**PATIENT INFORMATION SHEET**

**This study is about the Effectiveness of Eyelid Massager in Meibomian Gland Dysfunction (17/CER/EP1)**

We are inviting you to take part in a research study. Before you decide whether to participate or not it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and to decide whether or not you wish to be involved.

1. **What is the purpose of this study?**

The purpose of this study is to assess the benefit of using an eyelid massager in participants having Evaporative Dry Eye due to Meibomian Gland Dysfunction.

The surface of the eye is covered in a lining of tears called the tear ­lm. The tear ­lm is

made up of three layers:

1. Lipid (oil) layer which lubricates and prevents evaporation of the tears;
2. Aqueous (water) layer, which nourishes and protects the eye surface; and
3. Mucin layer, which adheres to the eye.

Since the tear ­lm is exposed directly to the air, the protective lipid layer is essential to maintaining a healthy tear ­lm on the eye. When the protective lipid layer of the tear film is lacking, the eye surface can become irritated and dry eye symptoms can occur. Evaporative Dry Eye is a disease that results from not having enough lipids in the tear film to protect the eye. Evaporative dry eye is most often caused by a blockage or obstruction of the eyelid glands, called the Meibomian Glands, which produce the lipid layer of the tear film. Meibomian Gland Dysfunction (MGD) is a disease that results from the formation of plugs inside the glands, which obstruct gland openings and limit the lipid secreted by the glands into the tears.

Warm compress therapy and eyelid massage is recommended treatment for Evaporative Dry Eye due to Meibomian Gland Dysfunction. Heat and massage to the eyelids to allow the oil from the blocked eyelid glands to flow into the tear film thus improving the functioning of blocked glands and associated dry eye symptoms

The possible treatments available to you with your optometrist, general practitioner (GP) and consultant are:

• Manual expression of your eyelid glands by your doctor or optometrist.

• Topical prescription medications

• Over-the-counter (OTC) tear replacements and lubricants

• Punctal plugs inserted in the tear ducts.

**2. Why have I been chosen?**

You have been chosen because you are 18 years of age or older and have been diagnosed with a Dry Eye Disease due to Meibomian Gland Dysfunction.

**3. Do I have to take part?**

It is up to you to decide whether or not to take part. You are free to withdraw at any time and without giving a reason.

**4. What will happen if I take part?**

To find out whether the eyelid massager with heat mask is beneficial or not, we need to make comparisons between different treatments. To do this we will randomly allocate you to one of the following options:

1. Eyelid massage along with heated eye mask

2. Eye mask only without heat

These are all safe and standard procedures. The benefits and problems associated with each treatment will be compared. This is called a randomised study.

**5. What do I have to do?**

If you agree to participate in this study (Effectiveness of Eyelid Massager in Meibomian Gland Dysfunction), we may ask you to visit Cathedral Eye Clinic for:

1. Enrolment assessment
2. Baseline assessment
3. 2nd week after treatment
4. 1-month after treatment
5. 2-months after treatment
6. 3-months after treatment (Last test day)

During these visits we will perform the follow non-invasive index tests (approximately one hour):

1. Tear film lipid layer thickness
2. Meibomian gland secretion evaluation
3. Tear osmolality
4. Corneal sensation
5. Tear break up time
6. Corneal staining score
7. OSDI questionnaire score
8. Quality of vision questionnaire and
9. D-III questionnaire

This study does NOT involve the retrieval of blood or tissue sample.

1. **Expenses and payments**

No payment will be made to any participants for taking part in the study, nor will travel expenses be paid. All assessments for the study performed during the 3-months study is free of charge. The ‘Eyepeace’ eyelid massager and the eye mask provided to the participants are also free and the participant can keep it with them after the completion of the study.

1. **What are the benefits of taking part?**

The biggest benefit of research is often not directly experienced by you, but is the increase in knowledge which benefits people in the future.

1. **What are the possible risks of taking part?**

Eyelid massage and heated eye masks are a safe and non-invasive technique to promote ocular health. Allergy questionnaire will be asked during the enrolment process to help identify and minimise any possible risks.

1. **Will my taking part be kept confidential?**

All patient information is stored on password protected computer databases or in locked filing cabinets. You will be allocated a study number and staff not directly involved with you will know you only by this number. When the results of the study are reported, individuals who have taken part will not be identified in any way.

1. **What if I change my mind about taking part?**

If you decide to withdraw from the study, your standard of care will not be affected. You will still be asked to attend the usual follow-up clinics required by your doctor and hospital. These will not be part of the study.

1. **Will my GP be informed of my involvement in the study?**

With your consent your GP will be notified of your participation in this study.

1. **How will the information I provide be used?**

We plan to publish the results in a health journal so others can read about and learn from the results of the study.

1. **Who is organising and funding the research?**

This study is being funded through the Cathedral Eye Research (CER) Programme, which

is part of the Cathedral Eye Clinic. You can access information about them on the CER website: ([www.catherdraleye-research.co.uk](http://www.catherdraleye-research.co.uk)).

1. **Further Information**

If you require more information about this study please call one of the telephone numbers provided to speak to a clinical member of the research team or, alternatively look at the study website

[www.catherdraleye-research.co.uk/eyepeace](http://www.catherdraleye-research.co.uk/eyepeace)

**Thank you for reading this.**

**If you have any questions or would like any more information, please contact the Eyepeace Study**

**Office by phone:**

**028 9032 2020**

**Or email info@cathedraleye.com**

**Please keep this information sheet for your records.**

**If you agree to enter the study, please sign the enclosed consent form and we will return a copy to you.**