of these treatments rely on patient adherence, which has shown to be lacking. Despite the recognized importance of adherence to HBE recommendations for positive clinical outcomes, measuring adherence accurately remains challenging, limiting our understanding of its impact on clinical outcomes.

The existing literature highlights the potential of digital health technologies, such as smartphone apps, to support adherence to HBE when integrated with existing physiotherapy methods. These blended care treatments aim to enhance engagement, adherence to therapeutic exercises, and overall self-management capabilities of patients. Based on this, we developed the e-Exercise LBP intervention, a novel approach combining an app with traditional face-to-face physiotherapy. The intervention is designed to match the content of the treatment with the patients' risk for persistent LBP. The app includes self-management themes, a tailored HBE program, and a goal-oriented physical activity module, aiming to support the patient's activity level and adherence.

However, adherence to HBE is complex construct and enhancing our understanding of it could enable clinicians better support their patients, potentially improving treatment outcomes. Therefore, the general aim of this thesis was to develop a new tool to measure adherence to HBE recommendations and use it to investigate adherence and its associations with clinical outcomes and recovery from LBP. Furthermore, we aimed to evaluate the results of the e-Exercise LBP intervention in patients with LBP and investigate patient perspectives regarding the use of a smartphone app as part of treatment.

Chapter 2 describes the development, validity testing, and reliability assessment of the Exercise Adherence Scale (EXAS), an instrument designed to measure adherence to HBE for patients with LBP. The EXAS evaluates patient adherence to frequency, intensity, and quality of performance recommendations by physiotherapists. Validity of the EXAS was supported by moderate correlations with lack of time (rho = 0.47) and lack of motivation (rho = 0.48) to exercise, indicating convergent validity, while low correlations with pain (rho = 0.005) and disability (rho = 0.24) confirmed its divergent validity. The instrument demonstrated excellent intrarater reliability (Kappa quadratic weights = 0.87) for the quality of performance score, though interrater reliability was significantly lower (Kappa quadratic weights = 0.36), suggesting poor agreement across different raters. The newly developed EXAS allowed us to investigate patient adherence to HBE recommendations during treatment in the e-Exercise LBP trial.

Chapter 3 investigates the patient's perspectives on the use of a smartphone app to support HBE during physiotherapy for LBP. Through qualitative interviews with nine participants, the study explored themes of acceptability, satisfaction, and performance. Our findings indicate that patients are willing to accept the app as part of their treatment, particularly valuing its ease of use, integration into daily routines, and the benefits it provides. Satisfaction with the app is primarily influenced by its perceived support in facilitating exercise adherence and enhancing exercise performance at home. Important features of the app that contribute to its effective performance include video and text instructions, reminder functions, and self-monitoring capabilities. However, the study also highlights the important role of physiotherapists in instructing patients on how to optimally utilize the app, underlining the app's role as a complement to, rather than a replacement for, physiotherapy intervention.

Chapter 4 introduces the methodology for a cluster randomized controlled trial aiming to evaluate the effectiveness and cost-effectiveness of the e-Exercise LBP intervention against usual physiotherapy care for patients with LBP. E-Exercise LBP combines face-to-face physiotherapy with support from a smartphone app to enhance self-management, adherence to HBE recommendations, and overall physical activity levels in patients with LBP. This innovative blended care intervention is hypothesized to not only improve short-term physical functioning but also to demonstrate sustained benefits and cost-effectiveness after 12 and 24 months. The aim was to include 208 patients with LBP to compare outcomes such as physical functioning, pain intensity, exercise adherence, self-efficacy, and health-related quality of life across these timelines. Measurements were scheduled at baseline, 3, 12, and 24 months, with additional economic evaluation from the societal and healthcare perspectives through retrospective self-reported questionnaires every 3 months. Although the trial was designed to investigate the short term and long term (cost-)effectiveness, we focused on the short term (3-month) effectiveness on physical functioning (chapter 5), with a particular focus on the role of adherence to HBE recommendations in patient recovery (chapter 6 and 7).

Chapter 5 presents the evaluation of the short-term (3 months) effectiveness of the e-Exercise LBP intervention in comparison to face-to-face physiotherapy for patients LBP. Our analysis revealed that while both the e-Exercise LBP and face-to-face physiotherapy groups showed statistically significant and clinically meaningful improvements in physical functioning, no significant superiority was found for the (cost)effectiveness of e-Exercise LBP. Nonetheless, benefits of e-Exercise LBP were observed in secondary outcomes; it significantly improved patients' fear-avoidance beliefs and self-reported adherence to HBE. Particularly, among patients with a high-risk for developing persistent LBP, e-Exercise LBP demonstrated statistically significant better outcomes in physical functioning and several secondary measures when compared to the control group. These findings suggest that certain subgroups of patients with LBP benefit more from e-Exercise LBP than others and warrants further investigation.

Chapter 6 investigates trajectories of adherence to HBE in patients with LBP and explores if baseline characteristics are related to these trajectories utilizing data from the e-Exercise LBP trial. Adherence was measured using the EXAS (chapter 2) and data were available from 173 participants. Through latent class growth analysis, three adherence trajectories were identified: "declining adherence" (12%), characterized by a decrease in adherence over time; "stable adherence" (45%), where adherence levels remained constant; and "increasing adherence" (43%), showing an increase in adherence over time. Surprisingly, no significant differences in baseline characteristics were observed among these groups, indicating that initial patient characteristics are not related to adherence trajectories. These findings underscore the complexity of adherence behavior in patients with LBP, highlighting that physiotherapists should monitor and support adherence throughout the treatment process rather than attempting to categorize patients into specific adherence groups at the onset of treatment.

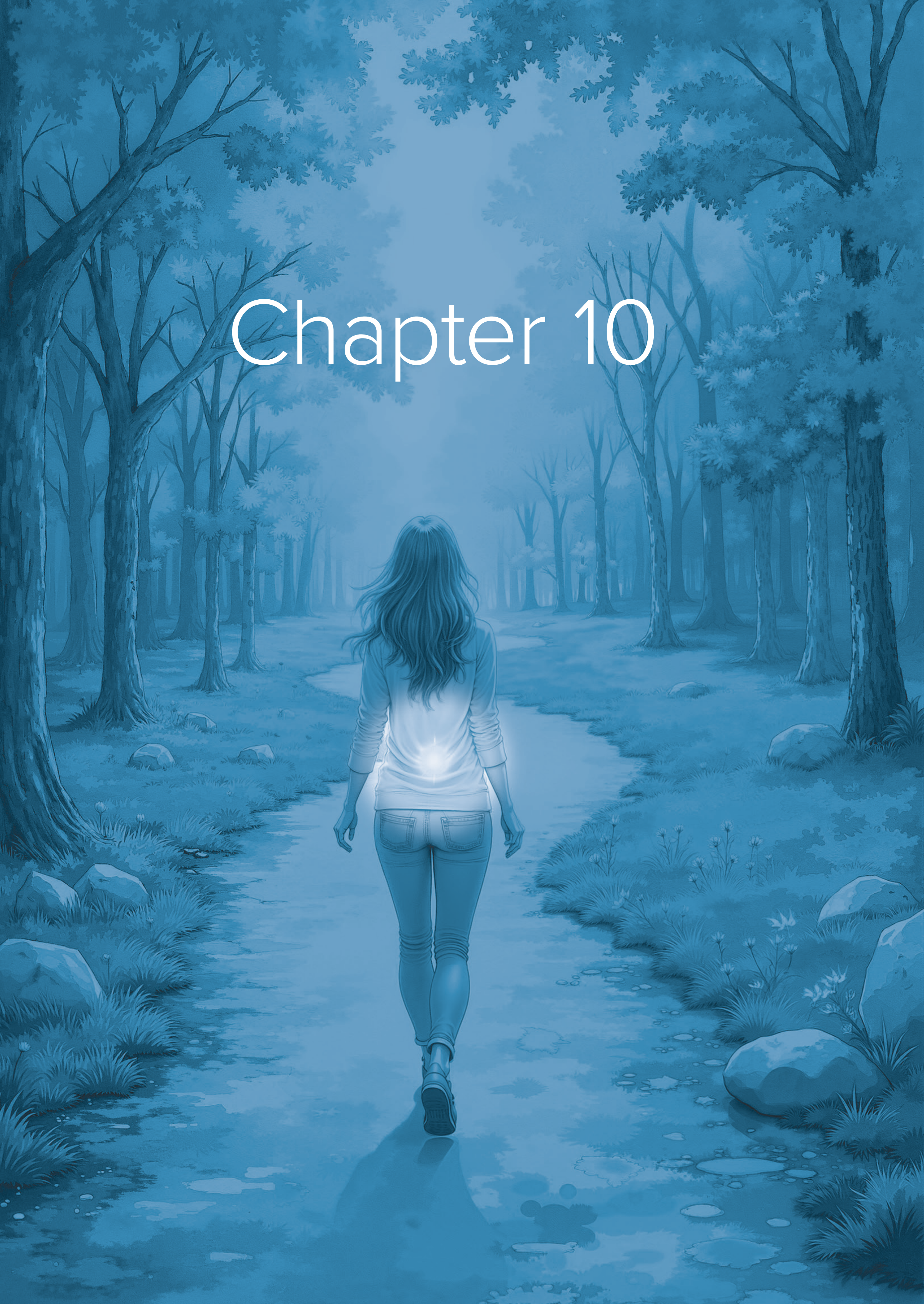
Chapter 7, explores the associations between adherence to HBE recommendations and changes in clinical outcomes in patients with LBP. Utilizing data from the same participants as described in chapter 6, the analysis also included previously established adherence trajectories ("declining," "stable," and "increasing" adherence), representing 12%, 45%, and 43% of the study population, respectively. Despite 28.5% of patients reporting recovery from LBP, analysis revealed no significant correlation between adherence levels and improvements in physical functioning or pain intensity. This absence of an association suggests a complex relationship between adherence to HBE recommendations and LBP recovery, underscoring the necessity for further exploration incorporating both longitudinal data and qualitative research into how adherence to HBE recommendations impacts clinical outcomes.

Chapter 8 presents the discussion on the study of adherence to HBE recommendations in patients with LBP as part of the e-Exercise LBP project. The role of physiotherapists in guiding patient adherence, the development and validation of a new adherence measurement instrument, and the exploration of the complex construct of adherence and its impact on treatment outcomes are emphasized. The research shows several

important results, including the development of the EXAS which showed good validity and reliability for adherence measurement, the acceptance and value of the smartphone app by patients for supporting HBE, and the identification of distinct adherence trajectories among patients. Surprisingly, no significant association was found between adherence trajectories and improvements in physical functioning or pain intensity, challenging previous assumptions about the straightforward relationship between exercise adherence and recovery from LBP. The stratified blended physiotherapy intervention, while not outperforming traditional physiotherapy in improving physical function, was effective in reducing fear-avoidance beliefs and enhancing self-reported adherence, particularly in patients with high risk for persistent LBP. Despite the rigorous design, the study acknowledged the complexity of properly measuring adherence and the potential for varied interpretations of adherence data. Further refinement of the EXAS and specialized research designs combining quantitative data collection with qualitative methods are recommended as the next steps.

The findings have significant implications for clinical practice, suggesting a need for personalized, technology-supported interventions to enhance adherence. The research underscores the important role of physiotherapists in motivating and supporting patients through tailored treatments. Future research should focus on personalized treatment incorporation technological advances such as gamification and Artificial Intelligence to ensure that patients receive the care that is best for them.

Chapter 10



Samenvatting

Lage rugpijn (LRP) is een musculoskeletale aandoening die een aanzienlijk deel van de volwassen bevolking wereldwijd treft en leidt tot aanzienlijke invaliditeit en economische lasten. Klinische richtlijnen bevelen het biopsychosociale model aan als basis voor het beheer van LRP en benadrukken patiënteducatie, zelfmanagement en interventies gericht op fysieke activiteit en oefeningen ter bevordering van pijnverlichting en fysiek welzijn.

Oefentherapie is effectief gebleken voor het behandelen van LRP, maar de effectiviteit ervan varieert aanzienlijk tussen patiënten. Oefentherapie kan face-to-face in klinieken worden geleverd, maar dit gaat gepaard met aanzienlijke kosten in tijd en middelen. Daarom wordt face-to-face fysiotherapie vaak gecombineerd met thuisoefenprogramma's (TOP) om de behandeldosis te verhogen zonder de kosten te verhogen. Echter, de effectiviteit van deze behandelingen is afhankelijk van de therapietrouw van de patiënt, die vaak tekortschiet. Ondanks het erkende belang van therapietrouw aan TOP-aanbevelingen voor positieve klinische resultaten, blijft het nauwkeurig meten van therapietrouw een uitdaging, wat ons begrip van de impact op klinische resultaten beperkt.

De bestaande literatuur benadrukt het potentieel van digitale gezondheidstechnologieën, zoals smartphone-apps, om de therapietrouw aan TOP te ondersteunen wanneer deze worden geïntegreerd met bestaande fysiotherapiemethoden. Deze gecombineerde zorgbehandelingen zijn bedoeld om de betrokkenheid, de therapietrouw aan therapeutische oefeningen en de algemene zelfmanagementcapaciteiten van patiënten te verbeteren. Op basis hiervan hebben we de e-Exercise LRP-interventie ontwikkeld, een nieuwe aanpak die een app combineert met traditionele face-to-face fysiotherapie. De interventie is ontworpen om de inhoud van de behandeling af te stemmen op het risico van de patiënten op aanhoudende LRP. De app omvat thema's voor zelfmanagement, een op maat gemaakt TOP-programma en een op doelen gericht fysiek activiteitenmodule, gericht op het ondersteunen van het activiteitenniveau en de therapietrouw van de patiënt.

Hoewel therapietrouw aan TOP een complexe constructie is, zou een beter begrip ervan clinici kunnen helpen hun patiënten beter te ondersteunen, wat mogelijk de behandelresultaten verbetert. Daarom was het algemene doel van deze scriptie om een nieuw instrument te ontwikkelen om de therapietrouw aan TOP-aanbevelingen te meten en het te gebruiken om therapietrouw en de associaties met klinische resultaten en herstel van LRP te onderzoeken. Verder was het doel om de resultaten van de e-Exercise LRP-interventie bij patiënten met LRP te evalueren en de patiëntperspectieven te onderzoeken met betrekking tot het gebruik van een smartphone-app als onderdeel van de behandeling.

Hoofdstuk 2 beschrijft de ontwikkeling, validiteitstesten en betrouwbaarheidsbeoordeling van de Exercise Adherence Scale (EXAS), een instrument ontworpen om therapietrouw aan TOP voor patiënten met LRP te meten. De EXAS evalueert therapietrouw van patiënten aan frequentie, intensiteit en kwaliteit van uitvoeringsaanbevelingen door fysiotherapeuten. De validiteit van de EXAS werd ondersteund door matige correlaties met tijdgebrek (rho = 0.47) en gebrek aan motivatie (rho = 0.48) om te oefenen, wat convergente validiteit aangeeft, terwijl lage correlaties met pijn (rho = 0.005) en handicap (rho = 0.24) de divergente validiteit bevestigden. Het instrument toonde uitstekende intrabeoordelaarbetrouwbaarheid (Kappa met kwadratische gewichten = 0.87) voor de kwaliteit van prestatiescore, hoewel de interbeoordelaarbetrouwbaarheid aanzienlijk lager was (Kappa met kwadratische gewichten = 0.36), wat wijst op onvoldoende overeenstemming tussen verschillende beoordelaars. De nieuw ontwikkelde EXAS stelde ons in staat om therapietrouw van patiënten aan TOP-aanbevelingen tijdens de behandeling als onderdeel van de e-Exercise LRP-studie te onderzoeken.

Hoofdstuk 3 onderzoekt de perspectieven van patiënten op het gebruik van een smartphone-app om TOP tijdens fysiotherapie voor LRP te ondersteunen. Via kwalitatieve interviews met negen deelnemers werden thema's van acceptatie, tevredenheid en prestatie verkend. Onze bevindingen geven aan dat patiënten bereid zijn de app als onderdeel van hun behandeling te accepteren, met name vanwege het gebruiksgemak, de integratie in dagelijkse routines en de voordelen die het biedt. Tevredenheid met de app wordt voornamelijk beïnvloed door de waargenomen ondersteuning bij het bevorderen van therapietrouw en het verbeteren van de oefenprestaties thuis. Belangrijke kenmerken van de app die bijdragen aan de effectieve prestatie ervan omvatten video- en tekst instructies, herinneringsfuncties en zelfmonitoringmogelijkheden. Echter, de studie benadrukt ook de belangrijke rol van fysiotherapeuten bij het instrueren van patiënten over hoe ze de app optimaal kunnen gebruiken, waarbij de rol van de app als aanvulling op, en niet als vervanging voor, fysiotherapeutische interventie wordt onderstreept.

Hoofdstuk 4 introduceert de methodologie voor een geclusterd gerandomiseerd gecontroleerd onderzoek dat gericht is op het evalueren van de effectiviteit en kosteneffectiviteit van de e-Exercise LRP-interventie in vergelijking met gebruikelijke fysiotherapeutische zorg voor patiënten met LRP. E-Exercise LRP combineert face-to-face fysiotherapie met ondersteuning van een smartphone-app om zelfmanagement, therapietrouw aan TOP-aanbevelingen en algemene fysieke activiteitenniveaus bij patiënten met LRP te verbeteren. Deze innovatieve gecombineerde zorginterventie wordt verondersteld niet alleen op de kort termijn het fysieke functioneren te verbeteren, maar ook duurzame voordelen en kosteneffectiviteit na 12 en 24 maanden aan te tonen. Het doel was om 208 patiënten met LRP te includeren om uitkomsten zoals fysiek functioneren, pijnintensiteit, therapietrouw, zelfeffectiviteit en gezondheid gerelateerde kwaliteit van leven over deze periodes te vergelijken. Metingen waren gepland bij aanvang, na 3, 12 en 24 maanden, met aanvullende economische evaluatie vanuit maatschappelijk en gezondheidszorgperspectief door middel van retrospectieve zelfrapportage vragenlijsten elke 3 maanden. Hoewel de studie ontworpen was om zowel de korte termijn als lange termijn (kosten-)effectiviteit te onderzoeken, richtten we ons op de korte termijn (3 maanden) effectiviteit op fysieke functionering (hoofdstuk 5), met een bijzondere focus op de rol van therapietrouw aan TOP-aanbevelingen in het herstel van patiënten (hoofdstuk 6 en 7).

Hoofdstuk 5 presenteert de evaluatie van de korte termijn (3 maanden) effectiviteit van de e-Exercise LRP-interventie in vergelijking met face-to-face fysiotherapie voor patiënten met LRP. Uit onze analyse bleek dat zowel de e-Exercise LRP als de face-to-face fysiotherapiegroepen statistisch significante en klinisch betekenisvolle verbeteringen in fysieke functionering toonden, maar er werd geen significante superioriteit gevonden voor de (kosten)effectiviteit van e-Exercise LRP. Desalniettemin werden voordelen van e-Exercise LRP waargenomen in secundaire uitkomsten; het verbeterde significant de angstvermijdingsopvattingen en zelfgerapporteerde therapietrouw aan TOP van patiënten. Met name bij patiënten met een hoog risico op het ontwikkelen van aanhoudende LRP toonde e-Exercise LRP statistisch significante betere uitkomsten in fysieke functionering en verschillende secundaire maten in vergelijking met de controlegroep. Deze bevindingen suggereren dat bepaalde subgroepen van patiënten met LRP meer baat hebben bij e-Exercise LRP dan anderen en verdere onderzoek rechtvaardigen.

Hoofdstuk 6 onderzoekt trajecten van therapietrouw aan TOP bij patiënten met LRP en onderzoekt of baseline kenmerken gerelateerd zijn aan deze trajecten met behulp van gegevens uit de e-Exercise LRP-studie. Therapietrouw werd gemeten met de EXAS (hoofdstuk 2) en gegevens waren beschikbaar van 173 deelnemers. Via ‘latent class growth analysis’ werden drie trajecten van therapietrouw geïdentificeerd: “afnemende therapietrouw” (12%), gekenmerkt door een afname van therapietrouw over de tijd; “stabiele therapietrouw” (45%), waarbij therapietrouw constant bleef; en “toenemende therapietrouw” (43%), waarbij een toename in therapietrouw over tijd werd getoond. Verrassend genoeg werden er geen significante verschillen in baseline kenmerken waargenomen onder deze groepen, wat aangeeft dat initiële patiëntkenmerken niet gerelateerd lijken te zijn aan trajecten van therapietrouw. Deze bevindingen onderstrepen de complexiteit van therapietrouw bij patiënten met LRP, en benadrukken dat fysiotherapeuten therapietrouw gedurende het behandelproces zouden moeten monitoren en ondersteunen in plaats van te proberen patiënten te categoriseren in specifieke groepen op basis van therapietrouw bij aanvang van de behandeling.

Hoofdstuk 7, verkent de associaties tussen therapietrouw aan TOP-aanbevelingen en veranderingen in klinische uitkomsten bij patiënten met LRP. Met behulp van gegevens van dezelfde deelnemers als beschreven in hoofdstuk 6, omvatte de analyse ook eerder vastgestelde trajecten van therapietrouw (“afnemende,” “stabiele,” en “toenemende” therapietrouw), die respectievelijk 12%, 45%, en 43% van de studiepopulatie vertegenwoordigden. Ondanks dat 28,5% van de patiënten herstel van LRP meldde, onthulde de analyse geen significante correlatie tussen therapietrouwniveaus en verbeteringen in fysieke functionering of pijnintensiteit. Deze afwezigheid van een associatie suggereert een complexe relatie tussen therapietrouw aan TOP-aanbevelingen en LRP-herstel, onderstrepend de noodzaak voor verder onderzoek waarbij zowel longitudinale gegevens als kwalitatief onderzoek naar hoe therapietrouw aan TOP-aanbevelingen klinische uitkomsten beïnvloedt worden opgenomen.

Hoofdstuk 8 presenteert de discussie over de studie van therapietrouw aan TOP-aanbevelingen bij patiënten met LRP als onderdeel van het e-Exercise LRP-project. De rol van fysiotherapeuten in het begeleiden van therapietrouw, de ontwikkeling en validatie van een nieuw therapietrouwmeetinstrument, en de verkenning van het complexe construct van therapietrouw en de impact ervan op behandelresultaten worden benadrukt. Het onderzoek toont verschillende belangrijke resultaten, waaronder de ontwikkeling van de EXAS die goede validiteit en betrouwbaarheid voor de meting van therapietrouw toonde, de acceptatie en waarde van de smartphone-app door patiënten voor het ondersteunen van TOP, en de identificatie van verschillende trajecten van therapietrouw onder patiënten. Verrassend genoeg werd er geen significante associatie gevonden tussen trajecten van therapietrouw en verbeteringen in fysiek functioneren of pijnintensiteit, waardoor eerdere veronderstellingen over de relatie tussen therapietrouw en herstel van LRP in twijfel werden getrokken. De gestratificeerde gecombineerde fysiotherapie-interventie, hoewel niet superieur aan traditionele fysiotherapie in het verbeteren van fysiek functioneren, was effectief in het verminderen van angstvermijdingsopvattingen en het verbeteren van zelf gerapporteerde therapietrouw, met name bij patiënten met een hoog risico op aanhoudende LRP. Ondanks het grondige ontwerp wordt de complexiteit van het correct meten van therapietrouw en de potentie voor gevarieerde interpretaties van therapietrouwgegevens erkend. Verdere verfijning van de EXAS en gespecialiseerde onderzoeksontwerpen die kwantitatieve gegevensverzameling combineren met kwalitatieve methoden worden aanbevolen als de volgende stappen.

De bevindingen hebben belangrijke implicaties voor de klinische praktijk en suggereren een behoefte aan gepersonaliseerde, technologie-ondersteunde interventies om therapietrouw te verbeteren. Het onderzoek benadrukt de belangrijke rol van fysiotherapeuten bij het motiveren en ondersteunen van patiënten door middel van op maat gemaakte behandelingen. Toekomstig onderzoek zou zich moeten richten op gepersonaliseerde behandelingen waarbij technologische vooruitgang zoals gamification en kunstmatige intelligentie worden opgenomen om ervoor te zorgen dat patiënten de zorg ontvangen die het beste voor hen is.

Appendices

Appendices

ABOUT THE AUTHOR

Remco Arensman was born on the 30th of May 1986 in Woerden, the Netherlands. He graduated cum laude from secondary school in Utrecht in 2004 followed by obtaining his bachelor's degree in Physiotherapy from THIM University of Applied Sciences in 2008. After this, he started working as a physiotherapist in primary care in a private practice focusing on the treatment of patients with musculoskeletal disorders and patients with neurological disorders. After working a few years, he completed the Master program in Clinical Health Sciences, Physiotherapy Research, at Utrecht University in 2014.

In the same year Remco started working as a lecturer in the pre-master program in Clinical Health Sciences at Utrecht University, while continuing his work as a primary care physiotherapist in a private practice. In 2016 he joined the Center for Physical Therapy Research and Innovation in Primary Care from the Leidsche Rijn Julius Health Care Centers in Utrecht as a physiotherapist combining working in the clinic with research activities. After the switch to working as a physiotherapist-researcher, Remco also focused his work on patients with musculoskeletal disorders and patients with complaints of the back, nek, or shoulder in particular. The next year, in 2017, he was provided the opportunity to focus his research on patient with low back pain in a PhD position as part of the e-Exercise low back pain project and combine the research with his work as a clinician and lecturer. The e-Exercise low back pain project allowed Remco to study patients' adherence behavior to home-based exercise recommendations and translate his clinical experience to the research project and vice versa. In 2021 Remco stopped working as a lecturer to focus on his research and clinical work, but returned to a teaching position at the Utrecht University of Applied Sciences in 2023 where he currently still teaches. He completed his PhD project in the first quarter of 2024.

Following the completion of his PhD, Remco continues his work as a lecturer at the Institute for Human Movement Studies and as a researcher for the Research Centre Healthy and Sustainable Living, both at the Utrecht University of Applied Sciences.

Remco lives together with Edith in Harmelen and is a proud father of Ryan (2009), Rens (2010), and Roos (2013), and loving dad to Amber (2011), Anouk (2014), and Maceál (2016).

LIST OF PUBLICATIONS

Peer reviewed publications

Arensman RM, Pisters MF, de Man-van Ginkel JM, Schuurmans MJ, Jette AM, de Bie RA. Translation, Validation, and Reliability of the Dutch Late-Life Function and Disability Instrument Computer Adaptive Test. Phys Ther. 2016;96(9):1430–7. doi:10.2522/ptj.20150265

Koppenaal T, **Arensman RM**, Van Dongen JM, Ostelo RWJG, Veenhof C, Kloek CJJ, et al. Effectiveness and cost-effectiveness of stratified blended physiotherapy in patients with non-specific low back pain: Study protocol of a cluster randomized controlled trial. BMC Musculoskelet Disord. 2020;21(1):265. doi:10.1186/s12891-020-3174-z

Koppenaal T, Pisters MF, Kloek CJ, **Arensman RM**, Ostelo RW, Veenhof C. The 3-Month Effectiveness of a Stratified Blended Physiotherapy Intervention in Patients With Nonspecific Low Back Pain: Cluster Randomized Controlled Trial. J Med Internet Res. 2022;24(2):e31675. doi:10.1186/ISRCTN94074203

Arensman RM, Geelen RH, Koppenaal T, Veenhof C, Pisters MF. Measuring exercise adherence in patients with low back pain: development, validity, and reliability of the EXercise Adherence Scale (EXAS). Physiother Theory Pract. 2022;38(7):928–37. doi:10.1080/09593985.2020.1818337

Arensman R, Kloek C, Pisters M, Koppenaal T, Ostelo R, Veenhof C. Patient perspectives on using a smartphone application to support home-based exercise during physical therapy treatment: a qualitative study. JMIR Hum Factors. 2022;9(3):e35316. doi:10.2196/35316

Arensman RM, Heymans MW, Kloek CJJ, Ostelo RJWG, Veenhof C, Koppenaal T, Pisters, MF. Trajectories of Adherence to Home-Based Exercise Recommendations Among People With Low Back Pain: A Longitudinal Analysis. Phys Ther. 2023;103(12):1–9. doi/10.1093/ptj/pzad091/7260579

Koppenaal T, van der Heiden J, Kloek CJJ, **Arensman RM**, Ostelo RWJG, Veenhof C, Pisters, MF. Characteristics and health outcomes associated with activation for self-management in patients with non-specific low back pain: A cross-sectional study. Musculoskelet Sci Pract. 2023;67:102830. doi:10.1016/j.msksp.2023.102830

Koppenaal T, Van Dongen JM, Kloek CJJ, **Arensman RM**, Veenhof C, Pisters MF, Ostelo, RWJG. Effectiveness and Cost-Effectiveness of a Stratified Blended Physiotherapy Intervention Compared With Face-to-Face Physiotherapy in Patients With Nonspecific Low Back Pain: Cluster Randomized Controlled Trial. J Med Internet Res 2023;25:e43034. doi:10.2196/43034

A

Submitted manuscripts

Arensman RM, Pisters MFP, Kloek CJJ, Koppenaal T, Veenhof C, Ostelo RJWG. Exploring the association between adherence to home-based exercise recommendations and recovery of nonspecific low back pain: a prospective cohort study. *2024 under review*

Moelands B, **Arensman RM**, Timmer MA, Kloek CJJ, Koppenaal T, Veenhof C, Pisters MF. The influence of prescribed frequency, intensity, and type of physiotherapeutic home-based exercises on adherence in patients with non-specific low back pain. *2024 submitted*

Other publications

Arensman RM, Pisters MF. PROMS 2.0: Computerized Adaptive Testing. Fysiopraxis. 2017;(1):28–30.

Morais-Pannekoek K, **Arensman RM**. Behandeling van sportgerelateerde spierkramp. Fysiopraxis. 2021 Mar;1(3):22–4.

AUTHOR'S CONTRIBUTIONS

Chapter 2 Measuring exercise adherence in patients with low back pain: development, validity, and reliability of the EXercise Adherence Scale (EXAS)

Study concept and design	RA, RG, TK, CV, MFP
Data collection	RA, RG
Data analysis and interpretation	RA, MFP
Drafting the manuscript	RA
Manuscript revision and review	RA, RG, TK, CV, MFP

Chapter 3 Patient perspectives on using a smartphone application to support home-based exercise during physical therapy treatment: a qualitative study

Study concept and design	RA, CK, MFP, TK, RO, CV
Data collection	RA
Data analysis and interpretation	RA, CK
Drafting the manuscript	RA, CK
Manuscript revision and review	RA, CK, MFP, TK, RO, CV

Chapter 4 Effectiveness and cost-effectiveness of stratified blended physiotherapy in patients with non- specific low back pain: study protocol of a cluster randomized controlled trial

Study concept and design	TK, RA, JD, RO, CV, CK, MFP
Drafting the manuscript	TK, RA
Manuscript revision and review	TK, RA, JD, RO, CV, CK, MFP

Chapter 5 The 3-Month Effectiveness of a Stratified Blended Physiotherapy Intervention in Patients With Nonspecific Low Back Pain: Cluster Randomized Controlled Trial

Study concept and design	TK, MFP, CK, RA, RO, CV
Data collection	TK, RA
Data analysis and interpretation	TK, RO, CV
Drafting the manuscript	TK, MFP
Manuscript revision and review	TK, MFP, CK, RA, RO, CV

Chapter 6 Trajectories of Adherence to Home-Based Exercise Recommendations Among People With Low Back Pain: A Longitudinal Analysis

Study concept and design	RA, CK, RO, CV, TK, MFP
Data collection	RA, TK
Data analysis and interpretation	RA, MH, MFP
Drafting the manuscript	RA
Manuscript revision and review	RA, CK, RO, CV, TK, MFP, MH

Chapter 7 Exploring the association between adherence to home-based exercise recommendations and recovery of nonspecific low back pain: a prospective cohort study.

Study concept and design	RA, MFP, CK, TK, CV, RO
Data collection	RA, TK
Data analysis and interpretation	RA, MFP
Drafting the manuscript	RA
Manuscript revision and review	RA, MFP, CK, TK, CV, RO

PHD PORTFOLIO

PhD period: 1-11-2017 to 30-4-2024

Name of PhD Supervisors: prof.dr. C. (Cindy) Veenhof
prof.dr. R.W.J.G. (Raymond) Ostelo
dr. M.F. (Martijn) Pisters
dr. C.J.J. (Corelien) Kloek

Training activities	Year	ECTS*
Courses		
Introduction course PhD program Clinical and Experimental Neuroscience	2017	0.5
Academic Writing in English	2017	2
Basic course on Regulation and Organization for Clinical Investigators (BROK)	2018	1
Basic Qualification in higher Education (BKO)	2019	3
Qualitative research	2019	0.5
Balance - Coping with Stress and Pressure	2020	0.15
National and international conference contributions		
Dag van de fysiotherapeut (Den Bosch 8-12 Dec) – platform presentation and panel discussion	2018	0.6
World Physiotherapy Congress (Geneva 10-13 May) – poster presentation	2019	0.9
FysioXperience (Eindhoven 14 Jun) – interactive workshop	2019	0.9
Symposium Fietsend vooruit (Almere 20 Nov) – keynote speaker	2019	0.9
Dag van de fysiotherapeut (Den Bosch 21 May) – poster presentation	2022	0.3
World Physiotherapy Congress (Dubai 2-4 Jun) – poster presentation	2023	1.0
Meetings		
Weekly research meeting physiotherapy sciences	2017 -2022	2
Monthly meetings Expert group Center for Physical Therapy Research and Innovation in Primary Care - Chair	2017 -2023	1.5
Teaching/supervising		
Supervising students Utrecht University of Applied Sciences (Bachelor Physiotherapy)	2017 -2022	5.0
Lectorate Health Innovations and Technology – Experience (H) IT	2022	0.1

A

Supervising students University Utrecht (Master Physiotherapy sciences)	2019 -2023	1.0
Lecturer pre-master program Physiotherapy sciences	2017 - 2021	5.0
Lecturer Institute for Human Movement Studies, University of Applied Sciences Utrecht	2023-2024	0.5
Other activities		
Peer reviewing for international journals (7 manuscripts)	2017-2023	

*1 ECTS = 28 hours, based on the European Credit Transfer System

DANKWOORD

Lange tijd alleen maar van kunnen dromen, maar ik ben nu toch echt het dankwoord van mijn proefschrift aan het schrijven. Een mooi einde van een ontzettend leerzame en soms ook moeilijke periode in mijn leven. Maar wat heb ik veel geleerd. Niet alleen over het doen van onderzoek, project management, data management, study file management, data analyse en wetenschappelijk schrijven, maar ook op persoonlijk vlak. De moeilijke en uitdagende momenten gedurende mijn traject hebben mij gedwongen om keuzes te maken, een balans te zoeken tussen werk en privé en hebben mij de waarde van doorzettingsvermogen geleerd. Meer onverwacht waren de inzichten die ik opgedaan heb gedurende het onderzoek. De contacten met de patiënten, het sparren met collega's uit het werkveld en collega's uit onderzoek hebben gemaakt dat ik heel anders naar de mens die centraal staat in wat we als klinisch onderzoekers doen ben gaan kijken. De "eenvoudige rugklacht" bestaat niet en ieder persoon heeft zijn eigen, unieke complexiteiten, die steeds weer op een andere manier invloed kunnen hebben op de behandeling en de interactie tussen de patiënt en de zorgverlener.

Daarom wil ik als eerste de participanten en fysiotherapeuten die dit project mogelijk gemaakt hebben bedanken. Zonder jullie investering in ons project had ik nu niets gehad om over te schrijven. Ondanks de extra belasting in tijd en administratie die het jullie opgeleverd hebben, waren jullie gemotiveerd om bij te dragen aan het ontwikkelen van nieuwe inzichten die mogelijk de zorg voor andere mensen kan verbeteren. Bedankt ook voor de gastvrijheid bij jullie thuis of op de praktijken, waar ik soms niet eens weg mocht voordat ik wat gegeten en gedronken had.

Mijn promotieteam kan ik niet genoeg bedanken voor hun ondersteuning.

Beste Cindy, jouw relativeringsvermogen en nuchterheid heeft mij ontzettend geholpen. Mijn vele ideeën en uiteenlopende gedachten terugbrengen naar de basis en reduceren tot de relevante zaken heeft veel geholpen om niet vast te lopen. Je wist steeds weer een probleem of oplossing van verschillende perspectieven te belichten, waardoor het lukte om steeds de koppeling te houden tussen het onderzoek en de zorgverleners in de dagelijkse praktijk die er wat aan moeten hebben. Gedurende mijn eigen persoonlijke moeilijkheden heb ik veel steun gehad aan je en je warme woorden. Bedankt daarvoor!

Beste Raymond, wat ben je toch ontzettend goed in het stellen van die vervelende vragen waarvan ik zelf steeds dacht "waarom heb ik daar niet aan gedacht?". Daar ben ik overigens nog steeds niet achter. Je scherpe blik heeft mij erg geholpen om de resultaten vanuit het onderzoek zo goed mogelijk weer te geven en de conclusies met een passende mate van (on)zekerheid te verwoorden. Nooit gedacht dat een simpele vraag als "maar wat betekent het nu precies?" zoveel waarde kan hebben voor de juiste interpretatie van de getallen die na een wekenlange periode van data analyse in de tabel terecht komen. Maar je was ook altijd heel betrokken bij het zoeken naar het juiste antwoord op diezelfde moeilijke vragen en voor dat alles wil ik je ontzettend bedanken.

Beste Martijn, vanaf de start van mijn wetenschappelijke carrière ben je betrokken geweest. Eerst als begeleider van mijn afstudeerscriptie van Fysiotherapiewetenschap, daarna als co-auteur van mijn eerste publicatie, en niet al te lang daarna kwam er een vacature bij de Academische Werkplaats Fysiotherapie waar ik op solliciteerde en aangenomen werd. Er was nog niet echt een concreet plan, maar er lag nog een project over therapietrouw waar ik mee aan de slag kon. Van het één kwam het ander en ineens was ik als promovendus aangehaakt bij het e-Exercise Lage rugpijn project en was jij mijn co-promotor. Ik bewonder hoe je in staat bent om mensen bij elkaar te brengen, projecten van de grond te krijgen en (vaak in veel te korte tijd) tot concrete subsidieaanvragen komt die ook nog eens gehonoreerd worden. Je hebt een duidelijke visie voor de ontwikkeling van de AWF en die draag je uit. Je hebt mij daarin laten zien hoe belangrijk het is om ook strategisch en politiek te zijn binnen onderzoek. Maar naast het professionele zorg je er ook voor dat er regelmatig wat te vieren valt. Borrels om een publicatie te vieren of uit eten en een drankje doen in de stad na een lange dag op een congres, het was altijd gezellig met de groep. Je hebt mij geleerd om trots te zijn op de kleine successen en die te vieren. Dat heeft enorm geholpen om het lange traject van promoveren stapje voor stapje te kunnen doorlopen en daar bedank ik je voor!

Beste Corelien, heel bijzonder om een vervolg te mogen geven aan jouw "kindje" e-Exercise artrose. Je hebt mij bijgestaan met de kennis en skills die je zelf opgedaan had met jouw project, waardoor ik heb kunnen doorbouwen zonder het wiel opnieuw te hoeven uitvinden. Je ervaringen met het rekruteren van deelnemende praktijken, je kennis van de problemen die deelnemende fysiotherapeuten konden ervaren en je technische kennis en ervaringen met een blended interventie zijn van grote waarde geweest. Ik heb ook veel van je geleerd bij de analyse van kwalitatieve data die we samen gedaan hebben, met name de waarde van het steeds weer focussen op het perspectief van de patiënt. Daarnaast heb je mij vaak geholpen om weer vooruit te komen of te kunnen kijken als ik even vast zat. Je stond steeds voor mij klaar met advies en feedback op momenten dat het nodig was en bood een luisterend oor als ik gefrustreerd was over een proces dat veel complexer was dan naar mijn idee nodig was. Het heeft mij geholpen om steeds weer vooruit te kunnen kijken en te werken naar de volgende mijlpaal. Ik heb het altijd erg gewaardeerd en mijn dank is groot!

Beste Tjarco, jij bent ook een belangrijk onderdeel geweest van het team. Je had al veel werk gedaan in de voorbereidingen voor het project met het schrijven van de subsidieaanvraag, waardoor we samen vlot konden starten met de voorbereidingen voor de daadwerkelijke aftrap van het e-Exercise lage rugpijn project. We konden bijna niet meer verschillen in onze werkwijze en aanpak, maar juist daardoor heb ik ontzettend veel van je geleerd. Waar mijn uitgangspunt meer het globale idee was waarbij nadenken over de details wel kwam als dat nodig was en problemen pas een oplossing nodig hadden als ze ontstonden, was jij veel meer van de gedetailleerde organisatie en planning vooraf. Wat ons verbond was dat linksom of rechtsom, het eindresultaat perfect moest zijn. Gedurende onze samenwerking heb ik door goed afkijken steeds meer geleerd om een balans te vinden tussen de pragmatische aanpak en een idealistische aanpak. Bij onze gezamenlijke werkdagen in Utrecht konden we altijd veel gedaan krijgen. Soms onze frustraties delen over administratieve rompslomp, andere keren snel schakelen vanwege nieuwe aanmeldingen voor het onderzoek of kort overleggen over inhoudelijke vraagstukken. Ik heb ook met bewondering gadeslagen hoe je tijdens het traject even een master Klinische Epidemiologie erbij deed. Ik heb met veel plezier samengewerkt en ik ben je dankbaar voor alles wat je betekend hebt voor mij.

Graag bedank ik de leden van de beoordelingscommissie Prof. dr. L.W. van Rhijn, Prof. dr. D.L.M. Zwart, Prof. dr. J.M.A. Visser-Meilij, Prof. dr. Ir. C.E.M.J. van Dijk en Dr. J.B. Staal. Het is mij een eer dat u de tijd genomen heeft om mijn proefschrift te lezen en te beoordelen en dat u mij de gelegenheid geeft om het proefschrift in het openbaar te verdedigen.

Ook de co-auteurs wil ik bedanken voor jullie bijdragen aan het tot stand komen van mijn proefschrift. Rianne voor het voorwerk dat je gedaan had voor de ontwikkeling van de Exercise Adherence Scale en Hanneke voor je bijdrage aan de analyse van de kosten effectiviteit van e-Exercise Lage rugpijn. Mijn bijzondere dank gaat uit naar Martijn Heymans voor de vele overlegmomenten over de statistiek en je hulp bij het zoeken naar (en vinden van) oplossingen voor de problemen waar ik tegenaan liep bij het programmeren in R. Het was een fikse leercurve om “even” te leren programmeren in R, maar dankzij jouw hulp is het goed gekomen.

Belangrijk onderdeel van de dataverwerking voor mijn onderzoek was het digitaliseren van al die ingevulde therapietrouw formulieren. Graag wil ik de studenten van de HU en in het bijzonder Eline bedanken voor de hulp met het invoeren van de gegevens in de databases.

Sue en Heidi, ondanks alle verschillende agenda’s van al die mensen die bij de overleggen of afspraken aanwezig moesten zijn kregen jullie het toch steeds weer voor elkaar om een moment te vinden voor een afspraak. Dank jullie wel daarvoor!

Dank ook aan alle collega’s van de onderzoeksgroep Fysiotherapiewetenschap voor de gezelligheid, het sparren, meedenken en bij tijd en wijle de gedeelde smart. Als ik een probleem had of een vraag, dan was er altijd wel iemand die wilde meedenken of meehelpen. Het hoogtepunt van gedeelde smart samenwerking is voor mij nog altijd dat iedereen die op de bewuste dag aanwezig was meehielp met het in elkaar zetten van de ‘slechts’ 57 study site files. Zelfs met een groep van ongeveer 10 sterk zijn we er een hele middag mee bezig geweest.

Roderick, Suze, Els, Wendy, Sander, Mark en Camille, dank voor de gezelligheid, het gesprek en het ontspannen bij de lunches op dinsdag en/of vrijdag. Het lotgenotencontact was erg fijn en door onze ervaringen te delen maakten we elkaars werk een beetje makkelijker.

Lieve (oud) collega’s van het LRJG en de AWF, ik heb altijd veel plezier met jullie samengewerkt in de praktijk en ook voor het e-Exercise lage rugpijn onderzoek. Bernie, Jaap, Mathilde, Meyke, en Erik-Jan, bedankt voor jullie hulp en inzet voor het onderzoek en de samenwerking binnen het expert team. Loes, Marjo, Lilly, Dennis, Annelies en Ramin, bedankt voor de samenwerking op locatie Parkwijk. Ik heb het altijd erg gezellig gehad en ik wil jullie bedanken voor jullie steun op de momenten dat ik het nodig had. Wytse en later Mirte, dank voor de mogelijkheden die ik gekregen heb om mij te ontwikkelen in mijn werk.

Lieve Annelieke, als jong guppie kwam je ooit als sollicitant voor een stageplaats bij het LRJG. Al snel was je niet meer weg te denken uit de praktijk door de tomeloze energie en vrolijkheid die je met je meebrengt. Na afloop van je stage ben je ook gewoon niet weggegaan (op een pauze van 3 maanden na dan) en heb ik nog jaren met veel plezier op de donderdagen op Terwijde met je samengewerkt. Je gezelschap en vriendschap is voor mij heel waardevol geweest en je vrolijkheid een welkome afleiding tijdens de lange dagen schrijven/lezen/data-analyseren. Ook toen het even niet zo makkelijk ging in mijn leven heb ik veel steun gehad van je, waar ik je nog steeds erg dankbaar voor ben.

Sjors, al sinds het eerste jaar van de opleiding fysiotherapie bij het THIM ben je een goede vriend en ik ken je inmiddels langer wel dan niet. Ondanks dat we het beiden altijd veel te druk hebben, hebben we te veel lief en leed gedeeld om op te noemen, maar als ik steun nodig heb kan ik altijd op je rekenen. Nog steeds is het gezellig, kunnen we heerlijk ontspannen en ook lekker eten als we met de hele bende samen komen. Ook al worden de kinderen groter, ze vinden het nog steeds heerlijk om met ons allen spelletjes te spelen, gezellig te kletsen of gewoon een beetje te hangen. Inmiddels zijn we echte BBQ experts, en hoop ik dat we nog jaren vooruit kunnen. Ik wil jou en natuurlijk ook Mascha bedanken dat jullie er bij waren toen de kinderen geboren werden, ze groter werden, we liefde en leed gedeeld hebben en dat jullie er altijd voor mij zijn geweest.

Lieve Joeri, sinds onze tienertijd zijn we al bevriend. Het begon met een vakantie naar Spanje en daarna zijn we altijd vrienden gebleven. We hebben veel meegemaakt samen.

Jij weet als geen ander hoe ingewikkeld het soms is geweest voor mij en ook al woon je niet om de hoek, ik kan je altijd bereiken. Door onze drukke levens kunnen we niet zo vaak afspreken als we zouden willen, maar dat maakt de keren dat het wel kan alleen maar mooier. Ik ben dan ook groot voorstander van het in ere houden van de jaarlijkse traditie "Avondje Outsiders"!

"True friendship isn't about being inseparable, it's being separated and nothing changes" – *Eleanor Roosevelt*. Een waarheid als een koe en ik kan jullie er niet genoeg voor bedanken!

Lieve Suus en Lud, jullie zijn geweldige grootouders voor de kinderen. Jullie hulp met opvangen van de kinderen of ze meenemen met dagjes uit om mij (en de kinderen) wat ruimte/rust te geven hebben zeker geholpen. Onze band blijft bijzonder en ik kan niet genoeg stellen hoeveel ik het waardeer dat ik voor raad en daad bij jullie terecht kan.

Lieve pa en ma, jullie onvoorwaardelijke steun en aanmoediging gedurende al die jaren heeft dit hele proefschrift mogelijk gemaakt. Vanaf mijn eerste jaren in de HBO opleiding fysiotherapie tot de dag van vandaag kan ik bij jullie terecht voor steun, een luisterend oor, maar ook om de overwinningen en successen te vieren. De jaren dat ik met de kinderen bij jullie terecht kon en het huis ineens weer vol was zal ik nooit vergeten en ik kan jullie niet genoeg bedanken voor alle kansen die ik heb gekregen en uitdagingen die ik heb durven aangaan dankzij jullie steun.

Lieve Stefan, mijn 'kleine' broertje en heerlijk relativerend. Simpele relativering als "als het kapot kan, dan kan je het ook weer repareren" maakte het toch makkelijker om ergens mee te beginnen ook al was ik niet zeker dat het ging lukken. "Even samen klussen" en voor we het weten zijn we 12 uur verder. Soms moet ik iets gewoon doen en er niet te veel over nadenken.

Lieve Angela, ik wil je bedanken voor je hulp op de heel drukke momenten. Ondanks je eigen drukke werk en studie was je er toch steeds om een handje te helpen als het nodig was. Je kon mij daarmee net dat extra zetje geven dat ik nodig had om weer door te kunnen. Na dit alles ben ik benieuwd wat jouw volgende stap in je leven gaat zijn.

Lieve opa en oma, ik kan altijd genieten van de verhalen over vroeger en hoe anders het voor jullie was destijds. Opa, wat heb ik een respect voor u dat u toch maar steeds bijblijft met de snelheid van de technologische ontwikkeling. Oma, ook al kunt u het niet meer herinneren, tot de dag van vandaag waardeer ik het enorm dat ik tijdens mijn studie bij jullie heb mogen wonen. Ik hoop dat ik in de toekomst er kan zijn voor jullie als jullie hulp nodig hebben.

Lieve Ryan, je bent een hele lieve jongen en wat kan je grappig zijn. Ik kan ontzettend genieten van onze momenten samen als wij samen als avondmensen een serie kijken als de rest van het huis al in rust is. Je bent al bijna langer dan ik, maar je zal altijd mijn kleine jongen blijven. Ik ben ontzettend trots op je dat je zo je best doet op school en met sporten.

Lieve Rens, net als je broer ben je een hele lieve en zorgzame jongen. Heerlijk om te zien hoe je kan genieten van meehelpen met het koken en het opeten van maaltijden. Je enthousiasme met het spelen en knuffelen met Hunter zijn zo mooi om te zien. Blijf zo goed je best doen voor school, ik weet zeker dat je het kan!

Lieve Amber, wat kan je heerlijk creatief zijn en ik vind het leuk om bij het thuiswerken te horen hoe je zingend en dansend bezig bent in je kamer. Je dagelijkse stoeisessies met je broers maken je steeds sterker en ik ben benieuwd hoe je jezelf gaat ontwikkelen. Vergeet niet dat je moeder en ik er zijn om je te steunen!

Lieve Roos, je bent een heerlijk energieke en lieve dochter. Je doet ontzettend goed je best op school en thuis en ik ben ontzettend trots op je. Je bent heel zorgzaam en net zo creatief als je zussen. Heerlijk om je samen met Anouk bezig te zien en te horen giechelen. Ik ben benieuwd wat de volgende dansroutine wordt die jullie samen ingestudeerd hebben.

Lieve Anouk, wat ben je hard aan het werk! Gelukkig heb je genoeg tijd (soms wat te veel) om met Roos samen te knutselen, gamen, giechelen, dansen, en meiden dingen doen. Heerlijk om te zien en durf vooral om ook op andere momenten zorgeloos bezig te zijn. Je hoeft je niet vast te houden, ik laat je niet vallen!

Lieve Maceál, het zal niet meevallen om op te boksen tegen al die oudere broers en zussen. Je doet ontzettend goed je best en ik ben trots op je dat zo hard oefent voor school en met judo. Je bent heerlijk enthousiast en er is altijd tijd voor een knuffel. Ik kan niet wachten om mee te maken hoe je opgroeit.

Allerliefste Edith, je bent wie je bent en daarom hou ik van je. Halverwege dit proces kwam je erbij en ondanks dat het hele wetenschapsgedoe nieuw voor je was heb je mijn verhalen liefdevol aangehoord. Je hebt mij gesteund waar je kon en dat was precies wat ik nodig had. Je denkt altijd mee in oplossingen en ontzorgt mij waar je kan. Inmiddels kan ik mij geen leven meer voorstellen zonder jou. We hebben al veel mooie momenten gehad samen en ik ben blij dat ik deze mijlpaal in mijn leven met je mag delen. Er gaan vast nog vele mooie momenten volgen en ik kan niet wachten om ze mee te maken.

UMC Utrecht

Universiteit Utrecht

ISBN 978-90-274-3962-2