A Comparative Study between Dissociative Treatment and Binocular Interactive Treatment in Amblyopia

Thesis

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In Partial Fulfillment of the Requirements of Doctorate Degree in Ophthalmology
By

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Faculty of Medicine

Ethical Committee of Scientific research

Informed consent form for parents or guardians of patients who are invited to participate in the research

Research title: A Comparative Study between Dissociative Treatment and Binocular Interactive Treatment in Amblyopia

Introduction and aim of the work:

Amblyopia is a unilateral or, infrequently, a bilateral reduction of best corrected visual acuity (BCVA) which cannot be attributed to coexisting eye or visual pathway disease. Several modalities of treatment for amblyopia are available, yet occlusion treatment is the gold standard involving covering the good eye with a patch for a prescribed period of time ranging from 10 minutes daily to all waking. However, its effectiveness decreases in older children and adults. Disadvantages include prolonged treatment leading to poor compliance, patching related distress, relationship strain and stigma. In extreme cases, non-compliance with patching results in a costly hospital admission to supervise the patching treatment. In addition, wearing a patch eliminates any advantage of binocularity. Not to mention that not all patients respond to patching and of those who do, many have residual amblyopia after treatment is stopped regardless of compliance. More importantly, binocular vision is not automatically restored once the vision in the amblyopic eye has been improved. In fact, once the patch is removed after therapy, the amblyopic eye could be suppressed by the better seeing eye and can lose some of the gains achieved as a result of therapy. Advances in amblyopia treatment include dichoptic training, perceptual learning, and video gaming. These depend on the fact that the adult brain has been shown to be much more plastic than it was once believed to be and hence have the advantage of expanding the age of response in adults. Perceptual learning approaches have the advantage of being a dichoptic (binocular treatment) approach which is

independent of age and type of amblyopia. Furthermore, it has been shown recently that therapy promotes binocular vision by strengthening stereopsis and reducing suppression. Therefore the aim of this work is to compare the gold standard occlusion therapy alone with dichoptic therapy

Place of work:

Ophthalmology Department, Ain Shams University Hospital

Number and Selection of participants:

Patients will be assigned randomly into two groups:

Group A: 50 patients will receive the gold standard occlusion therapy

Group B: 50 patients will receive dichoptic treatment in the form of playing a video game (Lazy Eye Tetris games such as Lazy Eye Blocks ®) while wearing a red/green goggle.

Each group will be subdivided according to age:

1. From 4 to 7 years.
2. From above 7 to 12 years.
3. From above 12 to 30 years.

Hours of occlusion will be classified according to the degree of amblyopia:

- Mild to moderate amblyopia (Best corrected visual acuity (BCVA)< 0.2): 2-4 hours occlusion
- Severe (BCVA> 0.2): 4-6 hours occlusion

Hours of dichoptic treatment in group B will be classified according to the degree of amblyopia:

- Mild to moderate amblyopia (BCVA< 0.2): 2-4 hours of treatment
- Severe (BCVA> 0.2): 4-6 hours of treatment

Plan of the work:

After your consent achievement and fully explained about the steps of research, the subjects of both groups will be subjected to the following:

Preoperative assessment:

All patients will undergo the following:

1) Full medical and ophthalmic history
2) Examination:
   A) External Appearance:

      Anomalous Head Position, globes (e.g., proptosis), lids (e.g. ptosis).

   B) Refraction:
      With and without cycloplegia.
   C) Visual acuity:
   D) With and without correction using Snellen acuity chart and preferential looking test for non-verbal patients.
   E) Motility:

      Ductions and versions (9 positions of gaze)

F) Angle of deviation if any
G) Fixation :

Fixation behavior (fixation preference) will be tested via base down 10 PD fixation preference test.

H) Quantitative Binocular vision assessment
I) Anterior segment examination.
J) Posterior segment examination using indirect ophthalmoscopy with a 20-D (diopter) lens through a dilated pupil.

Benefits expected from the study:

Benefits to the participants: treating amblyopia

Benefits to the community:

- Decreasing duration of treatment
- Increased compliance to treatment due to the factor of entertainment due to playing a game
- Ability to treat adults and children

Conducting the consent:

The consent will be conducted to the legal guardian or the patient by the investigator, Doctor Suha Ahmed Amin before starting the treatment. Literate individuals will be left to read the consent followed by its explanation by the mentioned investigator, while illiterate individuals will have the consent read and explained to them as well.

Risks and complications:

This research will not expose your patient to further risks or complications despite the standard risks of protocol of Ain Shams University Hospitals or resistance to treatment.

Reimbursements in cases of risks and complications:

Should your patient get physically injured as a result of research-related procedures, Doctor Suha Ahmed Amin will provide first – aid medical treatment although no such injuries are expected in this research

Alternatives to participating:

In case of refusing to participate in this research, your patient will be followed up and will receive his treatment as planned,

Confidentiality:

You will deal in complete confidentiality, and no one has right to read your patient medical information except the main researcher. After the research is complete, you will be informed regarding your patient's research results and also further information regarding your patient's health status.

Right to refuse or withdraw:

Any participant doesn't have to take part in this research if he/she or want. They may also stop participating at any time. If you have read this form and have decided to let your patient to participate in this study, please understand that your patient's participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which your patient is otherwise entitled. Your decision whether or not to participate in this study will not affect your patient's medical care Individual privacy will be maintained in all published and written data resulting from the study.

Contact Information:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the investigator, Suha Ahmed Amin at mobile number: 01147079403. You can also call the assistant supervisor Dr. Ahmad Taha Ismail at mobile number 01001790967 If you have any problems or concerns about the study, you can also call Prof. Dr. Hazem Hosny Nouh the main supervisor at mobile phone number: 01222125463

You do not have to sign this consent form. But if you do not, your patient will not be able to participate in this research study.

Certificate of consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I ask have been answered to my satisfaction. I consent voluntary to participate in this research and understand that I have the right to withdraw from the research at any time without in anyway affecting my patient's medical care.

- Name of participant:
- Signature of legal guardian:
- Or participant:
- Identity number or finger print: …….
- Date:

I have accurately read o witnessed the accurate reading of the consent to the potential participant. The individual has had the opportunity to ask questions I confirm that the individual has given consent freely.

- Name of researcher: Suha Ahmed Amin Moustafa Hussein
- Signature of researcher:
- Date:

This proposal has been reviewed and approved by Ethical Committee of Scientific research, which is committee whose task is to make sure that research participants are protected from harm.

If you wish to find more about Ethical Committee of Scientific research contact:
Name:
Address:
Telephone number: