A combined lifestyle intervention delivered by physio/exercise therapists for patients with persistent low back pain and overweight or obesity: a randomized controlled trial with parallel economic evaluation

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Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON56872

Source
ToetsingOnline

Brief title
Back2Health

Condition

- Joint disorders

Synonym
Low back pain, sciatica

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZONmw (nr. 10390022210014)

Intervention

Keyword: Lifestyle intervention, Obesity, Persistent back pain, Usual care

Outcome measures

Primary outcome

The physical function over 36 months will be measured using the Roland Morris Disability Questionnaire (RMDQ) and physical activity quantified by average number of daily steps over a week will be measured using the activPAL.

Secondary outcome

Secondary study parameters: LBP intensity(NPRS), LBP perceived recovery(GPE), BMI(electronic scale/ portable stadiometer), lifestyle behaviors, including physical activity(activPAL activity tracker); sleep quality (PSQI), and food intake frequency questionnaire(FFQ), quality of life(EQ-5D-5L), costs. The duration to complete the reliable and valid questionnaires is approximately 30 minutes. The activity tracker will be worn on the thigh for one week at four time moments (incl. baseline). At baseline, various possible confounding factors will be assessed, including pain beliefs(B-IPQ), pain self-efficacy(PSEQ), fear(TAMPA), and socio-economic status.

Clinical data will be collected at baseline, 6, 12, 24, and 36 months. Costs will be measured by cost questionnaires every 3 months during the first 12

months and every 6 months from months 13 to 36. As it is of utmost importance to maintain healthy behavior, 36 months after the baseline is the primary follow-up moment. Additionally, predictions to evaluate the cost-effectiveness of the intervention in the long-term with a time horizon of 5 and 10 years will be performed.

Blood withdrawal will per performed for the measurement of systemic inflammatory markers (TNF-alpha, high sensitive CRP) at baseline, 12 month and 36 months.

Study description

Background summary

Low back pain (LBP) is the leading cause of disability worldwide and is costly. Lifestyle factors, such as physical inactivity, stress, sleep, excess weight, and unhealthy diet contribute to the burden of LBP and the increasing demand for care. Moreover, ~65% of LBP patients who visit the hospital are overweight. This group is considered a complex patient group. Of the LBP patients who visit the hospital, 74% are referred back to primary care as medical specialists cannot offer them worthwhile care. Targeting lifestyle factors and clinical factors (e.g., muscle strength, endurance, mobility) is important in the management of this group of LBP patients to improve clinical outcomes (e.g., functioning, pain) and reduce costs. Addressing lifestyle factors may also offer additional health benefits like decreased risks of diabetes and cardiovascular diseases.

Study objective

The primary objective of this project is to improve the management of a complex group of LBP patients, that is, patients who are overweight or obese and who are referred back to primary care from the hospital because medical specialists cannot offer them worthwhile care, and to reduce healthcare and societal costs. The primary research question is: *Is a combined lifestyle intervention, integrated into specific care for LBP, delivered by physio/exercise therapists effective and cost-effective in improving physical functioning over a 36-month

period compared to usual care in overweight or obese LBP patients who are referred back from the hospital to primary care?*

Study design

A prospective randomized clinical trial (RCT) with a superiority design will be conducted, with economic and process evaluations.

Intervention

Patients in the experimental group will receive the intervention, specifically the GLI combined with standard care. The treatment approach will be individualized based on the patient's lifestyle risks (such as physical inactivity, unhealthy diet, sleep issues, and stress) and clinical factors related to lower back pain (such as unhelpful pain beliefs and poor muscle strength). This individualization will be achieved through shared decision-making, aligning with current lower back pain guidelines and GLI protocols.

Patients will actively define their treatment goals and retain control over the treatment process. The core component of the intervention will comprise both individual and group sessions spanning approximately six months (approximately 16 sessions). Spouses are welcome to partici-pate in individual sessions to provide social support. Evidence-based behavioral change tech-niques will be employed, including self-monitoring with activity trackers, goal setting, action and coping planning, enhancing self-efficacy through skills training, fostering positive patient-therapist interactions, and utilizing motivational interviewing to promote healthy behaviors.

To further support patients in sustaining healthy behaviors, promoting self-management, and preventing the recurrence of lower back pain, a combination of digital and face-to-face individual and group sessions (approximately 8 sessions) will be offered during the maintenance phase of the intervention (months 7 to 24). The number of sessions will be tailored to the individual needs of the patients. Patients can select from among five programs (Samen Sportief in Beweging, Beweegkuur, SLIMMER, Cool, or X-Fittt GLI) that reflect everyday practice, while also retaining access to standard care.

The control group will receive standard care, which may involve physiotherapy, exercise therapy, or general practitioner care in accordance with the existing Dutch physiotherapy (KNGF) and general practice (NHG) guidelines for lower back pain. Standard care can include educational components, exercise therapy, and the use of pain medication, as well as the possibility of hospital re-entry for further treatment.

Study burden and risks

In our research, we are committed to minimizing the burden imposed on participants during the course of this study. To this end, we have taken several measures:
Selection of Tests and Questionnaires: We have meticulously selected a subset of physical tests and questionnaires (as detailed in Table 1) to minimize the extent of physical examinations and questionnaire completion, ensuring that these measures do not unduly inconvenience participants.
Blood Sampling: Venous blood samples will be collected to assess systemic inflammatory markers, with a strict limit of 21 ml (7 ml each) over the duration of the study. This approach is designed to minimize the volume of blood withdrawn from participants. Blood withdrawal can be accompanied with small discomfort and hemorrhage.
Data Collection: Clinical data in the form of questionnaires will be administered at specific time points*baseline, 6, 12, 24, and 36 months. Additionally, cost questionnaires will be ad-ministered at regular intervals, every 3 months during the initial 12 months and every 6 months from months 13 to 36, to assess costs incurred by participants.
Questionnaire Completion: The questionnaires utilized in this study are known to be reliable and valid and can typically be completed in approximately 45 minutes, thus mitigating any un-due time burden on participants.
Activity Tracking: Participants will be required to wear an activity tracker on their thigh for one week at four different time points, facilitating data collection with minimal disruption to their daily routines.
Furthermore, it is essential to note that the interventions applied in this study, including physio-therapy, exercise therapy, and lifestyle modifications, are considered safe and have been as-sociated with negligible side effects in patients with lower back pain (LBP), particularly those who are overweight or obese. The potential side effects, such as soreness, fatigue, or stiff-ness, are mild and transient.
We conducted a comprehensive systematic review of relevant literature, and none of the included randomized controlled trials (RCTs) reported any adverse effects resulting from combined lifestyle interventions in LBP patients with overweight or obesity.
The findings from our systematic review strongly support the notion that combining lifestyle interventions (GLI) with LBP treatment in accordance with clinical guidelines can lead to improvements in physical activity, stress reduction, and the promotion of a healthy diet. These interventions hold promise in terms of cost-effectiveness and enhanced management of over-weight/obese patients with persistent LBP within the Dutch healthcare system.
It is important to highlight that combined lifestyle interventions (GLI) administered by certified physiotherapists and exercise specialists are covered and reimbursed as medical interventions through the basic Dutch health insurance package. Eligibility criteria for coverage include a BMI of >=30 or a BMI of >=25 with comorbid conditions such as osteoarthritis, sleep apnea, or risk factors for cardiovascular diseases or diabetes mellitus. Notably, patients with lower back pain meeting these criteria are not currently being

routinely referred to these interventions.

Contacts

Public
Vrije Universiteit

Van der Boechorsstraat 9
Amsterdam 1081BT
NL
Scientific
Vrije Universiteit

Van der Boechorsstraat 9
Amsterdam 1081BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Overweight or obese patients with persistent(i.e. >3 months), non-specific LBP, who are referred from the hospital back to primary care, are eligible and will be recruited at the 7 participating hospitals. Patients need to have either a BMI>=30 or a BMI>=25 with at least one of the following: osteoarthritis, sleep apnea, risk factors for cardiovascular diseases or type 2 diabetes in line with the criteria for combined lifestyle interventions(i.e., GLI-criteria); decreased physical functioning defined as a RMDQ score of >= 4 out of 24, an average of LBP intensity >= 3 out of 10 on a numeric pain rating scale over the past week, and aged >=18 years.

Exclusion criteria

Specific LBP(e.g. tumor, fracture), back surgery in the past 6 months, psychiatric diseases, pregnancy or postpartum <9 months.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	318
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	04-07-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85373.028.23