

December 2019

Update Newsletter – Number Four**Measuring the effects of eye alignment surgery - a feasibility study**

I am sending you this update newsletter because you have previously told me you would like to receive further information about the progress of my research.

I would like to thank all the volunteers that have taken part in the study so far. Your involvement has been very much appreciated and I know many of you feel strongly that research into your eye condition is important.

Without your support, the study would simply not be possible. Thank you very much.

Principal Investigator: Gemma Arblaster

Overview of the research:

Strabismus (or squint) is the when one eye turns so that both eyes aren't lined up in the same direction. Strabismus affects approximately 5% of the population. An operation (surgery) can be performed on the eye muscles in patients with strabismus. The aim of surgery is to realign the eyes into a straighter position. What happens to patients after 'eye alignment surgery' is the topic of the research study.

This research study aims to find out whether it is feasible to measure changes in vision and task performance in patients who have had eye alignment surgery for psychosocial reasons.

The NHS currently funds eye alignment surgery for strabismus because of the known visual and/or psychosocial benefits to patients. However, more evidence is needed about the outcomes of eye alignment surgery in adults.

Some areas in England have withdrawn funding for eye alignment surgery for psychosocial reasons over concern not enough patient benefit is proven. However, evidence suggests that there are aspects of patients' lives and their vision that can improve following eye alignment surgery for a planned psychosocial benefit.

The overall aim of the study is to find out more information and improve our understanding of the potential outcomes from eye alignment surgery. It aims to answer the questions that have not been addressed by smaller studies.

Key milestones in the research project:

The overall research study is being completed over 3 years, as part of a PhD. The first two years of the study have been completed and the study is in its final year.

Phase 1 - completed

Eleven patients who previously underwent eye alignment surgery at Sheffield Teaching Hospitals NHS Foundation Trust were interviewed during phase one.

All the patients who were interviewed had undergone surgery to improve their eye alignment for 'psychosocial reasons', meaning they wanted to have straighter eyes, but they were not expected to have any change in their vision or their abilities to do things in their daily lives after surgery. During the interviews patients were asked what they felt had changed, or had not changed, after having eye alignment surgery.

The results from phase one showed that most patients (but not all) felt their vision, task performance and/or physical symptoms, such as eye pain or headaches, improved in some way after having surgery. A small number of patients felt some of their physical symptoms were worse after surgery. All patients felt their confidence improved as result of having straighter eyes and all were pleased with their eye alignment after surgery. These results were used to plan phase two of the research study.

Phase 2 – still under way

Patients who are having eye alignment surgery for psychosocial reasons are taking part in the study in the 'patient group'. Volunteers with strabismus, who aren't having surgery, are taking part in the 'control group'.

Both the patient group and the control group are having 'extra' measurements, as well as standard clinical measurements during phase two of study. These extra measurements include a range of different tasks to measure vision, eye hand coordination, task performance, and eye movements. These study measurements are performed twice, before and after surgery, in the patient group and at least 3 months apart in the control group.

Currently recruitment to the patient group is from Sheffield Teaching Hospitals NHS Foundation Trust only. Recruitment of new patients to the study is continuing until the end of 2019.

Thirty-three patients have been recruited to phase two of the study so far, eighteen are in the patient group and fifteen are in the control group. Twelve of the patient group and nine of the control group have completed both study visits. No study participants have withdrawn from the study so far.

The final part of phase two will include recruitment of new patients (until the end of 2019), completing the final study visits and analysing the results.

Funding:

The research is currently being funded by the NIHR. Gemma Arblaster has been awarded a Clinical Doctoral Research Fellowship to undertake this research at the Academic Unit of Ophthalmology and Orthoptics, University of Sheffield. The research began in June 2017 and will end in May 2020.

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Data Protection

Since the study began, new regulations have come into effect – the new EU General Data Protection Regulation (or GDPR). You have previously chosen to receive study update newsletters, which have been offered to everyone involved in the study as a participant, advisor or supervisor. To be able to receive these update newsletters I have recorded your preferred contact details (email or postal address) on a document, which is kept securely on a password protected University of Sheffield computer system. This information will be destroyed 5 years after the study has been completed (study end - May 2020).

The University of Sheffield will act as the 'Data Controller' for this study. This means that the University is responsible for looking after your information and using it properly. The legal basis for me keeping your contact details is 'performance of a task carried out in the public interest'. If at any time if you no longer wish to receive these study update newsletters, please contact me and I will delete your contact details from my records.

The 'sponsor' of the research is Sheffield Teaching Hospitals NHS Foundation Trust.

If you have further questions about the study or your information, you can contact me directly.

If you would like to contact the sponsor directly you can contact:

Dr Dipak Patel, Clinical Research Office, Sheffield Teaching Hospitals NHS Foundation Trust. dipak.patel@sth.nhs.uk

Further information, including details about how and why the University processes your personal information, how we keep your information secure, and your legal rights (including how to complain if you feel that your personal information has not been handled correctly), can be found in the University's Privacy Notice

<https://www.sheffield.ac.uk/govern/data-protection/privacy/general>

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