ZEISS Project 'CONNECT': Spectacle Wearer Test
Participant Information Sheet

Invitation

We would like to invite you to take part in a research study.

Before you decide if you would like to participate, take time to read the following information carefully, and if you wish, discuss it with others, such as your family, friends or colleagues.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear, or if you would like more information before you make your decision.

What is the purpose of the study?

The study will assess the subjective performance of single vision, Digital (a new type of lens designed for people experiencing near vision discomfort for the first time) and multifocal (varifocal) spectacle lens designs, which are specifically tailored for an active and 'connected' lifestyle.

All the spectacles are CE marked meaning they are approved to be sold in Europe. Data from the study will enable the funders of the study to develop and refine future spectacles.

Why have I been chosen?

There are several reasons why you have been asked to participate in the study. Participants should be between 20 and 65 years of age with healthy eyes (except for the need for vision correction). You need to have successfully worn spectacles for at least 6 months prior to the study, for at least 5 hours per day and 5 days per week.

There are some lens requirements for the study:

- If you are between 20 and 39 years of age, you should be wearing single vision lenses, or 'Digital-style' lenses to be suitable for the study. You will be assigned to wear either single vision, or Digital lenses for the study, depending upon your visual needs.
- If you are between 40 and 49 years of age, you should be wearing single vision, 'Digital-style' or varifocal lenses to be suitable for the study. You will be assigned to wear either Digital or varifocal lenses for the study, depending upon your visual needs.
- If you are between 50 and 65 years of age, you should be wearing varifocal lenses to be suitable, and will be assigned varifocal lenses for the study.

If you are unsure of your lens type, or wish to discuss the lens options, please contact the Principal Investigator **(Please see the list of participating Bayfields practices and their contact details on pages 6-7)**.

You *should not* participate in this study if any of the following apply to you (these points will be reviewed by the study investigator):

- You are aphakic or pseudophakic (i.e. you have had one or both of the lenses inside your eyes removed and either not replaced, or replaced with an artificial intraocular lens).
- You have binocular vision problems (e.g. you suffer from double vision).
- You have any current eye diseases which might have an influence on your vision (e.g. age-related macular degeneration, glaucoma, etc.).
- You have had any previous eye surgery (e.g. iridectomy, refractive surgery, etc.).
- You have any systemic condition, which might have an influence on vision or interfere with study assessments (e.g. diabetes, uncontrolled high blood pressure, etc.).
- You are receiving any medical treatment or using any medication, which might have an influence on vision, or interfere with study assessments (e.g. antidepressants, etc.).
- You are pregnant.

The investigators will also consider your spectacle prescription and exclude participants on the following specific points (please feel free to ask the investigator to explain these terms if you are unsure of their nature):

- Unequal spectacle near additions in the right and left eyes.
- Your near spectacle addition is less than +0.75 D (+0.50 D for Digital lens) or more than +2.50 D.
- You are more than 2.00 D anisometropic (i.e. more than 2.00 D difference in distance prescription between eyes).
- You have an average distance refractive error less than -8.00 D (e.g. -9.00 D) or greater than +8.00 D (e.g. +9.00 D).
- The cylindrical component of your refractive error is less than -2.00 DC in either eye (e.g. -3.00 DC).

What will happen to me if I take part?

By volunteering to participate in this study, you will be invited to attend the **Bayfields Opticians optometric practice (Please see the list of participating Bayfields practices and their contact details on pages 6-7)** on four occasions, as detailed below.

In this study, you will be asked to wear an initial ‘washout’ pair of spectacles (either single vision, Digital or varifocal lenses) for 14 days; this is a pair of spectacles that will enable your eyes to adapt, to establish a standard starting point for all participants.

You will then wear a different type of spectacle lenses ('test' pair) on a daily basis for 14 days. You can ask the study investigator if you would like more information about the specific lens you are being asked to wear at the end of the study.

You will be required to attend four planned study visits. Study visits are when you visit the **Bayfields Opticians optometric practice (Please see the list of participating Bayfields practices and their contact details on pages 6-7)**. The duration of the study is expected to be up to seven weeks.

Visit 1 – Screening & dispense (approximately 45 minutes)
Once you have given your informed consent to participate in the study, an eye examination will be undertaken if you have not had an eye examination within the past six months. This will include:

- Demographical information (e.g. gender, age etc.)
- Your case history
- A description of your current spectacles
- Measurement of your new spectacle prescription (no eye drops will be used as part of the study)
- An assessment of how well your eyes work together (binocular vision assessment)
- An assessment of how 'tired' or strained your eyes are (questionnaire)

Some of these may also need to be conducted at this visit even if your eye examination was recent. If you meet the study's inclusion criteria, the study investigator will ask you to choose a spectacle frame. Further measurements will then be taken so that the two pairs of spectacles that you will wear for the duration of the study (the 'washout' pair of spectacles and the 'test' pair) can be ordered.

The assessments made throughout this study will be no different to those conducted at a routine eye examination.

Visit 2 – Collect washout spectacles (approximately 20 minutes)
You will be asked to return to collect the 'washout' pair of spectacles. Any necessary adjustments to make the spectacles fit will be made at this visit.

You should **wear the study spectacles for at least five hours a day, for a minimum of five days per week**. If you have any problems using the spectacles or problems with your eyes during the study, you should stop using the study spectacles and tell the study investigator immediately. You may need to come in for an unscheduled visit to check on any problems you are having.

Visit 3 – Test lens collection (approximately 20 minutes)
You will be asked to return, with the 'washout' spectacles, for a follow-up visit after approximately 14 days have elapsed since Visit 2. At this visit, you will be asked to complete a questionnaire to evaluate your experience with the 'washout' spectacles. You will then be issued a sample questionnaire, which you will be asked to fill in at the final study visit (Visit 4). The 'washout' spectacles must then be returned. You will be issued with the 'test' pair of spectacles being assessed in this study. Once again, any adjustments necessary to make the spectacles fit will be made.

Visit 4 – Final questionnaires (approximately 30 minutes)
You will be asked to return, with the 'test' spectacles, for a follow-up visit after approximately 14 days have elapsed since Visit 3. An assessment of your vision with both pairs of spectacles ('washout' and 'test') will then be made. The 'test' pair of spectacles must then be returned. You will then be asked to complete the same questionnaire issued at Visit 3. Additionally, you will be asked to fill in a final questionnaire to evaluate the performance of the 'test' lens and your experience over the study period, after which you will exit the study.

It is essential that you follow the visit and wearing schedule as instructed by the investigator.

These additional study visits do not replace your regular periodic eye examinations. You should continue to attend these as advised by your optometrist.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part.

If you do decide to participate, you will be asked to sign and date a consent form. You will still be free to withdraw from the study at any time without giving a reason.

Will my taking part in this study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

To ensure the quality of the research, Aston University may need to access your data to check that the data has been recorded accurately. If this is required your personal data will be treated as confidential by the individuals accessing your data.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will aid the development of spectacles in the future.

You will, however, be allowed to keep the spectacles which you wore during the 'washout' period of the study.

What are the possible risks and burdens of taking part?

The risks associated with all procedures and devices in this study are extremely low.

As an adapted single vision, Digital-type or varifocal lens wearer, the risks of wearing the spectacles in this study are the same as those of wearing any other type of commercially available spectacles. You may initially observe distortion in the periphery of your vision, or experience difficulty in judging distances whilst using the study spectacles; this is normal and typically resolves as you adapt to the lenses. If a complication should occur during the study (e.g. blurred vision), a longer appointment may be necessary, and you may be referred for medical treatment. If you experience any eye discomfort, vision changes, redness of the eye, or other problems, you should cease using the study spectacles and contact the Principal Investigator **(Please see the list of participating Bayfields practices and their contact details on pages 6-7)**.

In an emergency, if you are unable to reach the investigator team, please stop wearing the study spectacles and go to your nearest Accident and Emergency (A&E) department. Inform the attending staff of your participation in the study.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. If the results of the study are published, your identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The anonymised results will be shared with the company providing funding for this study.

Expenses and payments

As a thank you for your participation, you will be allowed to keep the spectacles you wore during the ‘washout’ period of the study. Alternatively, if you do not wish to keep these spectacles, you will receive a multi-retailer gift card worth £50.

Who is funding the research?

The study is being funded by ZEISS Vision Care.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix A.

Who has reviewed the study?

This study was given a favorable ethical opinion by the Aston University Research Ethics Committee Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about your participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Director of Governance, Mr. John Walter, j.g.walter@aston.ac.uk or telephone 0121 204 4869.

Research Team

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Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

In order to comply with the General Data Protection Regulation, Aston University is required to provide information about who is responsible for organising our research and how research data will be managed. This Appendix provides that information. Aston University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Aston University will keep identifiable information about you for 6 years after the study has finished.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at www.aston.ac.uk/dataprotection or by contacting our Data Protection Officer at dp_officer@aston.ac.uk.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). Our Data Protection Officer is Victoria Mee and you can contact her at: dp_officer@aston.ac.uk.