A Single Subject (N-of-1) Randomized Controlled Trial: application to comparing internet access through a ‘laptop’ or ‘tablet’ portable device by people with low vision

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Abstract

Introduction

This paper presents the results of a pilot trial, investigating the accessibility provided by a tablet computer (Apple iPad) to individuals with visual impairment. Twelve low vision participants took part in 6 short tests – three on a laptop (Windows-based, which is the most commonly used in the UK) and three on the tablet. The study also evaluates the use N-of-1 trials in studies involving people who are blind and of low vision.

Methods

The study conducted in Spring/Summer 2011 centred around an N-of-1 randomised controlled trial, comparing the accessibility provided by the control equipment (laptop computer) against the intervention equipment (tablet). Twelve participants identified by UK based charity RNIB conducted six tests on the equipment as per randomisation, followed by a quantitative based evaluation and short interviews

Results

One-sided individual randomisation tests showed a significant result for overall satisfaction in favour of the tablet at the 0.05 significance level for seven of the participants. Those who had a significant result tended to have a small preferred reading format. Simulations from a meta-analysis of the grouped data constructed a two-way test statistic which showed a significant result in favour of the tablet at the 0.05 significance level. A large overall effect size of 0.81 was calculated.

Discussion

Conducting the pilot project as an N-of-1 trial was found to be beneficial as it enabled the data to be analysed on an individual level, meaning that effects for individuals were not lost by averaging out results across the group. The results of randomisation tests and short interviews gave evidence of benefits to low vision users.

Implications for Practitioners

There has been limited research to substantiate positive reviews of the tablet computer for low vision users. The results of this pilot study gives evidence in support of these potential benefits, and demonstrates the importance of a more thorough investigation.

Background

The world wide web and electronic mail are becoming increasingly integral aspects of today's society. From job applications, to house listings, and from utility bills to concert tickets, use of the internet is becoming an essential part of day to day living.

This has two implications for people who are visually impaired or blind. Firstly, access to the internet using contemporary technology may present barriers. Secondly and positively, once accessibility barriers have been overcome, the internet offers them quick access to information that wasn't available to them before. For these reasons, there has been a lot of research into how the visually impaired people access the internet, what they use the internet for and the barriers that they face. This article explores these issues in relation to mobile laptop (Windows-based) and the touch screen tablet (Apple iPad).

Articles such as Chiang et al (2005) have reported on how information technology has seen rapid advances over recent years. They observed how this means that access to computers and the internet is becoming increasingly essential for typical daily tasks, and also in participating in education and employment. They acknowledge that this has been a positive development in society, but suggest that it creates a barrier for visually impaired people, as they may experience difficulty in using this medium. This demonstrates the importance of research into the technology available, to help inform blind and visually impaired users which equipment will suit them best. The value that the blind and visually impaired community place on computers and assistance technology is expressed in Gerber (2003), with one participant in their study expressing

how for some people, a computer is a luxury item, but for visually impaired people, it can fill a real need. Oppenheim and Selby (1999) focused specifically on the benefits of the internet to the visually impaired, even claiming it has the power 'to change the lives of disabled people' Gerber (2003) conducted focus groups looking at the benefits and barriers of computer use for individuals who are visually impaired. The study found various common uses of technology for visually impaired people. This included employment, access to information (such as reading the daily newspaper), and social/community networks. The main barriers that were identified were the lack of training in the assistive technology available and the lack of available, accessible information when choosing between products. Oppenheim and Selby (1999) focused on some of the more physical problems that can be faced by the blind and visually impaired when accessing the internet. They described how there can be a number of limitations for the visually impaired, such as screen design, font size, colour and excessive use of graphics on a page making the main text difficult to read.

When considering recent advancements in technology which could potentially benefit blind and visually impaired people, there are a number of online blogs and articles speaking positively of the accessibility that the Apple iPad provides to blind and visually impaired people in accessing the internet. The website Mac-cessibilty have published a series of articles looking at accessibility options on the iPad, in particular for the visually impaired. Peter Verhoeven from the website Magnifiers.org (2010) describes how they have found that the iPad provides a good alternative to the expensive equipment which can be bought from assistive technology companies, as add-ons to the standard Windows computers. Similarly, a review of the iPad, which was conducted by the Royal National Institute for the Blind (2010), concluded that the iPad

‘offers an excellent browsing experience’. However, these reviews tend to be the opinions of individuals, rather than as a result of any formal research.

Tablet computer

Testing for this project was conducted on a commonly-used tablet computer, the first generation Apple iPad. The Apple iPad is a tablet computer which is controlled by a multi touch display. Text is input using an onscreen keyboard (although it is possible to buy accessories, such as an external qwerty keyboard and Braille displays). There are a number of accessibility features which come as part of the operating system of the Apple iPad – these are described in Table 1.

Design of the study

A single subject study is a quantitative research approach, constructed around the principle that the subject acts as their own control in an experiment. In such a design, each participant is exposed to a control condition and an intervention condition, with comparisons between the two being made *within* the subject, rather than between *subjects* as in other experimental designs. Gast (2010) describes various types of single subject designs, such as a simple crossover trial involving one period of control and one period of intervention (AB), or a replication design involving multiple crossover periods (ABABAB).

A special type of single study design, which was adopted for this study, is the N-of-1 randomized trial. Backman et al (1999) explains the differences between this approach and a single-subject research design. The N-of-1 randomized trial has its roots in medical research. For example, a doctor may investigate which dosage to give a patient by alternating between treatments and keeping a record of any important

outcome data, such as blood pressure, comparing the outcomes and coming to a conclusion of which dosage best suits that patient. Unlike other single subject designs, no testing is conducted at a baseline level. To conduct an N-of-1 randomized trial, it is necessary to have an outcome which can be measured or scored. What also distinguishes it from other single subject designs is that it is also important that the intervention treatment is expected to have a rapid effect on the individual, and that this effect will end at the point at which the treatment is no longer being administered (so that the impact of alternative conditions can be observed independently).

This is an emerging methodology within the social sciences, and one of the aims of this study was to see how well it could be adapted for research amongst blind and visually impaired participants. A purpose for applying an N of 1 trial involving the visually impaired population is that it can take account of the variety of visual conditions and functions experienced by people. These different conditions affect individuals in different ways, and therefore they may benefit from assistive technology in different ways. By grouping together participants in a conventional trial, the effects of the intervention may be lost by analysing the data across the group of participants. Edgington (1987) describes how in trials involving multiple subjects, the effects on individuals can be missed due to the fact that the data are averaged across the heterogeneous group of subjects. However, by conducting an N of 1 trial it is possible to look at the effects of the intervention on an individual.

Methodology

The design and methods of the trial were written in a Trial Protocol. This was submitted to University of Birmingham Ethics Committee for ethical approval. Approval was received from the Ethics Committee prior to commencing recruitment and starting the testing procedure. The Research Protocol was peer reviewed by a Professor from Central Florida University with expertise in the use of single subject designs to evaluate educational interventions, and subsequently (minor) modifications were to some of the data capture methodology.

Recruitment

Participants were recruited in conjunction with the UK charities RNIB and Action for Blind People. A brief description of the study was prepared to be sent to potential participants. Anyone who was interested was invited to contact the Principal Investigator for an information pack. This information pack contained a covering letter, information sheet, consent form and participant questionnaire. The information sheet (and associated consent form) provided full details of what participation would involve. The eligibility criteria of the trial was that the person was eligible to be registered as partially sighted in the UK (similar to the World Health Organization definition of 'low vision') and that they were aged 18 years or over.

Trial design

Figure 1 shows the trial design for an example participant. Participants were randomized on an individual basis. The randomisation procedure was used to determine which equipment each participant would receive for each of the six tests. It was balanced to ensure that they would receive an equal allocation of three tests using a laptop and three tests using a tablet computer. The laptop used the most current Windows

operating system. It was decided this was the most appropriate comparator as this would be the most commonly used operating system in work, education and homes in the UK. This meant that there were (6!/3!*3!) = 20 possible allocations. The randomisation was conducted by an independent statistician from York Trial Units, United Kingdom. These allocations were then allocated to the participants according to the order in which they were scheduled to complete testing session 1. Randomisation was independent and concealed.

Testing sessions

Participants were involved in two sessions, each involving the completion of three tests. Before each session began, an introductory session to the equipment was given. This was scripted to ensure that each subject was exposed to the same conditions. Participants were assisted in setting up their devices to ensure that they were using the accessibility features to their maximum potential before continuing with the tests.

Materials

Testing material was provided to participants as a point of reference, but instructions were also read out to participants, so they would not be restricted by how long it took them to read through the information. Participants were tested individually, in well lit rooms, away from noise and distraction, with each test being conducted on either a laptop or a tablet computer, in accordance to their allocation for that particular test. Answers to questions were given verbally to the researcher, who recorded them on a predetermined mark sheet. Different participants worked at different rates and a maximum time of 15 minutes was allocated for each test. Following each test, they were requested to complete a questionnaire investigating how they found using the equipment, consisting of several questions based on a Likert scale. This was completed by

the researcher verbally reading out a series of statements and the participant selecting their response from a scale of 6 responses, ranging from ‘Strongly agree’ to ‘Strongly disagree’. This scale was printed on paper for participants to reference. The questions covered various factors such as how confident they felt that they were able to access all the necessary information, how well they felt they could navigate the website and how well they could use specific features on websites. These responses were then summed together to give an overall satisfaction score. At the end of each testing session, participants were given £40 in gift vouchers to cover travel costs and their time.

Controlling for bias and carryover effects

One of the main challenges of conducting a trial within a social science setting, rather than a medical one is the lack of control researchers have over the world around them. This is particularly true in this case, and there were a number of challenges that had to be overcome.

1. In order to be able to take repeated measurements it was necessary for the different tests to be as similar to each other as possible. By asking the participants to access the same information online for each test, it was inevitable that they would start to remember the information they would be seeking to obtain, and their performance would improve. Instead it was decided that what was required was a generic set of tasks which the participants would work through, but with the content slightly changed for each one. Through using the same websites to obtain the same amount of information on each occasion, the tests should have been directly comparable. It was also important that the same websites were used each time as some websites are more accessible than others, which would obviously impact on performance.

2. A further problem was that the participants would become more familiar with the websites that they were visiting, which would undoubtedly bias the results through a carryover effect. To minimise this form of bias, it was decided to use the training period prior to starting the tests to work through an example test with the participants. This meant they would be starting the tests already familiar with the websites that they would be visiting (which would be typical of the majority of most typical internet usage), and also the format and content of the tasks.

Demographics and characteristics of the participants

Table 1 shows the demographics and relevant characteristics of the twelve participants recruited within the project. We were particularly encouraged that there were a wide range of preferred reading formats across the participants. As it was anticipated that the usefulness of the tablet computer could depend upon the degree of visual impairment of the participants, having such a wide range was highly beneficial for this pilot trial.

Analysis of Evaluation Surveys

Figure 2 shows the results of the individual randomisation tests for the twelve participants. The null hypothesis was tested that there was no difference between the overall satisfaction of participants when using the tablet computer, compared to their overall satisfaction in using the laptop. There was only sufficient power in the design to conduct one-sided randomisation tests, so the test was only looking for a significant

difference in favour of the tablet computer (rather than a two sided test which could additionally identify results significantly in favour of the laptop computer). The individual randomisation tests were significant for 7 of the participants, allowing us to reject this null hypothesis and conclude that the satisfaction of these 7 was significantly higher on the tablet computer than the laptop. As we were using one sided tests, it is not possible to test to see whether the satisfaction for the other 5 was significantly higher on the tablet computer than the laptop. It was found that those who had a significant result in favour of the tablet computer tended to have a smaller preferred reading format, as demonstrated in Figure 3.

Randomisation tests were also conducted for the individual questions on the satisfaction survey. A number of significant results in favour of the tablet computer were obtained, with the most common being for how unrestricted the person felt using the equipment (5), lack of frustration in using the equipment (3), ability to navigate websites (3) and use of drop down lists (3).

A randomisation test was conducted using the grouped data, adopting an approach detailed by Todman and Duggard (2001). This involved using matrix code in SPSS and running 2000 simulations with the data, then taking the results of these simulations to construct a two-way test statistic. These simulations were run three times, and each time came back significant in favour of the tablet computer at the 0.05 significance level. As the result to this randomisation test was significant we can reject the null hypothesis that there is no significant difference in overall satisfaction

between the control and intervention, and conclude that there was a significant difference between the overall satisfaction of the grouped participants in favour of the tablet computer.

Finally, an overall effect size was calculated for the data, using guidance provided by Coe (2002). This gave an effect size of 0.81. This can be interpreted as meaning that 79% of those in the control group (using a laptop) would have a less positive satisfaction score than the average person in the intervention group (using a tablet computer).

Analysis of Interview Questions

The objective of the interview questions at the end of each testing session was firstly to explain the data which had been collected, and secondly to establish whether there was anything else of importance which had not been identified by the testing process, and could subsequently be adopted into a future study.

Participants were asked to explain in more detail the specific benefits and limitations of the two pieces of equipment they used. There were a number of common themes which were referred to.

Many of the participants were positive of the zoom and magnification functions on the tablet computer, considering them a real benefit, with some saying that they were better than the comparable options available on the laptop. Others highlighted how useful the touch screen element of the tablet computer was in enabling the participants to navigate the web pages. The main reason provided for this was that they did not have to

locate a mouse pointer, as this functionality is instead replaced by using your finger on the touch screen. The white on black contrast option was also viewed very favourably by those users who would normally choose to work this way.

Several people were positive about the fact that they could position the tablet computer more easily in a way which suited them best. The ergonomic positioning of equipment can be a very important consideration for low vision people, who may rely on having equipment as close to them as possible. With the tablet computer the user has more control of its positioning, and they are naturally able to get closer to the screen, as they do not have to allow space for an external keyboard between them and the screen.

The embedding of accessibility tools within the tablet computer was seen as a key benefit by the participants. They contrasted this to the experience of using accessibility software, which would not always be compatible with the program being used, and would quite often ‘crash’ in the middle of a task. This can be particularly difficult for someone with low vision as they may not be able to see what is happening, but no longer have any assistive technology running to help them rectify the problem.

Two participants reported an ease in being able to scroll through websites on the tablet computer, whilst another notable benefit was the tablet computers common interface with other products from the manufacturer, meaning you can get used to the accessibility options on an a phone and table computer simultaneously.

Although the laptop which was used in the testing session had a high definition screen, some participants still observed that the screen on the tablet computer met their needs as low vision users far better – despite the fact the tablet computer has a smaller screen. One participant who was

an Apple Mac and Apple iPhone user, commented that the iPad could become more accessible by the introduction of a retina screen, as on the iPhone.

There were some limitations observed in the experience provided by the tablet computer. The main criticism was the lack of functionality to use the zoom option at the same time as the Voiceover (screen reader) function, along with the fact that when you used the zoom function, it would magnify the keyboard at the same time. Others managed to interchange between the two functions more readily than others, serving as a reminder that although the technological capabilities may be present, it relies on the user being able to make use of them.

A number of the participants highlighted problems with the laptop accessibility features, both in comparison to the tablet computer, and in comparison to a standard computer running accessibility software such as screen magnification software. Problems included the colour inversion not working properly, being unable to use drop down menus properly when the screen was magnified in internet explorer, and a lack of flexibility with the windows magnification accessibility options as there are only minimum degrees of magnification which can be selected.

For those who were using the Voiceover and zoom functions, they commented on how it would be useful to try using the tablet computer along with an external keyboard to help them enter any text, as they felt that this was the main limitation that they faced. This equipment is available, but the decision was made not to provide it in this pilot trial. It would be interesting to investigate this further in a full study.

Discussion and Conclusions

This project has collected data to be able to successfully reach conclusions in testing two null hypotheses.

The first null hypothesis was that there is no difference between laptop and tablet computer in overall satisfaction of users in conducting web-related tasks. Randomisation tests for within subject tests showed that there was a significant difference, in favour of the laptop computer, for seven of the twelve participants, for their overall level of satisfaction of conducting web related tasks.

The second null hypothesis was that there is no difference between laptop and tablet in overall satisfaction of users in conducting web-related tasks when grouping together the individual data. Randomisation tests for within subject tests showed that there was a significant difference in favour of the tablet computer, with test statistics created by three simulations of the data being significant at the 0.05 level, with a large overall effect size 0.81.

It was initially intended to also measure speed of completion of the test. However, this proved to be an unreliable and inappropriate measure, due to the design of the tests and length of time available for testing.

Conducting the pilot project as an N-of-1 trial has been beneficial by enabling the data to be analysed both on an individual level, and on a grouped level. This was particularly important because, as anticipated, there was variation in the results according to preferred font size (with those who would typically use a lower font size finding the tablet computer more beneficial than those whose preferred reading format was of a much larger font size). Whilst such an approach is more common within medical literature, its application is becoming more common within

social science settings, and this study has shown that it is one which could be successfully adapted for use in further small N studies in which participants have a large range of individual differences in relation to particular variables, including level of vision. Through the nature of the design of the study, it was also possible to make inferences with less data than would be required with a standard crossover trial.

There are some limitations of this study, which should be taken into account when interpreting the results. One particular limitation of this study is that the participants were not recruited as a random sample, and this combined with the N-of-1 nature of the design makes it less valid to make inferences about the population as a whole. It should, however, be remembered that this project was a pilot trial, and was to form the basis of a larger project. In that context, this trial has shown that there is indeed some evidence that the tablet computer is beneficial for visually impaired people in terms of satisfaction accessing the internet, when compared with the standard option of a computer without additional accessibility software. This design and the useful information gained from the project can therefore be taken and applied to a larger trial with a familiar trial design which can be interpreted by the non statistician more easily.

As expected, those participants with more severe visual impairments took longer in learning to use the tablet computer. This was particularly the case for those users who would prefer to use a screen reader. Although some participants commented that they found using the gestures function to control Voice Over much easier, in comparison to learning to use hot keys on a conventional screen reader, it still could be questioned whether the Voice Over training session was sufficiently long.

One participant questioned how realistic it would be to have someone who would only want a product for surfing the internet and sending emails, suggesting that a Windows computer has the advantage of being far more flexible. Although the research question of this project was to specifically compare the two products in terms of the accessibility provided in accessing the internet, this is still an important consideration, and highlights the importance of setting the context of the original questions which were being addressed in the study.

Furthermore, the Apple iPad can still be considered as a 'gadget' which people can often get enthused about, and this is particularly likely to be the case with these participants, who decided to sign up because they are interested in technology. The potential problem which could stem from this is that for a participant, the 'fun factor' could possibly cloud their judgement on how useful it actually is. Equally, there is the danger that the policy makers might not take the potential of this device as seriously as they would be other specifically designed accessibility tools.

A number of interesting findings have been made in this study, which substantiate what has been written in reviews by low vision users. Of particular interest is how beneficial the participants found the touch screen functionality of the tablet computer, as historically, touch screen has been viewed as a barrier for those who are blind or with more severe low vision, due to the lack of tactile feedback. There are also potential barriers for the low vision user, the most obvious being the lack of a keyboard. The qwerty keyboard is usually highlighted as a key access tool for blind and low vision users because it can be used without vision. This problem can be overcome by using an external keyboard; the combination of keyboard and touch screen may be useful for some people. One important development of this project would be to incorporate

the use of an external keyboard into a future study. One interesting accessory which has recently been launched is a silicon keyboard overlay for the keyboard. This sits on top of the onscreen keyboard, and offers a more portable way of incorporating a tactile keyboard into the iPad experience.

Although tablet computers have been around for a number of years, it has only been in the past two years that a real market demand for them has appeared. Consequently there has been limited research into how they could benefit blind and low vision users. The results of data collected through the randomised testing sessions, along with the data collected through end of session evaluations demonstrate that for at least some people with low vision, the Apple iPad can positively assist them in accessing the internet. This could be within a wide range of settings, including in education, within the workplace, or at home. Those working in education are particularly enthused about the accessibility that tablet computers could provide, whilst those working with older people are seeing ways in which those who have not had the opportunity to use the internet before (both due to lack of confidence in using technology, and visual impairment) may now have access to equipment that makes it accessible to them. It is important to investigate this further, and also to consider the other tablet computers which have emerged since this study was conducted.

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Figure 1: Trial Design for an example participant

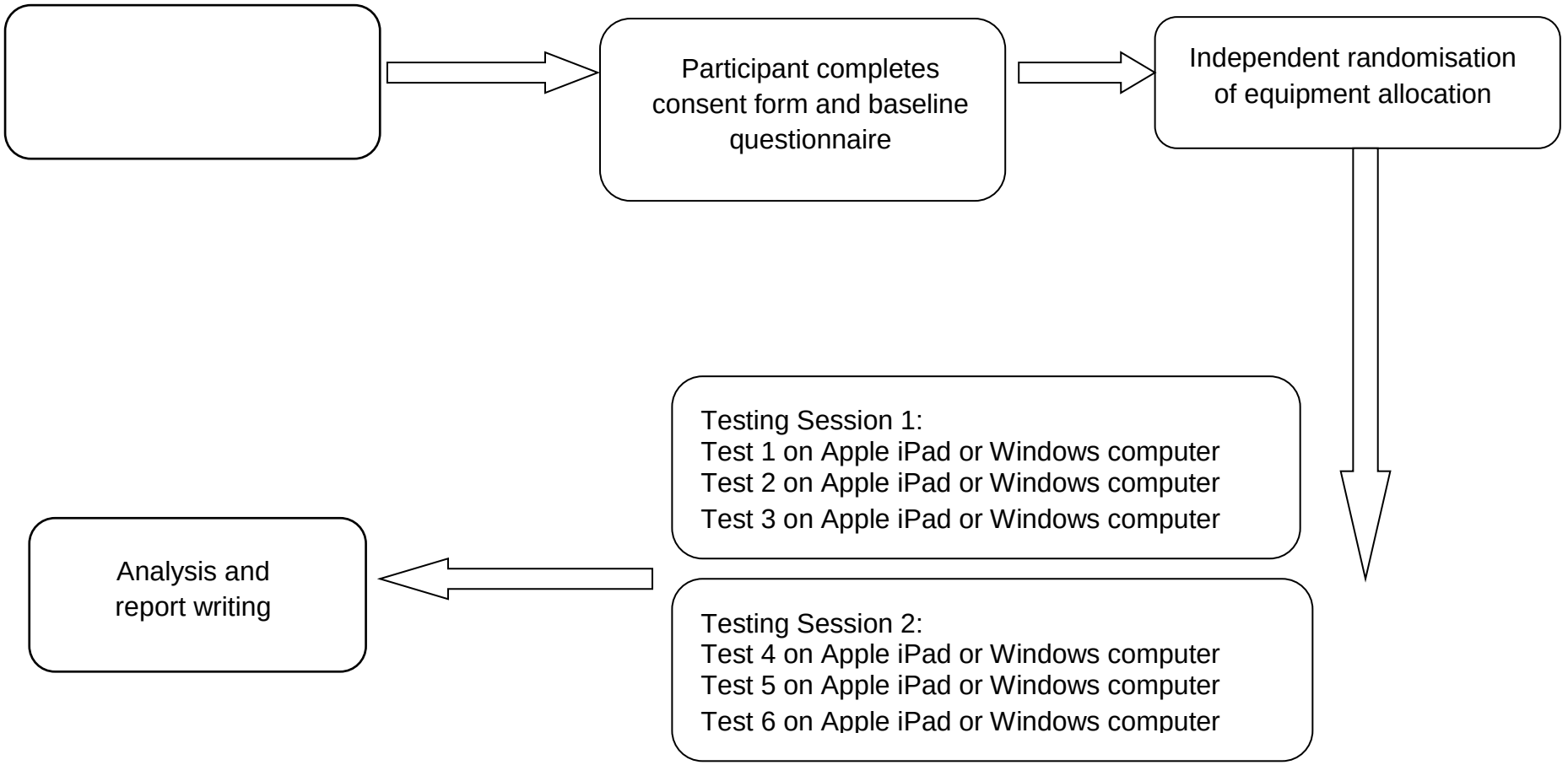

Table 1: A description of some of the accessibility features available on the first generation Apple iPad

Name of accessibility feature	Description
Pinch enlargement	It is possible to enlarge pictures and text on the screen by using a technique known as ‘pinching’. Two fingers are placed onto the touchscreen, and then dragged outwards, which in turn magnifies the content of the screen.
VoiceOver	This is an inbuilt screen reader which uses gestures made via the touchscreen. It also allows interaction with objects on the screen to enable the user to understand the location and context of, for example, web pages, icons. The speaking rate is adjustable and available in 36 languages. There is also a rotar available which allows control over how the screen reader will work through a document.
Wireless Braille displays	The iPad supports Braille displays that use Bluetooth wireless technology.
Zoom	This function allows you to magnify the entire screen between 100 to 500%, to help you see what’s on the display. This will magnify everything, rather than just text and images.
White on black	This changes the display so that all text appears white on a black background.
Large text	The text size can be increased in calendar, contacts, mail, messages and notes, up to 56 point.

Table 2: Descriptive statistics for demographics and characteristics of the 12 participants

Variable	Frequency	Percentage (%)
Gender		
Female	5	41.7%
Male	7	58.3%
Age		
18-24	5	41.7%
25-35	2	16.7%
35+	5	41.7%
Experience of using iProducts (iPhone, iPad or iPod touch)		
Yes	4	33.3%
No	8	66.7%
Preferred Font Size		
Normal to large print (12-17 point)	4	33.3%
Large print (18-27 point)	6	50.0%
Very large print (28 point and greater)	2	16.7%
I am confident in accessing the internet and electronic mail?		
Strongly agree	7	58.3%

Agree	4	33.3%
Mostly agree	1	8.3%
Mostly disagree	0	0.0%
Disagree	0	0.0%
Strongly disagree	0	0.0%
I like using new technology?		
Strongly agree	7	58.3%
Agree	3	25.0%
Mostly agree	2	16.7%
Mostly disagree	0	0.0%
Disagree	0	0.0%
Strongly disagree	0	0.0%
I feel confident in using new technology		
Strongly agree	5	41.7%
Agree	3	25.0%
Mostly agree	2	16.7%
Mostly disagree	0	0.0%
Disagree	1	8.3%
Strongly disagree	1	8.3%
I adapt quickly to using new technology		
Strongly agree	3	25.0%
Agree	6	50.0%

Mostly agree	2	16.7%
Mostly disagree	0	0.0%
Disagree	1	8.3%
Strongly disagree	0	0.0%

Figure 2: Number of subjects with a significant result, by Evaluation Type

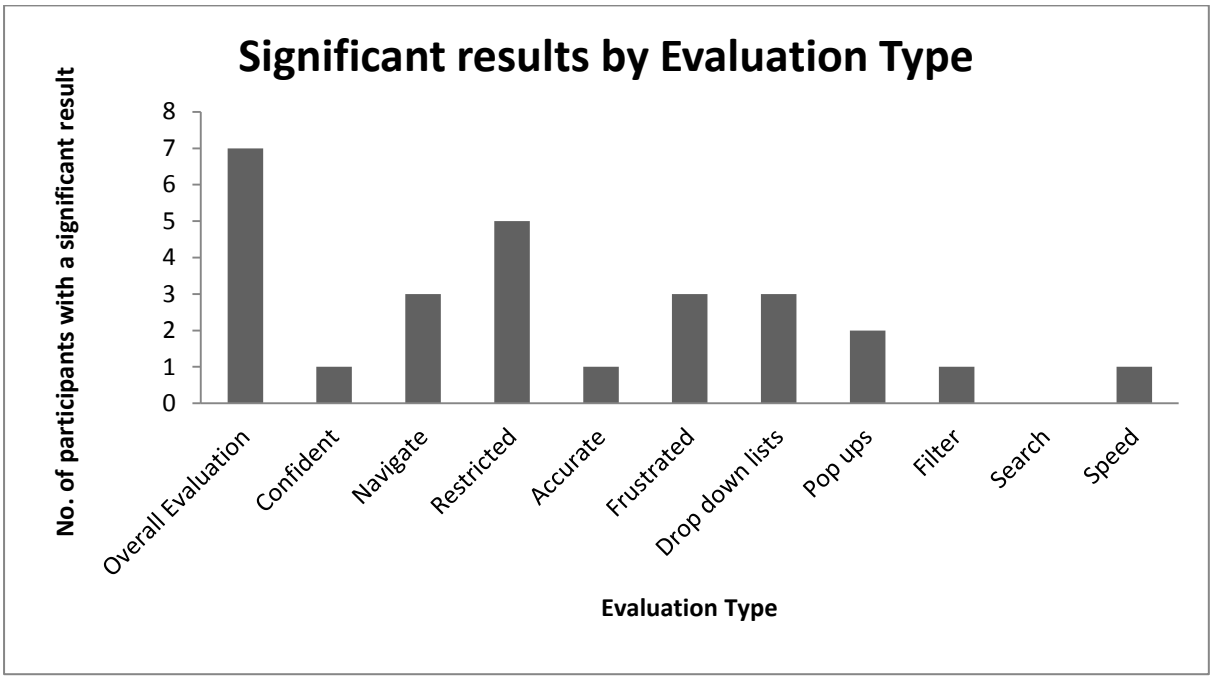

Figure 3: Subjects with a significant result for overall satisfaction, by preferred font size