



بسم الله الرحمن الرحيم

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مسئولية عن محتوى هذه الرسالة.

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Effectiveness of Integrated Education and Relaxation Program on Migraine Related Disability in Patients Attending Headache Clinic, Ain Shams University Hospitals: A Randomized Controlled Trial

Thesis

*Submitted for Partial Fulfillment of M.D. Degree in
Family Medicine*

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بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

قَالَ

سَبَّحَانَكَ لَا إِلَهَ إِلَّا مَا عَلَّمْتَنَا إِنَّكَ أَنْتَ
الْعَلِيمُ الْعَظِيمُ

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List of Abbreviations

Abb.	Full term
5-HTR1F.....	5-Hydroxytryptamine 1 F
AEs	Adverse Events
AUD	Alcohol Use Disorder
CBT.....	Cognitive Behavioral Therapy
CGRP	Calcitonin Gene-Related Peptide
COPD.....	Chronic Obstructive Pulmonary Disease
CSD.....	Cortical Spreading Depolarization
DALYs	Disability-Adjusted Life Years
DHE	Dihydroergotamine
EMR.....	Eastern Mediterranean Region
ER	Emergency Room
GAD	Generalized Anxiety Disorder
GBD	Global Burden of Disease
HRQoL.....	Health-Related Quality of Life
ICHD-3	International Classification of Headache Disorders
IHS	International Headache Society
MDD	Major Depressive Disorder
MOH	Medication Overuse Headaches
NRS	Numerical Rating Scale
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
PMR.....	Progressive Muscle Relaxation
QOL	Quality Of Life
TPE.....	Therapeutic Patient Education
TTH	Tension-Type Headache
VAS.....	Visual Analogue Scale
WHO.....	World Health Organization
YLDs.....	Years Lived With Disability

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Abstract

Background: Migraine is the most disabling primary headache disorder worldwide. The value of integrative strategies in migraine management has been raised due to the recurrent and provoked nature of migraine. **Aim:** to evaluate the effectiveness of implementing therapeutic patient education and relaxation training program versus usual pharmacological treatment alone on the frequency, severity, and duration of migraine attacks as primary outcome and migraine-related disability and quality of life as secondary outcome. **Methods:** A randomized controlled trial was conducted at the specialized headache clinic of a Tertiary Referral Centre. Sixty patients were randomly assigned to intervention or control groups. Participants in the intervention arm received the education and relaxation training program and were instructed to perform daily relaxation exercises in addition to their routine pharmacological treatment meanwhile the control group only received their routine treatments. Follow-up was done after 1, and 3 months using headache diary and migraine specific quality of life questionnaire (MSQ). **Result:** After implementation of the program there was a significant reduction in migraine attacks severity in the intervention group compared to the control group ($p < 0.001$), also they had significantly fewer migraine headache days/month and duration of migraine attacks compared to patients in control group ($p < 0.001$). Statistically significant improvement of Role-Function Restrictive, Role-Function Preventive and Emotional Function domains of MSQ ($p < 0.001$). **Conclusion:** An integrated migraine management program has a significant effect on reducing the burden of migraine attacks and improving the daily activities of migraine sufferers.

Keywords: Migraine prevention, Integrated education, Relaxation techniques, Quality of life.

PROTOCOL OF A THESIS FOR PARTIAL FULFILMENT OF M.D. DEGREE IN FAMILY MEDICINE

Title of the Protocol: Effectiveness of integrated education and relaxation program on migraine related disability in patients attending headache clinic, Ain Shams University Hospitals: A randomized controlled trial

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**What is already known on this subject? AND
What does this study add?**

Migraine causes severe impairment in quality of life (QOL) both during and between attacks. Migraine also increases absenteeism, reduces productivity at work as well as at home, disrupts social and family relationships, also is associated with increased healthcare costs.

The current study aiming to evaluate the effectiveness of an integrated therapeutic patient education and relaxation training intervention in order to decrease the burden of migraine headache among adult patients attending the headache clinic in Ain Shams University Hospitals.

1. INTRODUCTION/ REVIEW

Migraine is a common chronic neurological disabling primary headache disorder which not associated with an underlying pathology **(Roberto et al., 2018)**.

It takes the form of a recurrent attacks of headache lasting 4–72 hours, unilateral location, pulsating quality, moderate or severe intensity, aggravation by routine physical activity and association with nausea and/or vomiting, photophobia and phonophobia **(IHS, 2018)**.

In an updated version of the international classification of headache disorders (ICHD Beta 3) Migraine has two major types: Migraine without aura known as (Common migraine) and Migraine with aura (Classic migraine) **(Paul and William, 2018)**. About 80% of migraine patients have migraine without aura, whereas migraine with typical aura accounts for 15-20% of cases **(Rima et al., 2017)**.

Migraine physiopathology in unknown, recent evidence indicates that migraine is a disorder of brain dysfunction with both the genetic background and environment triggering **(Goadsby et al., 2017)**, although there are several studies that support a central sensitization mechanism at the level of trigemino-cervical complex to explain migraine **(Min and Shengyuan, 2018)**, Some authors suggest that it is a bio-behavioral disorder, the result of the interplay between cortical hypersensitivity and a social learning process **(Andrighi et al., 2016)**.

World Health Organization (WHO) ranks headache disorders amongst the ten most disabling conditions in the world. (**WHO, 2016**). In the Global Burden of Disease Study 2010, migraine was ranked as the third most prevalent disorder in the world (**GBD2010**).

Many epidemiological studies have documented high prevalence of migraine. A meta-analysis of 302 community based studies determined an average global migraine prevalence of 10.4% in Africa, 10.1% in Asia, 11.4% in Europe, 9.7% in North America, and 16.4% in Central and South America. This study estimated that 1 in 10 people worldwide were affected by migraine (**Woldeamanuel and Cowan, 2017**).

The epidemiology of headache in Arab countries reporting headache prevalence in the Arab nations of Qatar, Saudi Arabia (2 papers) and Oman. The migraine prevalence was 2.6-5% in Saudi Arabia and 7.9% in Qatar, while the 1-year migraine prevalence was 10.1% in Oman (**Benameret al., 2010**).

In Egypt, a study was performed to assess the Prevalence of primary headache disorders in Al-Fayoum Governorate demonstrated that 1-year migraine prevalence was 17.3 % (**Naglaa et al., 2015**). Another study performed to assess the risk factors of migraine in Assuit governorate reported that headache was found in 1668 subjects and Migraine prevalence was 10.51% (**Mahmoud et al., 2016**). In a multicenter primary care-based study showed that more than 90% of patients presenting to primary care with headache had migraine (**SIGN, 2018**).

Headache disorders are not perceived by the public as serious since they are mostly episodic, do not cause death, and are not contagious (**WHO, Fact sheet, 2016**) But migraine causes severe impairment in quality of life (QOL) both during and between attacks. Migraine also increases absenteeism, reduces productivity at work as well as at home, disrupts social and family relationships, also is associated with increased healthcare costs (**Swaleha et al., 2014**).

Literature shows that the best treatment for migraine was a multidisciplinary treatment including bio behavioral and pharmacological approaches. Bio behavioral treatments (BBTs) includes therapeutic patient education (TPE), cognitive behavioral interventions, and bio behavioral training (biofeedback, relaxation training, and stress management) which