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Protocol

The effectiveness of nurse-led visual rehabilitation on visual outcome among post-operative patients of sellar/suprasellar tumours-protocol of a randomized controlled trial

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ABSTRACT

Background: Tumour or mass of the suprasellar region are common pathologies and are also important due to their adjacency to the vital anterior visual apparatus. They may cause serious ocular signs and symptoms in addition to neurological complications resulting from increased intracranial pressure, cranial nerve impairment, or brain compression. Increased ICP may lead to headache, double vision and loss of peripheral vision, can lead to sinus pain or ear pain, drooping eyelid and seizures. After surgery, patients may continue to experience neuropsychological symptoms, physical symptoms and develop complications.
Methods: Randomized controlled trial. A computer random table with allocation concealment will be used to recruit and assign patients with visual complaints resulting from sellar/suprasellar tumors operated on at PGIMER to the experimental and control groups. Enrolment will be done on 5th to 7th day of surgery and intervention will be provided on the same day until discharge and booklet with nurse-led visual rehabilitation will be provided for continuous practice at home. The post-op follow-up will be done at 1 month and 3rd month of surgery.
Conclusions: This aim of the study is to determine the effectiveness of "nurse-led visual rehabilitation" on visual outcome among post-op patient with sellar/suprasellar tumours at 1 month and 3 months. The comprehensive nurse-led visual rehabilitation will be designed with the inputs from all nursing and clinical specialist in neurosurgery and ophthalmology, has the ability to work well with the dynamic care of postoperative patients experiencing visual problems from suprasellar and sellar tumors.
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Keywords: Nurse-led visual rehabilitation, Visual acuity, Visual symptoms

INTRODUCTION

Sellar and suprasellar refers to the structures located within and above the sella turcica, a bony saddle-shaped structure in the skull base. This anatomical area is in close proximity to the third ventricle and the hypothalamus, playing crucial roles in vision, hormonal regulation, and vascular supply to the brain.[1-4] Based on the size, the pituitary tumour can be classified as pituitary microadenoma (<10 mm) and pituitary macroadenoma (>10 mm).[5] As the tumour grow, it will push up the optic chiasm and resulting in visual symptoms. The primary approach for excising pituitary tumour is trans-nasal transsphenoidal (TSS) surgery, which can be highly effective.[6] However, exceptionally for large tumours with significant extension into the temporal or anterior cranial

fossa, transcranial (craniotomy) approaches are frequently more suitable.[7] Following surgery, patients may continue to experience neuropsychological symptoms, physical symptoms and develop complications. Patients with pituitary tumours may develop depression followed by psychosis and anxiety, and may also experience a poor quality of life.[8] Individualized nurse-led visual rehabilitation is necessary due to various vision problems experienced by patients pre and post operatively. These problems include trouble seeing street sign, difficulty recognizing face, difficulty in reading, blurred vision, double vision, visual field defect, eye strain, headache, impaired vision related quality of life, and health related quality of life. Implementing individualized nursing care could lead to improved post operative outcomes. Typically, patient undergoing postoperative care for pituitary tumours with visual symptoms do not receive individualized nurse-led visual rehabilitation aimed at improving vision.

Objectives

The objective of the current study is to assess the effectiveness of nurse-led visual rehabilitation on visual outcome, visual quality of life and health related quality of life of patients with visual symptoms (visual acuity, visual field, blurred vision, difficulty in near task) among postoperative patients of sellar/suprasellar tumours.

Null hypothesis (H_0)

H_0 (1): There will be no significant difference in visual outcome between postoperative sellar/suprasellar tumour patients managed with nurse-led visual rehabilitation and patients in control group.

H_0 (2): There will be no significant difference in visual quality of life (VQOL) and health related quality of life between postoperative sellar/suprasellar tumour patients managed with nurse-led visual rehabilitation and patients in control group.

METHODS

Design

A randomized control study with allocation concealment will be conducted to assess the effectiveness of nurse led visual rehabilitation on visual outcome (visual acuity, visual field and visual symptoms), visual quality of life and health related quality of life among postoperative patients of sellar/ suprasellar tumours. The randomized controlled trial will be carried out in accordance with the consolidated standards of reporting trials (CONSORT) statement (Figure 1).

Items of standard protocol: The randomized controlled trial study protocol will be created and presented using the guidelines for interventional trials (SPIRIT) statement.

Table 1: Representation of study design.

Groups				
Control group (C)	O_{0C}		O_{1C}	O_{2c}
Experimental group (E)	O_{0E}	X	O_{1E}	O_{2E}

O_{0C} and O_{0E}: Baseline assessment of control group and experimental group at enrolment within 5th to 7th post-operative days. X: Intervention of nurse-led visual rehabilitation on 5th day and continue with the help of booklet contain intervention. O_{1C} and O_{2C}: Assessment of the control group with routine care at 1 month and 3rd month of surgery. O_{1E} and O_{2E}: Post-interventional assessment of the experimental group at 1 month and 3rd month of surgery.

Intervention

The intervention in the present study is a nurse-led visual rehabilitation in present study aimed to improve visual symptoms and enhancing both visual and health-related quality of life will be given/implemented on post-op 5th to 7th day till discharge and received a booklet with visual rehabilitation exercises for further practice at home. Outcomes will be assessed among both the control group and experimental group at one month and three months of discharge. To achieve this, the nurse-led visual rehabilitation will be adopted, encompassing various rehabilitation exercises tailored to address specific aspects of visual function, such as eye scanning exercises which help patients by improving their ability to efficiently track and locate visual stimuli in their environment, enhancing visual attention and processing speed. Through repeated practice, patients develop better coordination and accuracy in eye movements, leading to improved visual scanning and information retrieval skills. Eye muscle strengthening exercises aid patients by enhancing the strength, flexibility, and coordination of the muscles responsible for controlling eye movements. This improvement leads to better control over eye movements, improved focusing ability and reduced eye strain, ultimately resulting in enhanced visual clarity and comfort for the patients. Compensatory exercises aid patients by mitigating visual impairment through alternative strategies such as enlarged print and high contrast background can enhance visibility. Similarly scanning and saccadic tasks help patients efficiently navigate their visual field despite limitations, while also improving eye movement coordination.[9] This exercise allowing the patients to better interact with their environment and perform daily tasks with greater ease despite existing visual challenges. And the neuroplasticity-based exercises harness the brain ability to adapt and reorganize neural connections.[10] By providing visual and verbal cues, patients can reinforce desired visual behaviours, facilitating learning and adaptation. Activities like walking while scanning and alternating reading from text in distal to proximal engage multiple sensory and motor pathways, promoting neuroplastic changes that enhance visual processing and integration.[11] These exercises collectively contributed to improving visual symptoms in patients participating in the present study.

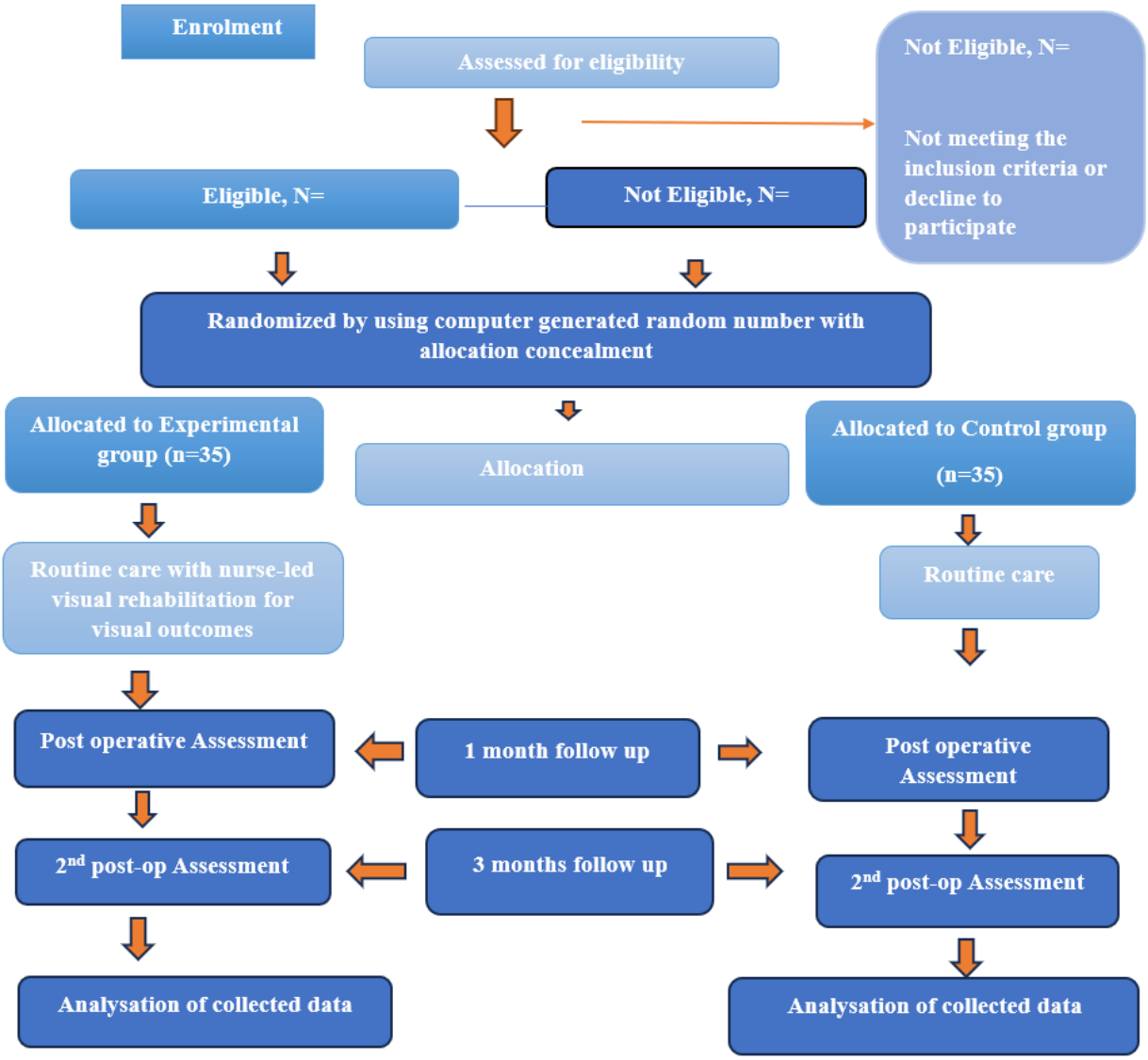

Figure 1: CONSORT diagram of the study.

Validation of intervention

The nurse-led visual rehabilitation was validated by nursing and clinical experts chosen from dept. of neurosurgery and ophthalmology.

Routine care

The control group, on the other hand, will have standard treatment from the medical staff until they are discharged. They will also be checked on at one and three months for changes in their hormonal profile, visual field, and visual acuity; if any of these are compromised, they will be referred to the endocrinology department.

Participants

Patient diagnosed with sellar/suprasellar tumours frequently exhibit impaired vision and report experiencing various visual symptoms. Patients who are clinically stable within five days of surgery and who were willing to participate will be enrolled. Patient with sellar/suprasellar tumour who exhibited additional vision-related problems such as cataract, blindness, glaucoma etc. and patient with impaired consciousness, disorientation or restlessness and Patients who could not follow the intervention due to any reason will be excluded from the study.

Sample size and sampling technique

Due to the lack of research on visual rehabilitation in

patients with sellar and suprasellar tumors, we intend to enroll 50 patients in each group. One hundred post-operative patients with visual complaints from sellar/suprasellar tumors will be recruited and randomly assigned to the experiment and control group using the total enumeration sampling technique.

Randomization and allocation concealment

Randomization will be used for patient enrollment, and a computer random table will be used to assign patients to the experimental and control groups while concealing the allocation process through the use of a non-transparent sealed envelope approach. The patients in the experimental group will get the intervention procedure. The control group's patients will get standard medical attention. Following discharge, patients in both groups experiencing visual complaints will be checked on one month and three months later.

Variables under the study

Independent variable of the study is nurse-led visual rehabilitation. Outcome variables of the study that will be measured at 1 month and 3 months are visual outcome (visual acuity, visual field and visual symptoms), visual quality of life and health related quality of life.

Table 2: Tool for data collection and its validity and reliability.

Tool no.	Name of tool	Purpose	Validity and reliability
Tool-1	Patient proforma Socio-demographic profile Clinical profile	To collect the socio -demographic data and clinical data of the patients.	
Tool-2	Snellen chart	To measure the visual acuity of patient.	Reliability: 0.94 [12]
Tool-3	Confrontation test	To measure the visual field of the patient.	Reliability: 0.23 [13]
Tool-4	Vision symptoms checklist	To observe the patient symptoms while doing the daily activities.	
Tool-5	VQOL (visual quality of life)	To assess the individual ability to perform the daily life activity with impaired vision	Cronbach alpha range: 0.739-0.932[14]
Tool-6	WHO-BREF scale	To measure the individual's health related quality of life.	Cronbach's alpha of 0.7[15]
Tool-7	Log sheet	To measure the compliance of patient with nurse-led visual rehabilitation	

Tools and techniques

Depending on the study variables, the tools were selected/developed after literature review and expert suggestions. Table 2 lists tools utilized in this investigation along with their objectives, validity, and reliability.

Data collection procedure

Data collection will commence from the fifth day following operation until discharge from PGIMER, Chandigarh's neurosurgery units. It is recommended that routine follow-ups be conducted in the neurosurgery OPD one month and three months after discharge. Patients will be recruited in the trial if they satisfy the inclusion criteria. Patients will be asked to provide written informed permission. Utilizing computer-generated random numbers with allocation concealment, patients will be randomized at random into the experimental and control groups. Pre-operated clinical profile will be collected from hospital documents, at post-operatively on 5th day, intervention was provided to experimental group on post-operative 5th day to 7th day until discharge and booklet with nurse-led visual rehabilitation was provided for continuous practice at home. The post-op follow-up was done at 1 month and 3 months of surgery. Booklet containing exercises that includes eye scanning exercises; eye muscles strengthening exercise were further divided into two categories which includes some specific exercises. Category 1: Oculomotor skill exercises: Directional tracking, clock rotations, near/far focussing, tromboning. Category 2: Visual perceptual eye exercises: Word or letter searches, hidden pictures puzzle, peripheral vision stimulation, mazes and visual tracing and computer games. Compensatory exercises such as enlarge print, high contrast background, scanning task and saccadic tasks. Neuroplasticity based interventions. A log sheet is provided at the end of the booklet for tick mark the number of exercises done daily.

Feasibility evaluation: pilot study

To determine whether the created tool and intervention regimen are feasible, pilot research will be carried out in the neurosurgery unit.

Plan for data analysis

MS excel 2007 will be used for data analysis, followed by IBM SPSS (Statistical package for social science) version 23.0 for data analysis. Depending on the type of data, all information will be shown as frequency, mean, and standard deviation. A p=0.05 on both sides will be regarded as statistically significant. The choice of tests, both parametric and non-parametric, will depend on how normal the data are. Chi-square test will be used to find homogeneity between two categorical variables. Independent t test will be used to compare continuous variables, among two categories if the data was normally

distributed. The analysed data of the study will be presented in the form of table.

Ethical considerations and dissemination

At every stage of the investigation, all pertinent ethical standards shall be adhered to. This study will involve the post-operative patients with visual symptoms due to sellar/suprasellar tumours. The researcher will aim at implementing nurse-led visual rehabilitation to them. The trial has been registered with the clinical trial registry of India (CTRI/2023/08/056030 on 2/8/23). The ethical approval of the study has been taken from the institute ethics committee, PGIMER, Chandigarh, India (Ethical clearance number: IEC-INT/2023/MSc-1045), which is an independent body. Each participant will receive a participation information sheet as well as early notification of the purpose of the study, the length of their involvement, and how they can participate in it. The participants' informed written consent will be obtained. Participants will have complete authority to leave the study at any time without fear of consequences to their ongoing care. The department of neurosurgery's relevant authority is consulted beforehand. The study will guarantee participant confidentiality and anonymity during data collecting and reportage.

DISCUSSION

The sellar and suprasellar tumor is one of the common pathologies which compresses the optic chiasma that can cause optic neuropathy and progressive deterioration of the visual field due to tumor compression is believed to ultimately reduce the visual acuity.[16] Patient may also feel some other symptoms like headache, nausea, drooping eye lid which will put impact on their day-to-day life activity, and diminishes the quality of life.[17] As the tumour grow in size these complications get worsen and can lead to permanent blindness. So, we need to put some intervention for visual outcome and to improve the quality of life among patient with sellar and suprasellar tumour.

Based on the size, the pituitary tumour can be classified as pituitary microadenoma (<10 mm) and pituitary macroadenoma (>10 mm). Another classification is a functional and non-functional pituitary tumour. Functional adenomas typically present with endocrinologic manifestation, involving an increase in hormones such as GH, TSH, FSH, LH, and prolactin hormone, and while non-functioning pituitary tumours are usually present with mass effects, which may include bitemporal hemianopia, diplopia, blurred vision and headache.[18]

The primary approach for excising pituitary tumour is TSS surgery, which can be highly effective. In this approach, an endoscope is used to access the pituitary gland through a small incision made back of the nasal septum. The instrument is then passed through the nose to open the sphenoid sinus and remove the tumour.[19] However, exceptionally for large tumours with significant extension into the temporal or anterior cranial fossa, transcranial (craniotomy) approaches are frequently more suitable, post operatively patients continue to exhibit these visual symptoms even worsened in some cases.[20]

There are various studies used the visual interventions as eye exercises, compensatory exercises, neuroplasticity-based intervention for different problems like stroke, traumatic brain injury, to overcome the same symptoms occurs with sellar and suprasellar tumour and their result shows the improvement in visual function after implementing this intervention and their quality of life is also improved and significantly results are seen. As there is lack of literature available for sellar and suprasellar tumour using visual rehabilitation, so researcher find the need to conduct the study and to provide nurse-led visual rehabilitation to post-operative patients of sellar and suprasellar tumour to improve the visual symptoms and vision related quality of life.

CONCLUSION

The study aims to determine the effectiveness of Nurse-led visual rehabilitation" on selected outcomes of patients with visual symptoms at 1 month and 3rd month post-operatively. The Nurse-led visual rehabilitation will be designed with the inputs from the nursing and clinical experts in department of neurosurgery and ophthalmology, has the potential to suit the dynamic nature of management of patients with the visual symptoms.

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