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Protocol

The effect of pedometer supported walking and telemonitoring after disc hernia surgery on pain, disability levels, and quality of life: study protocol

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ABSTRACT

Background: Surgical intervention is the most common among the methods used to treat LDH, and its success rate is high. Despite this, patients can experience mild to moderate pain and disability after surgery. In the management of this pain and disability, walking forms the first step of rehabilitation and is an easy and long term method. This study was planned to determine the effect of a pedometer supported walking program and telemonitoring after disc hernia surgery on pain, disability levels and quality of life.
Methods: This study was planned as a randomized controlled study. Patients will be randomized into the study and control groups through the closed envelope method. Patients in the study group will receive an intervention through a 12 week walking program and weekly telemonitoring. The pain levels of the patients included in the study will be evaluated using the short form Mcgill pain questionnaire, their disability levels will be evaluated using the Oswestry disability index, and their quality of life will be evaluated using the SF-36. Patients in both the study and control groups will be evaluated with regard to pain and disability levels in the follow ups in the 3rd, 7th, and 11th weeks, and with regard to pain, disability, and quality of life in the 15th week.
Conclusions: Daily regular walks have great importance in the management of mild lower back pain. This study was planned to determine the effect of walking with a pedometer after LDH surgery with weekly monitoring.

Keywords: Intervertebral disk, Surgery, Rehabilitation nursing

INTRODUCTION

Lower back pain is a common problem that causes loss of workforce. Back pain can negatively affect the functionality of patients as well as many of their basic activities such as standing, walking, sitting, and dressing up.[1] The lifelong prevalence of back pain can reach more than 80% and the yearly hospital admission rates can reach 15% in the adult population.[2,3] According to 2016 data from the Turkish Institute of Statistics, disc herniation, lower back pain, and lower back problems tied to other back defects are experienced by 27.1% of all individuals of 15 years of age and above. 2-3% of back pains develop because of lumbar disc hernia (LDH).[4] Disc hernia occurs because of nucleus pulposus exceeding the limits of the annulus fibrosus capsule. Bilateral lower extremity hypoesthesia, muscular weakness, and spreading pain are among the clinical symptoms of this disease.[5,6] Surgical intervention is the most common among the methods used to treat LDH, and its success rate is high.[7] As a result of the meta analyses performed, it has been reported that despite showing fast recovery in the first three months after surgery, patients experience mild to moderate pain and disability even five

years after the surgery, with the respective rates of pain and disability being 21% and 13.1%.[8] Certain studies also report that the quality of life of patients after surgery is lower compared to the normal population.[9] Patients are recommended pain related bed rest before the surgery and 2 to 3 weeks of rest after the surgery. A daily 1-3% and weekly 10-15% muscle strength loss has been reported for people at strict bed rest.[10] For patients to have decreased pain symptoms and regain their lost muscle function to return to normal life, the importance of exercise in the postoperative period is great. [10,11] Studies have shown that an active life and exercise therapy decreased pain and increased functionality in patients with chronic lower back pain.[10-14] Exercise starting at the early postoperative period after LDH surgery has great importance in this context. In the literature, yoga, aerobics, Pilates, and all physical therapies and group exercise to strengthen leg and back muscles have been shown to provide clinical and statistical improvement.[10-13] However, most interventions both remain short term and have to be performed with an expert. Additionally, the sustainability of these exercises is low, and individuals off all socio economic levels may not be able to reach them. However, walking is an accessible and sustainable basic human activity that can be easily performed by individuals of all socio economic levels that also has a low risk of injury and no cost.[15,16]

House based walking programs seem to be an efficient and safe method to increase physical activity.[17] Although studies have reported walking to be efficient in the treatment of low level back pain[13,14] people with spinal diseases can generally be seen to lead a sedentary life. In certain newer studies, people with chronic low level back pain were reported to not be able to reach the recommended 10000 daily steps and have significantly lower step numbers in their age appropriate health check ups.[18,19] In a study where the daily number of steps and walking distances of patients before lumbar spinal surgery were examined, the number of steps was found to be between 2.186 and 4.574 and the mean walking distance was found to be 1.7-3.4 km. In the same study, the daily numbers of steps of the patients after surgery were evaluated using a pedometer without intervention, and their number of steps were measured to be 2.186-4.574 in the first month, 3.112-7.135 in the second month, and 4.218-8312 in the third month.[20] The World Health Organization (WHO) has designated 5000-7499 steps a day to be low activity, 7500-9999 steps to be moderate activity, and 10000-12499 steps to be high activity.[21] When the results of the aforementioned study and the number of steps designated by the WHO are compared, it can be seen that people did not reach the active level after LDH surgery without intervention.[20] Clinical guidelines suggest that the physical activity level of patients should be increased in increments after the second week post LDH surgery.[17,22]

The objective measurement of walking distances and numbers of steps is important for the correct evaluation of results. Today, one of the most popular tools used for this aim is the pedometer. The pedometer is a cheap and easy to use tool designed to objectively measure number of steps and walking distance.[17,23] In a systematical review, strong evidence has been presented that pedometer supported walking in people with musculoskeletal problems increased physical activity and positively affected quality of life.[24] In a society based study conducted in England, pedometer supported walking was found to improve patient satisfaction and adjustment as well as physical function and decrease pain and disability, prompting the method to be suggested for chronic lower back pain in clinical guidelines.[25]

Increasing walking distance and physical activity in the treatment of mild back pain decreases pain and improves physical function.[17,22,26] However, there are no studies in the literature on the effectiveness of walking after LDH surgery and its use as an intervention strategy. The adaptation of the patient to his/her new lifestyle, the motivation of the patient, monitoring, and rehabilitation are among the basic duties of nurses. Through this study, the importance of nurses in postoperative patient rehabilitation will be once again highlighted.

In this context, this study was planned to determine the effect of a pedometer supported walking program and telemonitoring after disc hernia surgery on pain, disability levels and quality of life.

Hypotheses

H1: A pedometer supported walking program and telemonitoring after disc hernia surgery decreases the pain levels of individuals.

H2: A pedometer supported walking program and telemonitoring after disc hernia surgery decreases the disability levels of individuals.

H3: A pedometer supported walking program and telemonitoring after disc hernia surgery increases quality of life.

Aim

This study is a randomized controlled study planned to determine the effect of a pedometer supported walking program and telemonitoring after disc hernia surgery on pain, disability levels, and quality of life.

METHODS

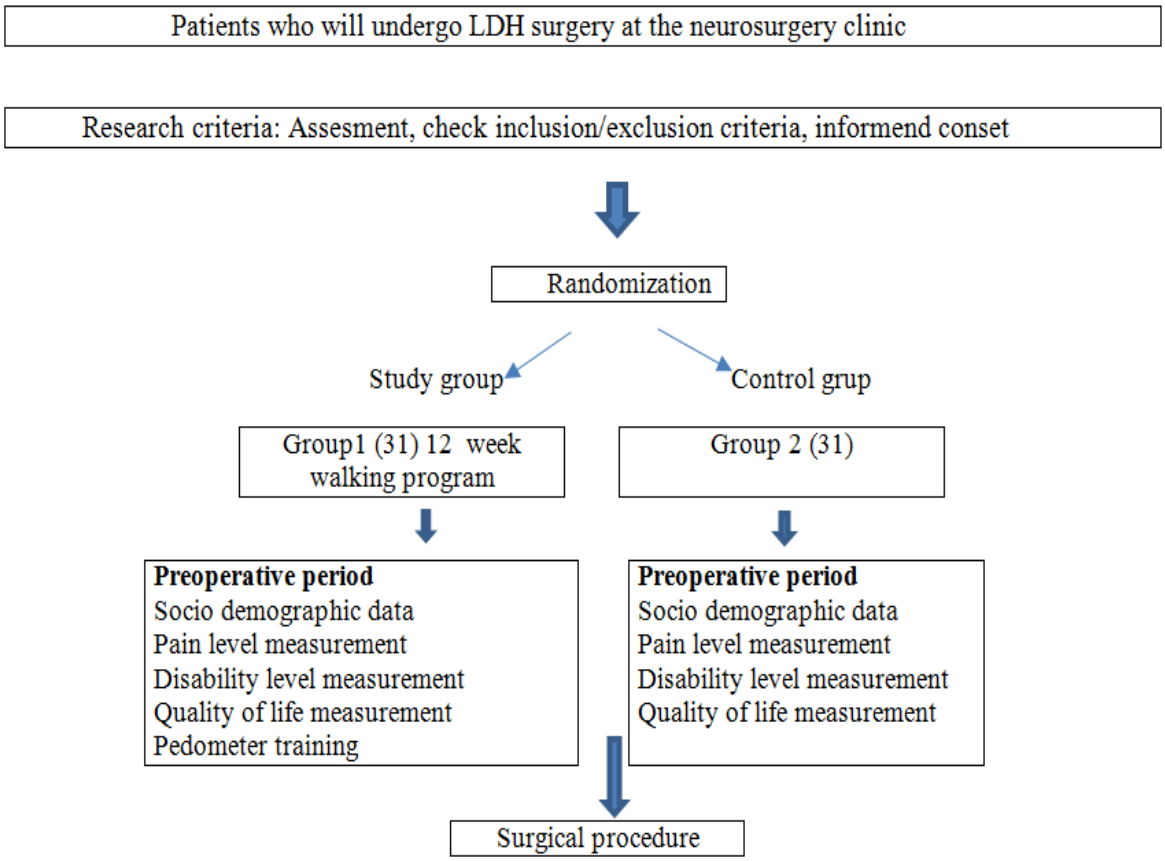
Determination of the sample size

In our study, planned according to scientific literature, the effect size regarding the McGill Pain Scale measurement difference was calculated to be 0.64. When the type I error margin was 0.05 and the strength off the test was

0.80(α= 0.05, 1-β= 0.80), the minimal sample size was found to be 62 (n=31 for each group) participants.

Ethical considerations

Permissions from the Marmara University Clinical Studies Board of Ethics (Decision No:09.2017.648) and the Cumhuriyet University Training and Research Hospital Head Physician's Office (Decision No: 93596471-000) were taken. Permission from the researchers who performed the Turkish validity and reliability tests of the scales used in the study were taken so that the scales could be used in the study. The aim and method of the study will explained to the patients who volunteered to participate in the study, and their written and oral informed consent will be taken.



Group 1 (12 week walk program group)	**Group 2 (Non-intervention group)**
3rd postoperative week Pain level measurement disability level measurement Starting the walking program	**3rd postoperative week** Pain level measurement disability level measurement
Weekly follow-up interviews Evaluation of weekly walking via phone	
7th postoperative weeks Pain level measurement disability level measurement Acquisition of walking chart data	**7th postoperative weeks** Pain level measurement disability level measurement
11th postoperative weeks Pain level measurement disability level measurement Acquisition of walking chart data	**11th postoperative weeks** Pain level measurement disability level measurement
15th postoperative week Pain level measurement Disability level measurement Quality of life measurement Acquisition of walking chart data	**15th postoperative week** Pain level measurement Disability level measurement Quality of life measurement

Figure 1: Study plan.

Population and randomization

Our study will be a randomized and controlled study, and its population will consist of patients who will undergo LDH surgery at the neurosurgery clinic of the Cumhuriyet University Health Services Application and Research Hospital.

The formation of the study and control groups will be determined through the closed envelope method. The patients will be asked to choose one of the envelopes containing cards where either "study group" or "control group" is written, and patients will be assigned to group according to the card emerging from the envelope they chose.

Inclusion criteria

Inclusion criteria were LDH surgery with minimally invasive procedure; males/females between 18–65 years; fluency in Turkish (verbal and written); access to a telephone (for follow-up support).

Exclusion criteria

Exclusion criteria were body mass ındex ıs up to 40; psychiatric disorders and/or cognitively impaired; recurrent LDH undergoing surgery; severe osteoarthrosis or arthritis of lower extremities causing limited walking ability; intermittent claudication due to vascular disease.

Intervention

The walking program

Since there is no walking guide prepared for patients in the postoperative period after LDH surgery, the incremental walking program suggested for sedentary individuals is planned to be used. According to this program, patients in the study group will start with the program suggesting a minimum of 10 minutes (approximately 1200 steps) four days a week, resting a day between two walks if possible.[19] The aim of this program is to sustain the 30 minutes of moderate intensity walking suggested in the American College of Sportive Medicine five days a week for five weeks and to keep this level of activity for the rest of the program.[17,27] According to the performance of the patients, the pace can be increased and the 30 minute walks can be divided into 2 or 3 periods of 15 or 10 minutes each for high paced walking.[28] Studies report important improvements in number of steps and walking distance in the first 3 months after lumbar spinal surgery.[20,29] In compliance with those studies, the walking program was planned to continue for 12 weeks (3 months).

Patient monitoring through telephone

Feedback is important in the walking program in order to determine patient performance, adaptation, and the reasons that prevent walking, to provide solutions for the participation of the individual in physical activity, and to form goals specific to the individual. The patients need to be monitored through phone calls weekly in order to achieve that.[30] Additionally, telemonitoring can increase the effectiveness of the intervention by increasing the motivations of patients and providing faster behavioral change. With a person supervising walking, motivation levels and the effort made to reach goals may increase.[31,32]

The phases of the study

Study group

First interview: Patients who gave consent to participate in the study and were assigned to the study group according to the envelope they chose will undergo measurements a day before surgery for disability with the Oswestry disability index, for quality of life with the SF-36 short form quality of life scale, for pain with the Mcgill pain index, and for BMI. The patient will be explained how to use the pedometer and how to record daily number of steps and walking distance, and will be handed the pedometer, the chart where daily number of steps and walking distance will be recorded, and the user's manual for the pedometer. The patients will be told they will be contacted via phone in the 2nd postoperative week and that they will start to use the pedometer and keep records from then on, and their addresses and contact information will be taken. Additionally, the patients will receive the discharge trainings provided by service nurses. This interview with the patients will be performed in the physical examination room in the clinic. There will be a table and chairs to facilitate face to face interviews in the room, and these will be assigned to only the patient and the researcher during the interview. All of the following face to face interviews will be conducted in this room inside the clinic, and the interviews will take approximately 30 minutes.

Second interview: The patients will be contacted via phone in the 2nd postoperative week. In this interview, the patients will be told to use a pedometer when walking and keep records on the walking chart for a week without assigning any goals for number of steps and walking distance. Thus, the walking duration, number of steps, and walking distance of each patient will be measured before starting the walking program.

Third interview: In the 3rd postoperative week, a face to face interview will be conducted with each patient, evaluating the seven day walking chart and measuring disability using the Oswestry disability index and pain using the Mcgill pain questionnaire. After evaluating the results obtained from the measurements and the one week walking chart, a weekly walking program will be formed with the patient if there are no circumstances preventing walking. The walking program will start with at least 10 minutes (approximately 1200 steps) four days a week. The program will be arranged to include one day of rest after each day of walking.

Following interviews: The patients will be contacted via phone every week, evaluating the number of steps and walking distance recorded the past week and planning for the next week. The total duration of the walking program is 12 weeks and thus this application will go on for 12 weeks. In the 7th and 11th postoperative weeks, face to face interviews with the patients will be conducted to reevaluate pain and disability levels, and the walking charts filled out by the patients will be taken from the patients at each 4 week period.

Last interview: In the 15th postoperative week, a face to face interview will be conducted with the patient, measuring disability with the Oswestry disability index, quality of life with the SF-36 short form quality of life scale, pain with the Mcgill pain index, and BMI. The walking charts of the last 4 weeks will then be taken from the patient.

Control group

First interview: Patients who gave consent to participate in the study and were assigned to the control group according to the envelope they chose will undergo measurements a day before surgery for disability with the Oswestry disability index, for quality of life with the SF-36 short form quality of life scale, for pain with the Mcgill pain index, and for BMI.

This interview with the patients will be performed in the physical examination room in the clinic, and all of the following face to face interviews will be conducted in this room. The interviews will take approximately 20 minutes.

Following interviews: Face to face interviews will be conducted with the patients in the 3rd, 7th, and 11th postoperative weeks, measuring disability using the Oswestry disability index and pain using the Mcgill pain questionnaire.

Last interview: In the 15th postoperative week, a face to face interview will be conducted with the patient, measuring disability with the Oswestry disability index, quality of life with the SF-36 short form quality of life scale, pain with the Mcgill pain index, and BMI.

Measurement tools

Pain: The short form Mcgill pain questionnaire (SF-MPQ) is a pain measurement tool tested for validity and reliability in Turkish by Yakut in 2007.[33] This form gives information on the sensory, perceptive, and intensity components of pain. 15 descriptive adjectives (11 sensory and 4 affective) are used to determine the perception of pain in the SFMPQ. The descriptive adjectives for the pain perceptions of the cases are evaluated through a numeric value scale (0=none, 1=mild, 2=moderate, 3=intense). Additionally, a 10 cm visual analog scale is used to measure the perceived pain intensity during evaluation. Patients are asked to mark the pain they feel during evaluation with an X on the 10 cm scale. Accordingly, the value "0" denotes no pain while the value "10" denotes the most intense pain ever felt. The distance between the marked point and the starting point is measured in centimeters. Then, the total pain intensity of the patient is evaluated using a 6 way likert type scale (0=no pain, 1=mild, 2=discomforting, 3=disturbing, 4=terrible, 5=unbearable).[34]

Quality of life: The Short Form SF-36 was developed by Ware and Sherbourne (1992) and tested for validity and reliability in Turkish by Koçyiğit et al (1999). This is a generic scale used widely for the evaluation of quality of life. The SF-36 is a self-report questionnaire that examines 8 dimensions of health, namely physical functionality, social functionality, role difficulties (physical and emotional), mental health, vitality, pain, and general perception of health, in 36 items. The scale provides a score that ranges between 0 and 100, and higher scores indicate better levels of health. The norm values of the SF-36 for the Turkish population were determined by Demiral et al.[35]

Functional disability: The modified Oswestry disability form created by Fairbanks (1980) and modified by Hudson-Cook is suggested as a sensitive scale for the measurement of the functional disabilities of patients with lower back pain for its value and repeatability. Its Turkish validity and reliability study was performed by Yakut et al. The form has 10 items with 6 choices each of values between 0 and 5 points. The patient is asked to choose the term that best suits his/her condition. The highest score attainable is 50, where scores of 1-10 are evaluated as mild functional disability, 11-30 are evaluated as moderate functional disability, and 31-50 are evaluated as severe functional disability.[36]

The walking program application chart: This form, prepared monthly to determine whether the patients in the study group perform regular walks or not, includes walking duration, number of steps, complaints during walking, and reasons for not walking. The form will be handed out to the patient in the first interview, and the patient will be told to fill out the form every day after starting the walking program (the patients will be reminded to keep regular records in the phone interviews). The forms will be taken back in the interviews in the 7th, 11th, and 15th weeks.

Pedometers: In order to determine the daily numbers of steps and walking durations of the patients in the study group, pedometers acquired by the researcher will be handed out. Pedometers are small devices that are easy to use. They can measure number of steps, walking distance, and duration.

Statistical analysis

Study data will be evaluated using descriptive statistical analyses (mean values, standard deviation), the Student t Test for the intergroup comparisons of normally

distributed quantitative variables, the Pearson's correlation coefficient test for the relationship between variables, regression analysis for the effectiveness of the intervention, the paired samples t test, and ANOVA for multiple variables.

DISCUSSION

Although accepted as a basic human activity, walking is underutilized in modern society. NO use of walking as an intervention strategy after disc hernia surgery has been found in the literature. However, it can be used in the postoperative period as an intervention to decrease mild lower back pain and pain related disability. This study, planned in order to fill this void in the literature, is a randomized controlled study designed to determine the effect of a pedometer supported walking program and telemonitoring after disc hernia surgery on pain, disability levels and quality of life. This study can be used as a source to show the effectiveness of walking as an intervention strategy after LDH surgery, and this can be accepted as a step of early postoperative rehabilitation in the future. Additionally, the findings on the walking durations, pain, and disability levels of the patients after LDH surgery can provide information for future studies. The nurse has a great role in health promotion, sustaining, prevention of diseases, health recovery and rehabilitation activities and can use these roles effectively to support the patient's optimum mobility, pain management and independence in activities. So the study can also stress the role and importance of nurses in postoperative patient monitoring.

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Conflict of interest: None declared
Ethical approval: The study was approved by Marmara University Clinical Studies Board of Ethics (Decision No:09.2017.648) and the Cumhuriyet University Training and Research Hospital Head Physician's Office (Decision No: 93596471-000)

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