

BMJ Open Physiotherapy after anterior cervical spine surgery for cervical disc disease: study protocol of a prospective randomised study to compare internet-based neck-specific exercise with prescribed physical activity

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ABSTRACT

Introduction Patients suffering from remaining disability after anterior cervical decompression and fusion (ACDF) surgery for cervical disc disease may be prescribed physical activity (PPA) or neck-specific exercises (NSEs). Currently, we lack data for the success of either approach. There is also a knowledge gap concerning the use of internet-based care for cervical disc disease. The scarcity of these data, and the high proportion of patients with various degrees of incapacity following ACDF, warrant increased efforts to investigate and improve cost-effective rehabilitation. The objective is to compare the effectiveness of a structured, internet-based NSE programme, versus PPA following ACDF surgery.

Methods and analysis This is a prospective, randomised, multicentre study that includes 140 patients with remaining disability ($\geq 30\%$ on the Neck Disability Index, NDI) following ACDF for radiculopathy due to cervical disc disease. Patient recruitment occurs following attendance at routine clinical appointments, scheduled at 3 months postsurgery. Patients are then randomised to one of two groups (70 patients/group) for a 3-month treatment programme/period of either internet-based NSE or PPA. Questionnaires on background data, pain and discomfort, physical and mental capacity, satisfaction with care, and health and workplace factors are completed, along with physical measures of neck-related function conducted by independent test leaders blinded to randomisation. Measures are collected at inclusion, after the 3-month treatments (end of treatment) and at a 2-year follow-up. Radiography will be completed at the 2-year follow-up. Preoperative data will be collected from the Swedish Spine Registry. Data on healthcare consumption, drug use and sick leave will be requested from the relevant national registers.

Ethical considerations This study was approved by the Regional Ethical Review Board in Linköping Ref. 2016/283–31 and 2017/91–32. The scientists are independent with no commercial ties. Patients are recruited after providing written informed consent. Patient data are presented at group level such that no connection to any individual can be made. All data are anonymised when reported, and subject to the Swedish Official Secrets Health Acts. The test leaders are independent and blinded for randomisation. Exercises, both

Strengths and limitations of this study

- The present internet-based treatment is new and innovative, and the study findings may contribute to the development of a more effective rehabilitation for those with residual disability after anterior cervical decompression and fusion.
- The study is a prospective randomised controlled study with test leaders/assessors blinded for randomisation and not involved in the treatment of the participants.
- The results from a multicentre study may be more generalisable than a one-site study and may also enhance implementation in outpatient clinical practice.
- A multicentre study offers less control of the interventions provided.
- Access to a computer/smartphone/tablet is needed for study participation which may exclude some individuals, although about 95% of Swedish people have access to a computer/smartphone/tablet and the internet.

general and neck-specific, have been used extensively in clinical practice and we anticipate no harm from their implementation other than a risk of muscle soreness. Both randomisation groups will receive care that is expected to relieve pain, although the group receiving NSE is expected to demonstrate a greater and more cost-effective improvement versus the PPA group. Any significant harm or unintended effects in each group will be collected by the test leaders. All questionnaires and test materials are coded by the research group, with code lists stored in locked, fireproof file cabinets, housed at the university in a room with controlled (card-based) access. Only individuals in receipt of a unique website address posted by the researchers can access the programme; patients can neither communicate with each other nor with caregivers via the programme. Study participation might lead to improved rehabilitation versus non-participation, and might therefore be of benefit. The results of this study should also

contribute to more effective and flexible rehabilitation, shorter waiting times, lower costs and the possibility to implement our findings on a wider level.

Dissemination If effective, the protocols used in this study can be implemented in existing healthcare structures. The results of the study will be presented in scientific journals and popular science magazines of relevance to health. The findings will also be presented at local, regional, national and international conferences and meetings, as well as in the education of university students and at public lectures. Information about the results will be communicated to the general population in cooperation with patient organisations and the media.

Trial registration NCT03036007.

INTRODUCTION

Radiculopathy due to cervical disc disease and its treatment

Anterior cervical decompression and fusion (ACDF) is an established method with which to treat radiculopathy for cervical disc disease,^{1–3} with several studies reporting favourable results that include reduced pain and neurological involvement, and a largely satisfied (80%) patient cohort.³ However, results from more detailed evaluations that include functional ability have been less optimistic,^{1 4–11} with approximately two-thirds of patients reporting poor self-rated neck-specific function, low neck-muscle endurance, daily neck pain, mental illness and low health-related quality of life.^{4 9–12} Three months after surgery 40% have a Neck Disability Index (NDI) rating of 30% or above, changing to 36% at 2-year follow-up (Peolsson *et al*, statistical analyses, Linköping University 7 March 2018). The majority of studies have focused on surgical technique rather than function or rehabilitation.

While ACDF on one or more segmental levels can be expected to reduce (specific) disc-related symptoms, it will not necessarily improve non-specific neck pain, or relieve disability/illness. Therefore there is an urgent need to investigate whether postoperative physical therapy may improve outcomes for those with remaining disability after ACDF.

Ideally, in studies of patients with radiculopathy due to cervical disc disease, their diagnosis should be confirmed by MRI (ie, clinical examination combined with consistent findings from MRI).^{8 13–17} However, few studies have investigated the success of physiotherapy for these ‘verified’ patients. Persson *et al*,¹³ in comparing ACDF surgery with physiotherapy and the use of a neck collar, reported no differences between the treatment strategies 15 months after enrolment. Peolsson *et al*⁸ and Engquist *et al*¹⁷ evaluated the benefits of ACDF beyond structured physiotherapy, by incorporating neck-specific exercises (NSEs) with a behavioural medicine approach. Besides reduced neck pain, no significant differences between the groups were identified at the 2-year follow-up.^{8 17} A follow-up of 5–8 years after intervention revealed that self-rated pain and neck-specific function were significantly better for the group that had received surgery versus those having received physical therapy alone.¹⁸ That study concluded that structured physiotherapy should precede any decisions on ACDF.^{8 17} One study^{19–21} comparing structured NSE in combination with a behavioural

medicine approach versus standard care (necessitating that patients proactively seek physiotherapy in primary healthcare settings) showed that those who completed structured rehabilitation reported a lower incidence of neck pain and were more satisfied with their care, with expectations of treatment that were more likely to be met. Although unique and innovative, design problems in the study^{19–21} included a random preoperative assignment to postoperative rehabilitation. This led to patients who felt well after surgery failing to report further improvements after physiotherapy, whereas those with postoperative complications were unable to complete their (planned) rehabilitation. Further, the structured rehabilitation was extensive, involving 30 visits to the physiotherapy clinic (optimally), which led to adherence difficulties (ie, problems fitting these physiotherapy visits into a busy work schedule). Ultimately, the majority (approximately 60%) of the patients randomised to standard care^{20 21} sought physiotherapy, demonstrating its need in postoperative rehabilitation, although this was ultimately a ‘confounding factor’^{20 21} given its lack of standardisation.

Internet-based care

Healthcare providers are facing substantial challenges, with care provision needing to evolve and improve in the face of increased demand and fiscal pressures. Consequently, new ways of providing healthcare should be investigated for their utility in increasing availability, reducing waiting times and costs, and increasing patient adherence, especially for those needing long-term physiotherapy. Equivalent or even improved efficacy for internet-based treatment versus face-to-face intervention with caregivers has already been demonstrated for a number of conditions,^{22–28} but not post-ACDF. Combining a few caregiver visits with internet-based support²⁹ should safeguard quality of care, while ensuring that exercises are being performed correctly.

Knowledge gaps for physiotherapy after ACDF

Multiple knowledge gaps exist. These include studies on: post-ACDF rehabilitation for individuals with residual disability; effect of postoperative NSE as a stand-alone treatment (in addition to advice/regimen recommended at surgical clinics) or prescribed physical activity (PPA). We also lack information on: muscle function following ACDF, work capacity or the cost benefits of rehabilitation post-ACDF, internet-based care for long-standing neck pain inclusive of cervical disc disease and postoperative rehabilitation. The high proportion of patients with residual problems after ACDF suggests an unmet need for evidence-based rehabilitation designed to improve future care.

Purpose

The main purpose of the study is to investigate whether internet-based, structured NSE differs from PPA after surgery for cervical disc disease, in relation to function, pain, work capacity, health-related quality of life,

	STUDY PERIOD					
	Enrollment	Allocation	Post-allocation			Close-out
TIMEPOINT *	0	0	t ₁	t ₂	t ₃	t _x
ENROLLMENT						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS **						
Internet-based neck-specific exercises			X	X	X	
Prescribed physical activity			X	X	X	
ASSESSMENTS ***						
Demographic data	X		X			
Self-reported outcomes (questionnaires)			X	X	X	X
Clinical outcomes			X	X	X	X

* t₁ = baseline, t₂ = 3 month follow-up (end of intervention in the study), t₃ = 24 month follow-up. t_x = 24 month follow-up (21 months post intervention).

** Internet-based neck-specific exercises = 12 weeks of neck-specific exercises with 4 appointments at physiotherapy clinic + internet support. Prescribed physical activity = 12 weeks of general exercises with 4 appointments at physiotherapy clinic.

*** Questionnaires on various aspects on disability, pain, psychosocial factors etc. including the main outcome Neck Disability Index. Clinical outcome measures including neck muscle endurance, range of motion, neurological tests etc.

Figure 1 The Standard Protocol Items: Recommendations for Interventional Trials schedule of enrolment, interventions and assessments.

satisfaction with care and cost effectiveness. Additional analyses may be performed.

Hypothesis

The hypothesis is that internet-based NSE will be superior to PPA in terms of primary outcome of NDI and secondary measures. The project is expected to lead to improved care, well-being and patient satisfaction.

Methods and analysis

Design

This is a prospective, randomised, experimental longitudinal multicentre study performed in Sweden, with a 2-year follow-up (figures 1 and 2). Questionnaires are distributed and physical tests are collected at baseline, at the end of treatment (3 months after enrolment) and after 2 years. Preoperative data are collected from the Swedish spine registry, Swespine. Patients are recruited from the surgical unit at the time of regular follow-up

visits to the physiotherapist/surgeon at approximately 3 months postoperatively (figures 1 and 2).

When the study criteria is met, and written and oral informed consent has been provided, the patient completes a questionnaire and undergoes physical measures of neck-related function. The patient is then randomised to one of two groups for 3 months of treatment with (1) Internet-based NSE with four visits to the physiotherapist or (2) PPA with four visits to the physiotherapist. The computerised block randomisation list is compiled by a statistician and the randomisation is stratified for gender with the aim of achieving equal numbers of men and women in the treatment groups. Patients in both groups are examined by a physiotherapist at the first visit in accordance with Swedish law.

The test leader is a physiotherapist at the surgical unit (obtains the written informed consent from the

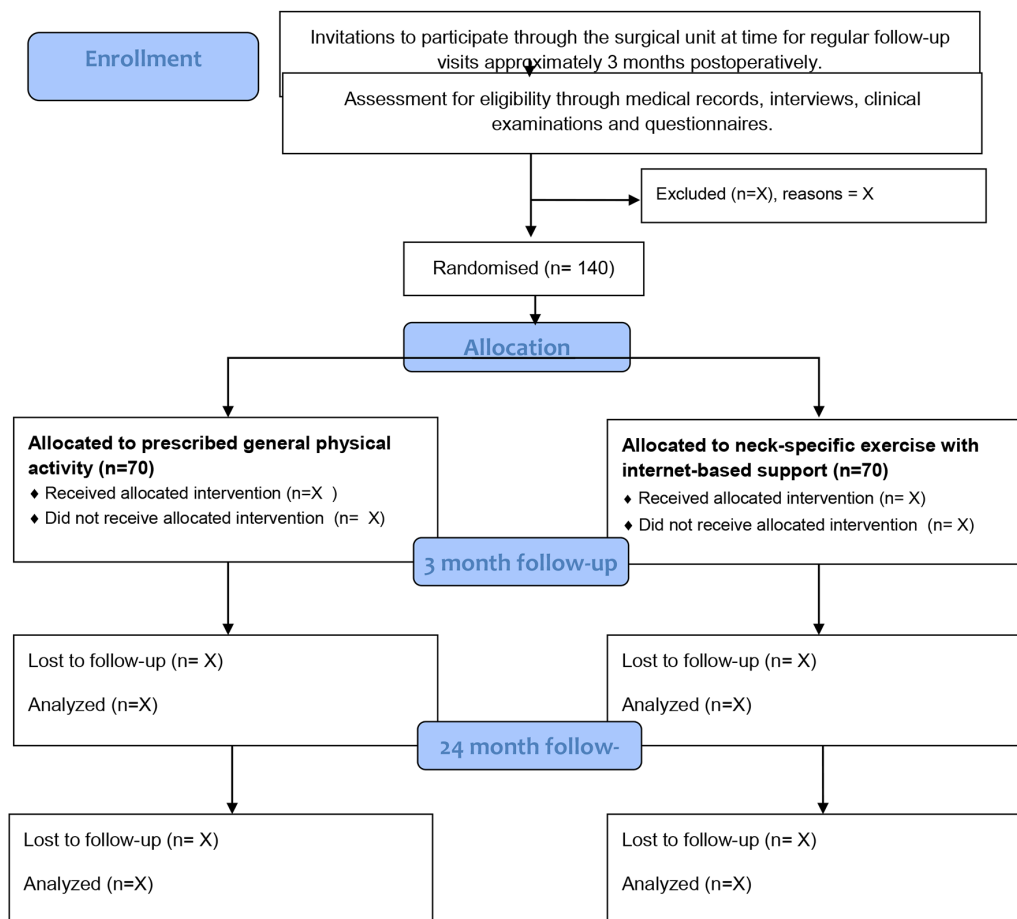


Figure 2 The Consolidated Standards of Reporting Trials flow diagram for 'Physiotherapy after anterior cervical spine surgery for cervical disc disease'.

study participant) who is not involved in study treatment and is blinded to the randomisation groups. Following randomisation, the results will be put into an opaque envelope that contains the name of the patient and their randomisation group, which is sent to the relevant physiotherapy outpatient care clinic. Questionnaires and tests of physical neck-related function are conducted at baseline (before randomisation), after 3 months (when the treatment ends) and after 2 years (figures 1 and 2). Participating physiotherapists will be provided with oral, written and practical training, and are able to consult project managers at any time. Exercise diaries and the number of care contacts will be recorded for both groups. Recruitment started on 14 February 2018.

Study criteria

Assessment for eligibility was conducted through preoperative recordings in Swespine by the surgical department, supplemented with medical records, questionnaires, interviews and clinical examinations.

Inclusion criteria

Preoperative criteria: cervical disc disease (disc herniation with or without osteophytes, or stenosis caused by osteophytes) in one or two segmental levels, confirmed

by MRI data compatible with clinical findings (neurological examination performed by a neck surgeon, ie, a neurosurgeon/orthopaedic surgeon) of nerve root compression in the cervical spine; radiculopathy with pain in one or both arms, with or without sensory and/or motor deficit; ACDF; at least 3 months of persistent arm pain; age 18–75 years. Postoperative criteria: remaining disability (approximately) 3 months after surgery (at the revisit to the surgeon/physiotherapist at the neurosurgery/neuro-orthopaedic clinic) in terms of an NDI^{30 31} Score of $\geq 30\%$; access to a computer/tablet/smartphone and the internet; motivated to exercise.

Exclusion criteria are as follows

Myelopathy; previous fracture or dislocation of the cervical spine; malignancy or benign spinal tumour (eg, neuromas); spinal infection; ongoing postoperative infection, or previous spondylodiscitis; previous cervical spine surgery; factors that are contraindicated for study participation or which hinder treatment or follow-up because of systemic disease, physical or mental illness, injury, inconvenience or postoperative complications; known alcohol/drug abuse; lack of ability to write/comprehend/express oneself in Swedish.

Patient and public involvement

The internet intervention programme and the questionnaires were pilot tested by people with neck pain before the study started and thereafter revised. Included in the questionnaires are specific questions regarding the experience of participating in the study, as well as their experiences of completing the questionnaires. A subgroup may also be interviewed regarding their expectations and experiences of participating in the intervention. The results of the study will be disseminated to patients through media and public conferences.

Intervention

NSEs are used due to their reported efficacy in reducing pain, and in improving function and health.^{32–38} General physical activity (PPA) has also been shown to alleviate chronic pain³⁹ and is recommended for patients with neck pain.^{40–41} It is recommended that participants not receive other physiotherapy intervention for their neck problems during the present study participation.

Internet-based NSEs

Participants will be provided with an explanation of their exercises and the objectives of these. The programme includes exercises to activate the deep neck muscles (initially daily), continuing with endurance training of the neck and shoulder muscles (three times/week for 12 weeks) (<https://liu.se/en/employee/annpe35>).

Exercises will be tailored to the individual's physical condition, and then scaled up progressively in terms of degree of difficulty and dose. Participants will undertake four visits to the physiotherapist (including the mandatory first visit for new clinical assessment as required by Swedish law), where the exercises will be introduced and repeated in order to establish and enable patient comprehension. The exercises are completed with the help of internet support outside of the healthcare system, which can be accessed anywhere, but most probably at home. Photos and videos of the exercises, information and answers to frequently asked questions are available on the internet-support platform. At the end of the treatment period, the patients are encouraged to continue practising the exercises on their own.

Prescribed physical activity

The training consists of general physical activity (three times/week for 12 weeks).^{42–43} The aim is to find a physical activity outside of the care unit that suits the individual, based on their specific needs and problems. The goal is that the individual should increase their overall level of physical activity, and that this activity is performed as part of a self-care/wellness routine. This may involve activities that can be performed at home, such as walking according to a set schedule, home exercises given by a physiotherapist (not neck-specific training), aerobic classes, and so on. To increase adherence, a motivational interview is conducted before the PPA schedule is provided. Patients are advised to contact the physiotherapist if their

prescribed activity is no longer suitable so that another activity can be identified. Four visits to the physiotherapist are provided (after the mandatory first visit for new clinical assessment), with the patient being encouraged to continue practising on their own at the end of the treatment period.

Outcome measures

Background data that will be collected include: surgery-related data including the number and segmental levels treated, surgical complications and reoperations during follow-up. Data regarding age, sex, symptom duration and onset, education, occupation, smoking, marital status, drug consumption, previous treatments and expectations of future treatment will be collected.

Primary main outcome measure: neck-specific functioning as measured by the NDI percentage score (0%–100%, where 0% denotes optimal function).^{30–31}

Secondary outcome measures that will be collected include: pain intensity of the neck, arm and head, measured using the Visual Analogue Scale (VAS 0–100 mm);⁴⁴ pain intensity for the neck and arm will also be assessed and registered using the numeric rating scale (NRS) 0–10 Scale⁴⁵ in line with the Swespine registry; pain frequency with a 5-point scale (never=1, constantly=5); pain drawing, an innovative new technology where painful areas are shaded on a human body image (male or female) using a tablet for instant digital computing, 'the Pain Sketch app';⁴⁶ registration of the use of pain medications; global perceived effect (modified Odom), on a 6-point scale (restored/much better to much worse);⁴⁷ dizziness/balance; Dizziness Handicap Inventory Scale⁴⁸ and VAS;⁴⁹ headache questions (the headache impact test and VAS);^{44–49} catastrophising; the Pain Catastrophising Scale (PCS);⁵⁰ confidence in one's own ability; Self-Efficacy Scale;⁵¹ estimation of neck-specific function related to participants' chosen activities (daily function, work, spare time); Patient-Specific Functional Scale;⁵² operating fear; Fear Avoidance Beliefs Questionnaire;^{53–54} depression, anxiety; Hospital Anxiety and Depression Scale;⁵⁵ health-related quality of life; EuroQuol and EQ thermometer;⁵⁶ self-rated work; Work Ability Index, short form;^{57–59} requirements-effort support in the workplace: Effort Reward Imbalance;⁶⁰ ergonomics questions; sickness presence (Stanford Presenteeism Scale);^{61–62} Swedish Standard Classification of Occupations (SSY) code;⁶³ expectations met and satisfaction with care; Cherkin symptom satisfaction;⁶⁴ Patient Enablement Instrument and VAS;⁶⁵ level of physical activity; Score 0–4;^{66–67} care consumption, exercise diary, sick days recorded. Sick data are also retrieved from the social insurance MiDAS register. Care consumption and medical prescriptions ordered through the healthcare databases of each region are used in cost-effectiveness analyses.

Tests conducted by the test leader will be: neck movement measured using the cervical range of motion device in degrees;⁶⁸ endurance in the dorsal and ventral neck

muscles, measured in seconds;⁶⁷ sensorimotor control of ventral neck muscles, in the supine position, with stabiliser (mm Hg);⁶⁹ examination of the sensation, force and reflexes in the arm/hand, nerve tension test, Spurling's test and manual examination/palpation of neck structures and movement in the upper cervical spine;⁷⁰ hand strength measured with a hand dynamometer;⁷¹ balance test, standing on one leg with eyes closed (Solec test);⁷² conventional radiography, with side views taken during neutral positioning and dynamic flexion/extension, as carried out routinely at the clinic for visits 3 months after surgery to examine implants and the degree of mobility of operated segments. Additional radiography will be taken at the 2-year follow-up to investigate fusion as well as possible subsidence of the cervical spine segment. In the event of pregnancy, radiography will be postponed until after birth (the extra X-ray examination was approved by the respective hospitals' radiation protection committee); data collected from national or regional registries: register data from Swespine, which provides the opportunity to follow participants over time (preoperatively, and then 1 year, 2 years, 5 years and 10 years postoperatively); register data for care use. To measure/monitor care use, the National Board of Health and Welfare patient register will be used, which collates all inpatient and outpatient care at hospitals, including operations and measures to be used. To follow patients' consumption of painkillers and antidepressants, the national Prescribed Drug Register will be consulted. To report those lost to follow-up, the Cause of Death Register and Statistics Sweden will be consulted, with variables on immigration and emigration checked. For data on sick leave, income, education, and so on, the LISA database (National Statistical Central Bureau) will be used (<http://www.socialstyrelsen.se/register>) (<http://www.scb.se/en/services/guidance-for-researchers-and-universities/vilka-mikrodata-finns/longitudinella-register/longitudinal-integration-database-for-health-insurance-and-labour-market-studies-lisa/>). Data on sick leave can also be requested from the Social Insurance Agency. Any important harms or unintended side effects will be collected by the test leaders, and adherence to treatment by an exercise diary.

Sample size calculation and statistics

Sample size calculations (conducted by a statistician) were based on a between-group difference of 10 score units in the primary outcome measure NDI (NDI percentage score).

Seventy participants per group are needed (assuming 80% power, and a level of significance of 5%), that is, a total of 140 participants are required. This calculation is based on group differences recorded in previous studies.^{17 18 32 33 73 74}

As we lack any studies on rehabilitation for patients with remaining disability after ACDF, this calculation remains hypothetical and our sample size may need to be adjusted. This number can also be adjusted in the event of participants dropping out, such that at least 70 individuals per

group complete the intervention. Data will be analysed using an intention-to-treat approach. Additional analyses will be carried out where the degree of implementation of treatment (adherence) is taken into account, as well as gender, dizziness, headaches, neurological findings and the number of segmental levels operated on. Analyses will be performed using parametrical or non-parametrical statistics, depending on the type of data, in consultation with statisticians as appropriate.

Trial limitations

The present study is a multicentre study, involving multiple treating therapists in several cities. This design offers less control of the interventions provided. To improve control, the treating physiotherapists will be educated by the project leaders and will have sufficient time to practise the standardised interventions in preparation for the study. Patients also follow exercise programmes within a standardised frame, which increases the similarity in intervention/information provided. Exercise diaries will be used in both randomisation groups to better control the intervention. The results from a multicentre study may be more generalisable than a single-site study because they will not depend on a single physiotherapist's knowledge, enthusiasm and charisma and may also enhance implementation in outpatient clinical practice. Access to a computer/smartphone/tablet is needed for study participation. Today, most people in both younger and older age groups have access to such devices and an internet connection.⁷⁵ To be able to complete the questionnaires and to understand the internet-based programme, participants need to speak and understand Swedish. If the results of the internet-based programme are successful, the web-based programme can be translated into other languages for wider implementation.

Collaboration

The research team will have access to the final data set. We are open to collaboration with others; please contact the principal investigator (AP) for scientific discussions.

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manuscript revision: AP, HL, GP, AH, MLL, ÅD. All authors approved the final version. Primary investigator: AP.

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Competing interests None declared.

Patient consent for publication Obtained.

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