AN ENHANCED VERSUS AN OPTOMETRIC LOW VISION REHABILITATION SERVICE FOR PEOPLE WITH AGE-RELATED MACULAR DEGENERATION: A RANDOMISED CONTROLLED TRIAL

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ABSTRACT

Purpose Firstly, to measure the effectiveness of an enhanced versus an optometric low vision rehabilitation service for patients with age-related macular degeneration. Secondly, to describe and monitor longitudinally a large sample of patients with age-related macular degeneration (AMD) with respect to socio-demographic factors, visual functions, low vision device use and a range of quality of life outcomes.

Design A 3-arm randomized controlled trial based at the Manchester Royal Eye Hospital. Patients in 'arm 1' received conventional hospital-based low vision care, patients in 'arm 2' received hospital-based care enhanced with home-based intervention provided by a rehabilitation officer, and patients in 'arm 3' (which served as a control against arm 2) received hospital-based care supplemented by generic intervention at home from a community care worker.

Participants Two hundred and twenty-six subjects were recruited at the Manchester Royal Eye Hospital and one hundred and ninety-four subjects completed the trial.

Outcomes A wide range of non-clinical outcomes were assessed at baseline and at 12 months. Generic quality of life was measured using the Short-Form 36 Health Survey Questionnaire, psychological dimensions in visual impairment were measured using the Nottingham Adjustment Scale, vision-related quality of life was measured using the VCM1 questionnaire, and task restrictions, patterns of use of low vision aids, and knowledge of AMD were addressed by the Manchester Low Vision Questionnaire.

Results Visual functions deteriorated significantly over time. The usage rates of low vision devices were very high for patients in all three arms. There was no evidence for benefit across the full range of outcome measures in subjects receiving enhanced care, in terms of self-rated task restriction and measured task performance, generic and vision specific quality of life and adjustment to vision loss.

Conclusion The enhanced low vision rehabilitation service delivered in this trial did not confer additional benefits over the traditional hospital service with respect to the outcomes used in this trial. Further research is needed to assess alternative models of enhanced or integrated care, in particular those which include a wider scope and intensity of low vision training strategies.

DECLARATION

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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LIST OF ABBREVIATIONS

ADL	Activity/activities of daily living
AMD	Age-related macular degeneration
ARM	Age-related maculopathy
DV	Distance vision
HES	Hospital Eye Service
IV	Intermediate vision
LVA	Low vision aid
MCQ	Multiple choice question
MCS	Mental Component Summary (score)
MLVQ	Manchester Low Vision Questionnaire
MREH	Manchester Royal Eye Hospital
NAS	Nottingham Adjustment Scale
NHS	National Health Service
NV	Near vision
PCS	Physical Component Summary (score)
QoL	Quality of life
RCT	Randomised controlled trial
RTS	Reading task score
SF-36	UK Short-Form 36 Health Survey Questionnaire
SRNVM	Sub-retinal neovascular membrane
VCM1	Revised abbreviation for: VQOL (Vision-Related Quality of Life Questionnaire)

CHAPTER 1: INTRODUCTION AND BACKGROUND

1.1 Summary

This thesis describes the study design, methodology and results of a trial which aims to address some of the deficiencies in previous work relating to the evaluation of low vision care, and to provide some of the evidence needed to inform the development of low vision services in response to an area of growing concern within the NHS. Implications of the findings are discussed and indications for future work are given.

1.2 Study background

Age-related macular degeneration (AMD) is the leading cause of visual impairment in the Western world (Klein *et al*, 1992; Fine, 1993; Howe, 1995; Freeman and Blumenkranz, 1998; O'Shea, 1998; Arnold and Sarks, 2000; Bressler and Gills, 2000; Hazel *et al,* 2000; VanNewkirk *et al,* 2000) and world-wide is second only to cataract as the most prevalent cause of blindness (Kelly, 1993). AMD is the principal reason for blind registration amongst older people in both the United Kingdom and the United States (Howe, 1995; Bernstein and Seddon, 1996; Evans and Wormald, 1996). In Britain, AMD accounts for approximately 50% of annual blind and partially sighted registrations (Evans, 1995). The number of people with AMD in England and Wales has risen dramatically over the past forty years (Evans and Wormald, 1996), with recent analyses showing a 30-40% increase in age-standardised blind registrations during this time. A study in Leicestershire, for example, has shown the rates of blind registrations due to AMD (for men and women aged 65 years and over per 100,000 population) have risen by 54.9%, and partially sighted registrations by 252.4% between 1965 and 1985 (Thompson *et al*, 1989). A considerable further rise in blind registrations due to AMD is anticipated owing to demographic trends over the next few decades (Pizzarello, 1987; Hyman, 1992; Kelly, 1993; Olshansky *et al*; 1993, Central Statistical Office, 1994; Metz, 1999; VanNewkirk *et al,* 2000), a rise that has important health policy implications.

Despite some advances in the treatment of AMD, the medical treatment options for this disease have important limitations (Hyman, 1992; Fine, 1993; Howe, 1995; Arnold *et al,* 1997; Maguire, 1997; Chong and Bird, 1998; Beatty *et al,* 1999; Arnold and Sarks, 2000; McLeod, 2000; Wong and Lois, 2000; Bird, 2001). However, although some forms of clinical treatment have been proven to be effective for some cases (see 2.3), such treatments are usually available to only a minority of patients, being dependent on the presence of specific clinical characteristics. Furthermore many of these patients will experience either a reduction in vision loss in the short-term and/or a delay in deterioration. Once a diagnosis has been made patients with AMD are usually referred to low vision rehabilitation services. These services (see section 3.4) aim to improve functioning and independence and thus enhance quality of life (QoL) by helping patients to adapt to their visual impairment and to achieve as independent a lifestyle as possible. In specific terms, this typically involves offering assistance in carrying out daily activities dependent on vision (Nilsson and Nilsson, 1986; Gieser, 1992; Nowakowski, 1994; Raasch *et al*, 1997).

Although some benefits of low vision rehabilitation have been documented (e.g. Kleen and Levoy, 1981; Culham *et al*, 1990; Leat *et al*, 1994) there has not been a randomised controlled trial (RCT) of alternative forms of low vision care. An RCT has been recognised as "the best way to compare the effectiveness of different interventions" when exploring patient care (Altman, 1996). Previous research has provided somewhat limited and sometimes contradictory evidence about the low vision services which they describe (e.g. see Dickinson, 1995; Harper *et al,* 1999; Scott *et al*, 1999). This limitation is perhaps not surprising due to the fact that "before-after" studies, or longitudinal case series are unable to provide the strength of evidence required due to methodological limitations including adequate duration of follow-up, the choice of outcomes measured or the selection process for the patient groups studied. Thus the results from various previous studies (e.g. Kleen and Levoy, 1981; Humphrey and Thompson, 1986; Hall *et al*, 1987; Temel, 1989; Culham *et al*, 1990; Nilsson, 1990; McIlwaine *et al*, 1991; Van Rens *et al*, 1991; Virtanen and Laatikainen, 1991; Leat *et al*, 1994; Shuttleworth *et al*, 1995; Warren, 1995; Watson *et al*, 1997a, 1997b; Harper *et al,* 1999; Scott *et al*, 1999) cannot be used to compare alternative interventions. For example, bias may arise from the following sources: the non-equivalence of 'conventional care' arms; non-blinding of outcome measurement; studies by 'interested parties'; and no attempt made to control

for placebo effects. Furthermore there may be a combination of issues arising from different aspects of care, for example training in the use of low vision aids (LVAs) may be viewed as a separate strategy (which may be complementary) to, say, low vision rehabilitation provided within the Hospital Eye Service (HES).

Different studies (though these have not been controlled trials), for example, have examined the effectiveness of low vision services and have shown that LVAs have been particularly useful to patients who have received adequate formal training in their use and where these patients have been adaptive in applying the prescribed LVAs to a variety of tasks (Warren, 1995; Watson *et al*, 1997a, 1997b). However, where training has not been given LVA use has been considerably less successful (e.g. Nilsson, 1990). Although this raises the question of how training is defined and also whether there has been adequate research into these issues (Raasch *et al*, 1997), the benefits of additional assessment and training in the use of LVAs within the home environment clearly requires further investigation.

In summary, there is a clear need for an RCT of low vision services on account of:

- the considerable scale of the low vision problem;

- the range of different models of care proposed by the providers of low vision rehabilitation (i.e. with respect to different professional services and suggestions for their integration, and with additional consideration surrounding specific aspects of training in low vision rehabilitation);

- the lack of high quality evidence (resulting from study design problems, the limited use of QoL and other appropriate outcomes, and a failure to use a suitable range of outcomes) in previous studies.

The merits of different approaches to low vision rehabilitation have therefore been difficult to determine.

Following the publication of the reports by the Visual Handicap Group (1996/97) and the Low Vision Services Consensus Group (1999) a framework for low vision services in the UK has been proposed and outlined to form part of a national strategy. This framework has been developed in response to a range of problems identified by the latter Group. This study has been designed to reduce some of the uncertainty about the effectiveness and cost-effectiveness of the traditional Hospital Eye Service (HES) versus an enhanced and multidisciplinary intervention for subjects with AMD. Whilst the enhanced model of care described in this thesis is not necessarily representative of the multi-disciplinary model proposed by the Low Vision Services Consensus Group, it nevertheless offers a low vision rehabilitation service which links patient information gathered by a range of care providers in order to address more comprehensively the rehabilitation needs of individual patients. This enhanced model of care constitutes a research strategy which has good face validity (i.e. in terms of the provision of home intervention to support patients in using their LVAs) in the light of previous research on low vision care which implies that additional training in the use of low vision devices is fundamental to successful rehabilitation. Furthermore, the Low Vision Services Consensus Group recommendations were published after the present trial had already been designed and was under way. Although the trial intervention did not match exactly the proposals made by the Consensus Group, the trial mirrored some of the suggestions in the Consensus Group's report. The results of the trial, therefore, will inform the continuing debate surrounding the development of appropriate low vision services.

CHAPTER 2: AGE-RELATED MACULAR DEGENERATION

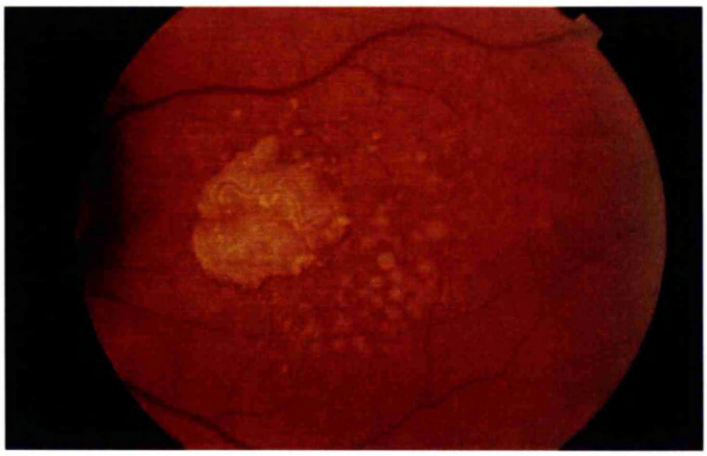
2.1 Pathology and symptoms of AMD

Kincaid (1992) summarises AMD as "a disease of the macular photoreceptors, retinal pigment epithelium, and Bruch's membrane". In his account of the pathogenesis of AMD, Bird (1996) describes the visual loss as essentially resulting from age-related changes in Bruch's membrane and "a sequence of events" which may lead to "the detachment of the retinal pigment epithelium and geographic atrophy". There are two forms of AMD, namely neovascular or exudative, and atrophic or nonexudative (Noble and Carr, 1985; Hyman, 1992; O'Shea, 1998). These are commonly referred to as 'wet' and 'dry' AMD respectively. The dry type of AMD is more prevalent than the wet (Schatz and McDonald, 1989; Arnold and Sarks, 2000) and has been estimated to account for as many as 80% of AMD cases (Hyman, 1992 citing Kahn *et al*, 1977a). The wet form of AMD, however, is responsible for approximately 90% of severe visual loss (Murphy, 1986; Hyman, 1992; Arnold and Sarks, 2000). There has recently been an increase in research activity to identify the pathogenic mechanisms of AMD, an area of research previously neglected, despite the high prevalence of the disease (Bird, 1996).

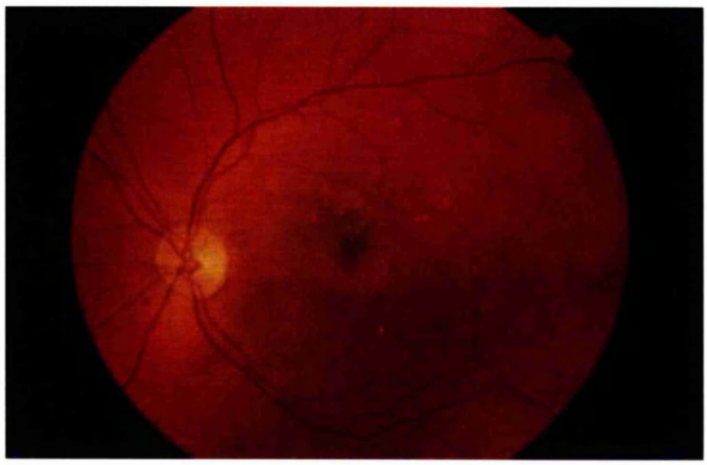
Specific clinical features of dry AMD, as shown in figure 2.1, include the presence of drusen formed on Bruch's membrane (deposits which may be discrete or well-defined masses from the underlying pigment epithelium) and are a recognised feature of ageing (Parr, 1982; Noble and Carr, 1985; Hyman, 1992; Freeman and Blumenkranz, 1998; Gibbs *et al,* 1998; O'Shea, 1998; Abdelsalam *et al*, 1999). The presence of drusen may result in thinning of the pigment epithelium and atrophy of the overlying retina, thus reducing visual function (Kincaid, 1992). Furthermore it has been observed that the drusen found in both eyes of individual patients follow a symmetrical pattern in their distribution and other characteristics (Coffrey and Brownstein, 1986; Barondes *et al*, 1990; Bird, 1992 citing Leibowitz *et al*, 1980). Atrophic AMD is also sometimes referred to as 'geographic' since the areas of pigment epithelial atrophy tend to be well defined (Schatz and McDonald, 1989).

Figure 2.1 AMD: (a) Geographic atrophic AMD with multiple drusen; (b) Development of sub-retinal neovascular membrane (SRNVM) in exudative AMD; (c) Disciform scar following exudative AMD *(Photographs supplied courtesy of Mr Paul Bishop, Honorary Consultant Ophthalmic Surgeon, MREH)*

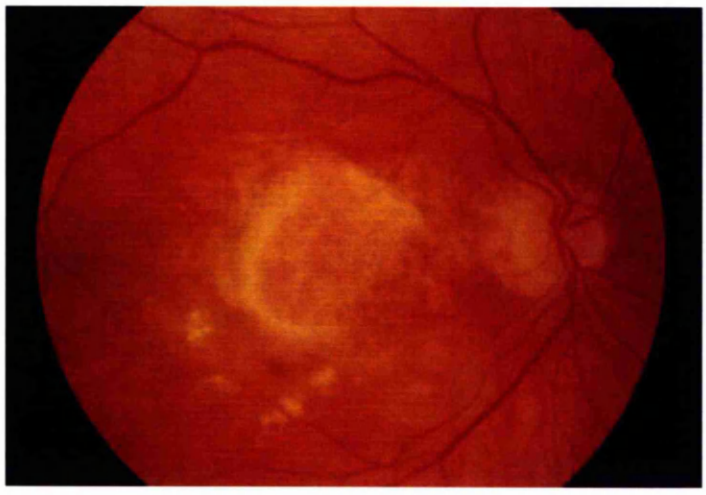
(a)



(b)



(c)



In wet AMD, which is believed to be preceded by dry AMD (Hyman, 1992), other developments occur, namely that the pigment epithelium may detach from the underlying Bruch's membrane, sub-pigment epithelial and sub-retinal new vessels may develop which may result in leakage of serous fluid under the retina and haemorrhages, and ultimately scarring may take place (Hyman, 1992; Gibbs *et al,* 1998; O'Shea, 1998; Arnold and Sarks, 2000; Bressler and Gills, 2000). These characteristics are illustrated in figure 2.1 (b) and (c). It is widely believed that there is not usually a single cause of AMD, but rather a combination of degenerative changes (Parr, 1982; Ferris *et al*, 1984). Bird (1991, 1992) describes AMD as a "spectrum of disease" due to the variability in the pathogenesis of the disease. Bird *et al* (The International ARM Epidemiological Study Group, 1995) have developed a grading scheme to serve the need for a classification system for epidemiological studies of age-related maculopathy (ARM), which at the same time defines the characteristics of AMD. This system defines ARM (as distinct from AMD) as "a degenerative disorder in persons $\geq$ 50 years of age" characterised by a set of pathological manifestations such as soft drusen (larger than a specified lower limit dimension), retinal pigment epithelial detachment, haemorrhages, geographic atrophy of the retinal pigment epithelium and scarring. Furthermore the Study Group states that the definition is independent of visual acuity. Definitions of early and late ARM are also propounded based upon the characteristics included in the overall definition. Whereas early ARM is characterised by the features described above, late ARM is classified as being "similar to age-related macular degeneration [i.e. AMD] .... and includes dry AMD (geographic atrophy of the retinal pigment epithelium in the absence of neovascular AMD) or neovascular AMD (retinal pigment epithelium detachment, haemorrhages, and/or scars as described above)."

In dry AMD vision loss is more gradual than in the wet form (Sunness *et al*, 1997, 1999). In their study of the rate of expansion of geographic atrophy of macular degeneration associated with visual loss, Schatz and MacDonald (1989) describe loss of vision as being "gradual and subtle, never sudden or dramatic" but leading to a significant loss of sight in nearly all cases. The slow progression of this form of AMD can take between 5 to 10 years to lead to severe loss of vision to the extent where the patient can be registered legally blind (Arnold and Sarks, 2000). In contrast, sub-retinal neo-vascularization can cause distortion in vision (such as a crooked perception of straight lines) (Sperduto and Hagler, 1983; Folk, 1985; Schatz and MacDonald, 1989; O'Shea, 1998) and is characterised by a more rapid loss of sight, developing over days,

weeks or months, typically following a sudden onset of deterioration in central vision (O'Shea, 1998; Arnold and Sarks, 2000). However, both forms of AMD result in the loss of central vision (Hyman, 1992), but it is rare for either form to progress to total blindness[†] since peripheral vision will remain (Fine, 1993; Arnold and Sarks, 2000). In AMD, typically the second eye becomes affected within months or years (Parr, 1982; Arnold and Sarks, 2000) of the first.

2.2 Epidemiology

2.2.1 Blindness, prevalence and incidence

The urgency for research into an understanding of risk factors in AMD and the treatment of AMD is underpinned by the escalating prevalence of blindness due to the disease (Bird, 1996; Gibbs *et al,* 1998). The extent and importance of AMD in Britain can be illustrated by considering that visual impairment is the most frequently occurring type of age-related disability reported (Martin *et al,* 1988). There are nearly one million visually impaired people in Britain, of whom 90% are over 65 years of age according to a Royal National Institute for the Blind (RNIB) estimate (Bruce *et al,* 1991). Among adults who are visually impaired those who are aged 60 or older amount to 82% (Martin *et al,* 1988). These high percentages of visual impairment among the older population may largely be attributed to AMD. For example, the prevalence of AMD in England alone has been estimated to be 41.5% for adults between the ages of 75 and 85 (Gibson *et al,* 1985; Hyman, 1992) and as previously noted approximately 50% of annual blind and partially sighted registrations in Britain are due to AMD (Evans, 1995).

There is a paucity of incidence data for AMD and the estimates which are available have been calculated using small population sizes. An incidence rate of between 3 to 6 per 100 person years which varies with age has been suggested (Moorman, 2000 citing Podgor *et al,* 1983). Furthermore Evans and Wormald (1996) have reported an increase of 30-40% in age-standardised blind registrations in England and Wales since 1960 (see also 1.2) based on various sources of published data. Arnold and Sarks (2000) have also used several sources of data to demonstrate that incidence rises with age with 0.7-1.4%

[†] Although AMD is a significant cause of blind and partially sighted registrations (see section 1.2), eligibility for registration does not require total blindness. The criteria used by the registration system are outlined in section 3.1.

in people in the 65-75 years age group developing AMD and 11.0-18.5% among those over 85 years of age.

It is also widely believed that the number of blind and partially sighted registrations has been substantially underestimated (Shankland-Cox, 1985; Warren, 1985; Kelly, 1993). This view is supported by the 1991 RNIB survey, which suggests that the number of registrations (albeit for all ophthalmic conditions) may be underestimated by well over 30%. This underestimation also implies that reported prevalence data for AMD will be lower than the true values. Thus the scale of the AMD 'problem' for the NHS is considerable.

2.2.2 Risk factors

Several potential risk factors are known to be associated with AMD. Hyman (1992) places these risk factors into seven key groups, namely: demographic factors, medical history and physiological measures, ocular co-morbidity, personal traits (e.g. eye colour), environmental exposures, nutritional determinants and genetic or familial factors. These categories have also been documented by others in more recent years (for example, Bressler and Bressler, 1995; O'Shea, 1998; Macular Photocoagulation Study Group, 1997; Pieramici and Bressler 1998; Arnold and Sarks, 2000). Both the categories of factors listed and the specific factors within these groups have been explored to varying degrees and with differing levels of evidence being made available upon which to draw conclusions (Hyman, 1992). Bird (1996) discusses that the reasons why only some individuals develop AMD have been questioned and thus certain theories have emerged.

2.2.2.1 Demographic factors

Firstly, as the medical name for the disease suggests, age is consistently a strong risk factor (Hyman, 1992; Maguire, 1997; American Academy of Ophthalmology, 2000a). This factor has no doubt contributed to the previously mentioned rising prevalence of AMD, owing to the trend of demographic ageing in Western populations including that in the UK (Pizzarello, 1987; Coleman and Salt, 1992; Hyman, 1992; Kelly, 1993; Olshansky *et al*, 1993; Central Statistical Office, 1994). Secondly, some studies suggest that there is a greater risk of AMD developing in women than in men (Lovie-Kitchin *et al*, 1983; Gibson *et al*, 1986; Klein *et al,* 1992; Mitchell *et al,* 1995). However, this finding is disputed by other researchers who suggest that there are other explanations

for why more women appear to have AMD, possibly including their higher motivation to seek health care, or a tendency towards higher proportions of women being recruited into epidemiological studies (Hyman, 1992). Finally, race has also been investigated as a possible risk factor in several research studies and with conflicting findings (Hyman, 1992). However, there is now growing evidence that due to demographic ageing, AMD will also become a significant problem in East Asia (Bird, 2001). Although European patients have not been shown to have a higher prevalence of AMD than Asian patients in Leicester (Das *et al,* 1994), it appears that white populations are more susceptible to AMD than black and Asian groups (Chumbley, 1977; Hoshino *et al*, 1984; Hyman, 1992 citing Gregor and Joffe, 1978; Muñoz *et al,* 2000). This suggestion supports one theory that darker pigmentation has a protective effect against ageing retinal changes.

2.2.2.2 Other risk factors and their interactions

According to Bird (1996) it is most likely that AMD occurs in people who have an "inherited predisposition" to the disease together with an exposure to "appropriate environmental factors". It has also been suggested that following loss of vision in one eye, there is an increased risk (dependent on the underlying disease process) for the development of AMD in the fellow eye (Pieramici and Bressler, 1998). Environmental factors are thought to include diet and smoking (Maltzman *et al*, 1979; Eye Disease Case-Control Study Group, 1993; Christen 1994; Seddon *et al*, 1994; Bird 1996 citing Kahn *et al*, 1977b; Seddon *et al,* 1996; Phelps Brown *et al,* 1998; Chan 1998). Hyman *et al* (1983) conducted a case-control study in Baltimore, USA, to evaluate risk factors for AMD and concluded that a family history of the disease, genetic factors, and personal characteristics (in this instance blue or medium pigmented eyes) were strongly linked to AMD. Further support for genetic factors increasing the risk of AMD has been shown in other investigations which have studied the eyes of sibling pairs (for example, Piguet *et al,* 1993; Heiba *et al,* 1994). Increasing evidence is becoming available with respect to genetic explanations of the risk of AMD (de Jong *et al*, 2001). Environmental factors, such as smoking and exposure to sunlight, do not show a significant association in the early study conducted by Hyman *et al* (1983). However, other studies conducted in more recent years have identified smoking as a risk factor for AMD and this therefore remains a controversial issue, as described in a review of smoking and AMD (Chan, 1998).

Other factors which emerged as being statistically significant in the study by Hyman *et al* (1983) were a decreased hand grip strength (an indicator of ageing) and hyperopia, while a history of cardiovascular disease and 'chemical work' exposures yielded borderline results. In contrast The Eye Disease Case-Control Study Group (1993) reported somewhat different results. This study involved 421 patients with neovascular AMD and 615 controls. An increased risk of AMD was associated with smoking, higher levels of serum cholesterol and parity greater than zero among women. The risk of AMD in this study decreased in line with higher levels of serum carotenoids and oestrogen use among postmenopausal women. No significant association was found for sunlight exposure, iris colour or serum zinc levels. This finding does not agree with the findings of a study of 132 white patients to determine whether the extent of disease in AMD is influenced by iris pigmentation (Sandberg *et al,* 1994). These investigators reported that 'light iris pigmentation was associated with more extensive macular disease than dark iris pigmentation in both eyes of patients with unilateral neovascular AMD'. Exposure to sunlight was rejected as a significant risk factor in a study carried out by West *et al* (1989) among a population of 838 watermen in Maryland State. No association between either UV-A or UV-B exposure and AMD was found. However this study did show a decreased risk of AMD amongst smokers and those with freckled skin, and an increased risk in cases with nuclear lens opacities. A study of Chesapeake Bay watermen in the USA also concluded that exposures to UV-A and UV-B had no association with AMD (Taylor *et al*, 1992), but a high exposure to blue or visible light was found to have a significant effect. A multifactorial case-control study carried out by Blumenkranz *et al* (1986), in which 26 patients with disciform AMD participated, supported Bird's assertion (1996) that an interaction between genetic and external factors increases the risk of AMD. Results from the study by Blumenkranz *et al* (1986) suggest that genetically determined factors, such as elastic fibre structures (found in Bruch's membrane) in combination with environmental stimuli such as light over time, are the major determinants of neovascular AMD. The study also found no significant association between other factors including hypertension, smoking and nutritional characteristics (such as glucose and vitamin levels of A, C and E) and neovascular AMD. Reviews of the literature concerning the association of nutritional supplements with AMD have provided conflicting evidence. Christen (1994) quotes several studies (Hayes, 1974; Katz *et al,* 1978; Organisciak *et al,* 1985) which have shown that antioxidant deficiency in the diet to be a risk factor and that dietary supplementation can have preventive effects. Other studies cited by Christen (1994) present differing results

regarding specific nutritional factors, for example: a study by Goldberg *et al,* (1988) suggested that vitamin A has a protective effect against AMD and that vitamin C did not demonstrate any benefits; another study by Blumenkranz *et al* (1986) did not find a protective effect for vitamins A, C or E. The Eye Disease Case-Control Study Group (1993) also failed to demonstrate any clear benefits for vitamins C or E but discovered a reduced risk of AMD for several different carotenoids, including beta-carotene. However, another study conduced by West *et al* (1994) reported a protective effect for vitamin E but not for vitamin C or beta-carotene. In their review of nutritional supplements and the eye, Phelps Brown *et al* (1998) refer to the study by Seddon *et al* (1994) which has reported the protective effects of carotenoids against AMD. A small pilot study carried out by Newsome *et al* (1988) has in addition observed a beneficial effect from zinc supplementation. Essential fatty acids have been shown to be protective against cardiovascular disease (Taylor *et al* (1991); Chen *et al* (1988)) and are thus assumed to have a positive effect generally on the health of the eye. Furthermore, Christen (1994) refers to a study which gives evidence for visible light as a risk factor in AMD (Young, 1988) which corresponds with the findings by Blumenkranz *et al* (1986). Due to insufficient corroboration between the findings from the various studies which have explored a range of nutritional hypotheses, relating for example to vitamins, trace elements and selenium, Hyman (1992), at the time, concluded that further research is required into the role of nutritional factors in AMD. Clearly, there are conflicting findings in the studies that have examined the association of various nutritional factors and AMD (Christen, 1994; Phelps Brown *et al,* 1998) and further research in this area is still required.

In summary, the major risks for AMD appear to relate to demographic factors such as age, sex and race, to genetic predisposition, and to a variety of environmental factors, for example behavioural factors such as smoking and nutrition, and external factors such as sunlight exposure. Bird (1996) argues that in the light of an escalating prevalence, the clear identification of risk factors is an important aspect of research into AMD. Bird (2001) has also highlighted that to succeed in this area of research ophthalmologists need the support of many other disciplines including epidemiology, gerontology, molecular genetics, cell biology and biochemistry. A better understanding of the risks for AMD is an essential prior requirement for the development of appropriate therapies.

2.3 Medical and surgical treatments for AMD

There are no medical treatment options for the dry forms of AMD. To date dry forms of AMD remain untreatable, and once diagnosed many cases require appropriate low vision management (see 3.1 below). Medical treatment of 'wet' AMD is available only for a minority of cases. There have been some advances in the treatment of the 'wet' form of the disease over recent years and various clinical trials are currently ongoing. However, these treatments have limitations (see below) and are appropriate only for cases which satisfy specific diagnostic criteria.

2.3.1 Laser photocoagulation

There has been much research into the treatment of neovascular AMD using laser photocoagulation. Laser treatments are a suitable option for only a minority of patients (Macular Photocoagulation Study Group, 1982, 1986, 1990, 1991a, 1991b, 1993). In these cases visual prognosis can be improved by early diagnosis and treatment (Ferris *et al*, 1984; Howe, 1995), however some controversy exists surrounding laser treatment. There is a potential risk of immediate vision loss and undesirable outcomes in the longer term (Bernstein and Seddon, 1996). In a recent review Arnold and Sarks (2000) reported that four large RCTs have shown that this treatment 'decreases the rate of severe visual loss and preserves contrast sensitivity in selected people with exudative age related macular degeneration (those with well demarcated lesions)' but they also summarise potential 'harms'. These include the risks of initial vision loss after treatment (Bernstein and Seddon, 1996; Macular Photocoagulation Study Group, 1993, 1994; Arnold and Sarks, 2000), and recurring neovascularisation in the longer term among as many as 50% of treated patients (Hyman, 1992). However, (Submacular Surgery Trials Pilot Study Investigators, 2000a and 2000b) conclude that laser photocoagulation should be used as the 'first treatment considered' amongst patients with similar lesions. Submacular Surgery Trials Pilot Study Investigators (2000a and 2000b) describe a recent small-scale pilot trial which randomly assigned a total of 70 patients to either laser photocoagulation or to submacular surgery, with a 2-year follow-up of participants to provide a comparison of outcomes between the two arms in the study. They concluded that there was 'no evidence .... of a beneficial effect of submacular surgery compared with laser photocoagulation'. However, due to the relatively low numbers of cases suitable for laser photocoagulation, this form of treatment is not often recommended readily by ophthalmologists (Bernstein and Seddon, 1996). A recent

survey (Beatty *et al,* 1999) reported that a surprisingly high proportion of practising ophthalmologists in the UK 'remain unconvinced' of the benefits of laser photocoagulation and that 86.4% choose not to follow the guidelines of the Macular Photocoagulation Study Group (1991b). The most frequently stated reason for this view appears to be the concern about 'the possibility of precipitating an immediate reduction in acuity'. Bird (1996) also reminds us that this approach to the treatment of wet AMD "will have little impact on blindness in age-related macular disease".

2.3.2 Photodynamic therapy

Photodynamic therapy, a newer form of laser treatment than conventional laser photocoagulation (described above), has also demonstrated some success in the treatment of neovascular or 'wet' AMD (Wu and Murphy, 1999; Bishop, 2000; Regillo, 2000). Bishop (2000) suggests that both photodynamic therapy and laser photocoagulation (described above) should be seen as "ways of preventing or slowing down the progression of further visual loss" since vision is not usually improved as a result of either method of treatment. Bressler and Gills (2000) describe photodynamic therapy as a 'two step process' whereby firstly, verteporfin, a photoactivating dye (Miller *et al,* 1995; Husain *et al,* 1996; Schmidt-Erfurth and Hasan, 2000), is infused intravenously, and secondly a laser is applied over the neovascular lesion. This process is presumed to destroy the lesion (Bressler and Gills, 2000). This treatment has been found to reduce the risk of vision loss in patients followed-up over a 2 year period but retreatments at approximately 3-monthly intervals (but averaging at 5 or 6 over 2 years) have been recommended to control progression of the disease (Schmidt-Erfurth *et al,* 1997; Freeman and Blumenkranz, 1998; Treatment of Age-related Macular Degeneration with Photodynamic Therapy (TAP) Study Group, 1999, 2001; Bressler and Gills, 2000; American Academy of Ophthalmology, 2000a). Several key areas of research into this treatment still need to be explored, including the retreatment requirements and the possible adverse effects that these may have, in addition to the clinical outcomes after 2 years from initial treatment (see Chong and Bird, 1998; Freeman and Blumenkranz, 1998; American Academy of Ophthalmology, 2000a). Comparisons with other forms of laser treatment for suitable patients are also lacking at present.

2.3.3 Radiotherapy

Radiotherapy has also been shown to be an effective treatment where favourable conditions exist, such as comparatively good baseline visual acuity, (Hart *et al,* 1996; Smith, 1999) but there is still some controversy surrounding this type of treatment. Radiotherapy involves the use of external beam radiation delivered at appropriate doses to the macula to halt the disease process in neovascular AMD (The Radiation Therapy for Age-Related Macular Degeneration (RAD) Study Group, 1999; Arnold and Sarks, 2000). However, there are some concerns about the potential toxicity of radiotherapy to the retina, optic nerve, lens and lachrymal system, which may manifest up to two years after treatment (Arnold and Sarks, 2000). A recent RCT of radiotherapy in exudative AMD with 2-year follow-up has supported beneficial findings (Kobayashi and Kobayashi, 2000) but has highlighted the need for further studies with a longer follow-up duration. A pilot study (on 28 patients with AMD) carried out in France also found radiotherapy to have beneficial effects, in either reducing or stabilising the growth of lesions for the majority of patients (80% in total). Final visual acuity after a 6 to 9 months follow-up period was found to be stable in 68% of cases (Donati *et al,* 1999). However, a large-scale multi-centre RCT in Germany which included 205 participants who were followed-up for a year, concluded that radiation therapy did not provide any benefit in the treatment of neovascular AMD (The Radiation Therapy for Age-related Macular Degeneration (RAD) Study Group, 1999). Other problems surrounding radiotherapy include resource issues and prioritisation for patients requiring radiotherapy for a variety of health care needs (Gibbs *et al,* 1998). There is also the requirement for adequate evaluation of safety in radiotherapy treatment (Arnold and Sarks, 2000) and investigation of the use of higher doses for selected patients (Fine and Maguire, 2001).

2.3.4 Surgical techniques

Some surgical techniques have demonstrated limited benefits, as in the case of submacular surgery to remove subfoveal neovascular membranes (Freeman and Blumenkranz, 1998; Chong and Bird, 1998 citing Lambert *et al,* 1992 and Thomas *et al,* 1994). The findings from a recent trial comparing submacular surgery with laser photocoagulation (see 2.3.1) suggested that submacular surgery did not result in beneficial effects compared with laser photocoagulation (Submacular Surgery Trials Pilot Study Investigators, 2000a and 2000b). The outcomes of the two patient groups in this latter trial showed little difference, but the findings confirmed previously reported

benefits of laser photocoagulation, and also highlighted some advantages for both techniques in relation to specific AMD characteristics. Other recent surgical developments have demonstrated some degree of success, for example macular translocation (Pieramici *et al,* 2000) and foveal relocation by redistribution of retinal tissue (Wong and Lois, 2000) but these techniques have yet to provide strong evidence for successful surgical treatment and thus further evaluation is necessary (American Academy of Ophthalmology, 2000b).

2.3.5 Other treatments

In addition to the surgical, laser and radiotherapy treatments described above, other forms of treatment for AMD exist, including the following: vitamins, minerals, and drug therapies (including interferon, vascular endothelial growth factor, steroids, integrins and thalidomide); however, these interventions currently remain unproved in their success (Hyman, 1992; Fine 1993; Chong and Bird, 1998; Danis *et al*, 2000). For all the clinical interventions described, in addition to asking questions about the comparison of available treatments, the suitability of specific cases, the complications and risks, and the visual outcomes, it has recently been suggested that it is also important to address the QoL of patients pre- and post-treatment (see American Academy of Ophthalmology, 2000a, 2000b).

CHAPTER 3: AMD, LOW VISION MANAGEMENT AND QUALITY OF LIFE

3.1 Low vision management of AMD

Since there is no effective medical treatment for the majority of cases of AMD (see 2.3 above), patients are usually referred for low vision care[†]. The Low Vision Services Consensus Group (1999) define a low vision service as *"a rehabilitative or habilitative process which provides a range of services for people with low vision to enable them to make use of their eyesight to achieve maximum potential"*. Low vision rehabilitation therefore aims to maximise the use of residual vision in people with visual impairment and thus aims to help the patient maintain as independent a lifestyle as possible. The main techniques employed are the provision of magnification, usually with a range of optical low vision aids (LVAs), and illumination control. Other techniques such as eccentric viewing and 'steady eye strategy' may also be utilised (Nilsson, 1990). Obtaining help with reading and other near vision activities of daily living (ADLs) are usually the primary objectives (Kleen and Levoy, 1981; Gold, 1992; Elliot *et al,* 1997; Rubin, 2001), although the patient's ability to perform other tasks is usually explored and specific goals are identified. Key areas are those which encompass communication, mobility and safety (Gold, 1992). Other activities which may also be addressed include leisure pursuits, personal hygiene and dressing, food preparation and taking medication. In broad terms, low vision rehabilitation attempts to facilitate adaptation to visual loss to achieve as independent a lifestyle as possible, and thus to enhance QoL (Nilsson and Nilsson, 1986; Gieser, 1992; Nowakowski, 1994; Raasch *et al*, 1997).

Different models of care exist and thus different professionals may be included within low vision services. Clinics vary in their approach with respect to follow up arrangements, the training offered and in the involvement of other professionals (Ryan

[†] Within the context of this thesis, 'low vision care' will be taken to be synonymous with 'low vision rehabilitation'. Low vision services are services which aim to provide low vision care or low vision rehabilitation.

and Culham, 1999). However, in the UK a typical low vision assessment may include the following stages (adopted after Rumney, 1995)[†]:

- The patient's understanding of their diagnosis is checked. A further explanation of the primary diagnosis is given to the patient, together with information on prognosis and treatment and information about any other ocular conditions present.

- In discussion with the patient, visual requirements and initial goals are identified and discussed, taking into account general health status and relevant social considerations.

- The clinician (often an optometrist) carries out a range of visual function assessments including the measurement of vision, refraction and optimisation of acuities, measurement of contrast sensitivity etc. Following the visual function tests, the goals for rehabilitation identified earlier are re-appraised to ensure that they are realistic and in order to improve the chances of successful progress.

- The optometrist demonstrates a range of LVAs, which may suit the particular task or range of tasks identified as being important and together with the patient decides which device(s) is/are likely to be the most helpful. The magnification necessary will depend upon the threshold and fluency without a device and the visual performance necessary to accomplish the task(s). An explanation and varying degrees of training in the use and handling of loaned devices, advice about lighting and other methods of vision enhancement, and large print supporting literature are provided.

- Finally, the patient may be referred to other inter-disciplinary services, for example, within the statutory social or voluntary sector, and as is usually deemed necessary, a follow-up appointment is made.

[†] It is assumed that the diagnosis has been established previously and discussed between the patient and their ophthalmologist.

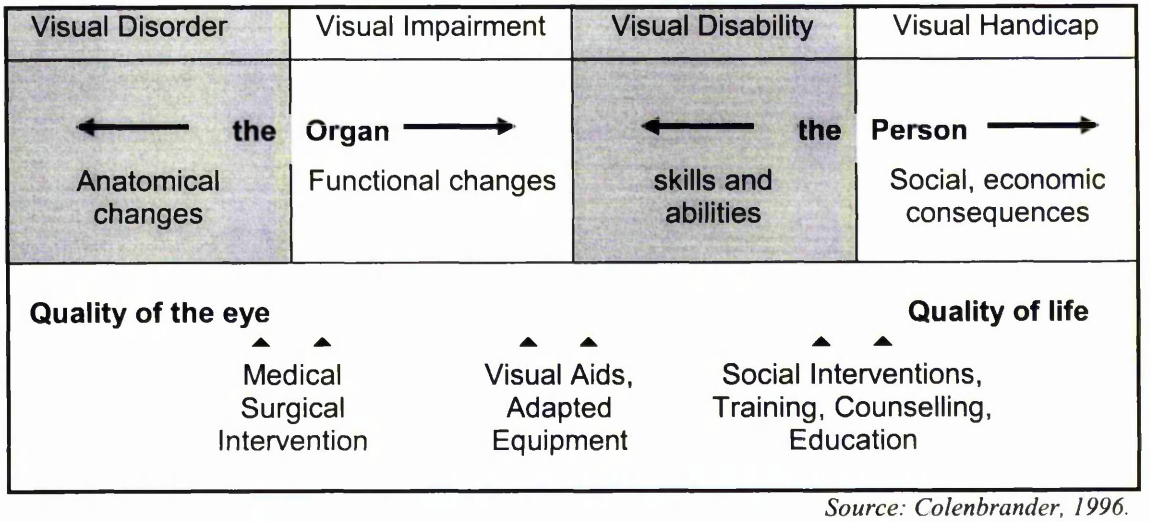
During the follow-up visit, LVAs may be returned or exchanged, or additional devices may be prescribed. Further appointments may be made if appropriate, in particular, if the needs are multiple, complex or if the vision is unstable (necessitating frequent changes in magnification requirements). However, in some clinics, the patient may self-refer at any time should a significant change in vision occur or alternate needs arise.

3.2 Dimensions of Vision Loss

Whilst the pathophysiology and epidemiology of AMD have been reviewed in chapter 2 it is important to discuss the concepts of visual impairment, disability and handicap, since it is these aspects of AMD which can be used to demonstrate the impact of the disease on an individual's QoL. Furthermore it is these aspects of AMD that are measured, assessed and addressed through low vision rehabilitation.

Colenbrander (1996; see also Colenbrander and Fletcher, 1995) explores the dimensions of vision loss and places them into the contexts of "the eye" and "the individual", as shown in figure 3.1 below.

Figure 3.1 Aspects of vision loss



Source: Colenbrander, 1996.

According to Colenbrander, functional changes in the eye (i.e. visual impairments), for example the clinical assessments of visual acuity, visual field, colour vision or contrast sensitivity should not be confused with the term "functional vision" which refers to "visual ability". The International Classification of Impairments, Disabilities and Handicaps (ICIDH), (WHO, 1980) describes impairment as the "functional consequences of a disease or disorder". AMD causes a number of impairments including reductions in visual acuity, the central visual field, contrast sensitivity, colour discrimination and problems with glare recovery (Swann and Lovie-Kitchen, 1990; Dutton, 2000; McClure *et al,* 2000). A 'more complete description of visual function' can be obtained by including the measures of visual field, contrast sensitivity, glare sensitivity and stereopsis as well as visual acuity (Rubin *et al,* 1997). These functional consequences in turn affect people's visual abilities in many ways, and to differing extents, depending on the nature of tasks involved (Dickinson, 1998). Abilities and skills affected typically include mobility, tasks such as reading and writing, face recognition, and various general activities of daily living dependent on vision (Lindö and Nordholm, 1999; Rubin *et al,* 2001). The ICIDH (WHO, 1980) defines disability as "any restriction or lack (resulting from an impairment) of ability to perform an activity in a manner or within a range considered normal for a human being". Visual handicap applies disabilities to a broader context, relating to a person's social and economic roles. For example, Colenbrander suggests that visual disabilities may lead to "a lack of independence and economic disadvantages". The extent of handicap is also determined by the reaction of the individual to his or her disabilities (Dickinson, 1998). The ICIDH (1980) definition of handicap is: "a disadvantage for a given individual (resulting from an impairment or disability) that limits or prevents the fulfilment of a role that is normal .... for that individual". Although the 'impairment / disability / handicap' model (WHO, 1980) is still referred to frequently, the terminology has since been revised to 'impairments / activities / participation' (Bowling, 2001).

AMD therefore plays a substantial role in terms of the concepts of impairment (i.e. with respect to reduced visual functions) and disability (through task restriction) as outlined above. Since AMD accounts for the majority of blind registrations in England and Wales (see section 1.2), there is a need therefore to consider also the definition of blindness used by the registration system. Individuals who are registered blind should be "so blind as to be unable to perform work for which eyesight is essential" (National

Assistance Act of 1948, the Ministry of Health; BD8 form, 1990). Partial sight registration, according to the National Assistance Act of 1948, requires that qualifying individuals should be "substantially and permanently handicapped by defective vision caused by a congenital defect, illness or injury" (National Assistance Act of 1948, the Ministry of Health; BD8 form, 1990). Although these are the formal definitions (O'Shea, 1998), in practice measures of central visual acuity and visual fields are used to define blindness. Blindness is categorised by visual acuity which is '3/60 or worse or, 6/60 or worse with markedly restricted fields' with best available spectacle correction; and partial sight as visual acuity of 3/60 – 6/60 with full visual field or, 6/24 or worse, with moderate field constriction or, 6/18 or better with gross field defect. However, the decision process with respect to registration can be problematic (Dutton, 2000) due to the impact that other measures of vision (for example, impaired contrast sensitivity or impaired colour vision) may have in addition to a visual acuity of 6/18 or better, which together can satisfy the requirements for partial sight registration as stated on the BD8.

3.3 Quality of Life

QoL is a complex concept which has many perspectives and many different settings, such as the individual or a community context. Bowling (2001) describes QoL as a concept which is 'vague', 'multidimensional', and one which incorporates 'all aspects of an individual's life'. 'Health-related QoL', has become a term which is interchangeable with 'health status', and as such is defined by Bowling (2001) as relating to "the ability to perform activities of daily living and fulfil role obligations (necessary for the functioning of society as a whole)". The formal definition of QoL which is provided by the WHO working party on QoL (WHOQOL Group, 1991) is as follows: *"Quality of life is defined as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by a person's physical health, psychological state, level of independence, social relationships, and their relationships to salient features of their environment."* There is therefore a clear link between the notion that QoL can be affected negatively by a deterioration in skill or performance, and the field of rehabilitation (Brown, 1988). According to Jenkinson (1994) any health intervention should aim to improve an

individual's QoL. This premise was noted for example by Katz (1987) who states that "the effectiveness and cost-effectiveness of treatments must be measured in terms of the quality of life". However, it is also important to note that, due to the complexity of QoL, health services research often requires the use of a range of different measurement scales to ensure that the various parameters which can contribute to an individual's QoL are accounted for.

AMD can have a substantial effect on QoL (Brenner *et al*, 1993; Scott *et al*, 1994; Brown *et al*, 2000; see also section 1.2). The definitions of QoL are strongly linked to the ICIDH definitions of impairment, disability and handicap given above (3.2) (van den Bos and Triemstra, 1999). In general, elderly people are more prone to suffer from other illnesses and disabilities as well as having an increased risk of eye disease (West *et al*, 1997). Therefore, QoL among the elderly is often reduced due to chronic illness and/or disabilities associated with ageing, and is frequently reflected by a loss of independence, depression and social problems such as isolation (Fallowfield, 1990). Failing sight is listed together with heart problems and arthritic conditions as being one of the most frequent causes of limitation of functional abilities in the over 65 year old age group (Farquhar *et al*, 1993). In a study which examined the relationship between functional health status and performance in activities of daily living among people 70 years and over, Whittle and Goldenberg (1996) found that a reduced ability to carry out activities such as housekeeping, shopping and managing transport needs (i.e. increased dependence) was significantly associated with a decline in health status. In this latter study, social functioning, health perception and physical functioning were found to be strong indicators of overall health status. The impacts of disabling conditions on QoL are not simply restricted to the person with the impairment and disability, but may also affect in turn the QoL of the carer, especially if there is considerable dependency on the latter for help with carrying out daily activities (Parker, 1990). In a study exploring the relationship between 'blindness' in a group of older subjects and the ability to perform everyday tasks, Tobin (1995) highlights the fact that living alone may generate different problems to those experienced by individuals living, for example, in a 'family home'. From their results of a cross-sectional survey of people over 65 years of age group, Farquhar *et al* (1993) observed poorer functional ability among those individuals with little support from family or friend networks. They also report that the uptake of social services was greater among the individuals who performed better in their tasks of daily

living. However, autonomy can be regained or retained among elderly people who lose their sight by appropriate training in specific areas pertaining to everyday activities (Tobin, 1995).

Within ophthalmic research there is now a growing awareness of the need to assess QoL, and indeed the perceptions of QoL amongst those providing care (Hart *et al*, 1998; Brown *et al*, 2000). This awareness has also been reflected by the recent development of various vision-specific instruments which measure either QoL explicitly or vision disability (see 3.5 below), especially in studies with respect to cataract extraction (for example, Mangione *et al*, 1994). In addition, a recent study has been carried out to determine the difference between ophthalmologists' and patients' perceptions of QoL associated with AMD (Brown *et al*, 2000). The result of this latter study showed that ophthalmologists underestimated the effects of AMD on patients' QoL.

3.4 Low vision rehabilitation and QoL

Gieser (1992) proposes that people with impaired vision can be helped to "lead more productive, independent lives" through rehabilitation which will make as much use of remaining vision as possible, thus improving the QoL. There appears to be a strong consensus of opinion that low vision care and the provision of LVAs can yield a positive gain to the lifestyles of the visually impaired (Kleen and Levoy, 1981; Culham *et al*,1990; Van Rens *et al*, 1991; Rumney, 1992; Leat *et al*, 1994; Howe, 1995; Raasch *et al*, 1997; Scott *et al*, 1999; Hinds, 2000). However, compliance in LVA use and therefore the benefits associated with LVAs are dependent on several factors, in particular psychological factors, such as patient motivation, and the handling skills required to use the device(s) prescribed (Robbins and McMurray, 1988; McIlwaine *et al*, 1991). Much has been written about the readiness of individuals to 'accept' the need for low vision rehabilitation and their motivation in applying the prescribed techniques (e.g. Greig *et al*, 1986; Inde, 1988), a factor that is frequently associated with a person's adjustment to their loss of vision. People may progress through a range of different emotions (shock, depression, anger, fear), underpinned by a growing realisation of being in a position of dependency upon others (Greig *et al*, 1986; Dodds, 1991). Furthermore, Greig *et al* (1986) believe that low vision rehabilitation is particularly

challenging amongst the elderly, because this group are at a higher risk to feelings of loss and depression due to increased morbidity, more frequent exposure to bereavement, and a greater sense of dependency on others in their lifestyle overall. Age *per se* has been reported as a key factor associated with a poor success rate in low vision rehabilitation, simply because older people find the use of LVAs difficult to master (Humphry and Thompson, 1986; Nilsson and Nilsson, 1986 citing: Rosenbloom, 1974, Sloan, 1977).

3.5 Effectiveness of low vision care

The best way to assess the effectiveness of an 'intervention' or 'treatment' is to conduct a "rigorous evaluation of the outcomes" associated with the intervention (Brooks, 1995). Thus, the outcomes used should be chosen carefully, to ensure that they reflect adequately the concept of QoL in the population being studied.

In evaluating the effectiveness of rehabilitative care, Grenville and Lyne (1995) stress that outcome measures should "represent progress in rehabilitation" and "provide a true reflection of a holistic approach to patient-centred care". Three components of assessment are recommended (Grenville and Lyne, 1995 citing Studenski and Woods Duncan, 1993), namely (i) identification and measurement of specific impairments, (ii) measurement of functional abilities, and (iii) general measurements of health status including social and mental dimensions. Therefore the responses captured using an instrument for assessing QoL should observe a multi-dimensional approach (Fletcher *et al*, 1992), including physical, emotional and social outcomes, task performance, and measurement of pain and disease specific symptoms (Fitzpatrick *et al*, 1992) (see also 3.3 above).

Using the correct outcome measures will ensure both the validity and reliability of the information collected (Grenville and Lyne, 1995; Ellwein *et al*, 1995). Ellwein *et al* (1995) urge that the choice of instruments should be based on their clear demonstration

of "validity, reliability and responsiveness" [†]. Questionnaires should also be practical in terms of administration within the study context (Fitzpatrick *et al,* 1992).

Overall, there are two types of quality of life instruments - generic and specific (Patrick and Deyo, 1989; Fitzpatrick *et al,* 1992; Bowling, 2001). The former may be used to measure outcomes in various types of studies dealing with different health issues, whereas the latter are designed for use with a particular disease or a group of similar conditions. Examples of widely used generic tools are the Short Form 36 (Ware and Sherbourne, 1992 – see 5.4.2), the Sickness Impact Profile (Bergner *et al,* 1981) and the Nottingham Health Profile (Hunt *et al,* 1986).

An example of a disease specific questionnaire is the VCM1, a vision-related quality of life questionnaire (Frost *et al,* 1998; Hazel *et al,* 2000; see section 5.4.2). Other examples of disease specific instruments include: the National Eye Institute Visual Function Questionnaire (NEIVFQ) (Mangione *et al,* 1998); the Visual Function 14 or 12 item scale (VF14 or VF12) (Steinberg *et al,* 1994; Tielsch *et al,* 1995; Armbrecht *et al,* 2000); and the Activities of Daily Vision Scale (ADVS) (Mangione *et al,* 1992). Both generic instruments which are designed to measure QoL and those which measure visual functioning indices provide 'a measure of patients' own perception of their disability, and have recently gained popularity for estimating visual function' (McClure *et al,* 2000 citing Scott *et al,* 1994 and Ellwein *et al,* 1995). There is increasing emphasis being placed on patient perception of QoL and level of function both in health services provision and in research (Ebbs *et al,* 1989; Patrick and Deyo, 1989; Jenkinson, *et al,* 1993; Fitzpatrick *et al,* 1992; Armbrecht *et al,* 2000; Brown *et al,* 2000; Hazel *et al,* 2000; Submacular Surgery Trials Pilot Study Investigators, 2000b) and this is reflected by ongoing efforts to develop appropriate instruments to allow the 'measurement' of these dimensions. Interestingly, however, a small survey of 45 UK ophthalmologists conducted at a major UK ophthalmology conference, demonstrated that awareness of QoL measures and instruments was very poor (Hart *et al,* 1998),

[†] Reliability is "concerned with the extent to which a questionnaire produces the same results under the same conditions" (Ellwein *et al,* 1995). Ellwein *et al* (1995) define validity in broad terms as "the extent to which an instrument measures what it claims to measure"; however this must be considered from two perspectives, namely content validity and construct validity. The former refers to whether the questionnaire includes all of the measurements relevant to the research being done; the latter is concerned with how well the questionnaire can yield expected results (i.e. can show convergent or divergent relationships between selected measurements) (Patrick and Deyo, 1989; Ellwein *et al,* 1995). Responsiveness, according to Ellwein *et al* (1995), is "the ability to detect changes that occur as a result of an intervention".

albeit that there was some doubt as to the representativeness of the sample of respondents in terms of the UK as a whole. However, there is some evidence for growing awareness with respect to QoL measures due to the recent development of new vision-specific instruments.

3.6 Evaluating the effectiveness of low vision care

There is currently much variation in the approach to low vision rehabilitation. To date there have been several studies which have examined the effectiveness of low vision clinic services (Humphry and Thompson, 1986; Hall *et al*, 1987; Temel, 1989; McIlwaine *et al*, 1991; Van Rens *et al*, 1991; Leat *et al*, 1994; Shuttleworth *et al*, 1995; Warren, 1995; Watson *et al*, 1997a and 1997b; Scott *et al*, 1999). These studies have, however, mainly been cross-sectional surveys with comparatively small sample sizes and have evaluated 'success' using a narrow selection of variables to report on a single dimension of low vision care, for example the usage of LVAs (Humphry and Thompson, 1986; McIlwaine *et al*, 1991; Van Rens *et al*, 1991). Although there is a growing trend to use questionnaire approaches which capture a more extensive set of information in order to measure the success of low vision care (Hall *et al*, 1987; Leat *et al*, 1994; Shuttleworth *et al*, 1995; Harper *et al*, 1999; also see 3.5 above), there is still a lack of systematic evidence world-wide about effectiveness in term of QoL which has been addressed by relatively few studies to date (e.g. Scott, 1994 and 1999; Mangione *et al*, 1999; Hinds, 2000).

In the UK, under the National Health Service (NHS), low vision care is usually provided by optometrists based within the Hospital Eye Service (HES) (Rumney, 1992). A recent national survey of UK low vision services shows that these are mainly based in hospitals (65% of appointments), although there are a variety of other service providers including primary care optometry (15%), local social service departments (6%) and voluntary agencies (10%) (Ryan and Culham, 1999). However, when optometric care is provided it is seldom integrated with community rehabilitation support, which may provide considerable assistance to visually impaired individuals. Low vision care based upon an 'integrated' or 'multi-disciplinary' approach which incorporates input from a range of professionals (including for example, an ophthalmologist, optometrist, low

vision rehabilitation officer and social worker) has been developed to a limited extent only in the UK (Giltrow-Tyler, 1988; Moore, 1994; Collins, 1995; Dickinson, 1995), although this model of care is not uncommon in the USA, Australia and Sweden. The integrated model usually has a strong emphasis on training programmes delivered by rehabilitation professionals to maximise vision with magnification techniques (Goodrich and Quillman, 1977; Goodrich and Mehr, 1986; Freeman and Jose, 1991). The recent survey and framework document for low vision services (Ryan and Culham, 1999; Low Vision Services Consensus Group, 1999) in highlighting a number of problems with UK low vision services (including fragmentation of services, lack of multi-disciplinary and multi-professional working, inadequate communication between those providing services), emphasised the lack of UK-based research about the effectiveness of low vision interventions. While a number of studies have evaluated the outcomes of low vision care (Nilsson and Nilsson, 1986; McIlwaine *et al,* 1991; Van Rens *et al,* 1991; Leat *et al,* 1994; Shuttleworth *et al,* 1995; Harper *et al,* 1999; Scott *et al,* 1999; Hinds, 2000), there is a lack of high quality comparative evidence about effectiveness and cost-effectiveness of alternative interventions (Raasch *et al*, 1997; Harper *et al,* 1999). The studies which have been conducted have usually been descriptions of small, longitudinal case series, either retrospective or prospective, but not RCTs, thus constituting relatively poor evidence for comparative effectiveness (see 1.2). Such studies include those that have shown that the traditional optometric service within the HES in the UK has generally resulted in poor compliance in the use of LVAs prescribed to patients (Humphry and Thompson, 1986; McIlwaine *et al*, 1991). These results have been largely attributed to a lack of formal training in the use of LVAs and a lack of integration of services (Collins, 1995; Dickinson, 1995; Shuttleworth *et al*, 1995), although there is some evidence demonstrating that a high success rate can be achieved with an optometric only approach (Leat *et al*, 1994).

The considerable scale of the low vision problem and the different models of care proposed by the providers of low vision rehabilitation have precipitated a need to measure the effectiveness of different models of care using an appropriate range of outcomes. By identifying effective forms of low vision care successfully, it is possible that improvements to independent living can be achieved through appropriate low vision rehabilitation services (Nilsson and Nilsson 1986; Nowakowski, 1994). This in turn may result in a reduced need for welfare provision due to decreased dependency in

carrying out activities of daily living. There has been a debate for some time about how the delivery of low vision care can be improved to achieve greater success in patient rehabilitation (e.g. Dickinson, 1995). Due to the interaction between QoL issues and loss of vision, arguments have been put forward in favour of integrating the role of the optometrist with other disciplines which also have an impact on the general well-being of a visually impaired individual (Worrall *et al*, 1993; Warren, 1995).

There is, therefore, a growing recognition of the value of exploring health-related QoL in addition to clinical outcomes in evaluating the effectiveness of interventions. In addition, since recent reports suggest benefit from multidisciplinary models of low vision care (Ryan and McCloughan, 1999; Ryan and Culham, 1999; Hinds, 2000) there is a clear need to explore the advantages of integrating clinical low vision services with rehabilitation work in the community. In proposing a multidisciplinary model of care which would consider a broad range of patient needs (e.g. social, psychological, and optometric among others), Dickinson (1995) emphasises that the necessary "range of expertise cannot be found in a single professional group" and highlights the urgency for further research. As previously mentioned, although some recent research work in low vision has utilised health-related QoL outcomes (Mangione *et al*, 1999, Scott *et al*, 1999; Hinds, 2000), such measures have not been used in RCTs or other systematic studies of low vision services.

CHAPTER 4: OBJECTIVES AND JUSTIFICATION FOR THE TRIAL

4.1 Evidence for the effectiveness of low vision care

Chapter 3 highlights the lack of systematic evidence with respect to the effectiveness of alternative models of low vision care. The scene is set by describing the purpose of low vision care, the dimensions of vision loss, and the importance of the concept of QoL in low vision research. The increasing awareness amongst those engaged in ophthalmic research of the importance of QoL has led to the development over recent years of a growing number of instruments which measure aspects of vision-related QoL. However, to date there has not been an RCT which compares different models of care by including outcome measures of QoL. This brief chapter summarises the justification for the present trial and the objectives of the trial.

4.2 Justification for the present study

In view of the multi-dimensional impacts of vision loss due to AMD (whether psychosocial or economic) on both the individual and society (Williams *et al*, 1998; Mangione *et al*, 1999) (see 3.2), the measurement of the effectiveness of low vision care using valid and reliable outcomes should provide important and timely benefits. In fulfilling its key objectives, this study responds directly and indirectly to some of the recently published recommendations for low vision services (Ryan and McCloughan, 1999; Ryan and Culham, 1999). Two key recommendations aimed at central Government and at both central Government and researchers, are stated respectively as follows: (i) "to give increased priority to the improvement in the quality of low vision services throughout the UK" (Ryan and McCloughan, 1999); and (ii) "the effectiveness of different models of low vision services should be assessed" (Ryan and Culham, 1999). Therefore the present study is a timely response to the need for a comparative, evidence-based evaluation of alternative low vision rehabilitation services, especially since there is a growing need for supportive care for patients with AMD.

4.3 Objectives of the trial

These are:

(i) to measure the effectiveness of different strategies of low vision rehabilitation for subjects with newly-diagnosed AMD.

(ii) to compare the cost-effectiveness of these different strategies of low vision rehabilitation.

(iii) to compare different outcome measures within subjects in order to identify (a) the underlying outcome dimensions of relevance to subjects and (b) a minimum outcome dataset to characterise these dimensions.

(iv) to describe and monitor a large sample of patients with AMD in terms of their socio-demographic characteristics, their pathway through low vision rehabilitation services, their understanding of AMD, their self-rated task restrictions, the devices loaned and patterns of use of LVAs, visual functions and outcome measures relating to generic and vision specific quality of life, and adjustment to visual impairment.

The findings for objectives (i) and (iv) are presented in this thesis, however, the findings for objectives (ii) and (iii) are beyond the scope of this thesis. The author also considers that it is important to address objective (iv) to complement the findings of the main objective outlined in (i). Furthermore, QoL outcome measures for the study population are compared against normative data. This trial presented a unique opportunity to allow a longitudinal analysis over 12 months of a population of elderly patients with AMD with respect to the range of characteristics and outcomes measured. This data will be of interest to those professionals involved in the low vision care of individuals diagnosed with AMD.

CHAPTER 5: STUDY DESIGN AND METHODOLOGY

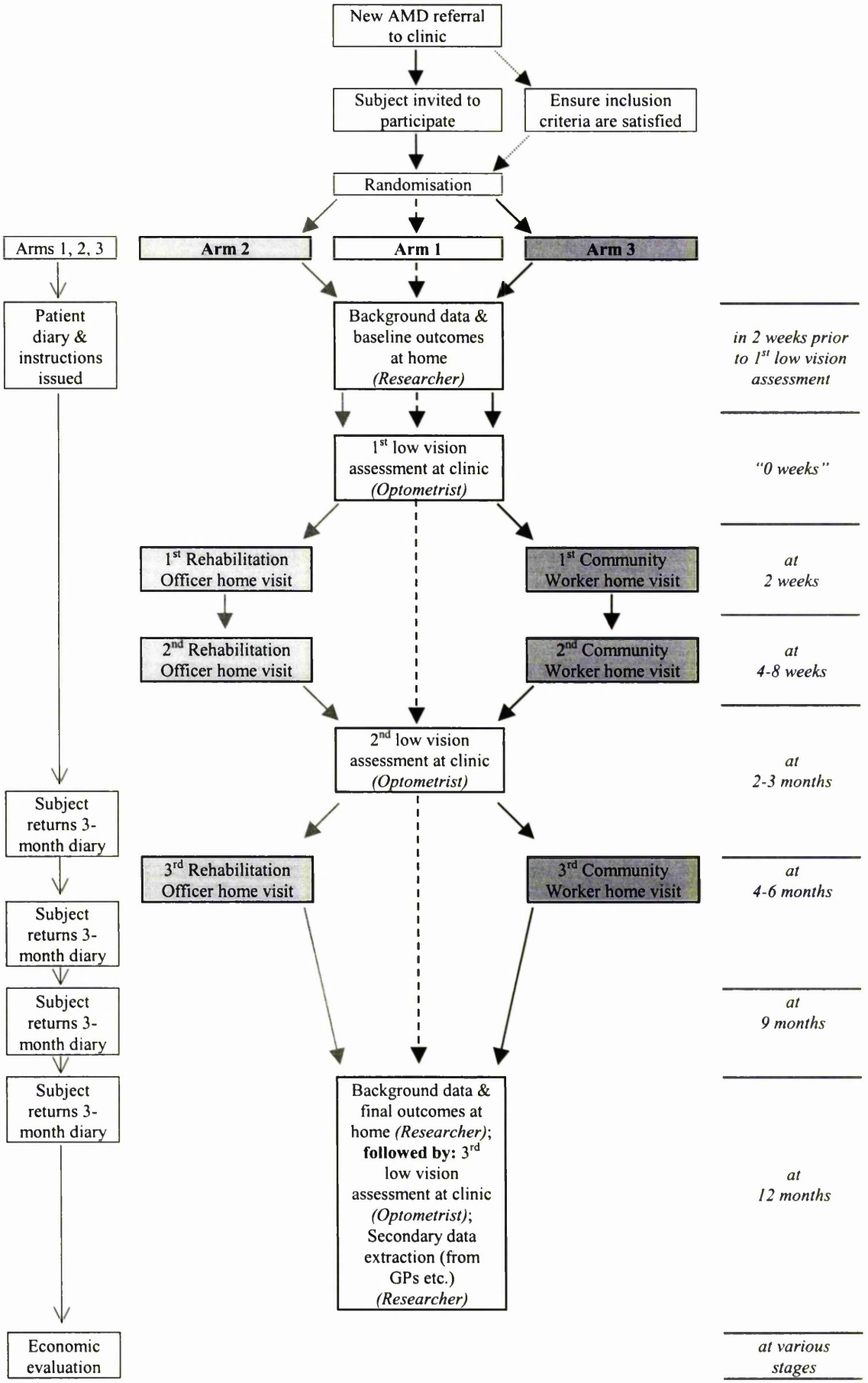
5.1 Experimental design

This longitudinal study is a 3-arm RCT to compare the effectiveness and cost-effectiveness of different models of low vision care for patients with AMD. An organisational flow chart which presents the path followed by subjects through the trial and key events in the study is shown in figure 5.1.

In this trial each eligible patient (who had consented to joining the study) was allocated randomly to one of three arms. Subjects randomised to 'arm 1' received conventional hospital-based low vision care whereas subjects randomised to 'arm 2' received the hospital-based care enhanced with home-based intervention provided by a low vision rehabilitation officer. These subjects received the same HES optometric care as the subjects in arm 1, but in addition were visited at home on up to three occasions by a trained rehabilitation officer. Subjects randomised to 'arm 3' received hospital-based care and in addition received 'generic' (i.e. not vision specific) intervention at home from a community care worker, thereby controlling for the contact time received by subjects in arm 2. These interventions are described below in more detail in sections 5.4.3, 5.4.4 and 5.4.5.

This trial uses the principle of 'intention-to-treat' analysis so that in the analysis of data subjects allocated to specific arms of the trial are analysed according to those arms whether or not they received their intended intervention (Bland, 1995). In this trial, blinding (or 'masking') was applied to the researcher to prevent the researcher from knowing to which intervention arms patients had been allocated. Although formal 'blinding' of patients was not possible, since patients participating in the trial had been informed that different intervention strategies of low vision care would be compared (see appendix 1), patients in two of the arms (i.e. arms 2 and 3) were not able to guess conclusively which of the two corresponding interventions was being delivered to them.

Figure 5.1 Organisational chart showing events during the trial



The patients in the remaining arm, who received the conventional form of low vision rehabilitation, may have been able similarly to draw only limited conclusions concerning the nature of their low vision care vis-à-vis the other interventions. These mechanisms therefore removed potential observer bias and reduced substantially subject bias respectively (Robson, 1993). Another source of bias, namely 'dropout bias' was also considered (see 8.2)

All of the patients in the trial were visited at home by the researcher (i.e. the author) within 2 weeks prior to their initial hospital assessment in order to collect baseline outcomes (see 5.4.2 below). Each patient also received a 'Patient Diary' (see 5.4.6) during this visit for completion. A second home visit was made by the researcher at approximately 12 months after the initial assessment and before a final low vision clinic visit, in order to record final outcomes. The researcher was not responsible for the provision of low vision care in the hospital clinic.

5.2 Study population

A total of 226 subjects with AMD were recruited at the Manchester Royal Eye Hospital (MREH) between November 1997 and August 1999. The progress of patients through the trial and a summary of the recruitment statistics are given in Chapter 6.

5.2.1 Eligibility criteria

Patients eligible for inclusion in the study and who were therefore invited to participate, were required to satisfy the following criteria:

- new referral to the low vision clinic at MREH
- primary diagnosis being AMD
- visual acuity worse than 6/18 (<0.5 logMAR) in both eyes, but equal to or better than 1/60 (~1.8 logMAR) in the 'better' eye
- proficiency in English
- not residing in a residential or nursing home
- not receiving full-time professional health care whilst living in own home
- not suffering from mental illness or dementia

5.2.2 Invitation to participate

Eligible patients were informed of the study and invited to participate by letter in the first instance. This letter, typed large-print (boldfaced Arial font, size 18 point), advised patients of the purpose of the study and of what would happen should they agree to take part (see appendix 1). The letter included a consent form for the patient to sign if they were willing to participate. On returning the signed consent form, patients were contacted by telephone to arrange a convenient time for an initial home visit (for collection of baseline outcomes). If a patient did not reply they were contacted by telephone and asked if they had been able to read the letter (or have had it read to them) and if so, if they were willing to participate. A recorded version on cassette was available for patients unable to read the letter, however, all of the patients approached were either able to read the letter or had it read to them by someone else. Finally, if a patient did not reply and was not contactable by telephone, a follow-up information letter (see appendix 2) and consent form was sent to the patient by post. If a reply was not obtained the patient was classed as 'having not replied' and was not included in the study. Numbers of consent and refusal are given in chapter 6 (6.2) and a brief account of reasons for refusal is given in appendix 3. Consenting patients were each allocated a unique study number at the time when an appointment for a home visit was made, and randomised into one of the three study intervention arms.

5.2.3 Ethical considerations

The information letter sent to eligible patients (appendix 1) reassured them that they would not be disadvantaged by not taking part and that they would receive assessment in the normal way at the low vision clinic. Patients were informed that there would be no risks to their health by taking part and that they had the right to withdraw from the study at any time. As has been described in 5.2.2 above, care was taken to ensure that every invited patient had read (or listened to) the information given about the study. Furthermore, each patient was given the opportunity to ask any questions if necessary before deciding whether to consent.

Ethical clearance had been granted for the study by the Central Research Ethics Committee of Manchester Health Authority (Reference CM/96/108) which reviewed the study design, including the proposed methods of patient recruitment.

5.2.4 Sample size

All of the proposed outcomes (see 5.4 below) give continuous or ordinal scores. A sample size of at least 75 obtained in each arm of the trial allows the study to detect a standardised difference in outcomes between any 2 groups of 0.46, with 80% power at a 5% (2-tailed) significance level. Since outcomes will be adjusted for baseline measures, this difference in effect size is small, implying that the study would be unlikely to miss any important differences in outcomes between the groups.

Audit of the low vision service at MREH prior to the start of recruitment had suggested that the desired sample size was feasible for this 3-arm RCT.

5.3 Randomisation and 'blinding'

Study patients were randomised in blocks to the three treatment arms, using sealed envelopes to conceal the "treatment" allocation (arm number) prior to recruitment and determination of eligibility. Each patient was so allocated to a specific arm of the study on completion of the first home visit which was used to record baseline outcomes (see below). Block size was varied across the sample and was not disclosed to the researcher. An academic colleague who was not involved in the conduct of the trial generated the random allocation sequence, and the principal optometrist at MREH kept the list of arm allocation 'codes' and was responsible for the process of allocating patients to the respective arms of the trial and for advising the staff involved in delivering the input in arms 2 and 3. Although it was not possible to 'blind' other research staff who had a role in the study (the optometrists, rehabilitation officer or community workers) or the subjects who were taking part, to avoid the possibility of bias every attempt was made to 'blind' the researcher responsible for measuring outcomes to arm allocation until all outcome data for the study had been collected (see also 5.1 above). Instances where blinding was inadvertently broken, for example when a subject disclosed details of the interventions he/she has received to the researcher, were noted both in accordance with the guidelines for reporting of RCTs (Altman, 1996) and to ensure that this would be taken into account during statistical analysis. The frequency of broken blinding is given in Chapter 6, section 6.8.

5.4 Data collection

Outcomes were assessed across all arms at recruitment and 12 months later using a broad range of measures including the following categories:

(a) visual functions;
(b) measured task performance (at 12 months only);
(c) vision specific and generic health-related QoL;
(d) the use of LVAs;
(e) self-rated task restriction;
(f) knowledge of AMD and visual impairment.

A range of outcome measures were employed owing to the complexity of the concept of QoL (e.g. Patrick and Deyo, 1989) and in order to ensure that the different objectives of the study could be met. Additional data including ocular co-morbidity, general health status, socio-economic information and uptake of social and welfare services was gathered. Blind and partial sight registration data were collected retrospectively after the trial had ended and are included in appendix 21 of this thesis. Whilst the registration data allowed a descriptive analysis of numbers of patients registered by arm to be conducted (e.g. to determine baseline equivalence as described in section 5.5.3) they did not provide detailed information concerning any subsequent specific inputs by social services or the timings of such interventions post registration for individual patients. However, the data collected on the uptake of social services were intended to capture the inputs which may have been precipitated by partial sight and blind registration and these data are explored in section 7.1 which presents the findings of the analyses of socio-demographic variables. Data were also collected at various stages of the study across all arms to facilitate an economic evaluation of the low vision strategies (see below), although these data do not form part of the present thesis.

5.4.1 Visual function outcomes

These were measured during low vision clinic assessments and included distance logMAR acuity (Bailey and Lovie, 1976) measured with the Lighthouse modified ETDRS charts, continuous text reading acuity measured with the MNREAD charts and contrast sensitivity measured with the Pelli-Robson low contrast letter chart (Pelli *et al*, 1988). Figure 5.2 shows an example of the MNREAD acuity charts and figure 5.3 shows a chart being used. (Inter-relationships between the different acuity notations for

Figure 5.2 Example of the *MNREAD ACUITY CHARTS*. (Actual charts are 11 by 14 inches)

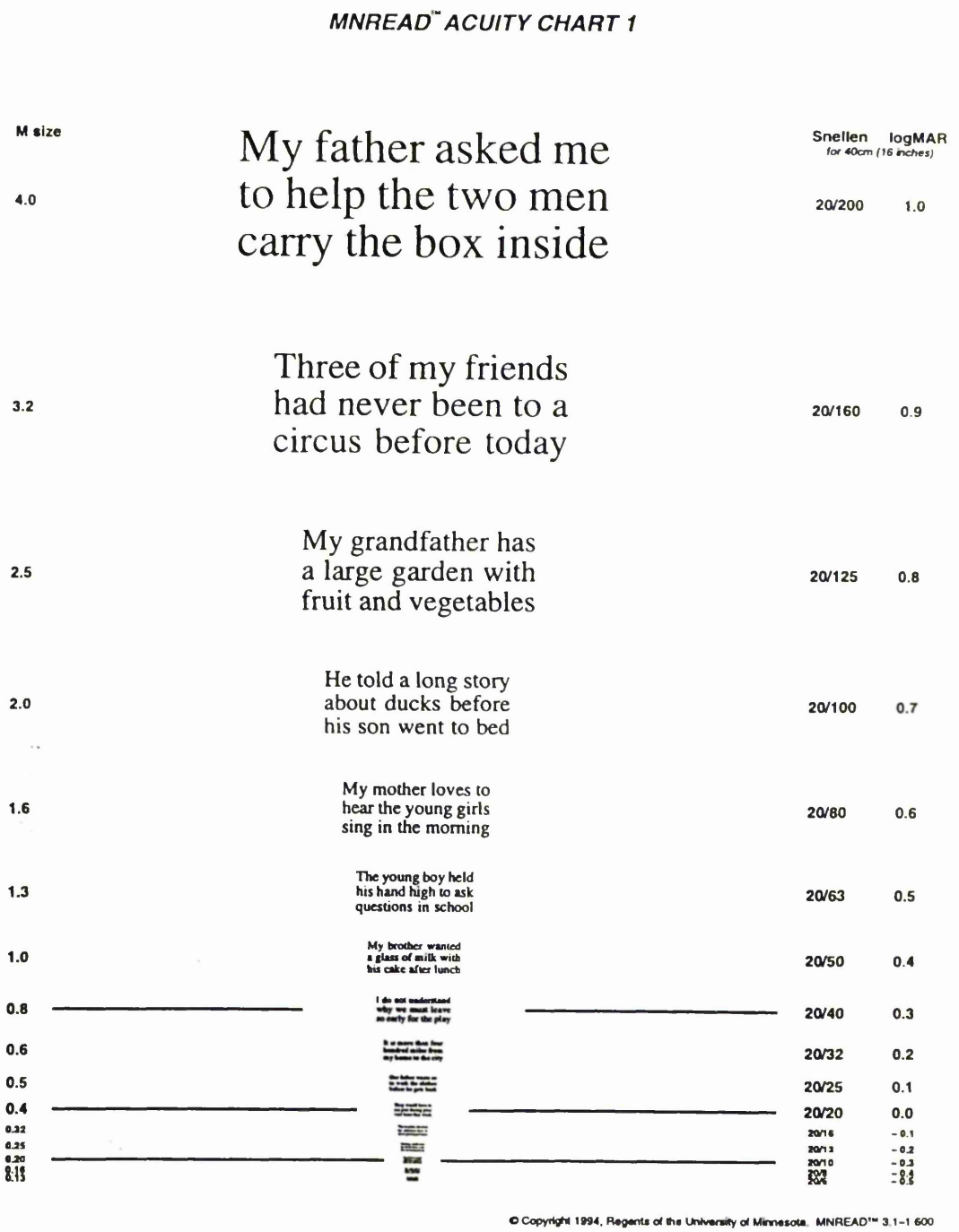
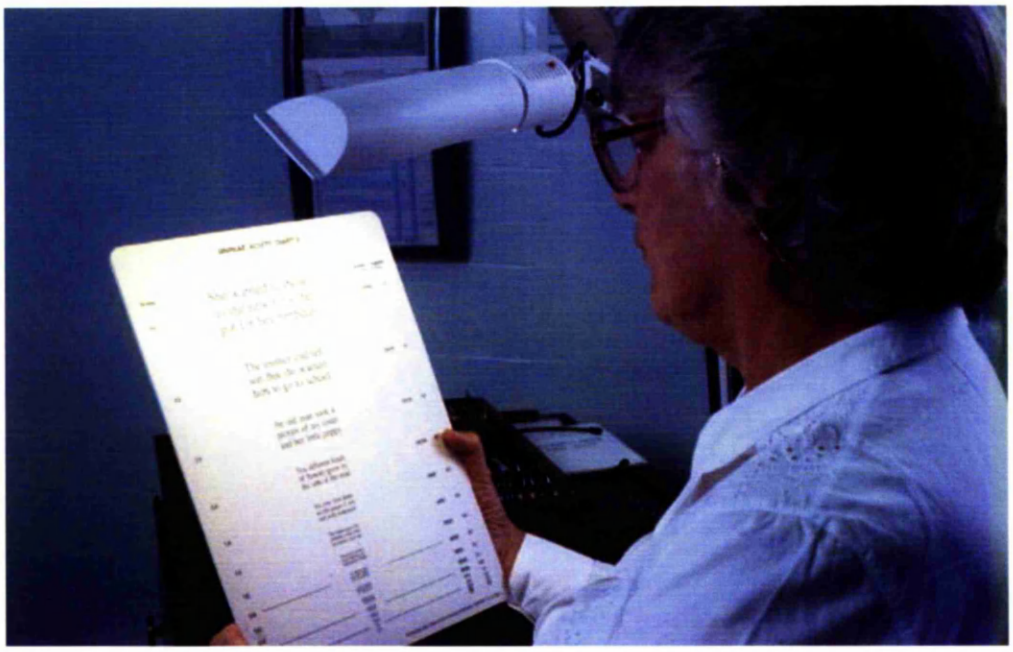


Figure 5.3 Continuous text reading acuity being measured using an *MNREAD ACUITY CHART*.



both distance and near acuity are given in appendix 4). Testing and scoring procedures for distance and near acuity and contrast sensitivity are given in appendix 20. In addition, the coding approaches for activities where no form vision was recorded are described in 6.9.2. Data capture sheets for the initial and follow-up low vision appointments are given in appendix 5. To obtain consistency in the measurement of visual function outcomes in the low vision clinic, optometrists attended an initial training session and were encouraged to adhere to a standardised protocol for the measurement of thresholds for each of the scheduled low vision appointments. However, in practice many optometrists were involved throughout the duration of the trial and strict adherence to the recommended conventions may not always have been possible, although this aspect of data collection was monitored regularly.

In addition to clinical measures of visual function outcomes, each patient's ability to perform five activities of daily living dependent on vision was assessed during the second home visit approximately 12 months after the initial clinic assessment. This task performance assessment included the following activities:

- To identify accurately the 'use-by-date' on two supermarket grocery labels, namely (a) for a meat item, and (b) for a bakery product. Both labels were different in appearance as were the position and typeface of the "use-by-date".
- To complete selected personal details on a mock application form for "Talking Books".
- To identify correctly the pharmacy instructions on a medicine bottle.
- To read a 'shopping list' of 20 everyday items.

The 'use-by-dates' and pharmacy instructions were scored by recording if the dates in the former task, and components of the latter task (name of the medicine and dosage) were correctly identified, thus yielding dichotomous responses. Figure 5.4 shows the two grocery labels used, and figure 5.5 shows the medicine bottle. To avoid the 'wear-and-tear' effects which would arise from many patients handling the same set of grocery labels and medicine bottle (thus introducing differences in the difficulty of performing tasks over time), several sets of grocery labels and pharmacy labels were produced in a continuous print run at the outset. Thus labels for each of the tasks were not appreciably different in any way, for example with respect to reduced contrast due to smudging or light exposure.

Figure 5.4 Grocery labels used as part of the task performance assessment at 12 months

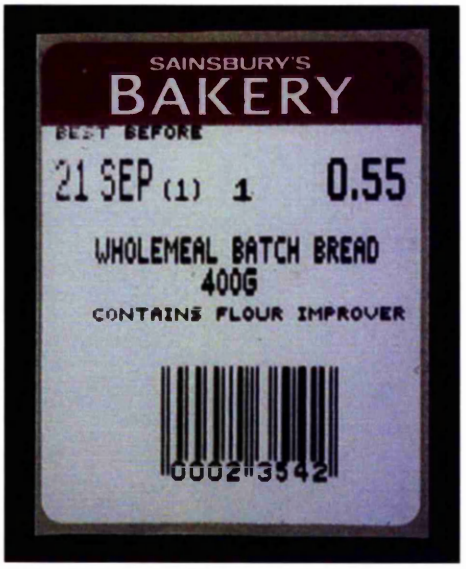
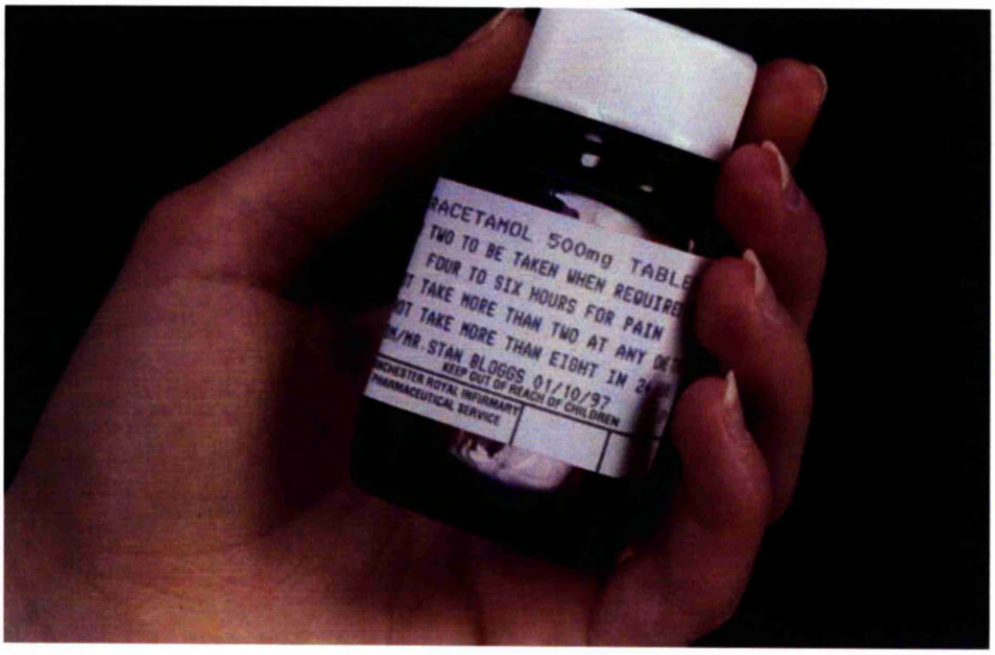


Figure 5.5 Pharmacy label used as part of the task performance assessment at 12 months



The completion of the mock form required the patient to print their name, telephone number, and to tick 2 boxes in response to 2 multiple choice questions. Legibility of the printed name and phone number were graded by an independent observer, who was unfamiliar with trial participant's names, to wholly legible, barely legible, and illegible. The ticked boxes were scored in dichotomous terms of being clearly or ambiguously ticked. The forms used for this activity were all printed using an ink-jet printer to ensure consistency in print quality. Figure 5.6 shows the form used for this task.

Reading speed and accuracy were assessed by asking the subject to read the 'shopping list'. The shopping list was printed using a fairly large typeface (Arial font size 14 point). Although this meant that the shopping list did not have the authentic appearance of a hand-written list, a word-processing method allowed the list to be re-printed at a consistent quality after several uses. Furthermore, it would not have been appropriate to ask patients to read a list written in unfamiliar handwriting. The shopping list demonstrating the size of print actually used for this task is shown in figure 5.7. For this task, the number of items (out of 12) identified correctly, i.e. exactly as written on the list, were counted and the time taken to read the list was recorded with a stopwatch.

For each activity, the subject was asked to complete the tasks using their magnifier if they wished to do so. The task performance was conducted at 12 months only so that all of the patients in the study will have had a minimum of 12 months to adapt to their visual impairment and will have been exposed to a number of LVAs where appropriate. These data were recorded on a 'Task Performance Questionnaire' (see appendix 6).

Figure 5.6 "Talking Books" application form used as part of the task performance assessment at 12 months

MTB

MANCHESTER TALKING BOOKS & MAGAZINES

I wish to become a member of MTB. I am unable to read printed books in the ordinary way. I will not copy or sell any cassettes which I receive from MTB.

Please print your name and address:

Name

_____

Address

_____

_____

Postcode _____ Tel No. _____

Tick box which represents your age group:

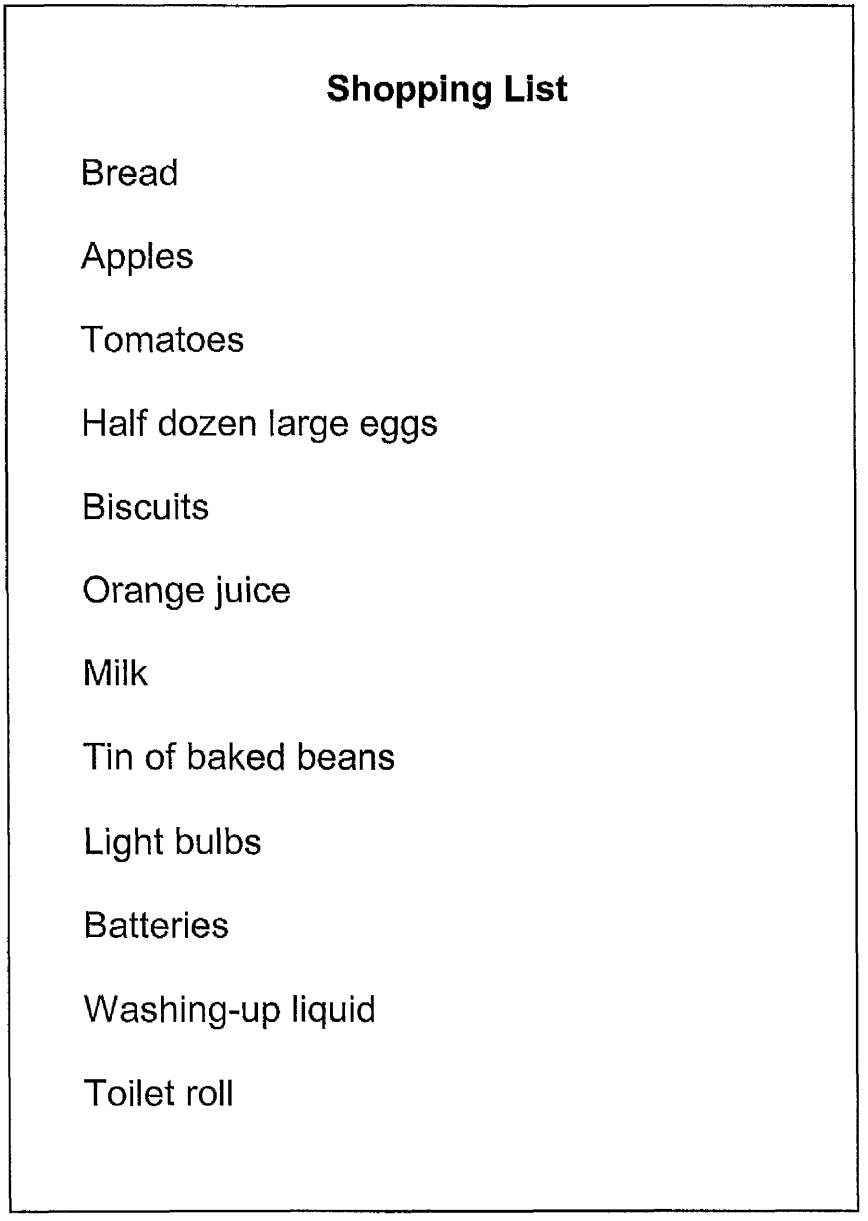
Under 40 ☐ 40-59 ☐ 60-79 ☐ 80 + ☐

Book and magazine application

We have a range of books covering topics such as history, art, music, sport and leisure, humour, animals and pets and many others. We also have a selection of magazines including gardening, radio and television, health, food and wine and women's titles. If you are interested in receiving a full list of books and magazines available and further details about how to apply, please tick the box marked 'YES' below. If you do not want us to send further information at the moment, please tick the box marked 'NO'.

YES ☐ NO ☐

Figure 5.7 Shopping list used as part of the task performance assessment at 12 months



5.4.2 Background data, baseline and final outcomes

These were assessed by the researcher. Five questionnaires in total were administered during home visits in face-to-face interviews. Firstly, a range of background variables were recorded for each patient including socio-economic information, medical history and expectations of attending the low vision clinic (see appendix 7), the latter by means of open-ended questions. Questions were included which explored the extent of social contact/support as social circumstances would possibly contribute to how individuals coped with their vision loss and also to an individual's QoL (see section 3.3). These questions were based on some of the questions included in the 'Health and Lifestyle Survey', a national survey of 9000 individuals in England, Wales and Scotland, carried out in 1984/5 (Blaxter, 1990). Secondly, four separate questionnaires were administered which covered a broad range of outcomes. The instruments included a generic health status questionnaire, a vision-specific QoL instrument, a questionnaire which measures pyschological adjustment to vision loss and a questionnaire relating to task restriction, patterns of LVA use and knowledge about AMD. This combination of questionnaires was chosen in order to be able to identify a suitable outcome dataset for research in low vision research. There is evidence to show that QoL outcome measures in clinical trials should include those which are disease-specific to ensure adequate sensitivity in detecting change when assessing interventions (Guyatt *et al*, 1986; Williams, 1998). However, Williams (1998) suggests that the measurement of QoL should include, in addition, other measures such as functioning and psychological well-being, which have also been established as QoL indicators. Thus a combination of instruments addressing a variety of dimensions was deemed necessary to prevent limitations in scope and to allow greater comparability with other research. It was considered important to use a widely accepted generic instrument to determine what impact, if any, low vision services may have on such measures. At the same time, since the former is likely to be relatively insensitive to vision rehabilitation, it was important to use vision specific measures with respect to QoL. Although vision specific measures clearly address issues of concern in vision welfare (see 3.5), they have not been developed with low vision care in mind and consequently it was considered appropriate to use a low vision questionnaire which addresses vision rehabilitation in addition. The order of administration of the questionnaires was balanced across participants in accordance with a Latin Square design (Winer, 1991) in order that bias would not be introduced, e.g. due to respondent fatigue.

The questionnaires used were as follows:

(i) The U.K. Short-Form 36 Health Survey Questionnaire (SF-36)

(Ware and Sherbourne, 1992)

This validated, widely-used generic quality of life questionnaire measures nine dimensions of general health. These include physical functioning, role limitations due to physical problems, role limitations due to emotional problems, social functioning, mental health, energy/vitality, pain, general health perceptions and change in health. The standard format of this questionnaire was slightly modified for this study to ensure its suitability for use with older adults, as recommended by Hayes *et al* (1995). A study version of this questionnaire is shown in appendix 8.

(ii) The Nottingham Adjustment Scale (NAS)

(Dodds *et al*, 1991, Dodds *et al*, 1993)

This is a validated assessment instrument which focuses on mental health and various psychological dimensions in relation to visual impairment. Whilst this instrument was originally developed for use with individuals of working age and was piloted on a population under the age of 66 years, at the time of designing this trial no other validated instruments existed which measured dimensions relating to psychological adjustment in individuals with vision loss. Therefore, four sections relevant to the study were selected from an eight-section questionnaire (Dodds, personal communication, 1997). These sections cover 'attitudes' to visual impairment, 'locus of control', 'acceptance' and 'self-efficacy' amongst the visually impaired. The abbreviated form used in the study is given in appendix 9.

(iii) A Vision-Related Quality of Life Questionnaire (VCM1)

(Frost *et al*, 1998)

This is a short 10-item questionnaire which has been specifically developed for QoL research amongst visually impaired individuals. The questions address patient feelings towards their visual impairment and the extent of impact that low vision has upon their lives. (See appendix 10).

(iv) The Manchester Low Vision Questionnaire (MLVQ)

(Harper *et al*, 1999)

This low vision specific questionnaire covers three aspects relating to low vision rehabilitation, namely restrictions in activities dependent on vision and patterns of LVA use, patient satisfaction with the clinic service, and patient knowledge of AMD and attitudes to low vision. In the section dealing with restrictions in activities, patients are presented with a list of typical daily activities dependent on vision, for example reading correspondence, signing their name, watching television, identifying money, pursuing hobbies such as sewing etc. For each task they are asked to rate the importance being able to do the task, whether they can manage to do so with/out the use of a magnifying device, who usually does the task and how much a magnifier is needed to carry out the task (see appendix 11). In this study the MLVQ was supplemented by a 'priority ranking' procedure (Welbourn, 1992) which ranks the importance of being able to carry out various daily activities (also in appendix 11). Although the opportunity for stating importance and/or need to do various tasks is recorded on the MLVQ, the priority ranking process added additional information relating to how various activities ranked in importance (i.e. for the patient to be able to carry out) within a list of 7 broad categories of activities derived from the content of the MLVQ, namely: 'reading', 'writing', 'TV', 'household chores', 'gardening, DIY and household repairs', 'special hobbies and interests', 'going out, e.g. shopping and various social events'.

A short form of the MLVQ (see appendix 11) was also administered by telephone at approximately 4 months into the study for each patient, and also 3 months after final outcomes had been collected. This questionnaire uses a subset of questions taken from the full MLVQ, namely concerning patterns of LVA use and satisfaction with the clinic service. Patients were also invited to make any other comments concerning these issues which were recorded as open responses (at 4 months into the study only). This therefore allowed a more complete picture of LVA use to be observed over time and issues relating to clinic follow-up to be revealed for the patients in the trial.

Table 5.1 summarises the generic and vision specific QoL outcomes measured at both baseline and 12 months post-intervention.

5.4.3 Arm 1 intervention

Patients in arm 1 received the traditional hospital-based model of care, which comprises an initial optometric assessment carried out in a low vision clinic. This initial assessment is usually arranged within 10-12 weeks of the initial referral by an ophthalmologist or a general practitioner. The initial assessment included the checking of the subject's understanding of the diagnosis and prognosis, a discussion of needs/visual requirements and initial goal setting, assessment of vision (including refraction and optimisation of acuities, measurement of contrast sensitivity, assessment of near acuities for threshold and fluency), a re-appraisal of goals, a demonstration of specific LVAs, an explanation in the use/handling of any prescribed device, advice about lighting and other methods of vision enhancement, provision of large print supporting literature, and referral to other services where necessary (e.g. to a hospital support worker). Typically patients who will have been certified partially sighted or blind by an ophthalmologist will have been notified to social services. However, registration with social services would not have necessarily resulted in defined interventions from rehabilitation professionals / sensory impairment teams working for social services (see 5.4). A first follow-up assessment was usually offered at approximately 3 months, with additional follow-up appointments being made as deemed appropriate by the clinician or if requested by the subject. Finally, each subject was given a further optometric assessment at the clinic 12 months *after recruitment* in order to reassess visual function at the time the final outcomes were recorded by the

researcher. An assessment at 12 months was also required in order that the service delivery reflected 'overall' input for this arm as opposed to input specific to individuals. All of the necessary clinical information for the study was recorded using study data collection sheets (appendix 5). The timings and frequencies of the low vision assessments are summarised in chapter 6, section 6.5.1. The average duration of these assessments is given in 6.5.2. The optometric care given to the study patients at the low

Table 5.1 The generic and vision specific QoL outcomes measured at both baseline and 12 months post-intervention

Name of instrument	Number of items	Dimensions	Comments
The U.K. Short-Form 36 Health Survey Questionnaire (SF-36) (Ware and Sherbourne, 1992)	36	• physical functioning • role limitations due to physical problems • role limitations due to emotional problems social functioning • mental health • energy/vitality • pain • general health perceptions • change in health	Modified to ensure suitability for use with older adults (Hayes *et al,* 1995)
The Nottingham Adjustment Scale (NAS) (Dodds *et al,* 1991, 1993)	28	• attitudes to visual impairment • locus of control • acceptance • self-efficacy	Four sections relevant to the study have been selected from an eight-section questionnaire.
A Vision Related Quality of Life Questionnaire (VCM1) (Frost *et al,* 1998)	10	• feelings towards visual impairment • impact of low vision upon daily life	Specifically developed for QoL research amongst the visually impaired
The Manchester Low Vision Questionnaire (MLVQ) (Harper *et al,* 1999)	142	• task analysis and patterns of LVA use • patient satisfaction with the clinic service • patient knowledge of AMD and attitudes to low vision	Supplemented by a 'priority ranking' procedure (Welbourn, 1992) which ranks the importance of being able to carry out various daily activities.

vision clinic at MREH was delivered by a number of optometrists (see 6.5.2). These were mainly registered optometrists (11 in total) but also included a smaller number of pre-registered optometrists (7 in total) who carried out assessments under supervision. Two dispensing opticians also carried out a small number of assessments (on 8 occasions) between them during the trial.

5.4.4 Arm 2 intervention

All subjects in this arm received the optometric assessment described above (arm 1) but in addition were visited by a trained rehabilitation officer who provided supplementary low vision input at home. This intervention was provided by a single rehabilitation officer (Richard Bounds) who had undergone additional low vision training, including attendance at MREH. Subjects received up to 3 visits which were scheduled to take place at approximately 2 weeks, 4-8 weeks and at 4-6 months after the first hospital low vision assessment. The frequency and timing of the home visits are described in chapter 6, section 6.6.1. During these visits the rehabilitation officer provided advice and training in the use of prescribed LVAs and considered the appropriateness of additional or alternative devices. This input extended the basic handling instructions in the use of LVAs provided by the optometrist in the clinic. Although the rehabilitation officer was familiar with the techniques of eccentric viewing and steady eye strategy, the main emphasis of this intervention was placed on LVA handling, the use of alternative devices and other strategies for enhancing vision (e.g. use of contrast/lighting) rather than in the training of these viewing strategies. The rehabilitation officer was also able to identify wider issues relating to a subject's needs. Although the activities of the rehabilitation officer were tailored to meet the needs of individual subjects, the broad areas were categorized at each visit to include 'vision difficulties', 'use of LVA(s)' and 'other input'. In the first of these areas the rehabilitation officer identified activities of daily living which presented a particular problem for the subject due to their visual impairment. In the second area, patterns of LVA use (for example, tasks attempted with device, frequency and duration of use) were assessed together with difficulties in the use of LVAs, using a similar approach to that employed within the MLVQ (Harper *et al,* 1999). The subject was asked to demonstrate using his or her LVA(s) and further training was provided where appropriate (e.g. working distance, use of spectacle correction, page navigation with a magnifier etc.). Alternative or additional LVAs were demonstrated if appropriate. In the third area, supplementary advice and information

was given about AMD, the range of services available to the subject and his/her welfare entitlements where applicable. Any other advice or information given, for example details of special equipment which might be suitable, was also recorded.

The rehabilitation officer was sent a report of the optometric assessment for each subject randomised to arm 2 in advance of their home visit. Similarly, the rehabilitation officer maintained a link with the low vision clinic through the provision of a report to the hospital following each home visit, the exchange/return of LVAs, and by regular visits to the low vision clinic. Details of all input provided and the exchange of information were systematically recorded on a purpose-designed data capture sheet using both coded and open responses (see appendix 12). Thus, integration was established by the routine exchange of information between the hospital clinic, the rehabilitation officer and/or the social voluntary sector. It is important to note that the rehabilitation officer's activities did not include the role of social services workers (for example, the provision and demonstration of non-optical aids such as tactile devices to assist in using cooker controls). Although referrals to such services may have been made from the HES (see 5.4.3 above) the rehabilitation officer will also have referred patients to such services where appropriate. The content of the intervention in arm 2 is described in chapter 6, section 6.6.2.

5.4.5 Arm 3 input

All subjects in this arm received the optometric assessment described above (arm 1), and in addition, were visited by a community care worker from 'Age Concern', a charity who are involved with caring for the elderly. These workers do not have general vision/eye awareness training, nor any formal training in low vision. Hence, they did not provide low vision specific advice or training as part of the arm 3 intervention. However, they provided general advice and support as normally offered by workers from Age Concern and their input was recorded, for example, under the broad areas of 'coping with daily activities', 'leisure activities' and 'problems or anything else which you would like to discuss'. Life events or issues of importance to the client may also have been discussed and advice given. Although this input is generic, a subject experiencing a simple vision/LVA problem, will have been offered advice by the community worker, since it would have been unethical for help not to have been offered (e.g. for a problem with a switch or batteries on an illuminated LVA). However,

in contrast to the rehabilitation officer input, there was no formal link with the HES via a reporting system. These arm 3 visits were intended to take place at the same intervals as those in arm 2 and the community worker completed a data sheet to record the input that had taken place, i.e. advice given, action taken and nature of discussion (see appendix 13). These visits were intended to serve as a control for the contact time provided to subjects by the rehabilitation officer in arm 2. The frequency and timing of the visits are summarised in chapter 6, section 6.6.1, and the input for this arm is described in section 6.6.3.

5.4.6 Patient diary and qualitative data

Each subject in the study received 4 successive three-month 'diaries' for completion during the course of the 12 months' follow-up in the study (see figure 5.1). The large print diary (16 point bold Arial font) was intended to capture information on the uptake of social and welfare services and the extent of social networking. The diary also included open questions to elicit concerns about low vision and overall health and life events, thereby permitting a complementary qualitative evaluation (Glaser and Strauss, 1966). These data will allow a content analysis approach to be applied and will mainly be used to assist in the economic evaluation. The diary may be of importance to the health economics perspective by generating information pertinent to community resource use and the uptake of health care services. However, the reporting of the qualitative analyses and economic evaluation are beyond the scope of this thesis and will be documented elsewhere at a later time. A sample page and instructions from the diary is given in appendix 14. Letters requesting the return of completed diaries and the issue of new diaries, which were sent to patients at three month intervals, are given in appendix 15.

Several qualitative 'open' questions were included in the set of questionnaires being used for baseline outcomes and in those which were used at 12 months. These questions explored patients' expectations of their low vision clinic appointments and their overall perceptions of the clinic service. This information supplemented the qualitative data that was recorded in the patient diaries throughout the study. Analysis of this qualitative data is outside the scope of this thesis.

5.5 Data analysis

5.5.1 Reporting of the trial

The reporting of this RCT has attempted to observe all the guidelines set out in the revised recommendations made by the CONSORT (Consolidated Standards of Reporting Trials) group (Moher *et al*, 2001). The CONSORT statement states that 'a report of a randomised controlled trial should convey to the reader, in a transparent manner, why the study was undertaken, and how it was conducted and analyzed'. The CONSORT group therefore recommend that, to this aim, a checklist of 22 items pertaining to the content of the title, abstract, introduction, methods, results and discussion, needs to be observed by authors reporting RCTs. This checklist is given in appendix 16, and is used to indicate the sections of the thesis where each item is reported.

Therefore, in order to comply with the CONSORT guidelines, the study results reported in Chapters 7 and 8 are preceded by a comprehensive overview in Chapter 6 of the trial events. For example, a flow chart was constructed to illustrate the progress of all patients through the trial (6.1) and subsequent sections describe recruitment statistics and the completeness of data collected at various stages of the trial. Whilst this chapter has described the intended interventions for the participants in the trial (5.4.3, 5.4.4 and 5.4.5), the actual content and timing of the interventions as delivered in practice are also described in Chapter 6. Similarly, the completeness and quality of the outcome measures collected at baseline and follow-up are described.

5.5.2 Descriptive analyses

Baseline and final outcome measures are described for the whole study population (see chapter 7) to complement the findings from the main effectiveness analysis (given in chapter 8). Each continuous variable was summarised by using measures of central tendency including the mean and median and using the standard deviation to provide the measure of dispersion (or variability) of the distribution from the mean. First and third quartiles (i.e. 25^{th} and 75^{th} percentiles) were also calculated to indicate the inter-quartile range for each given distribution, thus lessening any influence of distribution outliers which would otherwise be included had the overall range been used. Descriptive exploration of the study data for the purposes of monitoring missing values and data

quality allowed the identification and exclusion of outliers due to spurious values. QoL outcome measures were also compared against normative data (see 7.6).

5.5.3 Equivalence at baseline

Baseline data for outcome measures and other patient characteristics were compared across the three arms of the trial using 'intention-to-treat' analyses[†] (see chapter 8). One-way ANOVAs were carried out, i.e. simple univariate comparisons, as were independent-sample *t* tests (grouping by arm) on continuous data, to determine whether there were any significant differences in group means between arms. Nonparametric tests including the Kruskal-Wallis test (i.e. a nonparametric one-way ANOVA test of statistical significance involving more than two independent samples) and the Chi-square test (to see if statistically significant differences existed between the observed and expected frequencies between arms) were used for ordinal variables which had only a few ranked values and categorical (nominal) data.

5.5.4 Effectiveness of the interventions

Analysis of 12 month follow up data was carried out using a 'staged' approach. In the first stage, simple univariate ANOVAs of 12 month outcome variables, by arm, were carried out to test for differences between groups at follow up. The outcome (i.e. dependent) variables chosen for analysis included the SF-36 dimension scores, VCM1 domain and composite scores, NAS dimension scores, patterns of LVA use, self-rated task restriction and measured task performance, and knowledge about AMD/visual impairment/use of residual vision. Summary variables were derived for task parameters, patterns of LVA use and knowledge about AMD, from both the measured task performance assessments at 12 months and data collected using the MLVQ.

In the second stage, regressions of the outcomes which indicated statistically significant differences between arms were carried out to test for specific contrasts between arms. These regression analyses are statistically equivalent to the one-way ANOVAs but make explicit the contrasts between arms by reporting the regression coefficients for each arm separately.

[†] An analysis by 'intention-to-treat' is an approach whereby data are analysed in terms of 'a policy of offering' treatment as opposed to including in analysis only those patients who received a particular treatment or intervention (Bland, 1995). This approach reflects the 'reality' of healthcare interventions where not all patients will accept the intervention being offered.

During the third stage of analysis, one-way ANOVAs of 12 month outcomes, by arm, were carried out to test for differences between arms entering corresponding baseline measurements for outcomes of interest as covariates (analyses of variance and covariance), thereby 'adjusting' the comparison at 12 months for baseline measurements. Adjusting for baseline measurements as covariates is the preferred way of taking advantage of the longitudinal nature of the study design (Senn, 1997).

In the fourth stage of analysis, regressions of the outcomes which had indicated differences between groups at stage three were carried out, after adjusting for baseline values, to test for specific arm contrasts. As for stages 1 and 2, the regression analyses carried out in stage 4 are statistically equivalent to the one-way ANOVAs carried out in stage 3 but make explicit the contrasts between arms by reporting the regression coefficients for each arm separately.

Finally, in the fifth stage, outcome differences between groups at the end of the trial were analysed by regression modelling (multiple linear regression for continuous outcomes, and logistic regression for ordinal data), adjusting for baseline measures of the outcomes and covariates, i.e. for any other differences between groups in potential prognostic factors which may have arisen by chance through randomisation. Initially, a 'full' regression model was fitted for each outcome variable to include all identified covariates (see 5.5.5 below). However, a reduced model was subsequently fitted for all outcome variables, because too many degrees of freedom were being lost due to the number of variables (i.e. covariates) included in the full model, a factor that may have reduced the chance of showing significant arm differences. Apart from tests for baseline equivalence (see 5.5.5 below), statistical significance was identified at the 5% level throughout these analyses.

This approach of adjusting for baseline measurements as covariates was used in preference to carrying out repeated measures ANOVAs since the former, often referred to as a 'multiplicative model' is generally preferred to the latter 'additive model' for mathematical and theoretical reasons (Senn, 1997). Both models exploit the longitudinal nature of the study design by reducing the variation in 12 month outcomes between participants that remains unexplained. However, the two approaches take account of baseline measures in different ways. The approach of adjusting for the baseline values as

covariates assumes that the predicted value of a given outcome measure at follow-up is some constant multiplier of the measure at baseline; i.e. any change over time in the outcome as a function of baseline depends on the baseline value itself. In contrast, the repeated measures ANOVA approach assumes that the predicted value of a given outcome measure at follow-up is, on average, constant; i.e. any change over time in the outcome as a function of baseline is independent of the baseline value. In the adjusted regression analysis the main effect of arm adjusted for baseline covariate is of primary interest; whereas in a repeated measures ANOVA it is the extent to which change over time varies across arms that is of primary interest.

5.5.5 Identification of covariates

The analyses to test for baseline equivalence (described in 5.5.3 above) allowed important covariates to be identified that would need to be controlled for (i.e. variables for which the effects would be statistically subtracted) in the main multiple regression analysis used to determine the effectiveness of the interventions. Strong predictor (independent) variables were expected to be residential status, mental health status and visual functions. Individuals living alone, those who were depressed or anxious (either because of their vision loss or due to other reasons), and those with more severe loss of sight, may for instance, have been less motivated or less able to cope with the challenges posed by their impairment. The 0.2 level for statistical significance was applied as a cautious criterion in order to 'filter' out important potential imbalances between groups. Collinearity (i.e. the extent to which the predictor variables were correlated with one another in the multiple regression analysis) was examined, since the presence of collinearity would cause problems in discerning the separate effects of closely correlated predictor variables. Therefore, inter-correlation between potential confounding factors was examined for continuous data items by generating correlation co-efficients in the form of a correlation matrix. T-tests were used to check for associations between category and continuous variables. Pairs of covariates for continuous data where correlation co-efficients were greater than 0.4, either positively or negatively, or for which t-tests gave a statistically significant result ($p<0.05$), were identified. Regression models containing pairs of correlated covariates were changed to include only one covariate from each pair identified, in order to investigate arm effects. The results of these investigations are presented in chapter 8, together with the results of the main statistical analyses.

5.5.6 Hypotheses prior to analysis

The main research hypothesis for this trial is that patients allocated to arm 2 of the trial will have better scores at 12 months for final outcomes than those allocated to arms 1 and 3, and more so for vision-related measures, e.g. VCM1 scores, self-rated task restriction, measured task performance and patterns of LVA use. It is expected that the intervention delivered in arm 2 will be more conducive to a better vision-related QoL than the inputs in the other arms. This would result from greater use of LVAs which would enhance independence by increasing patients' abilities in carrying out a wider range of tasks or ADLs.

Other hypotheses include:

- That there will be a deterioration in visual functions over time for the whole population sample.
- That there will be a general decline for all of the generic health status dimensions included in the SF-36, since the study population is elderly with the anticipated decline possibly being more pronounced for dimensions which emphasise physical activities rather than those which focus on emotional/mental aspects of general health. However, patients in arm 2 are expected to experience a smaller degree of deterioration for these dimensions due to a reduction in task restriction resulting from the increased benefits of additional low vision specific training.
- That vision-related QoL outcomes improve over time for the whole population as patients become more accustomed to their loss of vision and recover from the initial shock of their diagnosis. Since all patients in the trial will receive low vision rehabilitation input it is expected that some benefits will be seen for the study sample as a whole, such as an increased capacity to cope with visual impairment and a better understanding of AMD.
- That the psychosocial dimensions measured using the NAS[†] will demonstrate better scores for patients in arm 2 than those in arms 1 and 3. This is expected due to the more successful use of LVAs in arm 2 which would help patients with respect to restrictions in daily activities, and therefore possibly lead to better adjustment to vision loss.

[†] The dimensions measured using the NAS ('attitude', 'acceptance', 'locus of control' and 'self-efficacy' could be viewed arguably as predictor characteristics (i.e. if interpreted as character traits) as opposed to outcome measures. However, the developers of NAS believe that an approach which utilises the NAS dimensions as outcome variables is equally valid (Dodds, 2001, personal communication).

CHAPTER 6: TRIAL PROGRESS AND DATA QUALITY

The organizational chart (figure 5.1) presented in chapter 5 (Study design and methodology) outlines the key stages and events of the trial. This chapter describes the extent to which the subjects in the trial adhered to the intended schedule and the quality of data collected for analysis.

6.1 Trial profile

A flow chart detailing the progress of patients through the RCT, as recommended by the CONSORT group guidelines (Altman, 1996; Moher *et al,* 2001) is shown in figure 6.1.

6.2 Recruitment

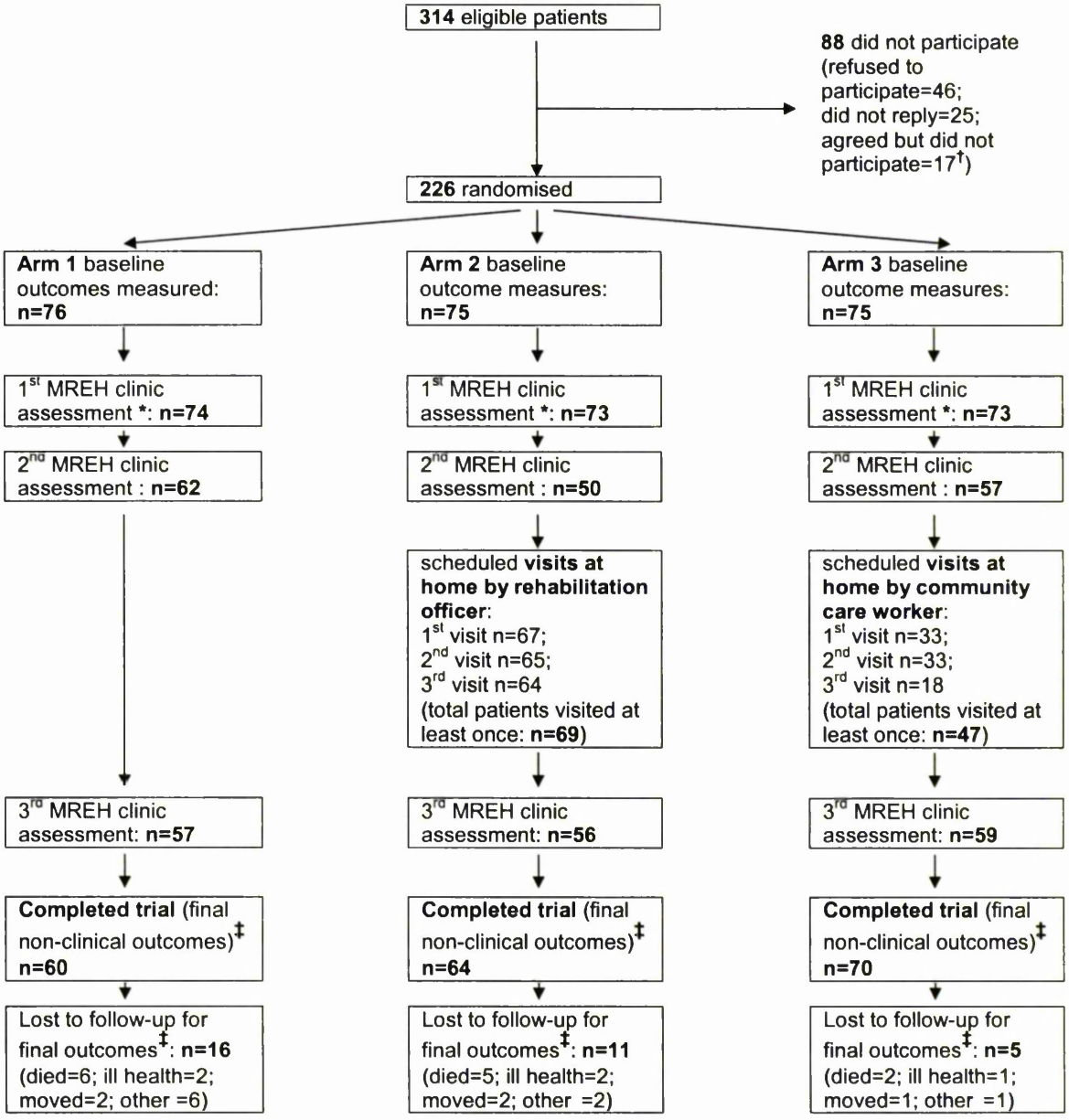
Patient recruitment commenced in November 1997 and ceased in August 1999 when a total of 226 subjects had been recruited into the trial. The recruitment process is described in section 5.2.2 of Chapter 5. A total of 330 patients were invited to participate in the study, but 16 of these patients were subsequently found to be ineligible. A full breakdown of the recruitment statistics based on the 314 eligible patients invited to participate is shown in table 6.2. The patient response rate was 92% (289/314) (i.e. only 8% of patients failed to reply to the invitation) and the consent rate was 77.4% (243/314). Of the 46 patients who refused to participate 44 declined when invited initially, and a further 2 patients changed their minds prior to their first home visit having consented initially. Reasons for refusal are summarised in appendix 3. Of the 289 patients who replied 78.2% (i.e. 226) were finally recruited into the study, i.e. slightly less than the consent rate as 17 patients who had consented to take part could not be recruited for various reasons (see table 6.1). The overall recruitment rate into the study (based on all eligible patients invited to participate, i.e. 226/314) was 72%. The majority of patients were very enthusiastic about taking part and were willing to be as helpful as possible. A frequently reason cited for their participation was the perceived

importance of any research which addresses the problems that the patients felt they were facing due to their loss of vision.

Table 6.1: Recruitment statistics

	No. of patients	**% (n=314)**
Total number of patients invited to join the study ((a) + (b) + (c) + (h)):	314	
(a) Total who have consented and been recruited	226	71.97
(b) Total who have refused to participate	46	14.65
(c) Total number of non-refusals who were not recruited ((d) + (e) + (f) + (g)) :	17	5.41
(d) Died soon after consenting	2	0.64
(e) Consented too late to take part	10	3.18
(f) Consented but lived too far away from MREH	4	1.27
(g) Researcher failed to visit due to ill health	1	0.32
(h) Total number of non-responses ((i) + (j)) :	25	7.96
(i) Deaths before reply obtained	2	0.64
(j) Patients did not reply to invitation and could not be contacted after several attempts	23	7.32

Figure 6.1: Trial profile



* 1st MREH clinic assessments

2 patients in arm 1 died prior to their appointments
2 patients in arm 2 did not attend, 1 due to ill health & 1 for unknown reasons
1 patient in arm 3 died prior to appointment & 1 did not attend due to ill health

† Non-refusals who were not recruited:

died soon after consenting=2
consented too late (i.e. had consented after attending their 1st clinic assessment)=10
consented but lived too far away from MREH=4
researcher failed to visit due to ill-health=1

‡ Final outcomes:

NB Final outcomes (i.e. health related and vision specific QoL, MLVQ and task performance) were assessed at home **prior to** the 3rd scheduled MREH clinic assessment. Patients with final outcomes recorded were included in analyses irrespective of whether the 3rd clinic assessment had been attended.

6.3 Completion of the trial

Patients who did not complete the trial were those who were lost to follow-up for final non-clinical outcomes measured at approximately a year after the measurement of outcomes at baseline. In total, 32/226 (14.16% of the total study sample) patients were lost to follow-up. The different proportion of dropouts between arms was found to be significant (chi-square test, $p<0.05$) but the reasons why patients did not complete the trial were fairly evenly balanced between those who dropped out per arm. Table 6.2 lists the reasons why these patients dropped out of the study.

Table 6.2: Reasons why patients did not complete the trial

Reason	Number of patients in study sample (n=226)				
	Total no. of patients	**Patients in arm 1 (n=76)**	**Patients in arm 2 (n=75)**	**Patients in arm 3 (n=75)**	**% of sample (n=226)**
Died before final outcomes follow-up home visit	13	6	5	2	5.75
Poor health	4	2	1	1	1.77
Severe mental deterioration	1	0	1	0	0.44
Recently bereaved and too distressed to receive home visit	2	2	0	0	0.88
Changed address and could not be traced	4	2	1	1	1.77
Moved long distance out of area	1	0	1	0	0.44
Disappointed in lack of medical treatment and refused home visit	1	1	0	0	0.44
Refused home visit without giving any specific reasons	5	2	2	1	2.21
Patient not at home for 2 attempted home visits at times previously arranged – efforts to visit abandoned	1	1	0	0	0.44
TOTAL	32	16	11	5	14.16
% of each arm *		21.05	14.67	6.67	

* p=0.039

Although many of the patients who dropped out had attended various permutations of scheduled clinic assessments at MREH and also had received interventions according to their arm allocations, this group of patients cannot be included in the main analyses of the trial, i.e. to compare the effectiveness of the care received by the three groups in the

study, since the outcome measures used for the purposes of comparison were not obtained for these cases. However, the data on clinic assessments and interventions for these patients were included in the analyses which were carried out to describe vision related characteristics of the study population and the quality of the interventions and inputs for the three arms. In addition a comparison across arms of the numbers of dropouts and their baseline characteristics was carried out as part of the analysis to test for equivalence across arms. These results are given in chapter 7, section 7.7.

6.4 Non-clinical follow-up outcomes at 12 months

All of the patients recruited into the trial, irrespective of allocation to the different arms and interventions received during the study period, were scheduled to have a follow-up visit at home for the collection of final non-clinical outcomes. These home visits were intended to take place post-intervention at approximately 12 months after the initial home visit for the measurement of baseline (non-clinical) outcomes. These home visits were also intended to take place before the final '12 month' (i.e. third) clinic assessment (see the organizational chart for the trial shown in figure 5.1). Patient recruitment into the study had initially been estimated to span a period of roughly 12 months in order to obtain the target total sample size of 225 subjects. However, the numbers of eligible patients identified prior to attending the low vision clinic at MREH for their first clinic assessment proved to be lower than originally anticipated. Thus, despite the good consent rate amongst patients invited to participate in the study, a longer recruitment phase of 22 months was needed to ensure an adequate sample size for the intended analyses with respect to the study objectives. Due to the consequent constraints on the time available for conducting the trial, the final home visits were carried out slightly sooner for the last 30 patients recruited into the study, at approximately 11 months after the initial home visit. These 30 patients were fairly evenly distributed across the 3 arms of the trial with 12 being in arm 1, 10 in arm 2, and 8 in arm 3. The author remained unaware of arm allocation data until all data collection had ceased.

In total, 194 patients were visited at home for final outcomes, the remaining 32 being lost to follow up for various reasons including death (13), ill health (5), change of address (new address unknown) or moving away from the study area (5) and unspecified reasons (9) (see 6.1 above). In nearly all cases the patients were visited before their scheduled 12-month clinic assessment at MREH when final clinical (visual function) outcomes were collected. Any intervention which was delivered to patients during the trial therefore excluded any input which occurred during the 12-month clinic assessment, since the latter took place post final non-clinical outcome measurement. Of the 172 patients who attended their 12 month clinic appointments, 164 had final home visits (the remaining 8 patients were lost to follow-up for final non-visual outcomes due to ill health (2), change of address (2), and refusal of a home visit for unspecified reasons (4)) and of these 164 patients only 11 (6.7%) were interviewed after their clinic assessments had taken place. The home visits for these 11 patients took place at 1, 3 (for 2 patients), 4, 11, 14, 16, 22 (for 2 patients), 24 and 31 days after the clinic assessment. The elapsed time between the initial home visits to patients made by the author to collect baseline outcomes and the corresponding final home visits made by the author is summarized in table 6.3(a). A distribution of elapsed time by intervals is shown in table 6.3(b). T-tests did not show any significant differences between arms for the time between the two home visits.

The duration of home visits at 12 months varied between patients, but for most lasted approximately 2 to 2.5 hours. The 12 month home visits took longer overall (by 30 minutes on average) than those at baseline since task performance measures (see 5.4.1) were included during this second visit.

6.4.1 MLVQ (short form)

An abbreviated version of the MLVQ was administered by telephone at approximately 4 months into the trial to gather additional data on patterns of LVA use (see 5.4.2). The number of patients telephoned was 200 and the mean elapsed time between the initial low vision assessments and respective phone calls was 117 days (S.D.=21.8, minimum=40, maximum=184, median=113).

Table 6.3(a): Time (days) from first home visit (baseline outcomes) to final home visit (final non-clinical outcomes)

Patient group	N	mean	SD	min.	max.
All patients	194	362.24	19.46	295.00	441.00
Arm 1	60	360.85	18.62	301.00	399.00
Arm 2	64	363.50	20.00	309.00	441.00
Arm 3	70	362.27	19.86	295.00	409.00

Table 6.3(b): Time from first home visit (baseline outcomes) to final home visit (final non-clinical outcomes)

Time to final visit	Arm 1 (n=60)	Arm 2 (n=64)	Arm 3 (n=70)	All patients (n=194)		
	number	Number	number	number	%	Cumulative %
9 to 9.9 months	0	0	1	1	0.52	0.5
10 to 10.9 months	5	4	5	14	7.22	7.7
11 to 11.9 months	13	17	16	46	23.71	31.4
12 to 12.9 months	40	39	47	126	64.95	96.4
13 to 13.9 months	2	3	1	6	3.09	99.5
14 to 14.9 months	0	1	0	1	0.52	100.00

6.5 Low vision assessments

6.5.1 Frequency and timing

Clinic assessments were expected to take place at least at three points in time during the trial. The first assessment (to identify patient goals, to measure baseline visual functions and to loan appropriate LVAs as described in section 5.4.3) was scheduled to take place within 2 weeks after the initial home visit for baseline non-clinical outcomes[†]. The second clinic assessment was scheduled for between 2-3 months after the first clinic assessment in order to assess progress, measure visual functions and to exchange LVAs

[†] Although interim follow-up visits were allowed for, it was assumed that one visit to the clinic (i.e. the initial assessment) would be the minimum input level for the purposes of the trial.

if necessary. Finally the third clinic assessment to measure final visual outcomes and monitor suitability of loaned LVAs was scheduled to take place at approximately 12 months after the first clinic assessment. This assessment was therefore carried out after all interventions had been delivered and the final home visit to collect non-clinical outcomes at 12 months had taken place, as described in 6.4.

Figure 6.2 shows the numbers of patients attending the three scheduled clinic assessments, and figure 6.3 shows the combinations of appointments attended by patients in each arm. Table 6.4 summarises further the values given in figure 6.3. There was no significant difference between arms (Chi-square test, p=0.4) with respect to the permutations of clinic assessments attended.

The initial clinic assessment at MREH was attended by 220 of the patients recruited into the trial. Six patients did not have their first assessments. Two had been allocated to arm 1; both died soon after their initial baseline outcomes visit. Two patients had been allocated to arm 2 of the trial; one had failed to attend their clinic appointment due to ill-health and the other did not attend for unknown reasons. Two patients had been allocated to arm 3; one had not attended their initial clinic assessment due to poor health and the other had died.

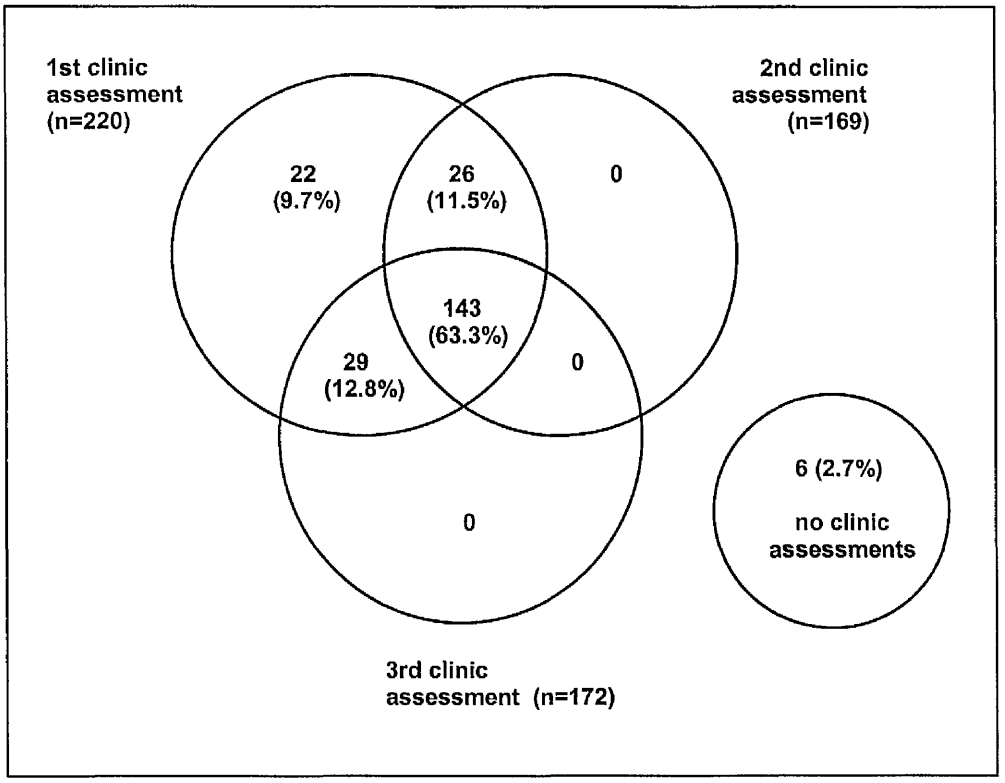
Two hundred and thirteen patients attended for low vision clinic appointments, within 14 days after being visited at home to obtain baseline outcomes. A further 7 patients attended late for their initial assessments. The elapsed times between the home visit and the clinic appointment for these cases were: 17, 23, 41, 96, 98, 104 and 110 days. Subsequent events in the trial (i.e. any intervention or second/third clinic assessments) occurred at later times in relation to the initial home visit to measure baseline outcomes for these patients. These delays were either due to ill-health or failure to keep appointments for non-specific reasons.

The second assessment occurred slightly later (see tables 6.6 and 6.7) for most patients than had been originally planned, in keeping with the usual appointments policy for patients with AMD attending MREH. The second (2-3 months) clinic assessment in the trial was offered to most patients at the time of the first clinic assessment, although some patients did not wish to commit themselves to this appointment preferring instead

the flexibility of requesting the appointment themselves at a later date if they felt they needed it. One hundred and sixty-nine patients attended their second clinic assessment.

One hundred and seventy-two patients attended their third (i.e. 12-month) appointment. A few months before their 12-month clinic assessments were due, all of the patients remaining in the trial were sent letters offering them their 12-month appointments, or in some instances reminding patients of 12-month appointments made previously in advance. The reasons why some patients failed to attend were not recorded but anecdotal evidence suggests that many of these patients were either disillusioned with the unavailability of medical treatment to restore their vision or were disappointed that glasses could not be provided which could offer a significant improvement in vision. Some other patients were too unwell to face the journey (either alone or with a carer) to the hospital and the assessment process itself.

Figure 6.2: Low vision assessments attended by patients in the trial



Note: Percentages shown are based on the 226 patients who were recruited

Figure 6.3: Low vision assessments attended by patients in each arm of the trial (percentages shown are based on the total number of patients allocated to each arm respectively)

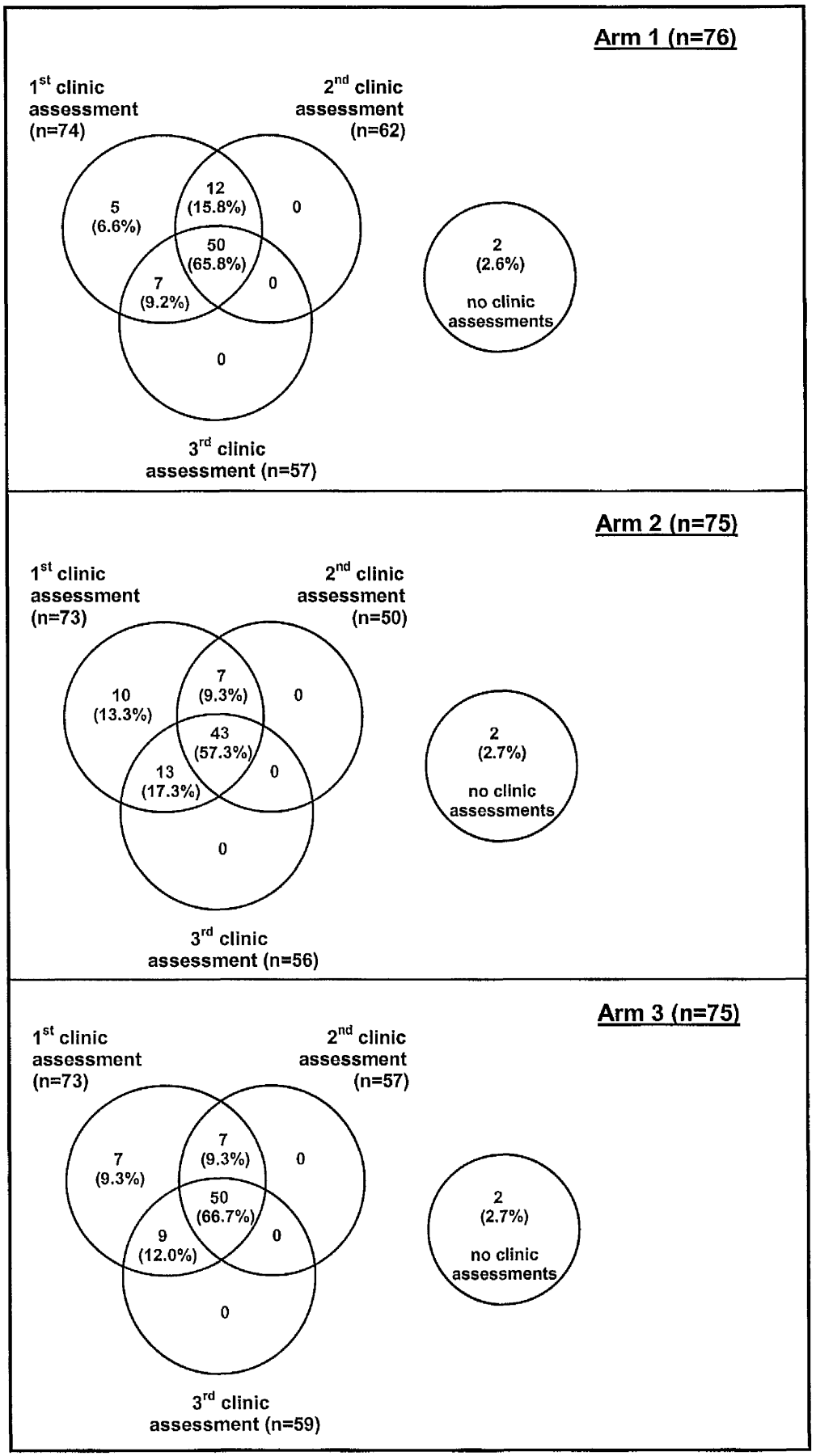


Table 6.4: Permutations of scheduled clinic assessments (numbers and percentages) attended in practice by patients in the trial

Clinic assessments attended by patients	Arm 1 (n=76)	Arm 2 (n=75)	Arm 3 (n=75)
First clinic assessment only	5 (6.6%)	10 (13.3%)	7 (9.3%)
First & second assessments	12 (15.8%)	7 (9.3%)	7 (9.3%)
First & third assessments	7 (9.5%)	13 (17.3%)	9 (12.0%)
First, second & third assessments	50 (67.6%)	43 (57.3%)	50 (66.7%)
Total patients who attended at least one (first) assessment	74 (97.4%)	73 (97.3%)	73 (97.3%)

In addition to the scheduled clinic assessments, some patients attended the low vision clinic at 'extra' times during the study, sometimes at their own request because of concerns regarding their vision, or because of referrals from, for example, low vision clinicians/practitioners. These extra appointments took place at a time which did not coincide with any of the 'scheduled' time intervals for the three clinic assessments in the trial. Forty patients in total attended extra low vision clinic appointments. Thirty-eight patients had one extra clinic appointment (4 patients had an extra appointment in addition to the first and second scheduled clinic assessments, 1 patient had an extra appointment in addition to the first and third scheduled assessments and the remaining 33 patients had their extra appointments in addition to all three scheduled clinic assessments). Two patients had two extra clinic appointments and these were in addition to all three scheduled clinic assessments in both cases. The distribution of these additional clinic appointments by arm is shown in table 6.5. Only one of these appointments took place in between the scheduled trial times for the first and second vision assessments with the rest falling between second and third scheduled clinic assessments[†].

[†] 'Extra' assessments were defined as assessments which occurred in between 2 scheduled visits. In the case of one patient who had a first and third scheduled clinic visit, the extra appointment was too close to the third scheduled appointment to be classified as a 2nd scheduled appointment.

Table 6.5: Extra clinic appointments (numbers and percentages) attended by patients in the trial

'Extra' clinic appointments	Arm 1 (n=76)	Arm 2 (n=75)	Arm 3 (n=75)	All arms (n=226)
Patients who had 1 extra	16[†] (21.1%)	9[‡] (12.0%)	13 (17.3%)	38 (16.8%)
Patients who had 2 extra	1 (1.3%)	1 (1.3%)	0 (0.0%)	2 (0.9%)
Total patients with >=1 extra appointments	17 (22.4%)	10 (13.3%)	13 (17.3%)	40 (17.7%)

[†] Two patients lost to follow-up for final outcomes (one patient changed address and could not be traced; one patient refused final home visit to collect final outcomes due to ill-health)

[‡] One patient had an extra clinic appointment between the first and second scheduled clinic assessments

The time intervals of the first, second and third scheduled clinic assessments in relation to the initial baseline outcomes visit are summarised in tables 6.6 and 6.7. The 7 patients who attended late for their first clinic assessment in relation to the initial home visit, consequently attended their second and third assessments at a relatively later time into the trial. Data on these patients have been included, whenever available, in each stage of analysis, as the ensuing intervals between key events in the trial were within acceptable limits other than the initial lag between the home visit to collect baseline non-visual outcomes and clinic assessment.

Table 6.6: Time (days) from first home visit to collect baseline non-visual outcomes and scheduled low vision assessments

Low vision assessment	Patient group	n	mean	SD	min.	Max.
1st clinic assessment	All patients	220	9.41	13.06	0	110
	Arm 1	74	7.95	10.76	1	94
	Arm 2	73	11.77	18.34	0	110
	Arm 3	73	8.53	7.52	1	50
2nd clinic assessment	All patients	169	117.01	31.28	61	251
	Arm 1	62	113.00	31.03	75	234
	Arm 2	50	115.74	27.99	61	209
	Arm 3	57	122.47	33.92	73	251
3rd clinic assessment	All patients	172	376.43	24.97	306	497
	Arm 1	57	373.67	19.80	316	430
	Arm 2	56	378.96	28.85	314	497
	Arm 3	59	376.69	25.63	306	469

Table 6.7: Time from first home visit to collect baseline non-visual outcomes and each clinic assessment

Low vision assessments	Time to clinic assessment (weeks)	Arm 1	Arm 2	Arm 3	All patients		
		No.	No.	No.	No.	%	Cumulative %
1st assessment		(n=74)	(n=73)	(n=73)	(n=220)		
	<= 1.0	47	33	38	118	53.6	53.6
	1.1 - 2.0	26	37	32	95	43.2	96.8
	2.1 – 4.0	0	0	1	1	0.5	97.3
	4.1 – 8.0	0	0	2	2	0.9	98.2
	8.1 – 12.0	0	0	0	0	0.0	98.2
	12.1 – 16.0	1	3	0	4	1.8	100
2nd assessment		(n=62)	(n=50)	(n=57)	(n=169)		
	8.1 – 12.0	2	2	1	5	3.0	3.0
	12.1 – 16.0	42	29	30	101	59.8	62.8
	16.1 – 20.0	11	13	14	38	22.5	85.3
	20.0 – 24.0	3	3	6	12	7.1	92.4
	24.1 – 28.0	1	1	3	5	3.0	95.4
	28.1 – 32.0	2	2	2	6	3.6	99.0
	32.1 – 36.0	1	0	1	2	1.2	100
3rd assessment		(n=57)	(n=56)	(n=59)	(n=172)		
	36.1 – 44.0	0	0	1	1	0.6	0.6
	44.1 – 52.0	12	9	12	33	19.2	19.8
	52.1 – 60.0	43	43	43	129	75.0	94.8
	60.1 – 68.0	2	3	3	8	4.7	99.5
	68.1 – 76.0	0	1	0	1	0.6	100

6.5.2 Assessments: duration and professionals involved

Figure 6.4 illustrates the distributions of the duration of the low vision assessments carried out at the first, second and third scheduled clinic appointments. The initial assessments are shown to have taken longer than those at the second and third appointments. The duration of assessments are compared for the three arms in table 6.8 and corresponding distributions of duration by arm at each of the three low vision assessments are shown in figure 6.5. Significant differences were found between arms 1 and 3 at both the first and second low vision assessments (p=0.005 and p=0.011) respectively (see section 6.3.4 Baseline comparability for key variables).

Figure 6.4: Distributions of the duration of the low vision assessments carried out at the first, second and third scheduled clinic appointments

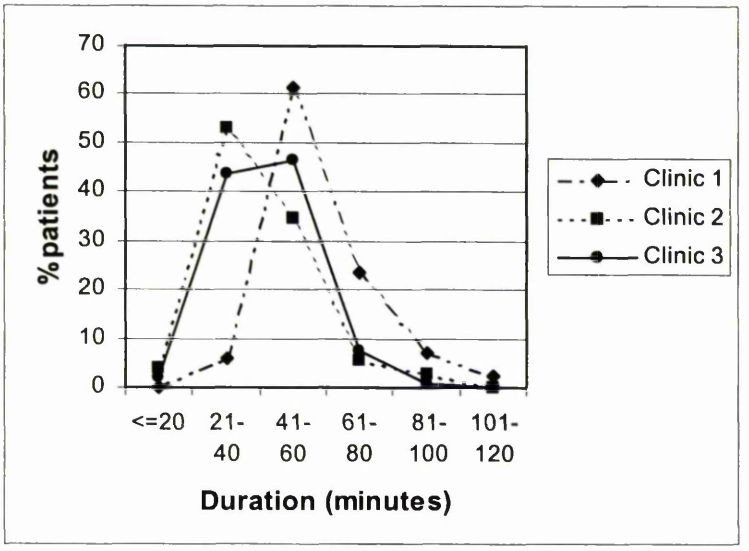


Table 6.8: Duration of low vision assessments at the first, second and third scheduled clinic appointments

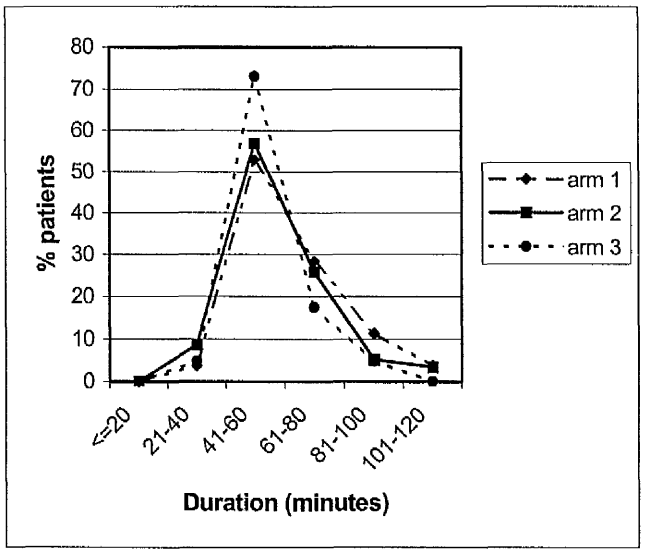
Low vision assessment	Patient group	N	mean	SD	min.	Max.
1st clinic appointment†	All patients	174	61.93	15.76	30	120
	Arm 1	53	66.04	17.19	40	120
	Arm 2	58	62.16	17.22	35	120
	Arm 3	63	58.25	12.02	30	90
2nd clinic appointment‡	All patients	147	43.12	15.28	15	95
	Arm 1	51	47.71	16.46	20	90
	Arm 2	45	41.22	15.96	15	95
	Arm 3	51	40.20	12.37	20	80
3rd clinic appointment	All patients	151	45.96	14.34	20	90
	Arm 1	50	46.40	14.92	25	90
	Arm 2	50	45.70	14.71	20	80
	Arm 3	51	45.78	13.65	20	80

† Significant between arms 1 and 3, p=0.005

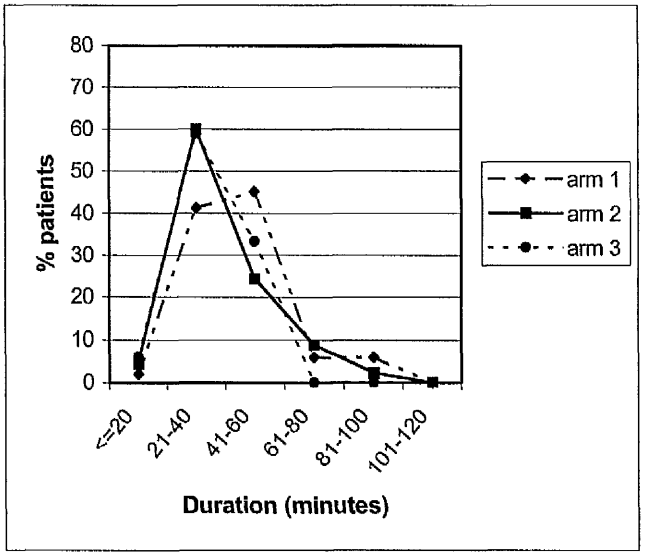
‡ Significant between arms 1 and 3, p=0.011

Figure 6.5: Distributions of the duration of the low vision assessments carried out for patients in the three study arms at the first, second and third scheduled clinic appointments

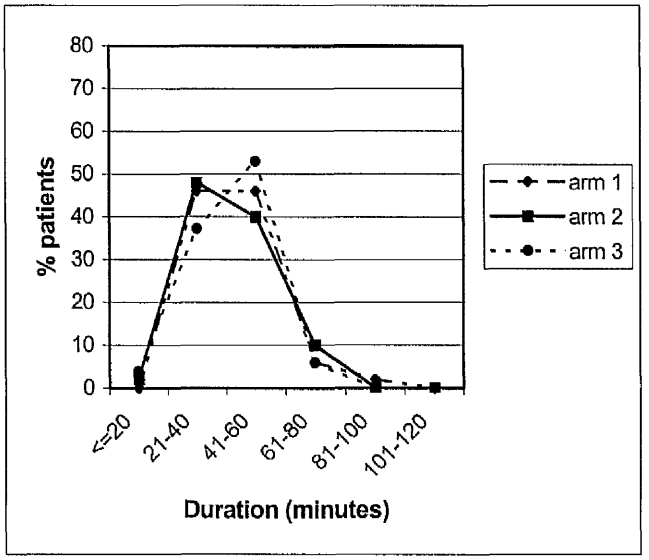
(a) First low vision assessment



(b) Second low vision assessment



(c) Third low vision assessment



(b) The majority of low vision assessments in the trial were carried out by registered optometrists. Pre-registered optometrists also carried out assessments but these did not amount to more than a third for any scheduled assessment. A smaller number of assessments were done by dispensing opticians. This reflects a typical allocation of patients to staff within a large teaching hospital setting. Table 6.9 shows the proportion of assessments carried out by staff categories based on available data. There was no significant difference across arms at any stage in the trial with respect to the staff categories involved in carrying out assessments.

Table 6.9: Numbers of low vision assessments carried out by staff categories at both scheduled and extra clinic appointments

Low vision assessments	MREH staff	Arm 1	Arm 2	Arm 3	All patients		
		No.	No.	No.	No.	%	Cumulative %
1st assessments		(n=74)	(n=73)	(n=73)	(n=220)		
	Registered optometrists	56	57	60	173	78.6	78.6
	Pre-registered optometrists	16	11	12	39	17.7	96.3
	Dispensing opticians	2	5	1	8	3.6	100
2nd assessments		(n=62)	(n=50)	(n=57)	(n=169)		
	Registered optometrists	46	33	45	124	73.4	73.4
	Pre-registered optometrists	8	10	10	28	16.6	90.0
	Dispensing opticians	6	7	1	14	8.3	98.3
	Qualification not recorded	2	0	1	3	1.8	100
3rd assessments		(n=57)	(n=56)	(n=59)	(n=172)		
	Registered optometrists	32	26	34	92	53.5	53.5
	Pre-registered optometrists	16	20	12	48	27.9	81.4
	Dispensing opticians	6	7	11	24	14.0	95.4
	Qualification not recorded	3	3	2	8	4.7	100
Extra Assessments†		(n=17)	(n=10)	(n=13)	(n=40)		
	Registered optometrists	10	6	5	21	52.5	52.5
	Pre-registered optometrists	5	3	4	12	30.0	82.5
	Dispensing opticians	2	1	4	7	17.5	100

† 2 patients had a second extra assessment, both by registered optometrists

The duration of assessments carried out by pre-registered optometrists tended to be longer and t-tests showed significant differences ($p<0.05$) between the duration of assessments by pre-registered optometrists and those by registered optometrists for each of the three scheduled clinic assessments. These comparisons, based on available data, are given in table 6.10 below.

Table 6.10: Duration of low vision assessments by registered and pre-registered optometrists

Low vision assessment	MREH staff	Duration of assessments				
		n	Mean	SD	min.	max.
1st clinic appointment†	Registered optometrists	141	60.07	13.64	30	120
	Pre-registered optometrists	29	73.10	20.24	45	120
2nd clinic appointment‡	Registered optometrists	107	42.04	14.01	15	90
	Pre-registered optometrists	24	53.13	19.72	30	95
3rd clinic appointment§	Registered optometrists	78	44.62	14.83	20	80
	Pre-registered optometrists	46	51.52	14.68	30	90

† Significant between staff groups, p=0.000

‡ Significant between staff groups, p=0.002

§ Significant between staff groups, p=0.013

6.6 Arm 2 and arm 3 intervention

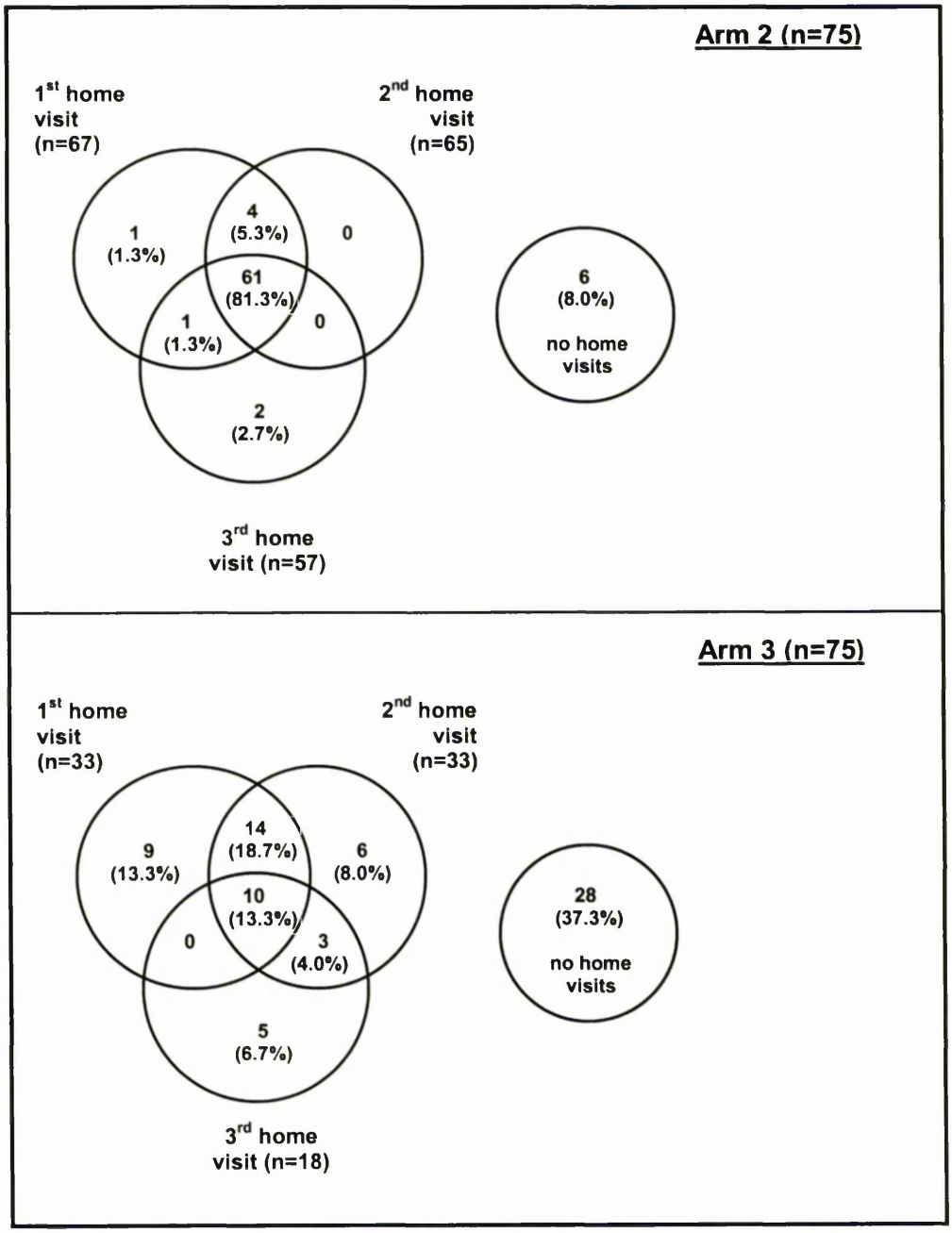
6.6.1 Frequency and timing

Intervention visits at home were scheduled to take place on three occasions for patients allocated to both arms 2 and 3. The first visit was intended to take place at approximately 2 weeks after the patient had attended their first low vision assessment (i.e. at between 2 to 4 weeks after the baseline outcomes visit). The second intervention visit was to take place at between 4 to 8 weeks after the first clinic assessment, and ideally before the patient attended a second clinic assessment where this had been offered to the patient. Lastly, the third intervention visit was scheduled for between 4 to 6 months after the first low vision assessment.

In total 69 patients of the 75 allocated to arm 2 received an intervention visit from the rehabilitation officer responsible for arm 2 intervention delivery, on at least one of the three scheduled occasions. In arm 3, fewer patients were visited at home by the community workers from Age Concern, namely 47 of the 75 patients allocated to this arm. The rehabilitation officer made a total of 196 visits throughout the trial period, whilst community workers made 84 visits in total. Therefore there were substantially more visits made to patient's homes in arm 2 than in arm 3. Overall, patients in arm 2 seemed to be happy to have home visits from a rehabilitation officer, whereas the patients in arm 3 appeared to be more reluctant to receive visits from community workers. Patients seldom refused the offer of a home visit by the rehabilitation officer and, in the majority of cases, the rehabilitation officer was able to arrange an appointment during a single phone call. On the other hand, the community workers providing input to arm 3 often needed to make repeated telephone calls to patients in order to book appointments. It is important to note that in contrast to arm 2, no link with the HES was revealed to patients in arm 3. The protocol followed by the community workers was to make two attempts to book appointments to visit patients who were either uncertain about receiving a home visit or who did not strongly refuse a home visit during the first phone call attempt. However, the optometrist at MREH responsible for notifying the community workers of patients allocated to arm 3 (see section 5.3) speculated that the community workers may have been less conscientious and enthusiastic in their efforts to adhere to this protocol and to provide input to this arm, than the rehabilitation officer was in his contribution to the trial. The numbers of home visits made to patients in arms 2 and 3 are shown in figure 6.6.

The time intervals of the first, second and third scheduled intervention visits in relation to the baseline outcomes visit are summarised in table 6.11. Figure 6.7 shows the distributions of the arm 2 and 3 interventions across time, calculated from the first low vision assessment at MREH. All of the first scheduled intervention visits in arms 2 and 3 took place between the first and second clinic assessments as intended, except for one instance where a second intervention visit in arm 2 took place after a second low vision assessment (by 2 days). All of the third intervention visits took place between second and third low vision assessments.

Figure 6.6: Home intervention visits received by patients in arms 2 and 3 of the trial

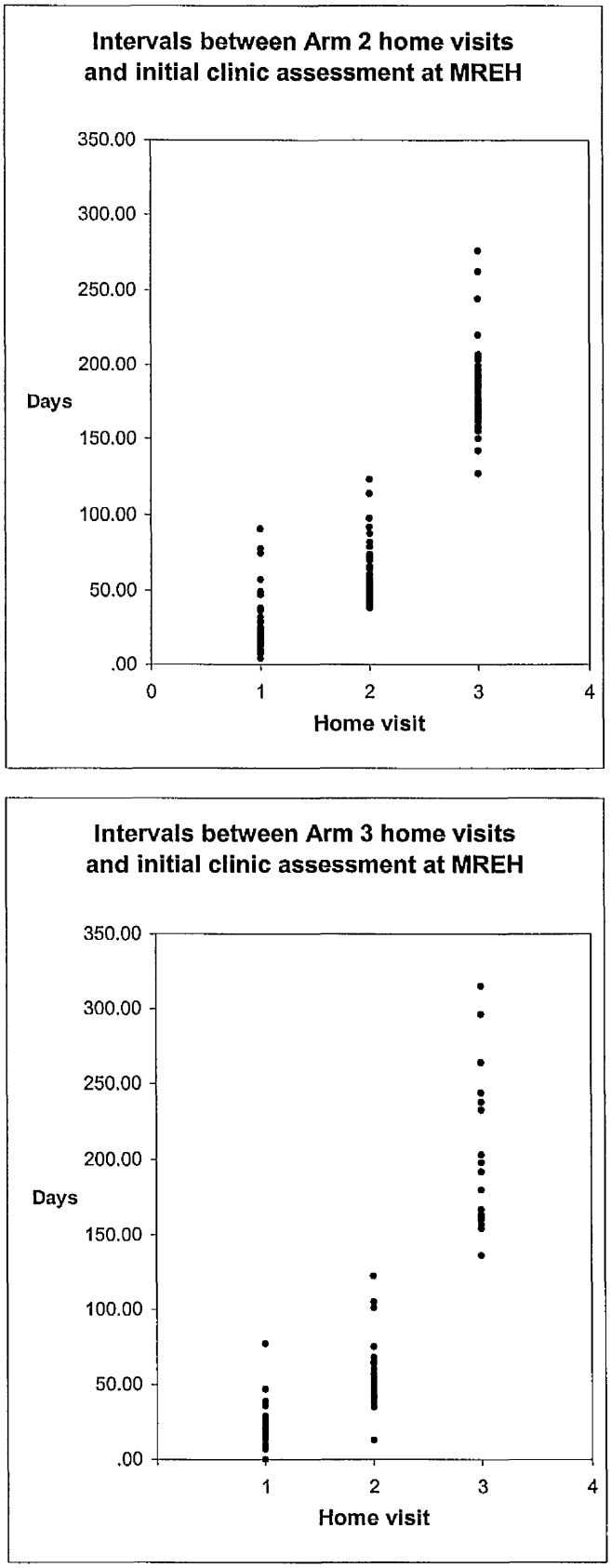


Note: Percentages shown are based on the total number of patients allocated to each arm

Table 6.11: Time (days) from baseline outcomes visit to scheduled home visits in arms 2 and 3

Intervention	Patient group	N	mean	SD	min.	max.
1st home visit	Arm 2	67	32.94	26.09	8	169
	Arm 3	33	30.64	14.85	12	84
2nd home visit	Arm 2	65	67.85	26.14	41	205
	Arm 3	33	66.67	22.12	27	135
3rd home visit	Arm 2	64	192.23	29.96	140	335
	Arm 3	18	211.44	57.88	144	356

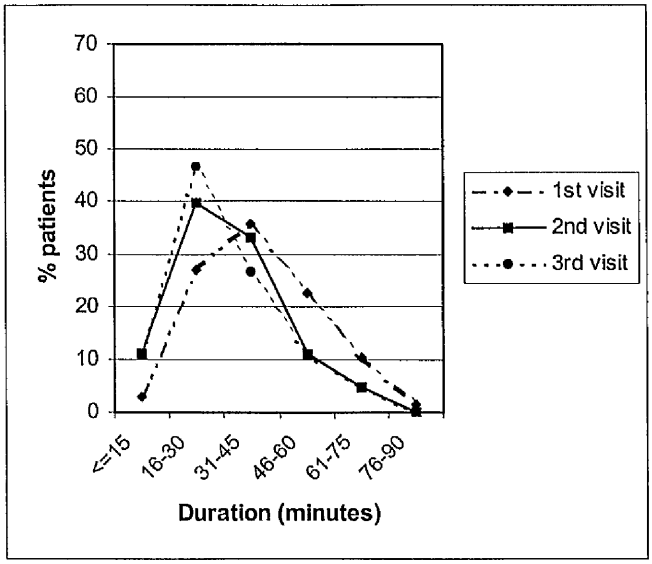
Figure 6.7: Time (days) from first low vision assessments to scheduled home intervention visits in arms 2 and 3



6.6.2 Content of intervention in arm 2

All of the home visits in this arm were carried out by one rehabilitation officer. The duration was recorded for 194/196 visits. The duration of all visits made ranged between 10 and 90 minutes with a mean time of 37 minutes (SD 15.6). Distributions of duration for each of the three visits are shown in figure 6.8.

Figure 6.8: Distributions of the duration of home visits carried out for patients in arm 2



The rehabilitation officer used a checklist of 12 items at each visit with respect to the use of magnifiers, e.g. frequency of use, and strategies for enhancing vision, e.g. lighting. During the visit each of these 12 items could simply be discussed and/or problems could be identified in relation to the topic in question. The items covered varied between patients and visits since the process was client-led. The rehabilitation officer could also give advice and/or take action with respect to the discussion topic or problem raised (see Chapter 5 Study design and methodology, and the data collection form used by the rehabilitation officer in appendix 12).

There was only one visit for which none of the 12 items on the item checklist were discussed. This visit was a third home visit to a patient who had recently lost his vision suddenly and had some perception of light only in his better eye. Therefore all 69 (100%) patients who had at least one home visit in this arm (see 6.6.1 above)

participated in a discussion regarding some of the checklist items during at least one home visit. The number of discussion items covered ranged from 2 to 10 (median 7.0) for 195/196 visits carried out in this arm. However, 2 items were discussed at only one visit, and for the remaining visits the range was between 7 and 10 items. The number of items discussed at each successive visit decreased slightly.

At least one problem was raised in relation to a discussed item for 43 (62.3%) patients of those who received at least one visit. In terms of visits, problems were raised during 58 out of the total 196 home visits made. The numbers of problems ranged between 1 to 5, but because only one problem was raised in the majority of visits where problems had been identified the mean number of problems recorded for these visits was 1.48 (SD 0.84).

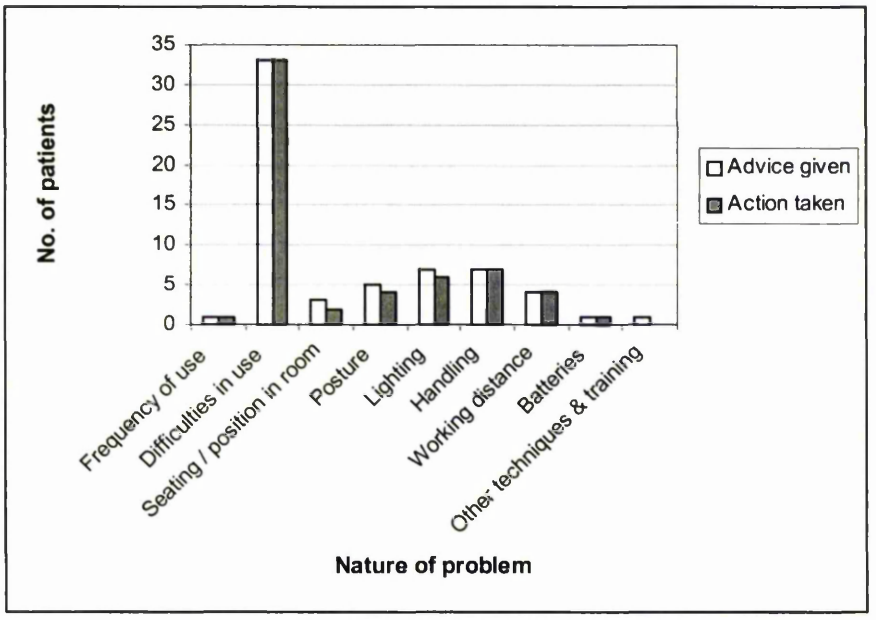
All of the patients for whom problems were recorded also received advice related to at least one of the items associated with a problem. In total 44 (63.8%) patients of those visited at least once were given advice on a minimum of one checklist item (one patient received advice for an item which had not been raised by the patient themselves as being problematic). The rehabilitation officer took action on a minimum of one checklist item for 43 (62.3%) of the patients visited at least once, all of whom had been advised on the item(s) acted upon. In terms of visits, advice was given on at least one vision-specific issue during 57/196 home visits, and action was taken with respect to at least one vision-specific issue for 54/196 visits made. Figure 6.9 shows the numbers of patients and the percentages both of those visited (i.e. who received intervention) and of the total number of patients allocated to arm 2 who received the different 'levels' of intervention for at least one vision specific issue. In addition the table shows the numbers of patients who received other forms of input. The nature of the problems where advice had either been given or action had been taken by the rehabilitation officer are shown in figure 6.10.

Figure 6.9 Levels of intervention delivered to patients in arm 2 with respect to vision specific items checklist

Level of intervention	No. of patients			% of patients visited at least once (n=69)	% of patients allocated to arm 2 (n=75)
>=1 item discussed	69			100.0	92.0
>=1 problems raised	43			62.3	57.3
>=1 items advised upon	43	+	1	63.8	58.7
>=1 items acted upon	43			62.3	57.3
Information on AMD and range of services	3			4.3	4.0
Referral to Social Services & invitation to a day at Henshaws*	18			26.1	24.0
Information of equipment entitlements through Social Services	17			24.6	22.7
Other input, e.g. assistance in home safety	21			30.4	28.0

* A local voluntary society.

Figure 6.10 The nature of the problems associated with LVA use where advice had either been given or action had been taken by the rehabilitation officer for patients in arm 2



As part of the intervention delivered in arm 2, the rehabilitation officer also loaned additional magnifiers and/or facilitated the return of inappropriate LVAs as deemed necessary. Of the 69 patients who were visited at least once 56 (81.2%) patients had either at least one additional/alternative magnifier loaned to them or had returned at least one magnifier. Fifty-five (79.7%) patients had at least one LVA loaned to them by the rehabilitation officer during the trial and 37 (53.6%) patients returned at least one LVA to MREH via the rehabilitation officer (only one patient who returned an LVA did not receive an alternative device). More devices were loaned at the first scheduled home visit than at the later visits and most were returned at the second of the three visits. Figure 6.11 shows the numbers of LVAs loaned and those returned at each scheduled home visit, and the total numbers of LVAs loaned and returned for all visits by device category are shown in figure 6.12.

Figure 6.11 Numbers of LVAs loaned to/returned from patients during the three scheduled home visits in arm 2

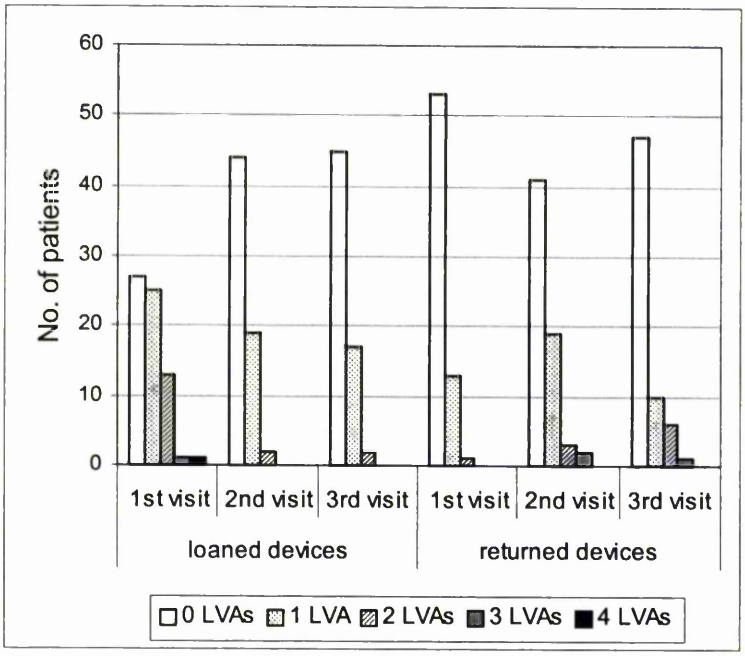
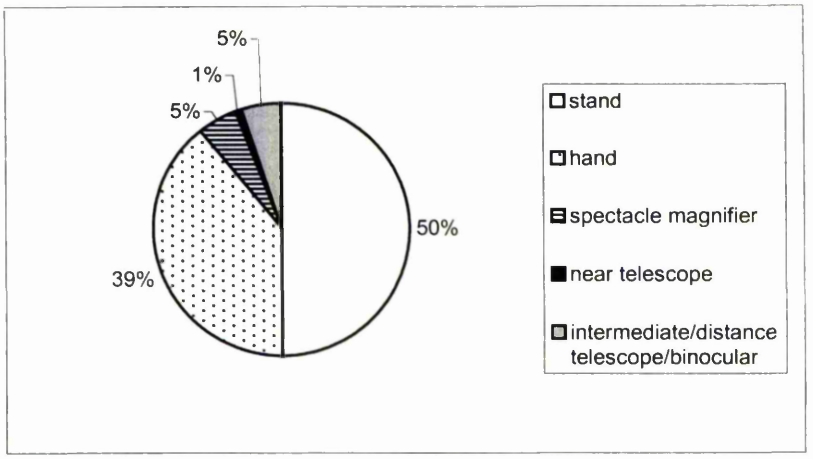
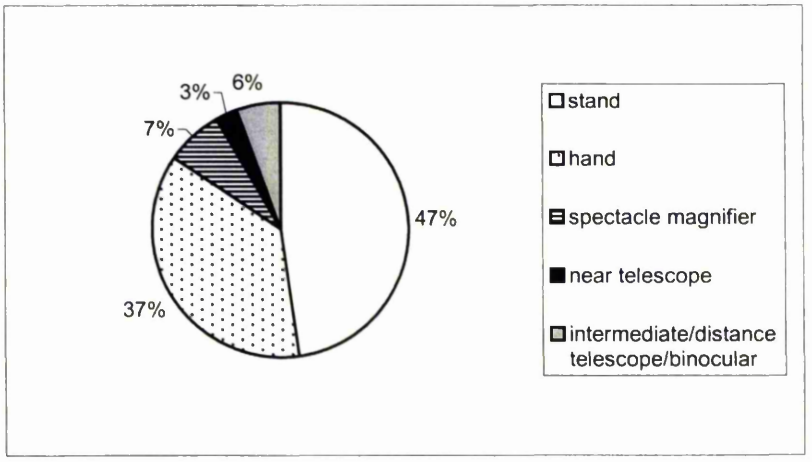


Figure 6.12 Numbers of LVAs (a) loaned (total devices=102), and (b) returned (total devices=71) for all visits by device category

(a) *Total devices=102*



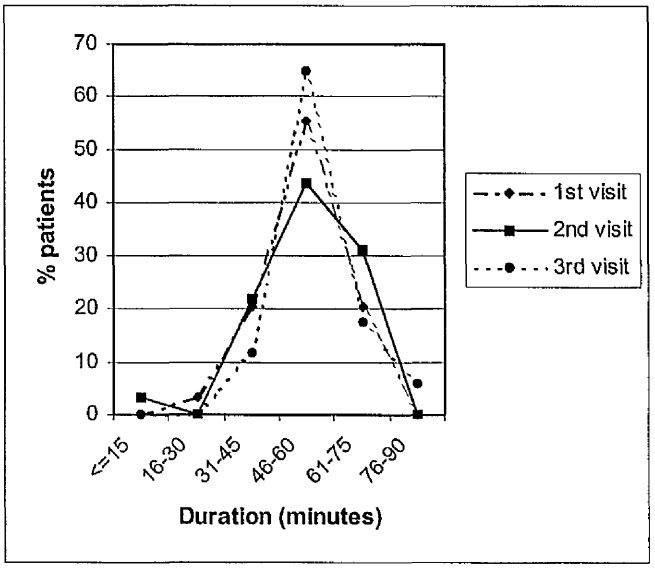
(b) *Total devices=71*



6.6.3 Content of input in arm 3

The home visits in this arm were carried out by three community workers from Age Concern, who made 3, 49 and 32 visits each. The duration was recorded for 78/84 visits. The duration of all visits made ranged between 5 and 90 minutes with a mean value of 57.1 minutes (SD 12.9). Distributions of duration for each of the three visits are shown in figure 6.13. These visits were therefore comparatively longer than those carried out in arm 2 (see 6.6.2 above).

Figure 6.13: Distributions of the duration of home visits carried out for patients in arm 3



During the home visits patients had the opportunity to discuss various aspects of their daily lives in the context of the general areas of advice and support which are typically offered by community workers from Age Concern (see Chapter 5, Study design and methodology, section 5.4.5). The topics covered during the home visits were client-led although the community worker was able to use a checklist to record the issues raised and/or as a prompt during the visit.

The checklist allowed up to 20 discussion items to be recorded. These items covered topics such as daily activities, leisure activities and other general areas concerning health, safety or social issues. During the visit each item raised could simply be discussed and/or problems could be identified in relation to the topic in question. Furthermore, the community worker could give advice and/or take action with respect to the discussion topic or problem raised (see Chapter 5 Study design and methodology, and the data collection form used by the community worker in appendix 13).

All of the 47 (100%) patients who had at least one home visit in this arm (see 6.6.1 above) participated in a discussion regarding some of the checklist items during at least one visit. The number of discussion items covered ranged from 4 to 16 (median 8.0). Discussion of checklist topics occurred during each of the 84 visits which took place in this arm. The mean number of items discussed at each successive visit decreased slightly for the first, second and third visits respectively.

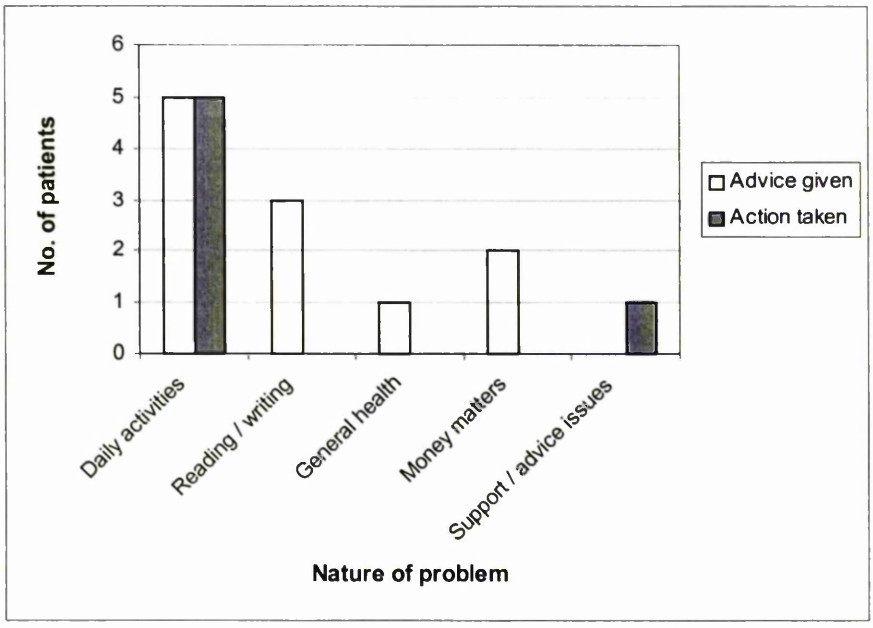
At least one problem was raised in relation to a discussed item for 44 (93.6%) patients of those who received at least one visit. In terms of visits, problems were raised during 73 out of the total 84 home visits made. The number of problems ranged between 1 to 10, with a mean number of problems for these visits of 3.53 (SD 2.01).

Eleven of the patients for whom problems were recorded also received advice related to at least one of the items associated with a problem. Therefore 23.4% of patients visited at least once were given advice on a minimum of one checklist item. The community workers took action on a minimum of one checklist item for 5 (10.6%) of the patients visited at least once, 3 of whom had been advised on the item(s) acted upon. In terms of visits, advice was given on at least one 'Age Concern' issue during 13/84 home visits, and action was taken with respect to at least one issue for 7/84 visits made. Figure 6.14 shows the numbers of patients and the percentages both of those visited (i.e. who received intervention) and of the total number of patients allocated to arm 3 who received the different 'levels' of intervention for at least one general Age Concern issue. The nature of the problems where advice had either been given or action had been taken by a community worker are shown in figure 6.15.

Figure 6.14 Levels of intervention delivered to patients in arm 3 with respect to a general non vision-specific items checklist

Level of intervention	No. of patients	% of patients visited at least once (n=47)	% of patients allocated to arm 3 (n=75)
>=1 item discussed	47	100.0	62.7
>=1 problems raised	44	93.6	58.7
>=1 items advised upon	11	23.4	14.7
>=1 items acted upon	3 + 2	10.6	6.7

Figure 6.15 The nature of the general problems raised where advice had either been given or action had been taken by community workers for patients in arm 3



6.7 Patient diaries

Patient compliance with respect to diary completion of the set of four 3-month diaries was unexpectedly high (see appendix 14 and chapter 5, section 5.4.6). Although the vast majority of patients in the trial clearly experienced difficulties with reading and writing activities, nevertheless many patients were very willing to complete their diaries on a regular basis for research purposes, often for the whole of the 12-month trial period. Many patients commented that they hoped to contribute to a greater understanding of the impact to AMD on daily life by sharing their experiences and feelings in terms of their sight problems. Most patients completed the diaries on their own, however some patients asked family members or friends to write their entries into the diaries for them. The author both requested and stressed that the views and comments written into the diaries should reflect only those of the patient. The author contacted by telephone all patients who had agreed to keep a diary at approximately one month after the home visit to collect baseline outcomes. The purpose of the phone call was to encourage patients to continue with diary completion and to ascertain that the patient was able to do so on their own or, if they were being assisted in diary completion, that only the responses of the patient were being recorded. The content of individual diaries together with patient feedback suggest that the diaries for the study population overall genuinely contain the views of the patients taking part in the trial.

The 3-month diaries were graded as either 'completed' or 'partially completed'. A completed 3-month diary was one where the patient had filled in both a weekly matrix over all 12 weeks showing the extent of social contact and the uptake of health and social services throughout an entire 3-month diary, and in addition, had entered comments in response to a set of open questions regarding concerns about low vision and overall health and life events on a weekly basis throughout the diary (see appendix 14 for diary structure). A partially completed diary included one where either only the social contact matrix had been filled in for at least one week, and/or the open questions had all been answered for at least one week. Partially completed diaries typically included the completion of the matrix only for most of the 12 weeks in the diary, or several weeks of full completion in a 3-month diary (indicating in the latter case that the patient had been conscientious initially but then had stopped the whole process of completion at a given point in time). In total, 365 completed and 27 partially completed diaries were returned by patients during the trial. The willingness to fill in a 3-month

diary was greater for the first of the set of four diaries amongst the patients who had agreed to keep a diary from baseline, but not surprisingly, cooperation declined with successive 3-month diaries. In some cases, patients completed the first of their four diaries, then may have omitted the second and/or third 3-month diaries before continuing with their next available quarterly diary. Table 6.12 shows the number of completed and partially-completed diaries returned by patients over their 12-month study period in the each of the three arms. The total number of diaries pooled together for full and partial completion, returned per patient (i.e. irrespective of quarterly order of completion and return), is shown by arm in table 6.13. There were no significant differences found between arms in a Chi-square test using 4 groups of diary completion (to allow for sufficiently large frequencies to carry out the test), namely 0 diaries completed, 1 diary, 2 or 3 diaries, or all 4 diaries completed.

Table 6.12: Completed and partially completed quarterly diaries returned by patients by arm

3-month diaries		Patient group							
		Arm 1 (n=76)		Arm 2 (n=75)		Arm 3 (n=75)		All patients (n=226)	
		No.	%	No.	%	No.	%	No.	%
Diary 1	Completed	38	50.0	47	62.7	47	62.7	132	58.4
	Partially completed	8	10.5	5	6.7	5	6.7	18	8.0
Diary 2	Completed	25	32.9	38	50.7	31	41.3	94	41.6
	Partially completed	1	1.3	0	0.0	3	4.0	4	1.8
Diary 3	Completed	18	23.7	31	41.3	25	33.3	74	32.7
	Partially completed	1	1.3	2	2.7	1	1.3	4	1.8
Diary 4	Completed	18	23.7	27	36.0	20	26.7	65	28.8
	Partially completed	0	0.0	0	0.0	1	1.3	1	0.4

Table 6.13: Total number of completed and partially completed diaries returned by patients

No. of diaries returned (completed and partially completed)	Patient group							
	Arm 1 (n=76)		Arm 2 (n=75)		Arm 3 (n=75)		All patients (n=226)	
	No.	%	No.	%	No.	%	No.	%
0 diaries	27	35.5	22	29.3	22	29.3	71	31.4
1 diary	25	32.9	14	18.7	18	24.0	57	25.2
2 diaries	4	5.3	6	8.0	9	12.0	19	8.4
3 diaries	4	5.3	8	10.7	7	9.3	19	8.4
4 diaries	16	21.1	25	33.3	19	25.3	60	26.5

6.8 Broken blinding

Although every effort was made to 'blind' the author who was responsible for measuring non-clinical baseline and final outcomes to arm allocation until data collection had ceased (see chapter 5, section 5.3), blinding was inadvertently broken in some cases nonetheless. All instances of broken blinding occurred as a result of the patient disclosing information which gave some degree of indication of their arm allocation. The author became of the intervention being received by patients through several possible situations :

- during phone calls which the author made to patients to monitor diary completion (see 6.7 above);
- during phone calls which the author made to establish appointments with patients for home visits to collect final outcome measures;
- during phone calls to administer the short version of the MLVQ;
- at the start of, or at a point in time during the home visit to collect final outcome measures;
- during phone calls which the author occasionally received from patients who contacted the author with a variety of queries concerning their vision or low vision care throughout the trial.

The last of the above scenarios was infrequent though unavoidable, since all patients had access to the author's contact details for the administrative purposes of appointment bookings and queries regarding diaries. Therefore some patients, especially having met the author at the baseline interview, perceived that the author would be able to address their queries even though the author had endeavoured to clarify her role in the trial. In these instances the patients' queries were referred to appropriate professionals, e.g. optometrists in the low vision clinic.

A system was therefore devised to record instances of broken blinding. Whenever the author became aware of arm allocation, patient identification details and the suspected arm allocation were noted together with the date broken blinding had occurred. The author did not refer to this log of broken blinding throughout the data collection phase, but immediately prior to each final home visit the author recorded a 'guess' with respect to the arm allocation for each patient visited. This 'guess' was graded in terms of certainty, i.e. in terms of whether the author was sure of arm allocation, suspicious of an arm allocation, or simply did not know and therefore had made a complete guess. However this process did not take into account instances of broken blinding which occurred during the final home visit itself. The extent of broken blinding and the author's personal observation that this latter situation had happened infrequently, suggests that this data, had it been recorded, would probably not have made any difference to the significance of the findings between arms with respect to this design issue. The extent of broken blinding prior to the final home visits was explored after data collection had stopped for all patients in the trial. Although the extent of bias, if any, on the part of the author due to prior knowledge of arm allocation when collecting final outcome measures cannot be determined, nevertheless the extent of broken blinding has been evaluated to comply with the CONSORT group guidelines for the reporting of RCTs (Altman, 1996; Moher *et al*, 2001). Tables 6.14 (a), (b) and (c) show the number and proportion of broken blinding which occurred for each level of certainty used by the author to 'predict' the arm allocation for patients immediately prior to their final home visit. Instances where the author had correctly identified arm allocation prior to the final home visit are presented in a bold typeface. Table 6.14 (c) includes 'guesses' for arm 1 allocation only since complete guesses defaulted to an assumption of arm 1 allocation due to the lack of any information which the author could recall that might have otherwise led to either a suspicion or certainty that arm 2 or arm 3 intervention had been delivered. A binomial test for large N returned a significant difference between

arms for the 'certain' category (i.e. table 6.14 (c)) of broken blinding ($p<0.00001$). Table 6.15 shows the number and proportion of correct 'predictions' pooled for suspected and certain predictions made by the author for 120/194 patients who had their final visit. There was no significant difference found at the 2% level ($p=0.076$) between arms in a Chi-square test comparing the frequencies of correct and incorrect predictions.

Table 6.14 (a), (b) and (c): Number and proportion (percentages shown are of table totals) of broken blinding which occurred for each level of certainty used by the author to 'predict' the arm allocation for patients immediately prior to their final home visit

(a) Author was certain

Author's 'prediction' of arm allocation prior to final home visit (n=41)	**Actual arm allocation**					
	Arm 1		**Arm 2**		**Arm 3**	
	No.	**%**	**No.**	**%**	**No.**	**%**
Arm 1	**3**	**7.3**	1	2.4	1	2.4
Arm 2	0	0.0	**19**	**46.3**	1	2.4
Arm 3	2	4.9	1	2.4	**13**	**31.7**

(b) Author suspected

Author's 'prediction' of arm allocation prior to final home visit (n=79)	**Actual arm allocation**					
	Arm 1		**Arm 2**		**Arm 3**	
	No.	**%**	**No.**	**%**	**No.**	**%**
Arm 1	**21**	**26.6**	16	20.3	12	15.2
Arm 2	3	3.8	**7**	**8.9**	6	7.6
Arm 3	3	3.8	4	5.1	**7**	**8.9**

(c) Author guessed

Author's 'prediction' of arm allocation prior to final home visit (n=74)	**Actual arm allocation**					
	Arm 1		**Arm 2**		**Arm 3**	
	No.	**%**	**No.**	**%**	**No.**	**%**
Arm 1	**28**	**37.8**	16	21.6	30	40.5
Arm 2	0	0.0	**0**	**0.0**	0	0.0
Arm 3	0	0.0	0	0.0	**0**	**0.0**

Table 6.15: Number and proportion of correct 'predictions' of arm allocation pooled for suspected and certain predictions made for patients immediately prior to their final home visit

Author's 'prediction' of arm allocation prior to final home visit (n=120)	Actual arm allocation					
	Arm 1		Arm 2		Arm 3	
	No.	% (of total)	No.	% (of total)	No.	% (of total)
Correct	24	20.0	26	21.7	20	16.7
Incorrect	8	6.7	22	18.3	20	16.7

6.9 Data quality

6.9.1 Missing values

The data collection during this trial involved a number of individuals, including the author (who was responsible for collecting and recording non-clinical outcomes at baseline and at 12 months), optometrists (who were responsible for recording visual function data during clinic assessments), a rehabilitation officer (who recorded data which describes the intervention delivered in arm 2), and three community workers from Age Concern (who recorded data which describes arm 3 input). Sections 6.5 and 6.6 above describe the involvement of individuals with respect to arm 1, 2 and 3 activities. Despite the number of individuals who contributed to data collection the standard of data capture was very good overall, and not surprisingly, better for aspects of data collection involving fewer individuals. The results presented in this thesis show the numbers of cases (these will usually be numbers of patients, but may also be for example numbers of home visits or clinic assessments) included in each analysis (i.e. the denominator).

The main reason for missing clinic assessment data is the fact that patients failed to attend for their scheduled appointments. However, a relatively small number of data are missing for attended assessments because the optometrist concerned may have chosen not to measure all of the visual outcomes which were being recorded during the trial. Contrast sensitivity, for example, has a higher proportion of missing data than other clinical data, since this visual function is not routinely measured in low vision clinics

and optometrists may have felt that it was more important to measure visual acuities as part of clinical management. The descriptive results for visual outcomes given in chapter 7 (sections 7.3 and 7.4) state the denominators for all of the visual functions measured.

It is not possible to determine the extent of missing data, i.e. where failure to ask questions or to record responses/events occurred in arms 2 and 3 because of the techniques used to capture information. Arm 2 and arm 3 data which describe the content of intervention and input in these arms were collected mainly using checklist mechanisms to record events which were client-led (see data capture sheets in appendices 12 and 13). Therefore it was assumed that any item on a checklist which had not been ticked represented input which had not taken place. Any omission with respect to ticking a checklist item could not be identified. However, the extent and pattern of data recorded on the data capture sheets for arms 2 and 3 suggest that the amount of missing data was very low, especially for arm 2.

The main reason for missing data for final non-clinical outcomes is patient drop-out. Task performance data, however, is substantially unavailable for the 'writing' task which required patients to complete an application form for Talking Books (see section 5.4.1). This was due partly to many patients being reluctant to complete their personal details on any kind of form, even though they were informed that the form being used was a 'mock form' for research purposes only. Many patients in addition felt more uncomfortable with carrying out a writing task than one which involved reading, and therefore declined to do the former even though they were willing to try the remaining tasks. Very few data variables are otherwise missing for the data collected by the author at baseline and final home visits. In these cases the failure to record specific values during the course of the interview was a simple oversight on the author's part.

The issue of missing data is not strictly relevant to patient diaries, in which the patient volunteers information. The completion of patient diaries is described in 6.7 above.

6.9.2 Coding conventions for visual function outcomes

Distance acuity for some patients in the trial was too poor to measure on a logMAR scale. The conventions for handling such data were as follows:

- Patients without form vision were given a nominal value of 2.0 logMAR for distance acuity for the purposes of inclusion in statistical analyses. This value was therefore used to represent distance acuity recorded on data sheets as 'hand movement', 'light perception only', and 'too poor to measure'.

- Patients who had 'no perception of light' were excluded from any analyses involving distance acuity.

- In very few cases (e.g. on 5 occasions out of the initial low vision assessments) optometrists failed to follow the study protocol and recorded patients with very low form vision as 'count fingers' ('CF'). These cases were assumed to have a visual acuity <1/60 and were therefore given a nominal value of 1.8 logMAR.

Near vision data was excluded from analysis for patients whose vision was too poor to measure using an MNREAD chart. Chapter 5, section 5.4.1 outlines the methods used for measuring visual function outcomes and the data capture sheets used during clinic assessments are given in appendix 5.

6.9.3 Questionnaire administration problems

The author observed that some questionnaires were more difficult to administer than others to an elderly population. The patient background information questionnaire (see appendix 7(a)) contained a section about general health which presented several problems during administration. For example, patients were asked whether they were taking any prescribed medication which they had been taking 'for a long time'. This question yielded inconsistency in the quality of responses due to patient interpretation of duration associated with medication, but also failed to capture instances where patients had been recently prescribed medication which was intended for long-term use. Furthermore, patient knowledge of the illnesses being treated was poor. The author also believes that in many cases patients failed to remember all of the medicines they were taking at the time of the interview. The next question about general health explored whether patients were attending a hospital or clinic for non-vision health problems. This

question yielded responses which described a variety of health problems of varying degrees of severity. This question failed to distinguish between routine monitoring and medical intervention and did not provide the frequency of such activities. Similarly problems were experienced with a question which was included to determine whether patients had other disabilities. The author believes that the information obtained in answer to this particular question is of poor quality due to the variability in patient interpretation of this question.

Of the questionnaires used to measure outcomes the NAS (see appendix 9) was especially time consuming and problematic. Many patients requested statements to be read to them repeatedly and also struggled to choose a response from those available. Furthermore, respondent interpretation of the first of the four dimensions of NAS used in the trial, namely the section concerned with 'attitudes', was such that patients invariably reflected statements onto themselves when giving their answers. The developers of the NAS had intended that subjects thought of individuals other than themselves when responding to items in this dimension (Dodds, 2001). The SF-36 (see appendix 8) also presented some difficulties. Whilst some patients continued to focus on their eyesight problems in answering questions regarding general health, others excluded their eyesight in the process of giving responses to the SF-36 questions. In general and for all of the questionnaires used, questions which offered more than 3 or 4 multiple choice responses posed some problems. Patients often forgot which categories were available to them, even if the same categories were used for a successive batch of questions. This necessitated frequent repetition of response options. Due to the age profile of the study patients, many interviewees struggled to answer questions which sought answers based on perceptions relating to retrospective health events, both in a short term context such as '4 weeks ago' and a longer term such as 'a year ago'. Throughout the interviews the author endeavoured to maintain a consistent approach in administering the questionnaires and order effects (i.e. any influence that may have arisen through administering the questionnaires in the same order for all patients) were avoided by using a Latin Square procedure which rotated the order of questionnaire administration (see also section 5.4.2).

CHAPTER 7: RESULTS I. THE STUDY POPULATION AT BASELINE AND FOLLOW-UP

This chapter presents descriptive analyses of baseline and follow-up data. In addition outcome measures for the SF-36 (used to measure generic quality of life) and for the VCM1 (used to measure vision-specific quality of life) are compared against normative data.

7.1 Socio-demographic characteristics at baseline and at 12 months

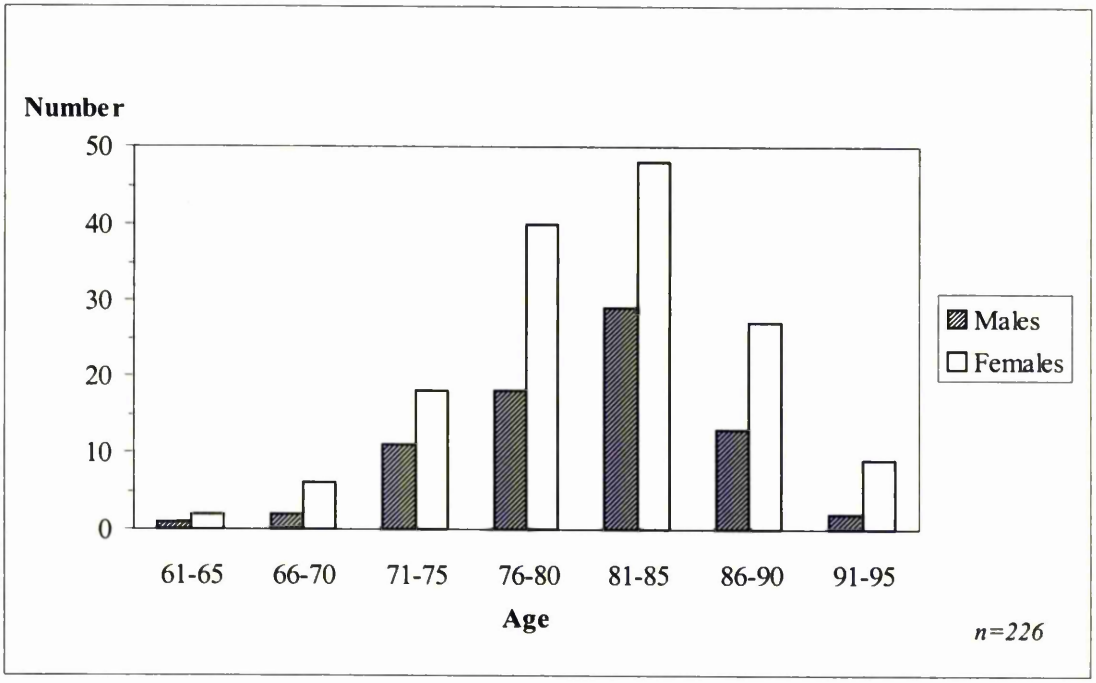
Key socio-demographic characteristics of the study population are shown in table 7.1 and the age/sex distribution of the entire study population at baseline is shown in figure 7.1. The male to female ratio (33.6% and 66.4% respectively) and age distribution of the sample is in keeping with the epidemiology of AMD (Gibson *et al,* 1986; Hyman, 1992). The sample has a median age of 82.4 years which indicates a slight negative skewness to the age distribution. The mean age at recruitment of the female subjects (81.7 years) is very comparable to that of the male subjects (81.5 years). Two hundred and twenty five patients in the sample were of white European ethnic origin and 1 subject was Asian, thus reflecting the known prevalence of AMD in white versus black populations (Hyman, 1992), especially given the multi-ethnic population pool within the geographic region served by the MREH.

Over half of the subjects (123) were widowed (54.7%) at recruitment into the study and the vast majority of this group (102, 82.9%) were living on their own. The remaining patients who lived on their own were either divorced (6) or never married (7) and one patient declined to disclose marital status. The baseline data shows little difference between the numbers living alone or with spouse/family, but a high proportion of the subjects living on their own were female. Eighty-seven (38.5%) patients who did not live alone at recruitment, lived with their spouse and 23 (10.2%) with other members of their family.

Table 7.1: Socio-demographic characteristics at baseline

Characteristic	**All** (n=226)	**Male** (n=76)	**Female** (n=150)	**Living alone** (n=116)	**Not living alone** (n=110)
Age					
Mean	81.62	81.51	81.67	82.93	80.23
Standard deviation	6.06	5.81	6.20	5.71	6.13
Min – max	64.8 – 95.5	65.7 – 92.7	64.8 – 95.5	68.9 – 93.9	64.8 – 95.5
Living alone					
n (%)	116 (51.3)	22 (28.9)	94 (62.7)		

Figure 7.1: Age/sex distribution of study sample at baseline



The proportion of widowed patients at follow-up increased slightly to 58.0%, i.e. 112/194, although just 2 patients became widowed during the trial, the increase is accounted for by the larger number of drop-outs in the other marital status categories than in the widowed group. Of the 112 patients who completed the trial and who were widowed, 87 (77.7%) were living on their own at follow-up. This proportion of lone residential status amongst an elderly widowed group has shown a small decrease after a 12 month follow-up period.

Additional socio-demographic data at baseline relating to education, employment and hobbies are summarised in table 7.2(a). The table shows that the vast majority of patients had achieved secondary education, were no longer working (either in formal employment or in a voluntary capacity), and with many still managing to enjoy some leisure activities. Details of the hobbies which patients included amongst those which they either could do, or would like to be able to do, are given in appendix 17. Table 7.2(b) shows little difference in the proportions of patients who were involved in voluntary work (3 patients in this category at baseline did not complete the trial) and who could still enjoy their hobbies.

Data about general health at both baseline and at follow-up were not analysed due to various problems in collecting this information in the format set out in the patient background questionnaire (see appendix 7(a)). These difficulties affected the validity of these data as described in section 6.9.2. However, data which describe the types of regular assistance with ADLs that patients were receiving at baseline and at 12 months are summarised in figure 7.2. The total number of patients who were receiving at least one of the categories of assistance shown numbered 92/226 (40.7%) at baseline and 115/194 (59.3%) at follow-up. Therefore, individual patients may be included in more than one category in the bar chart. The chart shows that uptake increased for most of the categories, especially for adaptive devices, i.e. devices which use a sensory substitution approach (for example tactile or auditory methods). This is not surprising, since an increase in various health and social needs would be anticipated in an elderly population after 12 months have elapsed, especially in the presence of visual impairment. Partial sight and blind registration amongst patients will also have been a major factor in obtaining adequate devices (see appendix 21 which presents registration data). Registration data collected retrospectively after the end of the trial from hospital records which were readily available (i.e. for 185 patients) show that 29/185 (15.7%) patients

had been registered blind, 57/185 (30.8%) patients had been registered partially sighted, and 99/185 (53.5%) patients had not been registered at all at baseline, i.e. prior to their initial clinic assessment. At 12 months, i.e. at the time of the final clinic assessment, blind registrations amongst the patients had increased to 55/185 (29.7%), and partial sight registrations had also increased to 70/185 (37.8%), thus reducing the number of patients unregistered to 60/185 (32.4%).

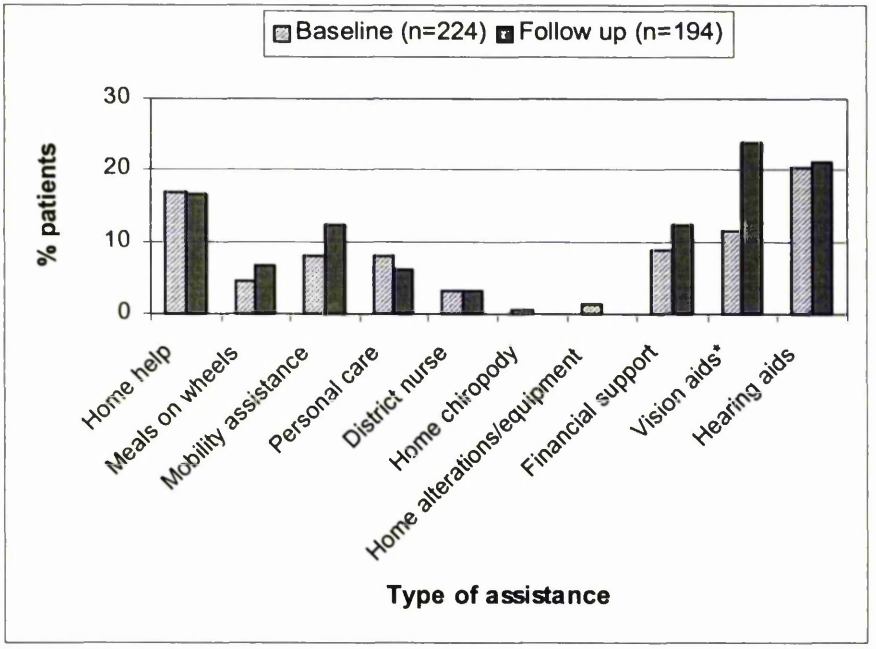
Table 7.2 (a): Additional socio-demographic characteristics at baseline

Characteristic	Categories	No. of patients	%	Mean (SD)	Median	Min.	Max.
Level of education achieved (n=226)	Primary Secondary Tertiary	2 215 9	0.9 95.1 4.0				
Age when left education (n=226)				14.72 (2.07)	14.0	6.0	29.0
Working at baseline (n=226)	Part-time Retired Never worked	1 221 4	0.4 97.8 1.8				
Involved in regular voluntary work (n=226)	No Yes	213 13	94.2 5.8				
Hours/week voluntary work (n=13)				7.31 (8.95)	4.0	2.0	28.0
Number of hobbies which can still be enjoyed (n=226)	None 1 to 3 4 to 7	14 153 59	6.2 67.7 26.1	2.7 (1.56)	2.5	0.0	7.0

Table 7.2 (b): Additional socio-demographic characteristics at follow-up

Characteristic	Categories	No. of patients	%	Mean (SD)	Median	Min.	Max.
Involved in regular voluntary work (n=191)	No Yes	183 8	95.8 4.2				
Hours/week voluntary work (n=8)				8.0 (10.18)	3.0	1.0	28.0
Number of hobbies which can still be enjoyed (n=194)	None 1 to 3 4 to 7	2 119 73	0.01 61.3 37.6	3.1 (1.44)	3.0	0.0	8.0

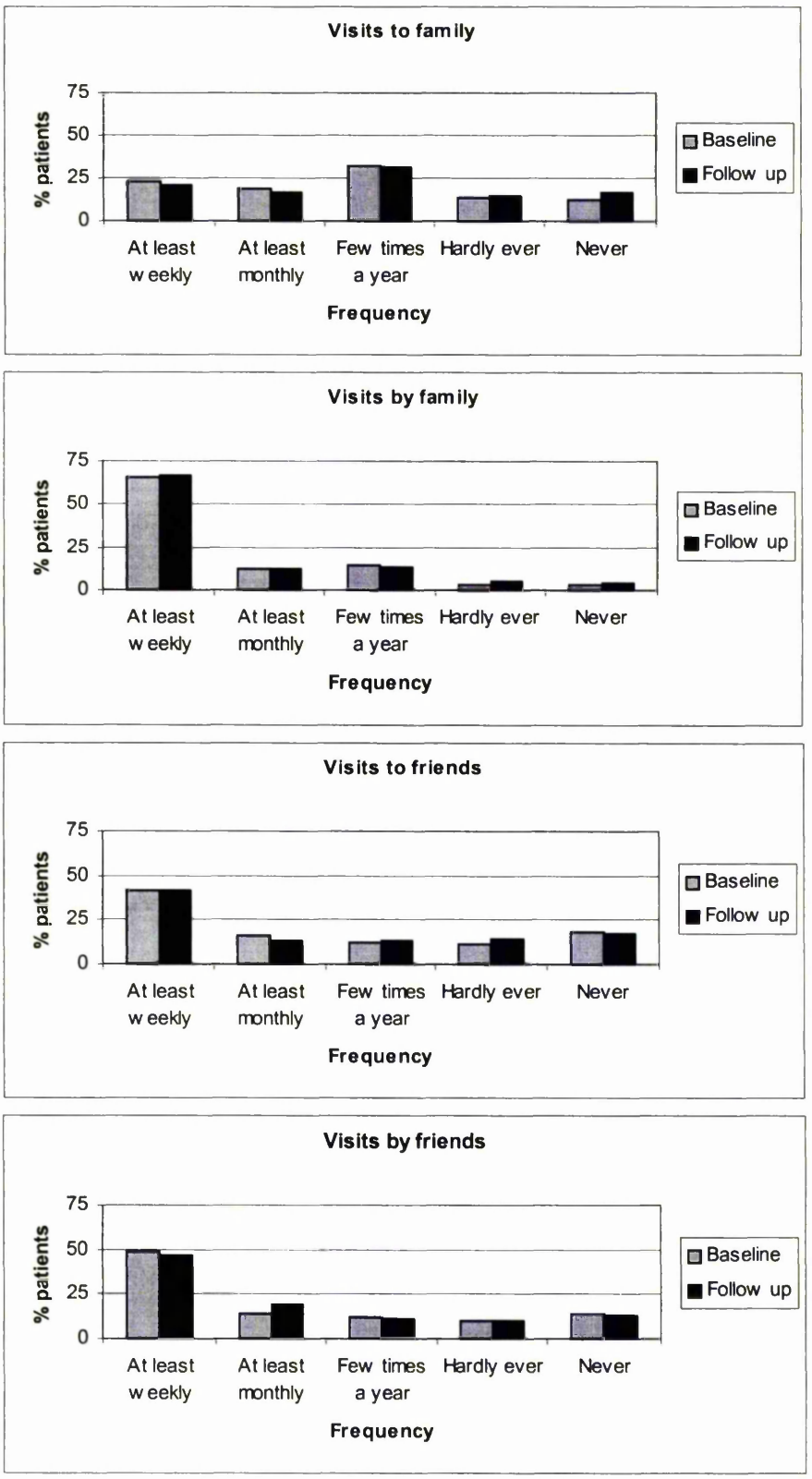
Figure 7.2: Numbers of patients receiving different types of regular assistance with ADLs from health / social services



* Vision aids refers to adaptive devices which use tactile or sensory systems, e.g. talking/vibrating clocks and liquid level indicators.

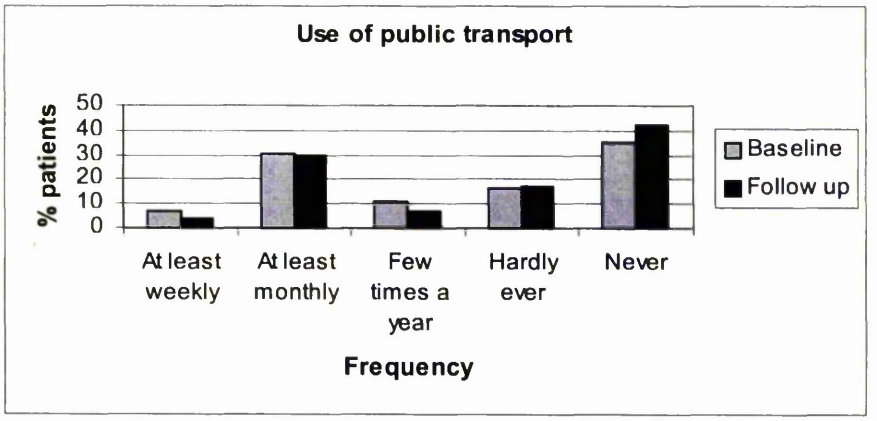
The extent of social and family contact was analysed in terms of the frequency of visits which the patient made to family and to friends, and the frequency of visits which the patient received in turn from family and from friends. This information is summarised in figure 7.3. Other variables relating to social contact including the use of public transport and shopping patterns at baseline and follow-up are summarised in figure 7.4. Questions about involvement in community/social activities during the preceding fortnight and availability of car transport were omitted from these descriptive summaries. Both of these two questions were considered to be redundant since their responses and their conceptual meanings (i.e. pertaining to social contact and isolation issues) were being dealt with by other questions. However, a question which was asked to determine whether patients had attended a place of worship within two weeks prior to interview was analysed. The results showed that 49/226 (21.7%) of patients had attended at baseline and 40/194 (20.6%) at follow-up.

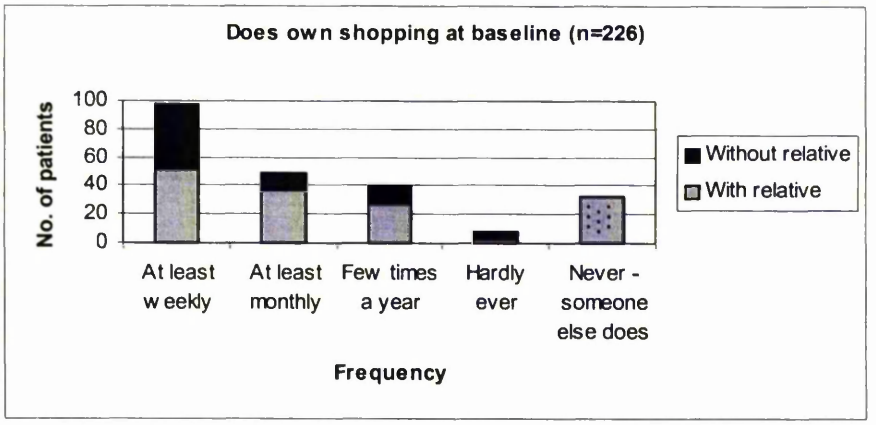
Figure 7.3: Extent of social and family contact at baseline and follow-up

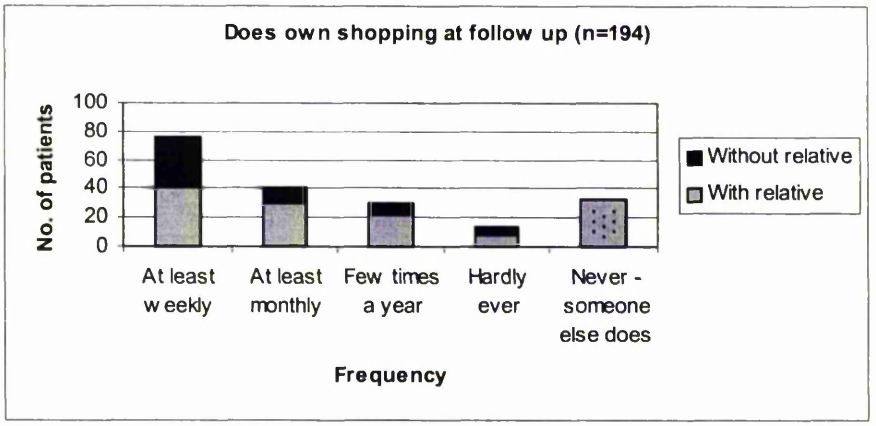


Baseline: n=226; Follow-up: n=194

Figure 7.4: The use of public transport and shopping patterns at baseline and follow-up







Baseline: n=226; Follow-up: n=194

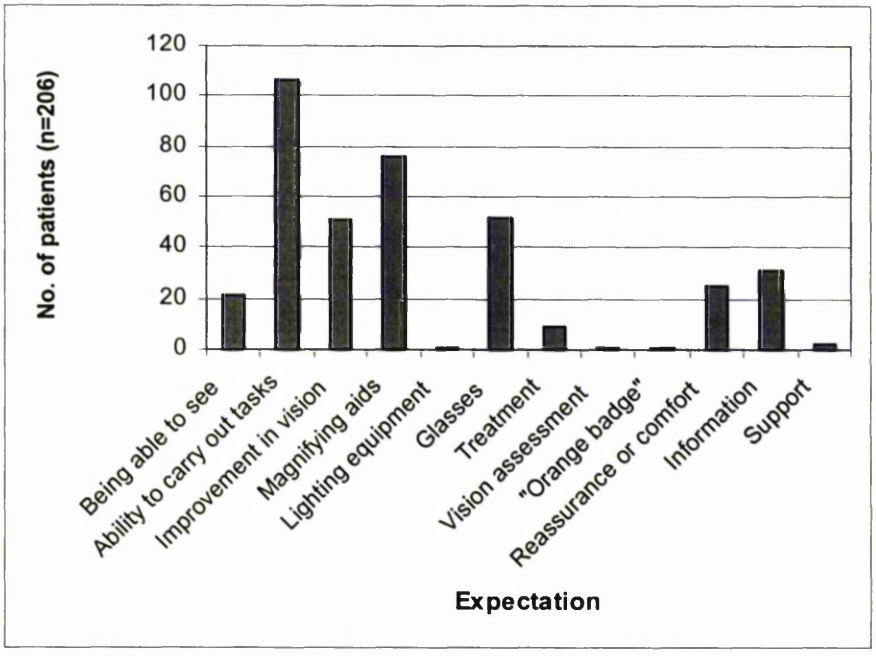
Patients were also asked how long they had been living at their current address at the time of interview. The majority of patients had been living at the same address for over five years, but 7/226 (3.1%) had changed address within a year prior to the interview, and 27/226 (11.9%) had moved house between 1-5 years prior to the interview. This question was asked on the premise that individuals with recent vision loss might experience problems associated with isolation arising from living in new and less familiar surroundings. However, the percentage of patients who do not have regular contact from family and/or friends on at least a weekly basis was lower amongst those who had changed address in the last five years, i.e. 4/34 patients (11.8%), compared to the 27/192 (14.1%) patients who had not moved house in the previous 5 years. Although a chi-square test shows that this difference is not statistically significant, this finding suggests that patients who moved house may have done so in order to live in closer proximity to their family or friends during their later years of life. Of the 194 patients interviewed at 12 months, only 2 patients had moved house. A further 5 patients who were lost to follow-up had also changed address (4 could not be traced and one had moved a long distance away) (see section 6.3). Four other patients had moved into nursing homes during the trial but were included in follow-up interviews.

Several composite variables were derived subsequently from combined responses taken from the patient background questionnaire for the purposes of testing for baseline comparability across arms (see section 8.1).

7.1.1 Patient expectations of the low vision clinic

The patient background questionnaire used at baseline also included a checklist for recording patient expectations of the first low vision clinic appointment. These findings are presented in this section since these data were gathered prior to the low vision assessment, and 7.2 below reports the findings for clinical data. Figure 7.5 presents patient expectations. Individual patients may be included in more than one category in the bar chart. The total number of patients who quoted at least one of the 'expectations' shown numbered 206/226 (91.2%). Fifteen patients (6.6%) had 'no expectations' of their appointment at the clinic and 5 (2.2%) said that they were 'unsure' of their expectations.

Figure 7.5: Patient expectations at baseline of their initial appointment at the low vision clinic



Note: 15 patients had 'no expectations' and 5 were 'unsure' of their expectations

7.2 Visual function outcomes at baseline and at follow-up

A total of 220 patients of the 226 patients recruited into the study attended their first clinic assessment. Of these patients 169 patients attended a follow-up clinic assessment scheduled to take place 2-3 months later (however, the mean elapsed time between the home visit to collect baseline outcomes and this assessment was 4 months). A total of 172 attended a scheduled 12 month follow-up assessment of whom 143 had attended the earlier follow-up assessment. Some patients had extra assessments in addition to the three scheduled clinic appointments. The frequency, timing and permutations of these assessments are described in more detail in section 6.5.1. The duration of the assessments and the staff who were involved in conducting them are described in 6.5.2.

Entering visions[†] (i.e. without correction) and visual acuities (i.e. with optimal spectacle correction), and best eye vision with or without correction at follow-up assessments are given in table 7.3 below.

Table 7.3: Best eye distance and near visions at the initial, interim and final 12-month assessments.

Assessment		n	mean	SD	min.	max.	25%ile	median	75%ile
Initial low vision assessment	**Distance unaided (logMAR)**	215	1.01	0.36	0.20	2.00	0.74	1.00	1.30
	Distance with correction (logMAR)	217	0.79	0.38	0.10	2.00	0.46	0.80	1.02
	Near unaided (M units)	163	4.51	2.43	0.32	8.00	2.50	4.00	6.30
	Near (M units with +4.00 add.)	209	2.70	2.11	0.32	8.00	1.00	2.00	4.00
2nd scheduled low vision assessment (at approx. 4 months)	**Distance with/without correction (logMAR)***	169	0.87	0.36	0.04	1.62	0.57	0.90	1.11
	Near with/without correction (M units)*	159	3.25	2.42	0.40	8.00	1.30	2.50	5.00
3rd scheduled low vision assessment (at approx. 12 months)	**Distance with/without correction (logMAR)***	172	0.96	0.39	0.02	2.00	0.70	1.01	1.18
	Near with/without correction (M units)*	151	3.75	2.56	0.40	8.00	1.60	3.20	6.3

* Note: Patients who brought their spectacles with them to the assessment and who wore the spectacles regularly, will have been asked to wear the spectacles during the assessment and therefore 'corrected' values will have been recorded; otherwise if they did not have spectacles with them or if their spectacles were of no benefit, unaided visions will have been recorded.

[†] Throughout this thesis the term "vision" is used for uncorrected or habitual visual acuity. Millodot (2000) states that both the terms "vision" and "unaided vision" are each synonymous with the term "unaided visual acuity", i.e. "visual acuity without any correction" (pages 10 and 325). The term "visual acuity" is therefore used for "best corrected acuity" in this thesis.

Figures 7.6 and 7.7 show the distributions of unaided distance vision and best eye distance acuity with correction respectively at the initial assessment. Figure 7.8 compares the distributions of best eye distance vision (i.e. with or without correction) using available data for the initial assessment and the follow-up assessments which were carried out at approximately 4 months and 12 months. Figures 7.9 and 7.10 show distributions of unaided near vision in the 'best eye' and near acuity with correction in the 'best eye' at the initial assessment. A floor effect can be seen for unaided vision[†]. As for distance vision, distributions of best eye near vision (with or without correction) are shown for each of the three scheduled assessments in figure 7.11. Not surprisingly, both distance and near vision can be seen to deteriorate over time. Table 7.4 below shows the results of t-tests (paired, two-tailed) carried out to test for statistical significance of change over time (i.e. between the initial low vision assessment and 12 month follow-up) for distance and near vision.

Table 7.4: Change over time (from initial low vision assessment to 12 month follow-up) for distance and near vision

Visual function	n	mean difference	(95% confidence interval)	t-value	p-value
Distance acuity with correction in the best eye (logMAR)	169	0.20	0.16 to 0.25	9.01	0.000*
Near acuity with correction in the best eye (M units with +4.00 add.)	150	1.13	0.81 to 1.46	6.81	0.000*

Significance levels: * $p<0.0001$

[†] A 'floor effect' occurs when many cases in a sample have measures which are near the lower limit of the scale being used. This can cause some problems in analysis since the amount of variation is reduced in the variable. The converse of this situation is described as a 'ceiling effect'.

Figure 7.6: Distribution of unaided distance vision in the 'best eye' at the initial assessment

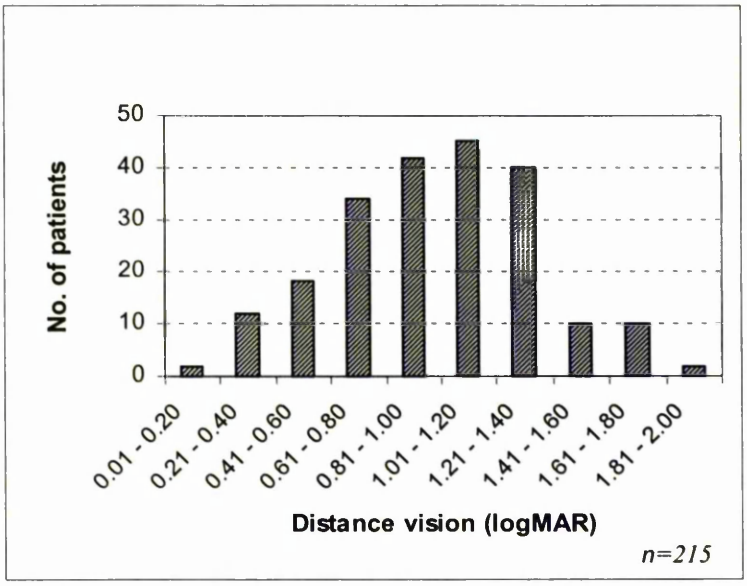


Figure 7.7: Distribution of distance acuity with correction in the 'best eye' at the initial assessment

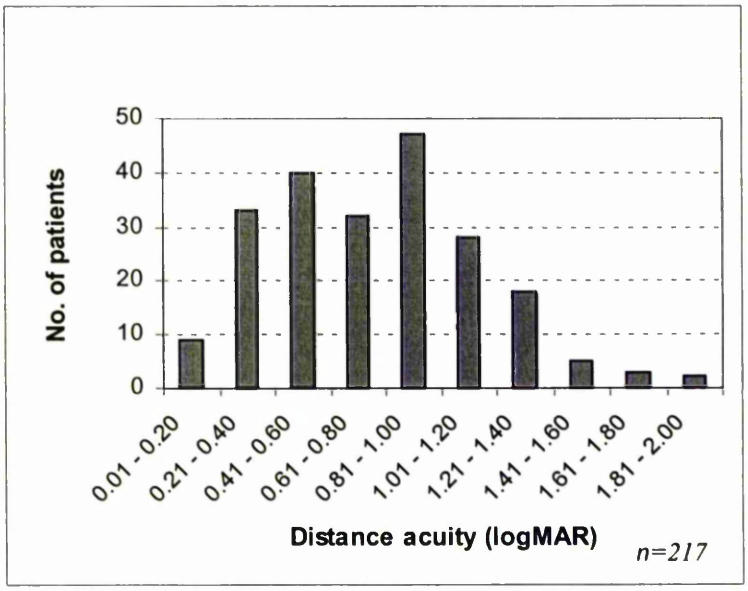


Figure 7.8: Distributions of distance vision (i.e. with or without correction) in the 'best eye' using available data for the initial assessment and the follow-up assessments which were carried out at approximately 4 months and 12 months

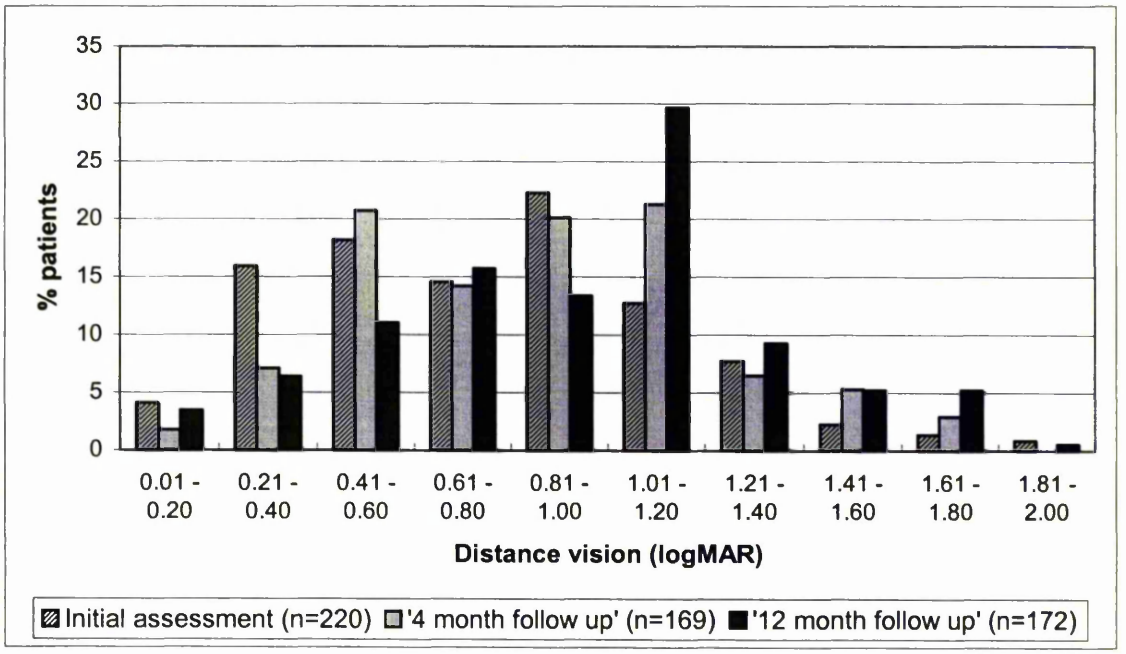


Figure 7.9: Distribution of unaided near vision in the 'best eye' at the initial assessment

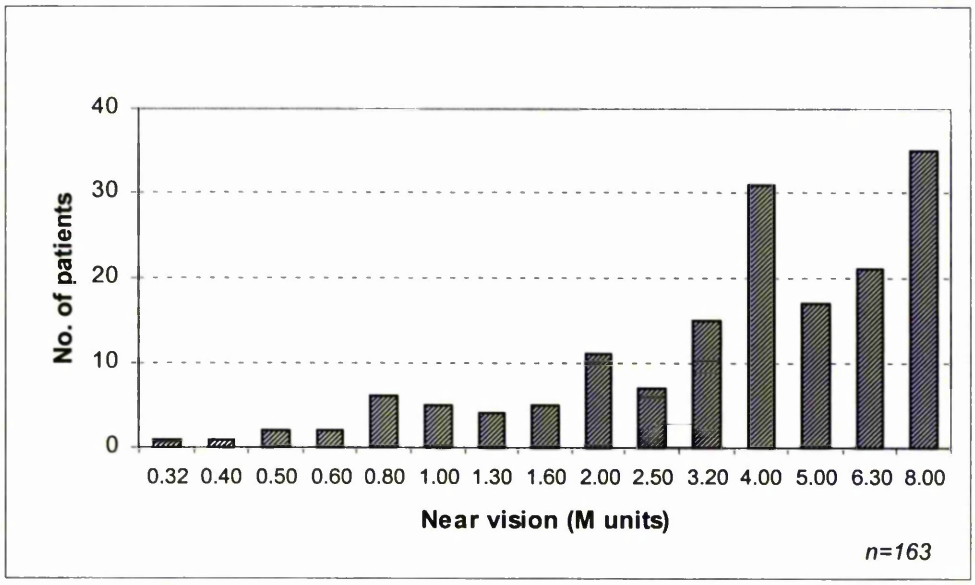


Figure 7.10: Distribution of near acuity with correction in the 'best eye' at the initial assessment

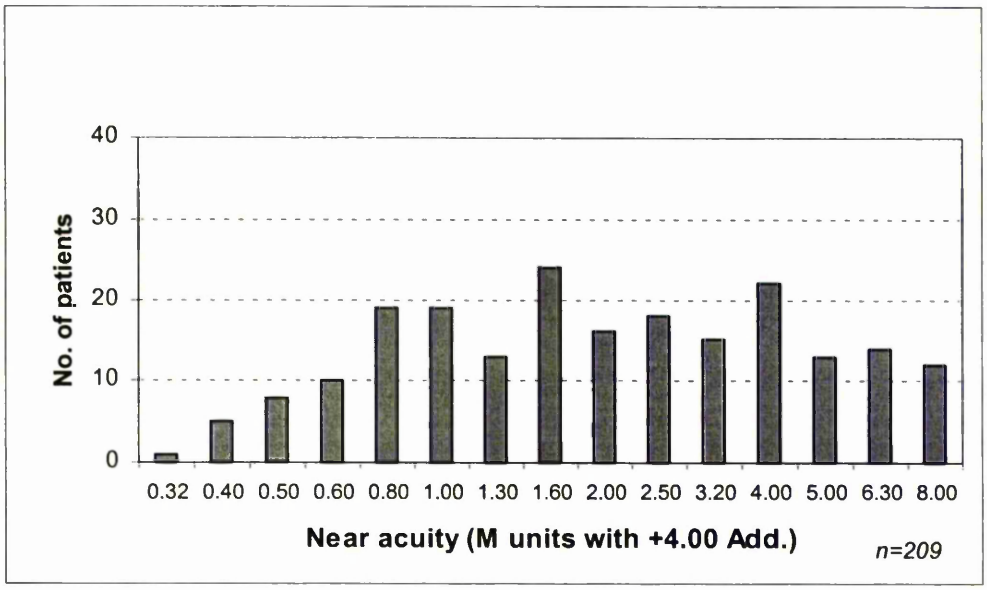
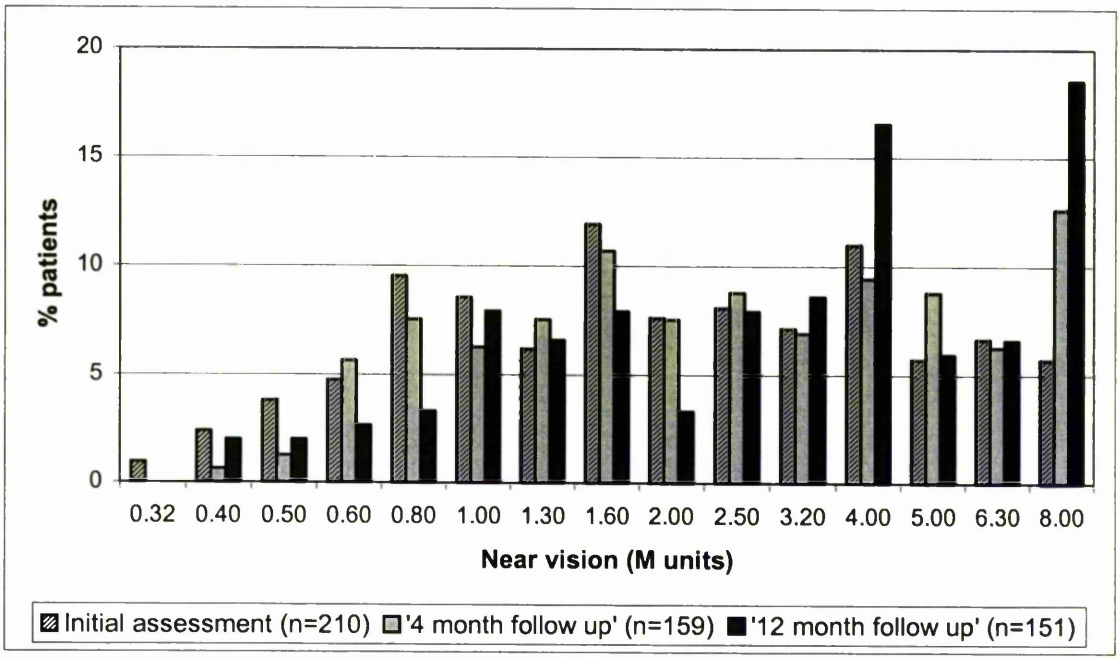


Figure 7.11: Distributions of near vision (i.e. with or without correction) in the 'best eye' using available data for the initial assessment and the follow-up assessments which were carried out at approximately 4 months and at 12 months



The distributions of contrast sensitivity in the better eye both at the initial and final 12 month assessments are shown in table 7.5. The initial and final distributions are compared in figure 7.12. The bar chart shows deterioration in contrast sensitivity over time. The results of a t-test (paired, two-tailed), given in table 7.6, show a statistically significant change over time (i.e. between baseline and 12 month follow-up) for contrast sensitivity.

Table 7.5: Contrast sensitivity in the 'best eye' at the initial and final 12-month assessments.

Assessment	n	mean	SD	min.	max.	25%ile	median	75%ile
Contrast sensitivity in the better eye at the initial assessment (logCS)	175	0.82	0.34	0.15	1.65	0.45	0.90	1.05
Contrast sensitivity in the better eye at the final 12-month assessment (logCS)	142	0.72	0.38	0.00	1.65	0.45	0.75	1.05

Figure 7.12: Distributions of best contrast sensitivity at baseline and at 12 months

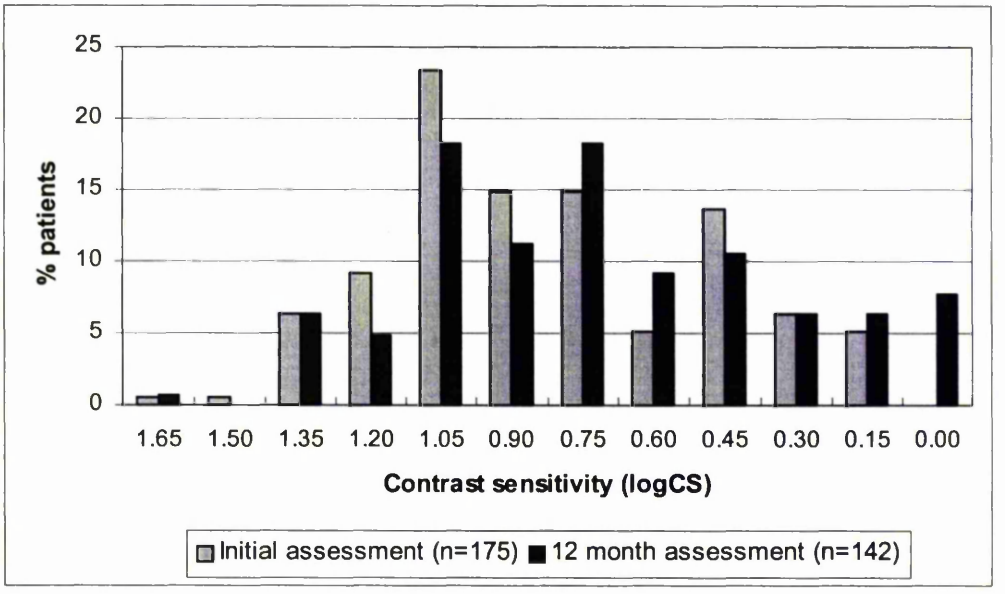


Table 7.6: Change over time (from baseline to 12 month follow-up) for contrast sensitivity

Visual function	N	mean difference	(95% confidence interval)	t-value	p-value
Contrast sensitivity (logCS)	121	0.11	0.05 to 0.17	3.49	0.001*

Significance levels: * $p<0.001$

7.3 Goals, task restriction, task performance, devices loaned and motivation

Information about rehabilitation goals, patients' abilities to carry out various ADLs, and data about the types of LVAs loaned to patients in the trial were recorded at various stages from baseline through to final 12 month follow-up. Patterns of LVA use were also recorded (see chapter 5). All of these data are described in sections 7.3.1 to 7.3.5 below.

7.3.1 Goals identified at the initial low vision assessment

Visual requirements were recorded for each patient at the initial low vision clinic assessment in order to identify initial goals (see section 3.1). These requirements are summarised in table 7.7. Reading activities, such as reading ordinary print and correspondence, were the most important requirements, and just under half of the patients wanted help with watching TV. Being able to read shop prices and labels was also frequently identified as a requirement.

Table 7.7: Main goals identified at the initial low vision assessment

Requirement	No. of patients (n=220)	% patients
Read ordinary print	171	77.7
Read large print	47	21.4
Read correspondence	121	55.0
Read shop prices, labels etc.	96	43.6
Read time on watch	15	6.8
Identify money	44	20.0
Write letters, cards etc.	53	24.1
Watch TV	109	49.5
Hobbies & interests	42	19.1
Read bus numbers, signs etc.	33	15.0
Other distance tasks	4	1.8

7.3.2 Loaned LVAs

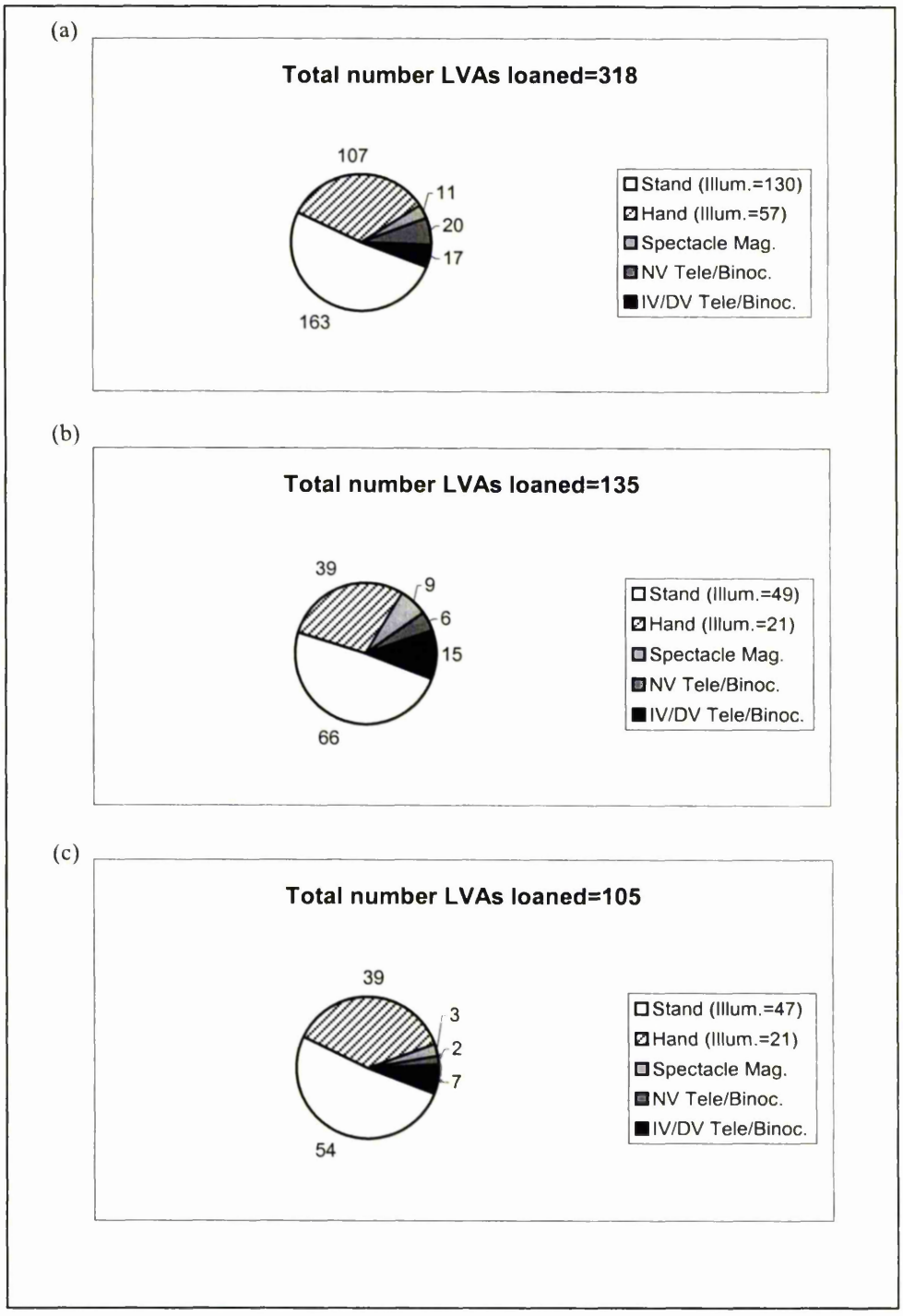
Information was recorded concerning the LVAs which were loaned to each patient. For the present purpose five categories of device were drawn up (table 7.8), to facilitate LVA analysis. Figure 7.13 shows the total numbers of LVAs by category, loaned to all patients at each of the 3 scheduled assessments.

Table 7.8: Category groups of LVAs

Types of LVAs	**LVA category group**
Hand magnifiers (illuminated & non-illuminated)	HAND
Stand magnifiers (illuminated & non-illuminated); bar; chest/suspended magnifier; flat-field/brightfield; sheet; lampstand	STAND
High reading addition; prismatic 'half-eyes'; hyperocular	SPECTACLE MAGNIFIER
Monocular/binocular telescopic devices (near vision)	NEAR VISION (NV) TELESCOPE
Monocular/binocular telescopic devices (intermediate/distance vision)	INTERMEDIATE/DISTANCE VISION (IV/DV) TELESCOPE

LVAs were also loaned/exchanged/returned sometimes at extra clinic assessments which were carried out during the trial (see 6.5.1). Furthermore, LVAs could also be exchanged during the intervention visits which took place for patients in arm 2. Therefore, in order to provide a picture over time of LVAs loaned, the percentage of patients in the trial having at least one LVA in each of the different categories of LVA were calculated for 5 time points in the trial. These percentages are shown in the individual radar plots per LVA category group figure 7.14. A further analysis of 12 month data with respect to the number of LVAs which subjects had at home and also the number reported as being used is given in section 7.3.4 below, which describes the patterns of LVA use.

Figure 7.13: Total numbers of LVAs by category, loaned to all patients at (a) the initial low vision assessment, (b) the interim scheduled assessment (at approximately 4 months), and (c) the final 12 month assessment.



Note: Numbers of patients attending assessments: (a) initial low vision assessment, n=220; (b) 4 month assessment, n=169; (c) 12 month assessment, n=172.

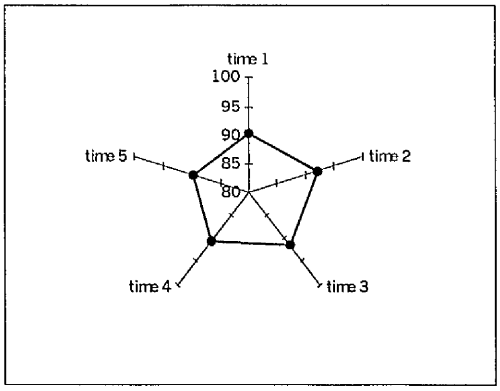
The radar plots in figure 7.14 are also used to summarise the percentage of patients with at least one LVA of any type, and at least one near vision LVA. The five time points used are: immediately after the initial assessment ('time 1'), immediately prior to the interim follow-up assessment at approximately 4 months ('time 2'), immediately after the second assessment ('time 3'), immediately prior to the final assessment at 12 months ('time 4'), and after the third assessment ('time 5'). Each plot displays changes in values (i.e. percentages of patients) relative to a centre point (i.e. the lowest value on the percentage scale) at the different points in time. For example, the change in the percentage of patients between the time points 'time 1' and 'time 2' will be explained either by new LVAs loaned and/or existing LVAs returned during any additional assessments which may been attended by patients in between the scheduled initial and second assessments, or, for patients in arm 2 due to rehabilitation officer intervention. To display changes between time points more clearly, the plots use different minimum and maximum values for their percentage scales, which are based on the range of patient percentages for each LVA category.

The radar plots show little fluctuation in the percentages of patients with at least one LVA at the different time points per LVA category group. For example, the percentage of patients with at least one LVA in any category changes little with time. The biggest change is seen in the percentage of patients with at least one hand magnifier. The percentage rises slowly but steadily with time so that at the end of 12 months participation in the trial, the percentage of patients with at least one hand magnifier increases by 9.3%. Although the percentage use of near vision telescopes / binocular devices is low overall, there is a large increase in percentage use after the second assessment, but this decreases at the subsequent time point. This reflects the emphasis placed on primary goals such as reading, requiring near vision LVAs, during the initial low vision assessment. Table 7.9 shows the values presented in the radar plots together with the number of cases (n) used in calculating each percentage value for LVA loans.

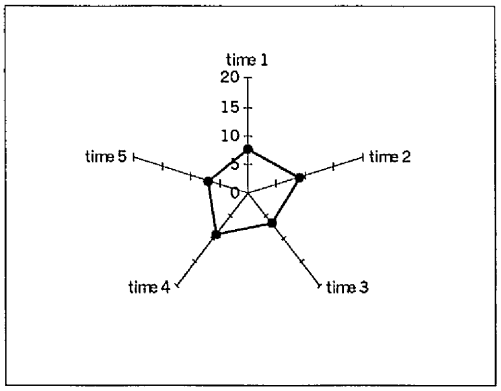
Since these plots show percentages of patients with at least one LVA on loan for each type of device category, table 7.10 provides a descriptive statistical summary of the actual numbers of LVAs which patients had on loan over time per category. There was no overall increase in the number of distance LVAs loaned to patients, however, there was a small increase in the numbers of near vision devices (apart from spectacle magnifiers) loaned to patients over time.

Figure 7.14: The percentage of patients with at least one loaned LVA for different category groups of LVAs shown over time.

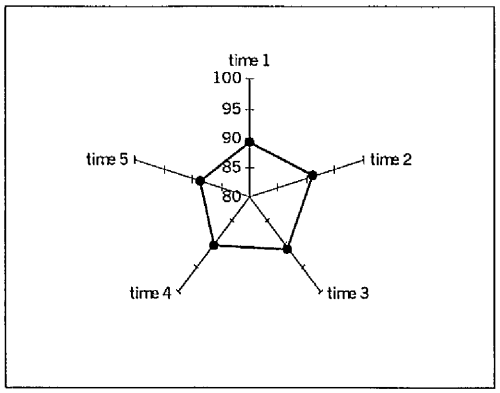
At least one LVA (any type)



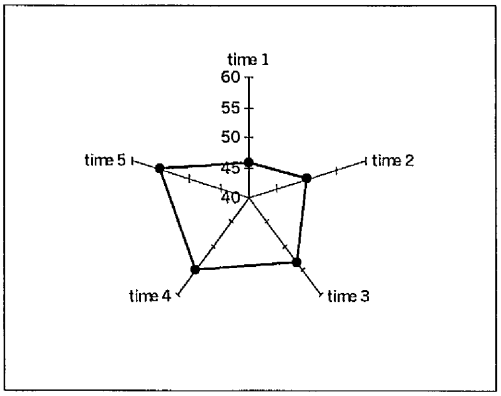
At least one distance vision LVA



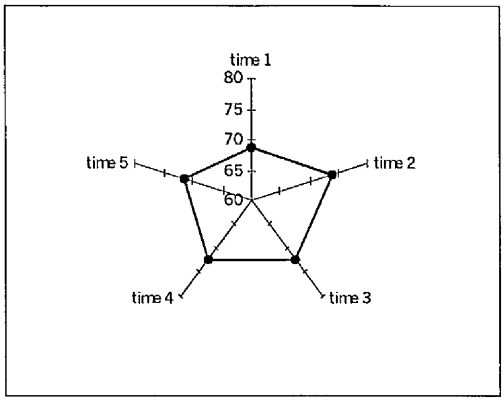
At least one near vision LVA



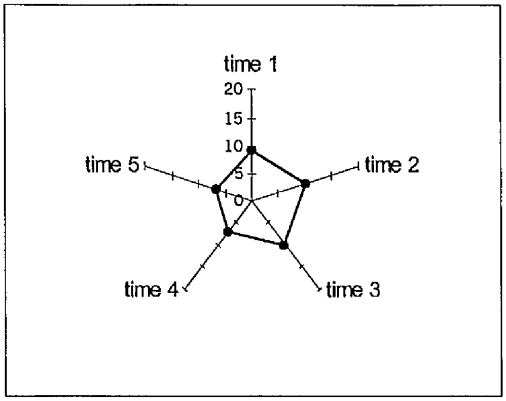
At least one hand magnifier



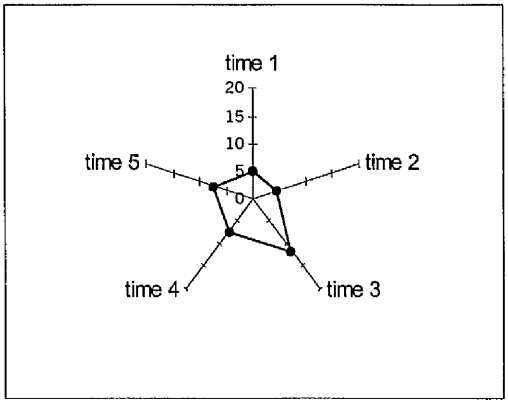
At least one stand magnifier



At least one spectacle magnifier



At least one near vision telescope/binocular device



Time points:

Time 1 = post initial assessment
Time 2 = prior to second assessment (at approximately 4 months)
Time 3 = post second assessment
Time 4 = prior to third (final) 12 months assessment
Time 5 = post third assessment

Table 7.9: The percentage of patients with at least one loaned LVA for different category groups of LVAs shown over time.

Type of LVA	Post initial assessment		Prior to 2nd ('4 month') assessment		Post 2nd assessment		Prior to 3rd (final) follow-up assessment		Post 3rd assessment	
	% patients	n	% patients	n	% patients	n	% patients	n	% patients	N
Any (distance or near)	90.0	220	92.1	215	91.6	215	90.6	203	89.5	200
Any distance vision	7.7	220	8.9	214	6.5	215	8.8	204	7.0	201
Any near vision	89.1	220	91.2	215	90.7	215	90.1	203	88.5	200
Hand	45.9	220	50.0	214	53.3	214	54.7	203	55.2	201
Stand	68.6	220	74.0	215	72.1	215	72.1	201	71.5	200
Spectacle magnifier	9.1	220	9.8	215	9.8	214	6.9	203	6.5	201
Near vision telescope/binocular	5.0	220	4.7	215	11.6	215	7.4	204	7.5	201

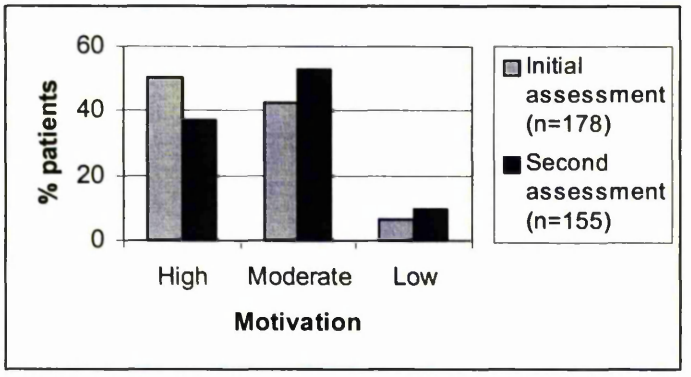
Table 7.10: Summary of the numbers of LVAs (per LVA category) which patients had on loan over time

LVA group	Post initial assessment			Prior to 2nd ('4 month') assessment			Post 2nd assessment			Prior to 3rd (final) follow-up assessment			Post 3rd assessment		
	mean no.	median	range	mean no.	median	range	mean no.	median	range	mean no.	median	range	mean no.	median	range
All (distance or near)	1.48	1.0	0 – 4	1.66	2.0	0 – 5	1.80	2.0	0 – 5	1.80	2.0	0 – 5	1.86	2.0	0 – 6
All distance vision	0.08	0.0	0 – 1	0.09	0.0	0 – 2	0.07	0.0	0 – 1	0.10	0.0	0 – 2	0.07	0.0	0 – 2
All near vision	1.37	1.0	0 – 4	1.54	2.0	0 – 4	1.53	1.0	0 – 4	1.55	1.0	0 – 4	1.75	2.0	0 – 6
Hand	0.49	0.0	0 – 2	0.56	0.5	0 – 4	0.61	1.0	0 – 2	0.64	1.0	0 – 2	0.66	1.0	0 – 3
Stand	0.74	1.0	0 - 2	0.84	1.0	0 – 2	0.90	1.0	0 – 4	0.93	1.0	0 – 4	0.94	1.0	0 – 4
Spec. mag.	0.09	0.0	0 – 1	0.10	0.0	0 – 1	0.10	0.0	0 – 1	0.07	0.0	0 – 2	0.06	0.0	0 – 1
Near vision telescope /binoc.	0.05	0.0	0 – 1	0.05	0.0	0 – 2	0.07	0.0	0 – 1	0.08	0.0	0 -2	0.08	0.0	0 - 2

(see Table 7.9 above for n values).

At the end of each clinic assessment optometrists also graded a subject's 'motivation', which was intended to estimate their subjective rating of patient motivation in the use of the LVAs loaned during the assessment (see appendix 5 for the data sheet used during the initial clinic assessment). The motivation rating was only recorded at the initial and first scheduled follow-up (i.e. at approximately 4 months) assessments in the trial. Optometrist ranked patient motivation scores are presented in figure 7.15. The chart shows that optometrists' perception of patient motivation declined between the initial and second assessments.

Figure 7.15: Optometrist rated patient motivation with respect to LVA use at the initial and second low vision assessments



7.3.3 Self-rated task restriction measures and task performance

Patients were asked about restrictions in common ADLs and/or leisure activities at both baseline and final home visits (see MLVQ in appendix 11). They were also asked about the helpfulness of LVAs (which some patients may have obtained prior to their initial low vision assessment from sources outside of the HES) in carrying out such activities, and the extent of dependency on others. These data were also recorded at the final home visit (see the 'tasks and use of LVAs' matrix of the MLVQ given in appendix 11). Two composite variables representing an overall average task restriction measure and an average reading restriction measure were calculated using individual items of information. The former was calculated by dividing the number of activities which a patient wanted to do 'a lot' but was unable to carry out (with or without an LVA), by the total number of activities which the patient wanted to do 'a lot'. A subject was excluded from this analysis (i.e. did not have a restriction measure allocated) if the total

number of tasks which they wanted to do numbered fewer than 10/20[†]. This composite self-rated restriction measure can take any value between 0 to 1 on a continuous scale where 0 represents no restriction and 1 represents the highest level of restriction i.e. where the individual is unable to do any of the tasks that they wanted to be able to do. Similarly, an average reading restriction measure was calculated using a subset of the six reading tasks from the MLVQ. Subjects who wanted to do less than five of these tasks were excluded from analysis. The average restriction measures at both baseline and at 12 months are shown in table 7.11 and distributions of both scores are shown in figure 7.16. The difference in average reading restriction scores over time was not found to be statistically significant (t-test, paired, two-tailed). However, the overall average task restriction score showed borderline significance in a t-test (paired, two-tailed) on 172 subjects for whom data was available at baseline and follow-up (mean difference=0.02, 95% confidence intervals of 0.003 to 0.05, t-value=1.75, p=0.082).

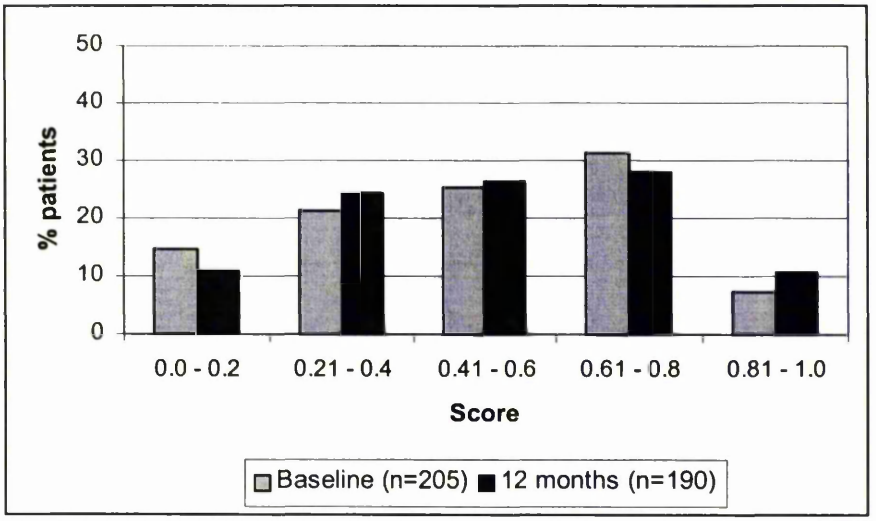
Table 7.11: Average restriction measures at baseline and at 12 month follow-up

Score	N	mean	SD	min.	max.	25% ile	median	75% ile
Average task restriction at baseline	205/226	0.49	0.25	0.00	0.94	0.31	0.53	0.71
Average reading restriction at baseline	146/226	0.62	0.33	0.00	1.00	0.40	0.67	1.00
Average task restriction at follow-up	190/194	0.50	0.23	0.00	1.00	0.29	0.53	0.67
Average reading restriction at follow-up	91/194	0.56	0.35	0.00	1.00	0.20	0.60	1.00

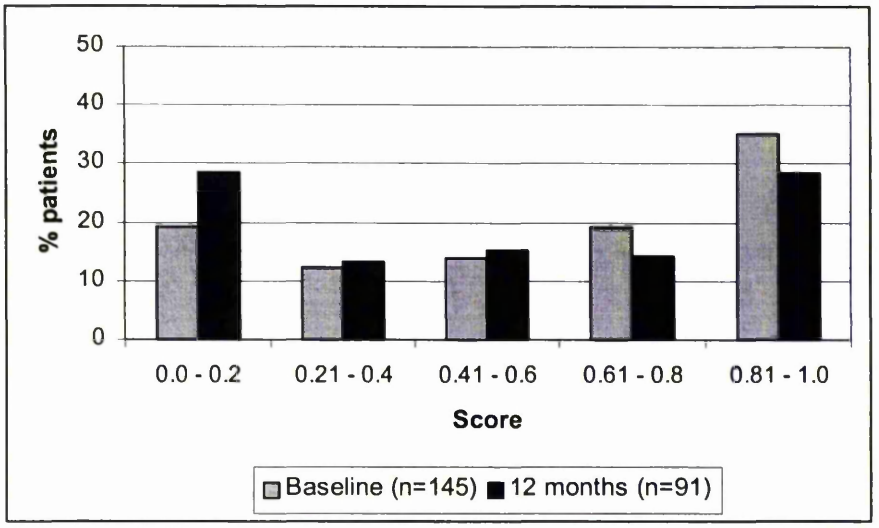
[†] The size of n decreased relative to the reduction in the number of tasks which a patient wanted to do. The criteria used for subject exclusion from score derivation (i.e. less than 10/20 ADLs and less than 5/6 reading tasks) were chosen to improve the precision of the calculation of task restriction scores.

Figure 7.16: Distributions of (a) average task restriction measures, and (b) average reading restriction measures, at baseline and at 12 month follow-up

(a) Average task restriction measures



(b) Average reading restriction measures



Note: 0 represents no restriction, 1.0 represents the highest level of restriction (i.e. inability to do any of the tasks included in the scoring process).

Measures of task performance were completed at the 12 month home visit as part of the final outcomes dataset (see 5.4.1). Each patient's ability to perform five ADLs dependent on vision was assessed, all of which necessitated reading. Patients were instructed to use an LVA (of their own preference) if they wished to do so in attempting each task. Two of the tasks involved reading the 'use-by-date' on grocery items, i.e. a meat item and a bakery product. The third task was to read the pharmacy instructions (two components, namely the name of the medicine and the dosage) on a medicine bottle label. For the fourth task the subject was timed when asked to read twelve items on a shopping list. The fifth task of completing an application form for 'Talking Books', which involved both reading and writing activities, was not analysed due to a reluctance amongst patients to try the task (see 6.9.1). For each of the four remaining tasks included in the analysis, the minority of patients who declined to attempt a particular task were pooled together with those who failed to achieve the task. Therefore the number of cases (n) represented in each analysis included patients who attempted and declined to attempt each task. Since 194 patients were visited at 12 months follow-up the difference between 'n' and 194 represents missing data. The extent of successful achievement of these tasks is given in table 7.12(a).

From the four reading tasks that were widely completed, a 'reading task score' (RTS) was calculated, based on a 'points' system. The maximum number of points possible is 18, which in turn gives the 'best' reading percentage score of 100%. Three points were given for each correct 'use-by-date' identification (derived on the basis of one point for locating the date, plus one point for reading the day component of the date, and one point for reading the month correctly). Six points were given for the correct identification of the pharmacy instructions (three points for the name of the medicine and three points for the correct dosage). Finally up to 6 points were given for the shopping list reading task, i.e. half a point for each of the twelve items correctly read. The percentage scores obtained are summarised in table 7.12(b) and a distribution of the scores is shown in figure 7.17. The average time taken by subjects to read the shopping list was 60 seconds (S.D.=61.6; minimum=10; maximum=300; 25%ile=22; 75%ile=80).

Table 7.12(c) shows the proportion of patients who used a magnifier for each specific task.

Table 7.12: Measured task performance at 12 months

(a) The extent of successful achievement of tasks at 12 months

Task	Task achievement							
	N	No. of patients	%	No. of patients	%	No. of patients	%	
Identify use-by-date on meat & bakery items	192	*Neither date read*		*One date read*		*Both dates read*		
		60	31.3	63	32.8	69	35.9	
Identify name & dosage of medicine	192	*Neither part read*		*Medicine / dose read*		*Medicine and dose read*		
		87	45.3	13	6.8	92	47.9	
Read 12 items on a shopping list	N	mean	SD	Min	max	25%ile	50%ile	75%ile
	171	9.66	3.67	0.0	12.0	9.0	12.0	12.0

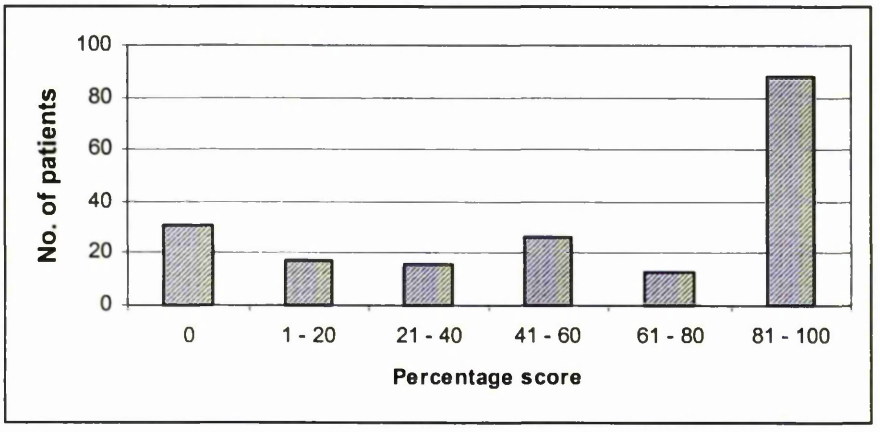
(b) RTS (%) at 12 months

Percentage reading score based on task components in table 7.12(a)	N	mean	SD	min	max	25%ile	50%ile	75%ile
	191	58.48	38.44	0.0	100.0	19.44	66.67	100.0

(c) The proportion of patients who used a magnifier for each specific task.

Task	n	No. of patients who used LVA	%
Identify use-by-date on meat item	192	150	78.1
Identify use-by-date on bakery item	192	144	75.0
Identify medicine & dosage	192	143	74.5
Read shopping list	171	132	77.2

Figure 7.17: Distribution of RTS (%) at 12 months



Note: 0 % = worst RTS, 100 % = best RTS

7.3.4 LVA process measures

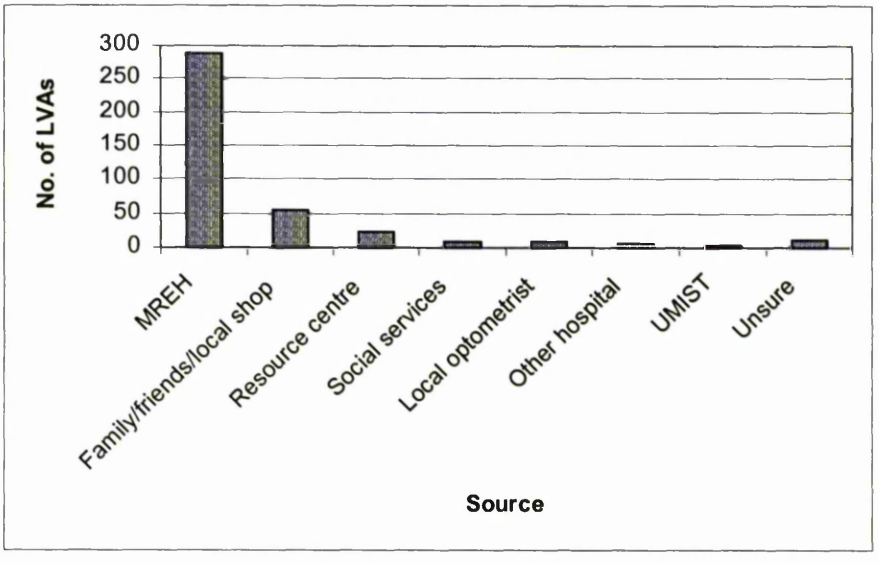
LVA process measures (frequency and average duration of use, longest duration of continuous use and difficulties experienced in using LVAs) were recorded as part of the MLVQ at the final home visit (see appendix 11). In addition a short version of the MLVQ was administered by telephone at approximately 4 months into the trial in order to gain additional information about the patterns of LVA use after a few months had elapsed since the initial low vision assessment (see sections 5.4.2 and 6.4.1, and also appendix 11), and again at approximately 15 months (i.e. after the final outcomes had been assessed, but also after the 12 month low vision assessment). The data obtained at 15 months are outside the scope of this thesis, but were included to inform possible follow-up needs.

Because of the complexity of the MLVQ data concerning patterns of LVA use at 12 months follow-up, and for the purposes of analysis, it was necessary to reduce the data into a set of composite variables. The MLVQ collected information about frequency and duration of use as well as difficulties in use for up to five LVAs per patient. These LVAs were not all necessarily loaned by the MREH since patients may have obtained some LVAs from other sources. LVAs could have been obtained, for example, from social services, the optometry department at UMIST (University of Manchester Institute for Science and Technology), a different hospital, a resource centre (e.g. Henshaws), from a high-street optometrist, a retail outlet, or from family or friends. The bar chart in figure 7.18 below presents this information, showing that the majority of LVAs were provided by the HES clinic. When describing patterns of LVA use, all of the LVAs irrespective of source, were included in the analysis.

Firstly, one LVA was identified for each patient as being the 'most important', i.e. primary, aid. The percentage of patients who had at least one LVA at home was 93.8% (182/194). If a patient only had one LVA at home, this LVA became identified as the primary aid by default. For those patients who had two or more LVAs at home, the designation of the primary aid was based on the following nested criteria: the LVA used most often, then the longest average period of continuous use, then the longest period of continuous use during the preceding 4 weeks, and then on the least number (if any) of specific difficulties the patient had reported with respect to the use of the LVA. Secondly, having identified a primary aid, the patterns of use associated with this aid with respect to frequency, duration and difficulties in use were identified per patient.

Similarly, since 66% (128/194) patients had at least 2 LVAs at home at 12 months, the secondary aid and associated patterns of use were also identified for these patients. At least three devices were reported as loaned to or owned by 25.8% of patients. Twelve patients (i.e. 12/194, 6.2%) did not have any LVAs at 12 month follow-up. Therefore, patterns of use for the primary aid, at 12 months, are based on data for 182/194 subjects, and patterns of use for the secondary aid are based on data for 128/194 subjects..

Figure 7.18: Sources of LVAs on loan to / owned by patients at 12 months



When the short version of the MLVQ was administered at 4 months, however, patients were asked how often they had used any magnifier in the previous week, and what the longest period of continuous use had been, taking all LVAs which the patient had at home into account. Since the short MLVQ did not capture information on patterns of use per LVA it was inappropriate to gauge the average duration of continuous use when referring to potentially more than one LVA. The short version MLVQ recorded the number of different LVAs each patient had used in the preceding 4 weeks. In addition, patients were asked to report the nature of different tasks attempted with an LVA.

The bar chart in figure 7.19 shows the number of LVAs which patients reported being used at approximately 4 months into the trial compared with the numbers of LVAs which were reported being used at 12 months. At least one device was reported being used by 86.1% of subjects at 4 months, and by 94.5% of subjects (i.e. those who had at least one LVA at home) at 12 months. The types of primary aid (using the LVA

categories as defined in section 7.3.2) derived for patients at 12 months are shown in figure 7.20. Figure 7.22(a) and (b) show the frequency and longest duration of LVA use compared for 4 month data with 12 month data respectively, based on 'any magnifier' for the former, and the primary aid for the latter. Figure 7.22(c) shows the average duration of continuous use based on the primary aid for 12 month data only. The types of secondary aid are shown in figure 7.21, and the distributions of the frequency of use, average duration of continuous use and the longest duration of continuous use of the secondary aid are shown in figure 7.23. Of the subjects who had at least two LVAs (i.e. those included in analyses of the secondary aid), 78.9% reported having used the secondary aid during the 4 weeks prior to the 12 month interview. The number of patients reporting various activities attempted with a magnifier are compared with the visual goals identified at the initial low vision assessment a few months before (see 7.3.1 above) in figure 7.24.

Figure 7.19: The number of LVAs which patients had reported being used at approximately 4 months into the trial compared with the numbers of LVAs which were being used at 12 months

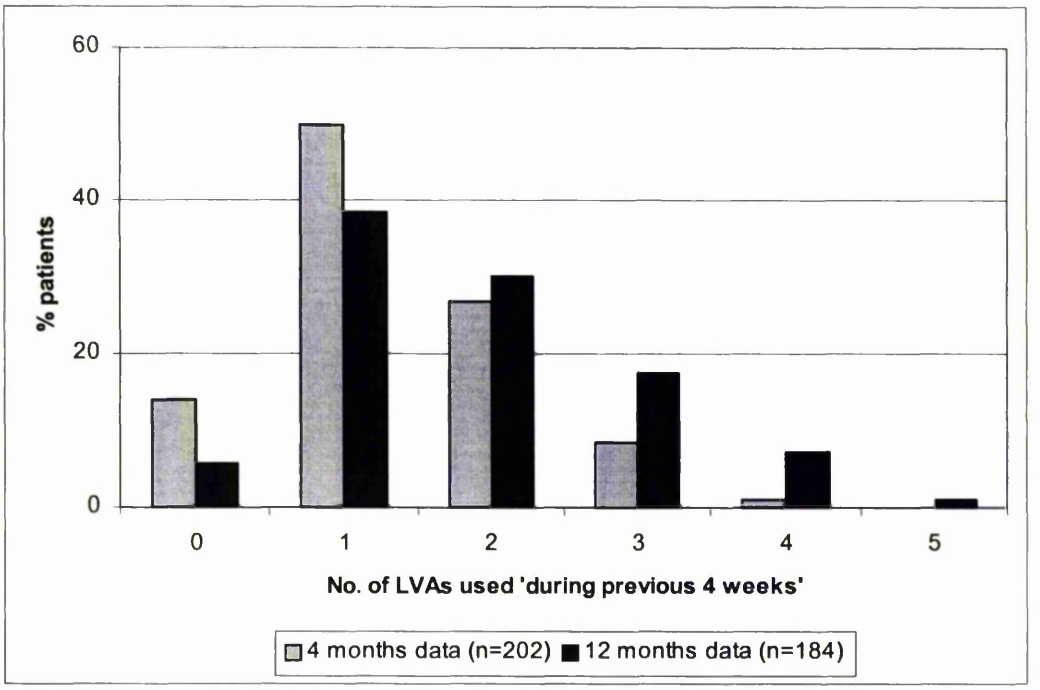
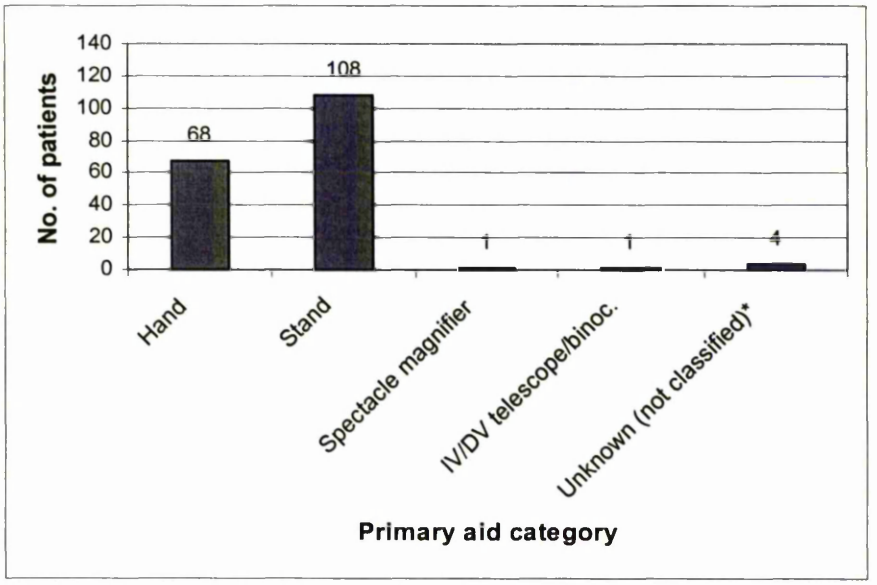


Figure 7.20: The types of primary aid derived for patients at 12 months



* Subjects were unable to locate their LVAs for the researcher to classify during the final interview

Figure 7.21: The types of secondary aid derived for patients at 12 months

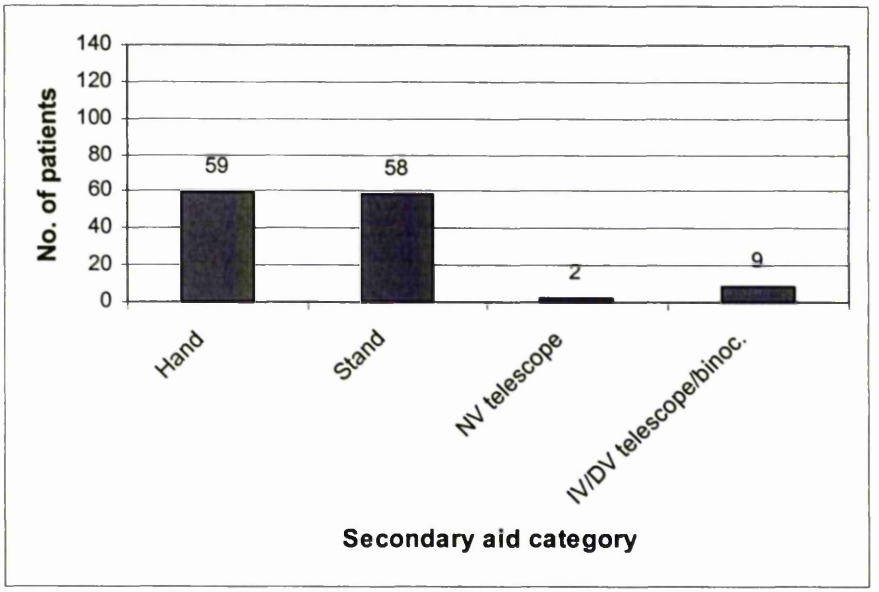
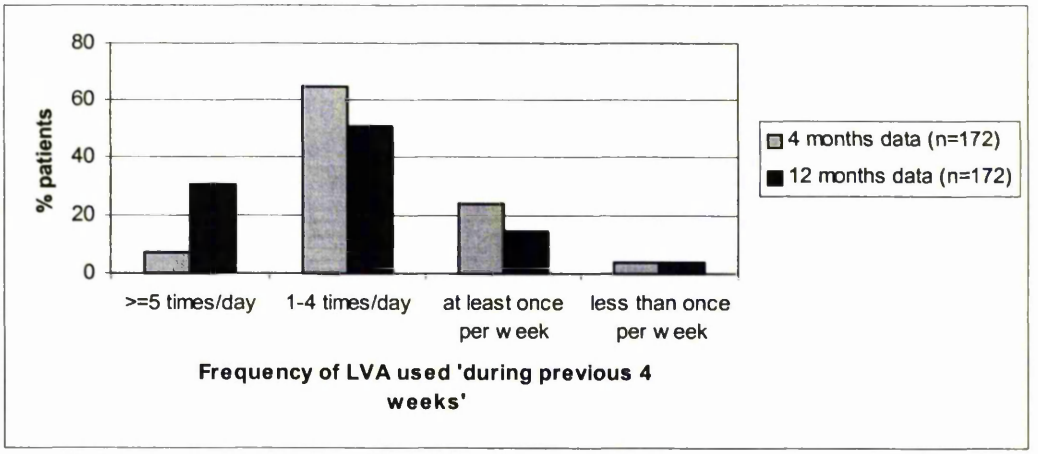
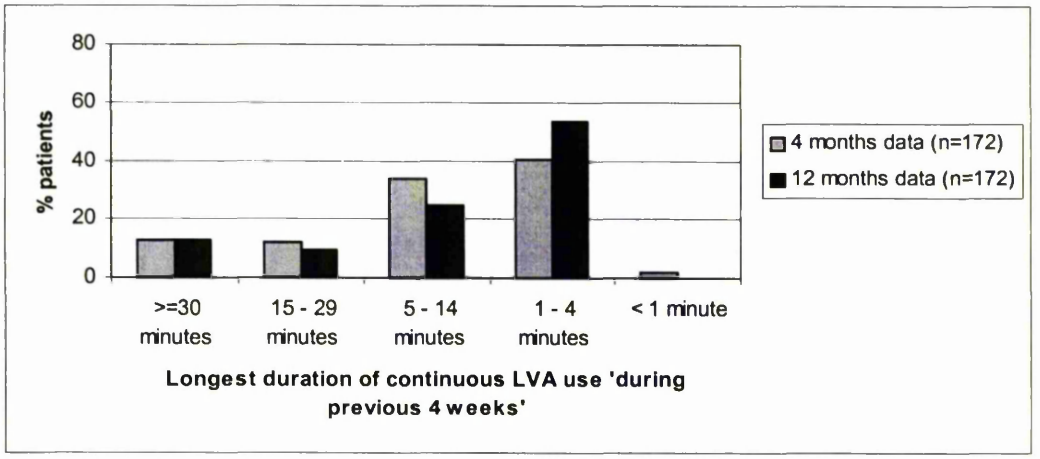


Figure 7.22: Patterns of LVA use for the 86.1% and 94.5% of patients using at least one device at 4 months and at 12 months respectively

(a) Frequency of LVA use 'during previous 4 weeks' compared for data collected at 4 months (for any magnifier) with data collected at 12 months (for the primary aid)



(b) Longest duration of continuous LVA use 'during previous 4 weeks' compared for data collected at 4 months (for any magnifier) with data collected at 12 months (for the primary aid)



(c) Average duration of continuous LVA use 'during previous 4 weeks' at 12 months (for the primary aid)

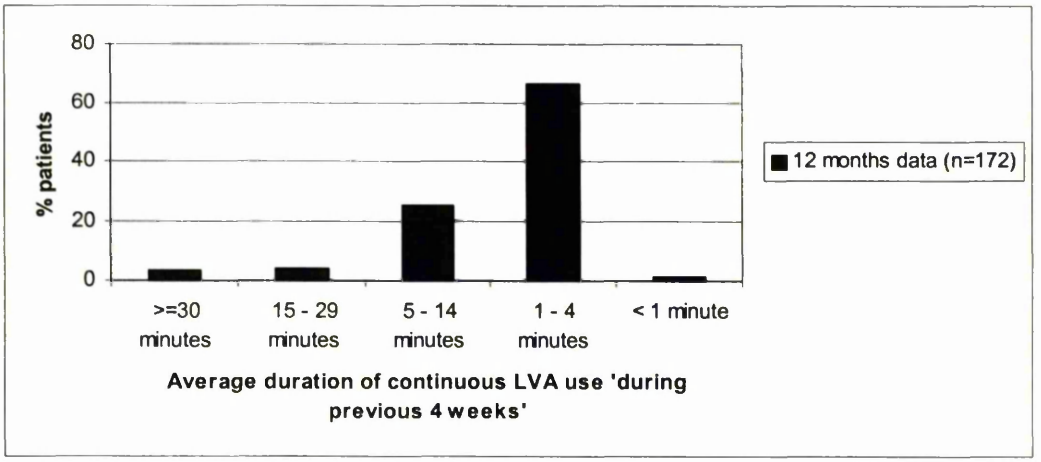
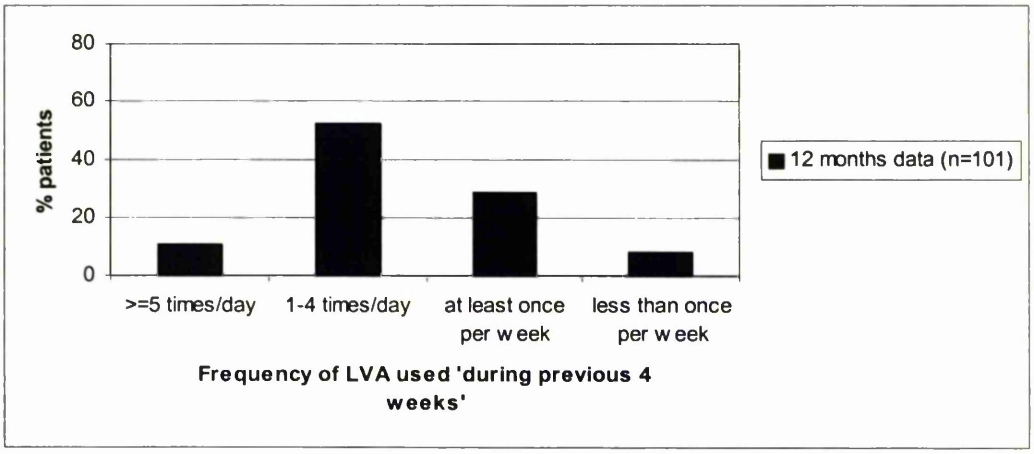
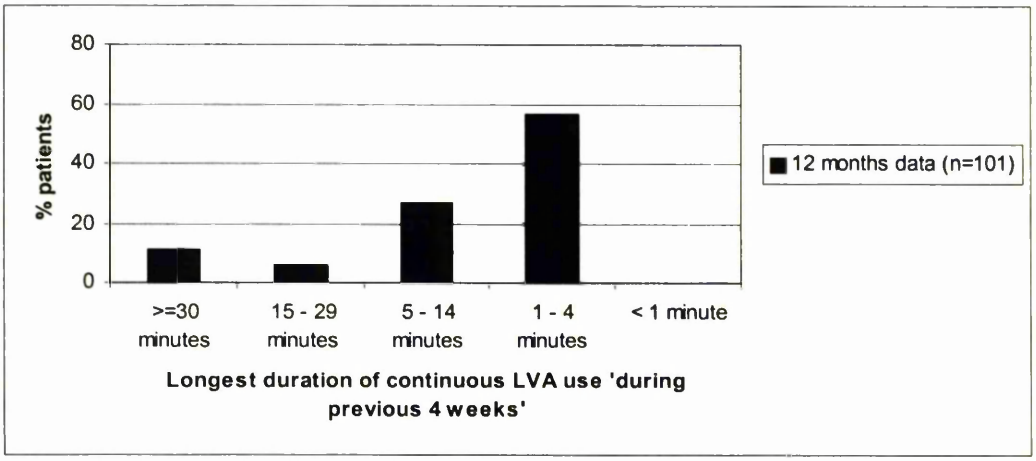


Figure 7.23: Patterns of device use for the 78.9% of patients using their secondary aid at 12 months

(a) Frequency of LVA use 'during previous 4 weeks' at 12 months (for the secondary aid)



(b) Longest duration of continuous LVA use 'during previous 4 weeks' at 12 months (for the secondary aid)



(c) Average duration of continuous LVA use 'during previous 4 weeks' at 12 months (for the secondary aid)

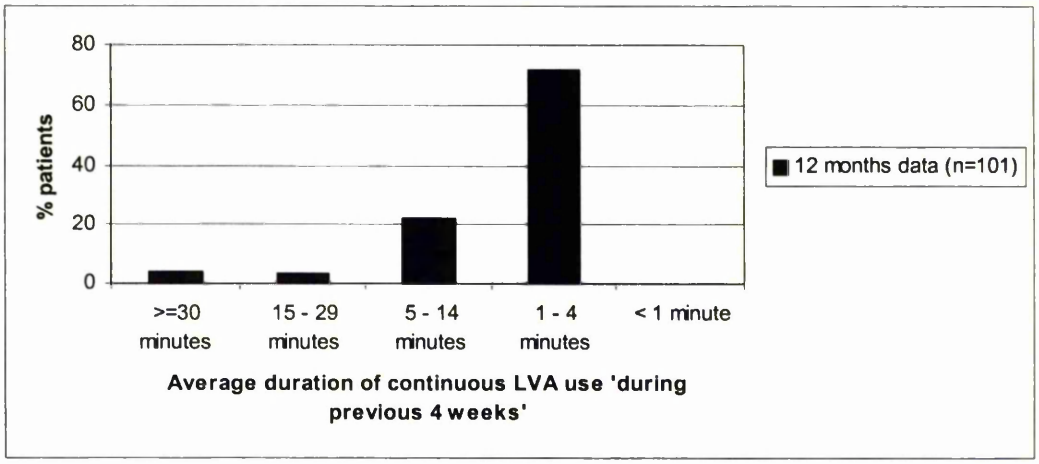
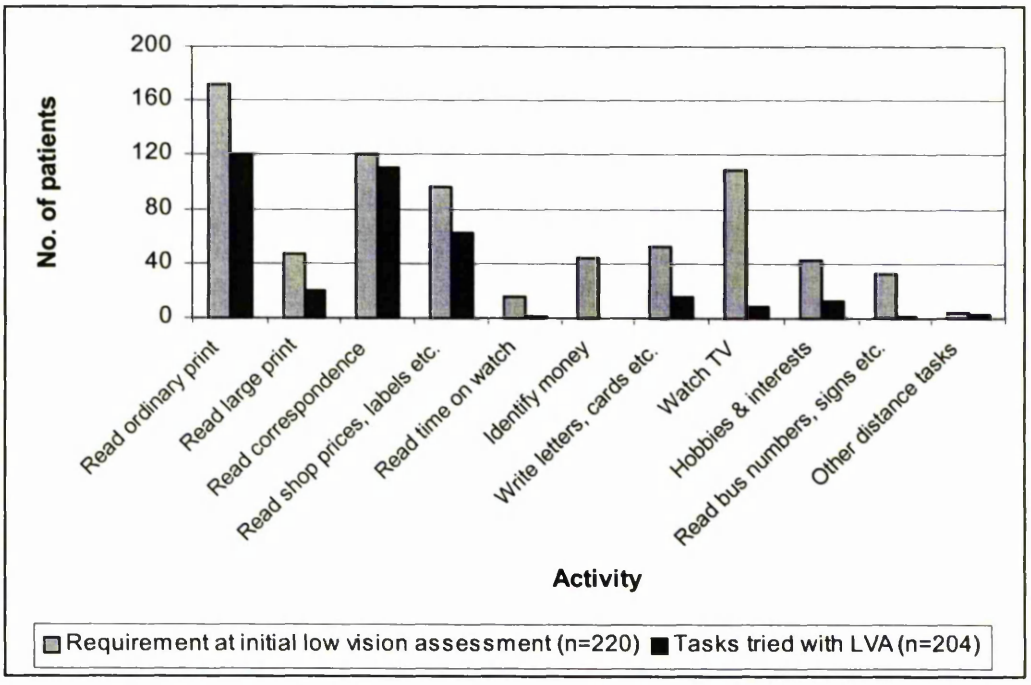


Figure 7.24: The number of patients reporting various activities attempted with an LVA at 4 months, compared with the goals* identified at the initial low vision assessment



* clearly some goals are met through non-optical strategies, e.g. sitting close to the TV, the use of coin holders etc.

The level of difficulty experienced by patients in using LVAs was also recorded at 12 months. Figure 7.25 shows the frequency of use for a total of 385 LVAs for 182 patients as a function of the extent of difficulties experienced. Not surprisingly, the frequency of use is greater where less difficulty is experienced. The reasons for difficulty are shown in figure 7.26.

Figure 7.25: Frequency of use of LVAs in relation to the extent of difficulties experienced at 12 months

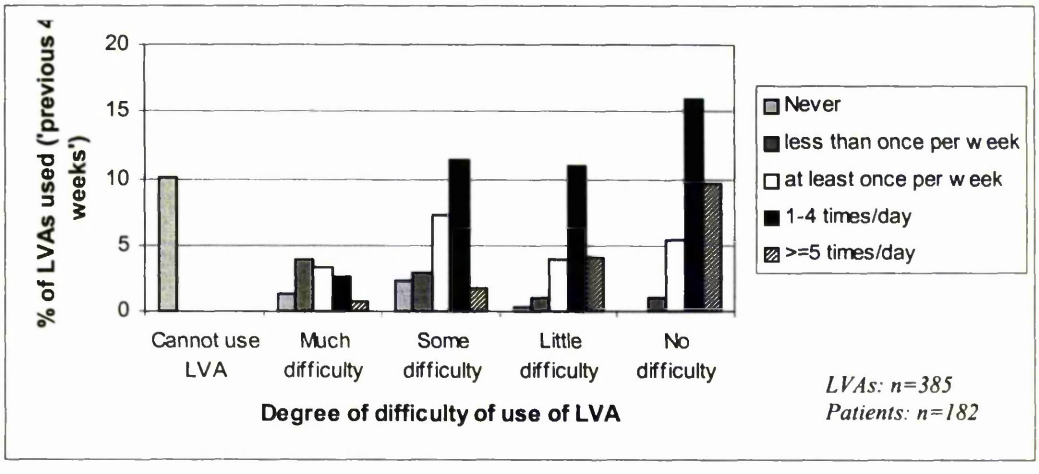
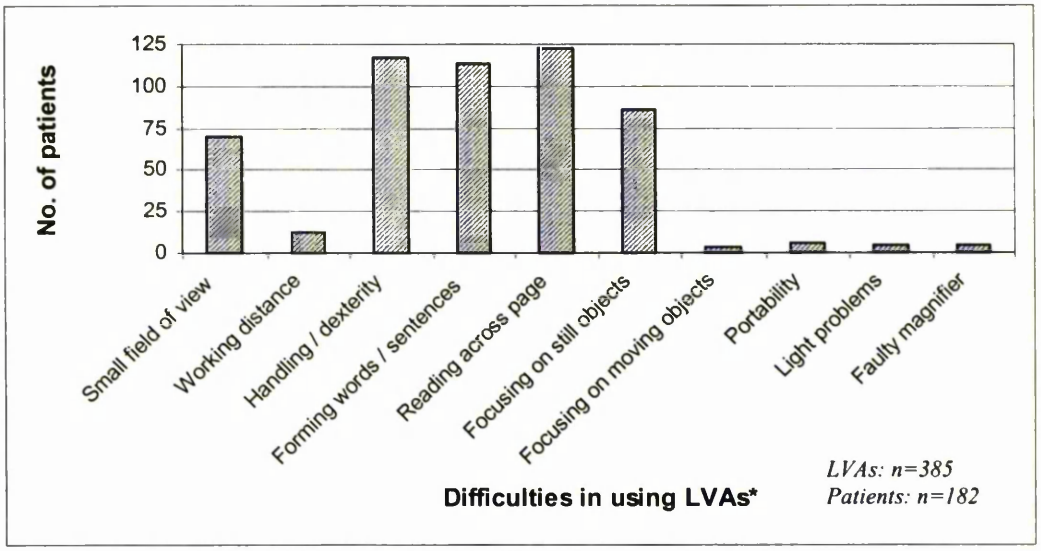


Figure 7.26: Reasons specified for difficulty in using LVAs (during the previous 4 weeks) at 12 months



* Some patients stated more than one reason per LVA

In summary, the key findings concerning LVA process measures are:

- The majority of LVAs were provided to patients through the HES
- At 12 months (n=194), 93.8% of patients had one or more LVAs at home, 66% had two or more LVAs, and 25.8% had three or more LVAs; 6.2% had no LVAs
- 86.1% of patients (n=202) and 94.5% of patients (n=182) had used at least one LVA during the previous 4 weeks, at 4 months and at 12 months in the trial respectively
- 78.9% (n=128) of patients at 12 months reported using their 'secondary aid' during the previous 4 weeks
- an analysis of patterns of LVA use was conducted for the 'primary aid' (at 4 months and at 12 months in the trial) and also for the 'secondary aid' (at 12 months only):
    - the majority of patients reported using both their primary aids and their secondary aids between 1-4 times daily during the study
    - the majority of patients reported the longest period of continuous use for both primary and secondary aids was between 1-4 minutes
    - the majority of patients reported that the average duration of continuous use for both primary and secondary aids was between 1-4 minutes
    - the frequency of LVA use was greater where less difficulty in use was experienced
    - the most frequently cited difficulties in using LVAs (based on 182 patients and 385 LVAs, at 12 months) were: 'reading across page', 'forming words/sentences', 'handling/dexterity', 'focusing on still objects', and 'small field of view'
- the most commonly used LVAs were stand and hand devices
- the types of activities attempted with an LVA at 4 months reported by 204 patients showed that fewer patients were using their LVAs than the number of patients (n=220) who had originally identified the same required activities at their initial low vision assessment; the activities most frequently attempted included reading tasks (e.g. correspondence, shop prices and labels, and ordinary print)

7.3.5 Task group priorities

Data was collected with respect to goals and self-rated restriction for specific tasks, (see section 7.3.3), and patients were also asked to prioritise different 'task groupings' in a ranking exercise. This process took place during the home visits to collect baseline and final outcomes. Appendix 11 shows the priority ranking matrix appended to the MLVQ. Patients rated the importance of each 'task group' in the matrix over the other 'task groups', thereby allowing ranking to be determined for the task groups. Since there were 7 task groups in the matrix, each group could rank between 1 (highest priority) and 7 (lowest priority). The task group priorities at baseline and 12 months are shown in table 7.13, in order of decreasing priority at 12 months, and showing some changes in priority over time. It is of note that reading is not ranked highest at baseline (although there is little difference between the mean rank values for reading, going out/socialising, and special interests/hobbies) given the importance placed on reading as a primary goal in low vision rehabilitation.

Table 7.13: Task group priorities at baseline and at 12 months, in order of decreasing priority at 12 months

Task group	Ranking data								
	Baseline/ 12 mths	n	Mean (overall priority ranking)	SD	min.	max.	25 %ile	median	75 %ile
Reading activities (e.g. correspondence, books, papers)	Baseline	226	3.00 **(3)**	1.77	1.0	7.0	1.0	3.0	4.0
	12 mths	192	1.88 **(1)**	1.27	1.0	6.0	1.0	1.0	3.0
Going out / socialising (e.g. shopping, pub, day trips)	Baseline	226	2.81 **(1)**	1.81	1.0	7.0	1.0	2.0	4.0
	12 mths	192	3.09 **(2)**	1.68	1.0	7.0	2.0	3.0	4.0
Interests / hobbies	Baseline	226	2.88 **(2)**	1.47	1.0	7.0	2.0	3.0	4.0
	12 mths	192	3.32 **(3)**	1.35	1.0	7.0	2.0	3.0	4.0
Writing activities (e.g. letters, cards, form filling)	Baseline	226	5.08 **(6)**	1.66	1.0	7.0	4.0	6.0	6.0
	12 mths	192	4.08 **(4)**	1.75	1.0	7.0	2.0	4.0	6.0
Watching TV	Baseline	226	4.80 **(5)**	1.58	1.0	7.0	4.0	5.0	6.0
	12 mths	192	5.00 **(5)**	1.63	1.0	7.0	4.0	5.25	6.0
Housework (e.g. cleaning, cooking, washing)	Baseline	226	4.27 **(4)**	1.73	1.0	7.0	3.0	4.0	6.0
	12 mths	192	5.09 **(6)**	1.43	1.0	7.0	4.0	5.0	6.0
Maintenance activities (e.g. household repairs)	Baseline	226	5.16 **(7)**	1.96	1.0	7.0	3.0	6.0	7.0
	12 mths	192	5.53 **(7)**	1.79	1.0	7.0	4.0	6.25	7.0

7.4 Knowledge of AMD and use of residual vision, and perceived benefit of attending the clinic

The MLVQ administered at baseline and 12 month follow-up contained multiple choice questions (MCQs) which tested patients' basic knowledge of AMD and the use of residual vision. Both the MLVQ used at 12 month follow-up and the short version of the MLVQ (see appendix 11) administered at approximately 4 months included a mix of closed and open questions to obtain patient views on the low vision clinic service (these questions were not asked at baseline, since the first home interview occurred prior to the initial low vision assessment).

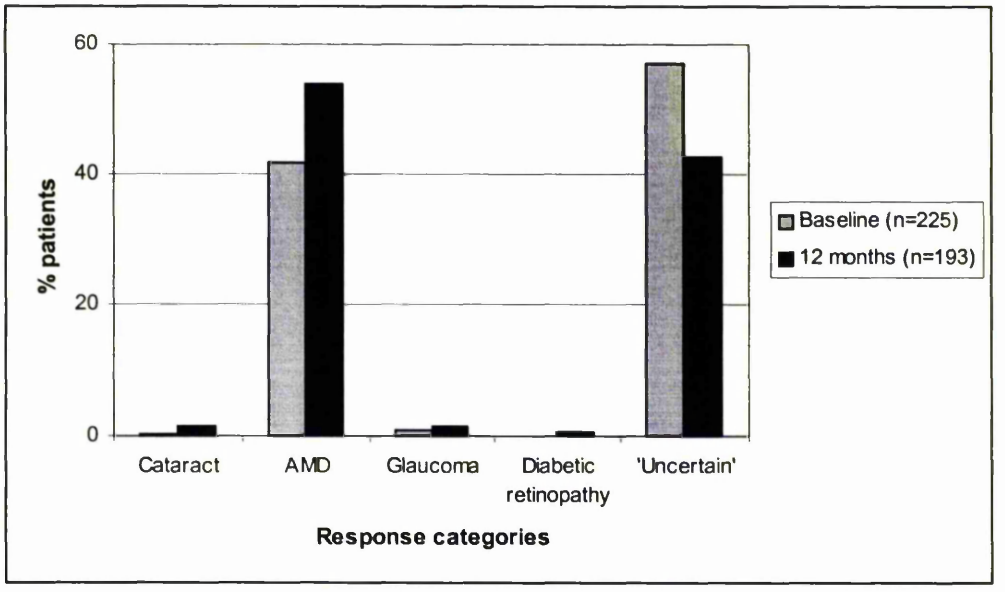
7.4.1 Knowledge of AMD and the use of residual vision

Two MCQs were used to assess basic understanding of AMD. One question required the patient to choose the correct medical name for their eye condition from a list of five MCQ answers, and for the other question the patient was asked to identify correctly the part of the eye affected by AMD, again from a list of five answers. For each of these questions a residual category response of 'uncertain' was not offered to the patient and this category was used by the researcher only if the patient was clearly unable to choose from the other responses offered. Figure 7.27 (a) and (b) shows the percentage of patients who provided the correct answers to each question (i.e. 'AMD' and 'the central part of the retina at the back of the eye' respectively), as well as the percentages who gave each of the wrong answers, both at baseline and 12 month follow-up. The results show that although knowledge of AMD improved during the 12 months of the trial, at follow-up only ~54% of patients knew the correct answer with respect to the cause of their low vision, and ~40% were aware of the part of the eye affected. These findings are disappointing since, in addition to the explanations offered by the ophthalmologist at the time of diagnosis, large print literature about AMD was also provided by the optometrist at the low vision assessment. Furthermore, a patient support worker also aimed to reinforce information on diagnosis and prognosis on a routine basis.

Patient understanding of the use of their residual vision was assessed using three statements about key issues with respect to education in the use of residual vision. Patients were asked to agree / disagree with each statement by choosing a response from a five-point Likert scale. The topics covered by these statements and numbers of correct answers given at baseline and follow-up are shown in figure 7.28 (a), (b) and (c).

Figure 7.27: Percentages of patients for each response to (a) an MCQ concerning the medical name for the main cause of their vision loss, and (b) an MCQ concerning the part of the eye affected, compared for baseline with 12 month follow-up

(a) 'cause of low vision'



(b) 'part of the eye affected'

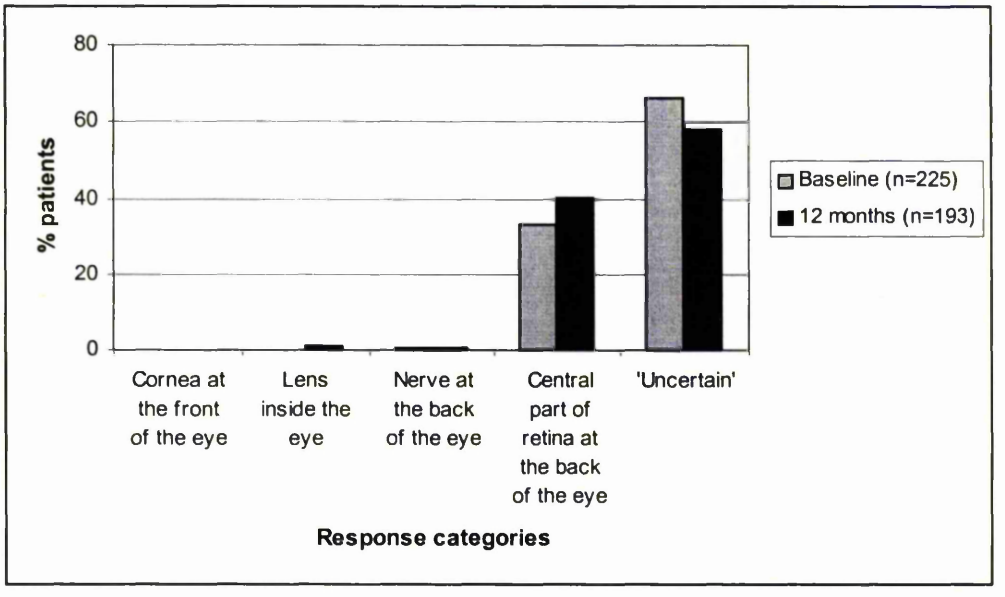
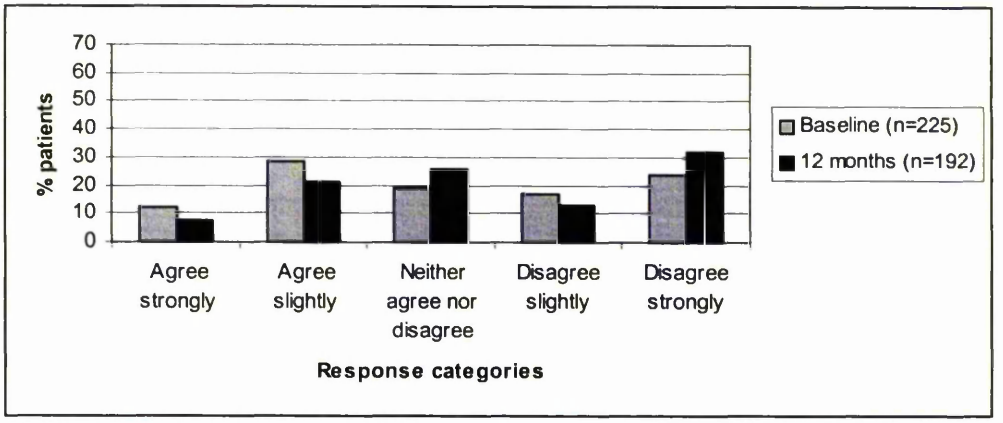


Figure 7.28: Assessment of patients' understanding of the use of their residual vision at baseline and at 12 month follow-up

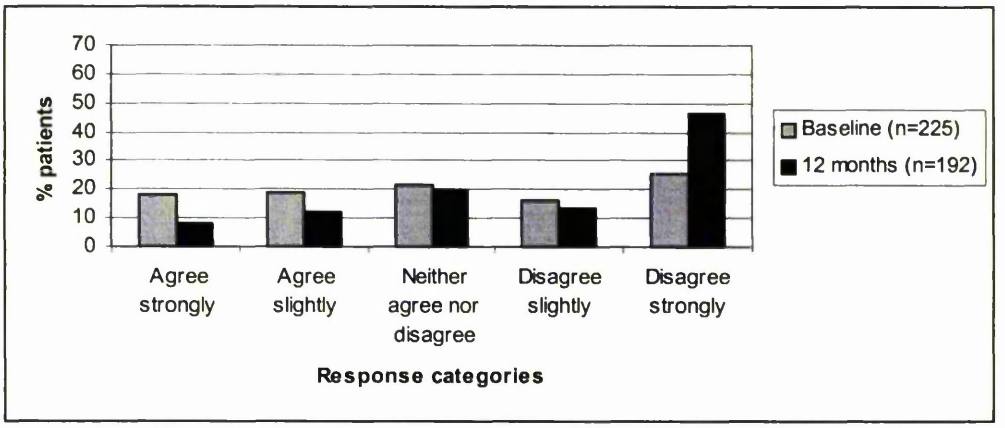
(a) Patient percentages for responses to the statement:

"Using your eyes too much will make your remaining vision worse"



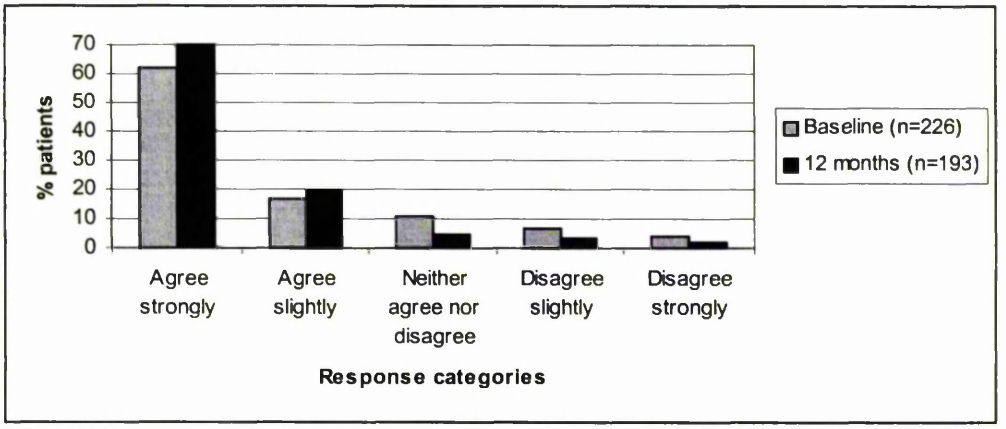
(b) Patient percentages for responses to the statement:

"Sitting too close to the TV causes your eyesight to worsen"



(c) Patient percentages for responses to the statement:

"When you are reading, more light will improve your ability to see"



The findings at 12 months showed some improvement in the awareness of the issues assessed compared to those at baseline. However, many patients still demonstrated some uncertainty with respect to these issues. For example, at baseline ~41% of patients correctly disagreed to some extent that *'using your eyes too much will make your remaining vision worse'*. At 12 month follow-up this percentage was comparable at ~45%. This change was not significant (McNemar's Chi-square test[†], p=0.52). Furthermore, although the percentage of patients who incorrectly agreed with this statement decreased from 40% to 29%, the percentage of patients who were uncertain of the correct response rose from 19% to 26%. There was a significant improvement in awareness over time with respect to sitting close to a TV (McNemar's Chi-square test, p=0.000). At baseline 41.3% correctly disagreed to some extent that *'sitting too close to the TV causes your eyesight to worsen'*. This percentage increased to 59.9% at 12 months. The final statement that *'when you are reading, more light will improve your ability to see'* had the highest percentage of correct response both at baseline and follow-up, with a significant increase in understanding demonstrated over time (McNemar's Chi-square test, p=0.003). The percentage of responses which correctly agreed to some extent with this statement rose from 78.7% at baseline to 90.1% at 12 months.

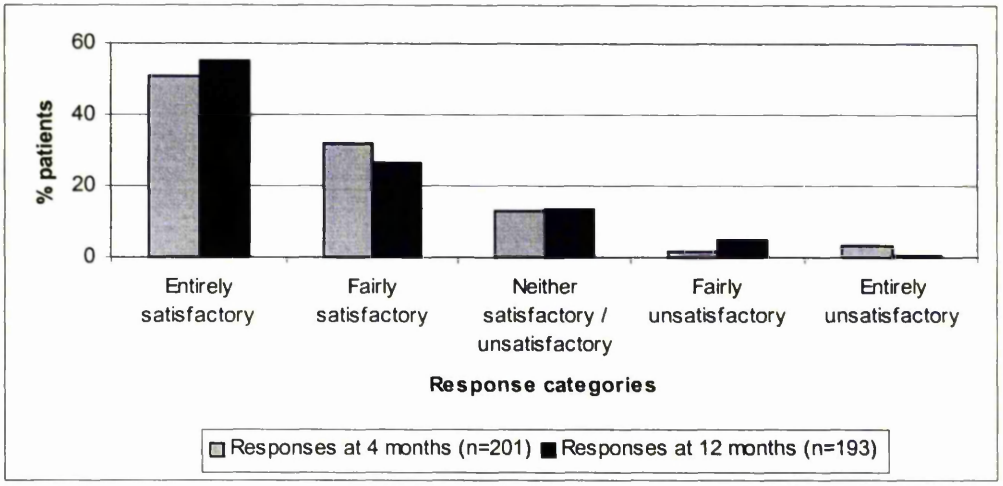
7.4.2 Benefits of attending the clinic

Patients were asked to rate how satisfactory the explanation about the use of LVAs had been at the most recent low vision assessment attended and also how helpful the visit(s) to the clinic had been overall. In addition, by using open questions, patients were invited to say what they had been most satisfied or pleased with, and conversely what they had been most disappointed with, in relation to attending the clinic. Patient views on each of the closed questions are compared at both 4 and 12 months follow-up in figure 7.29(a) and (b) respectively. The comments made in response to the open questions closely matched some of the categories which emerged on expectations of the low vision clinic that patients stated at baseline (described in section 7.1.1). Comments relating to satisfaction with the clinic service at 4 months and at 12 months are compared against the initial expectations at baseline in figure 7.30(a). Figure 7.30(b) shows the aspects of the clinic service with which patients felt most disappointed.

[†] McNemar's Chi-square test is used to test for differences in the same sample such as in 'before-and-after' studies (Bland, 1995).

Figure 7.29: Responses to questions about the low vision clinic service

(a) Patient satisfaction with the explanation received on the use of magnifiers from low vision clinic staff



(b) Patient responses relating to the 'helpfulness' of their visits to the low vision clinic

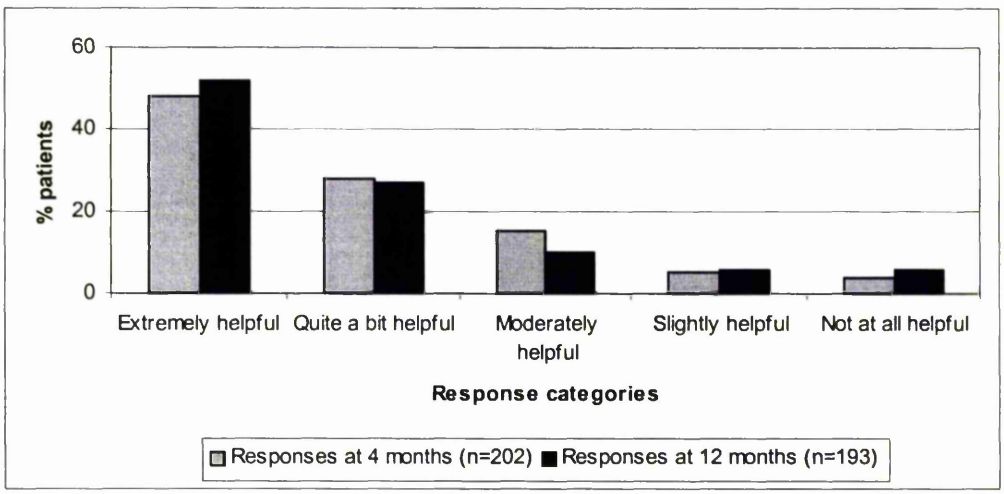
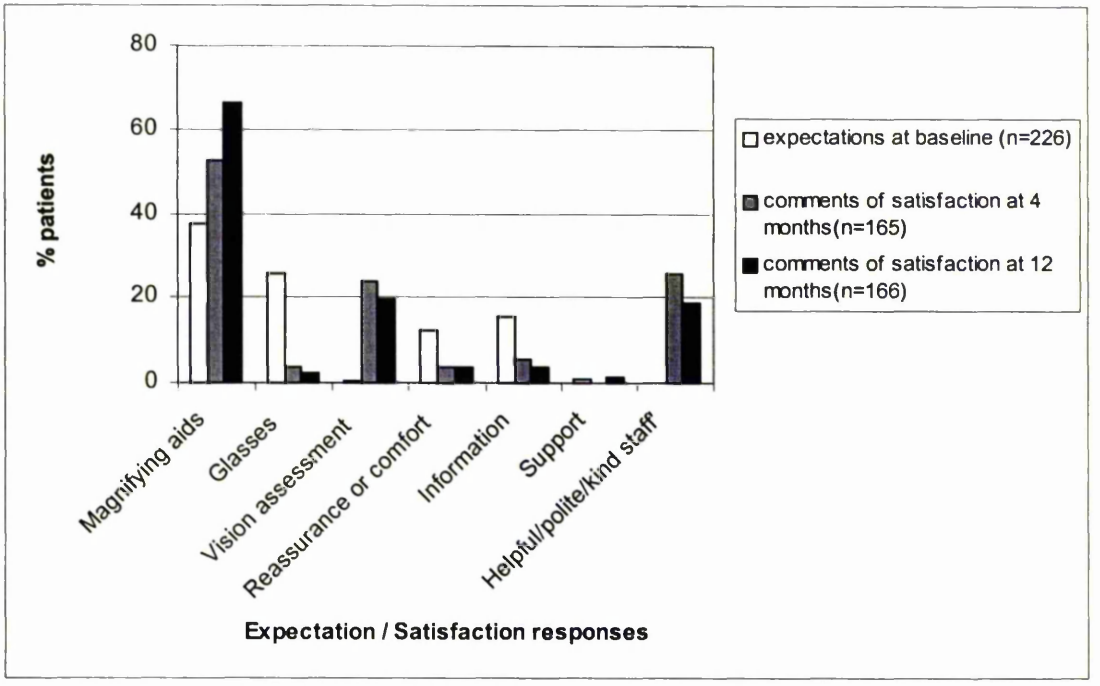
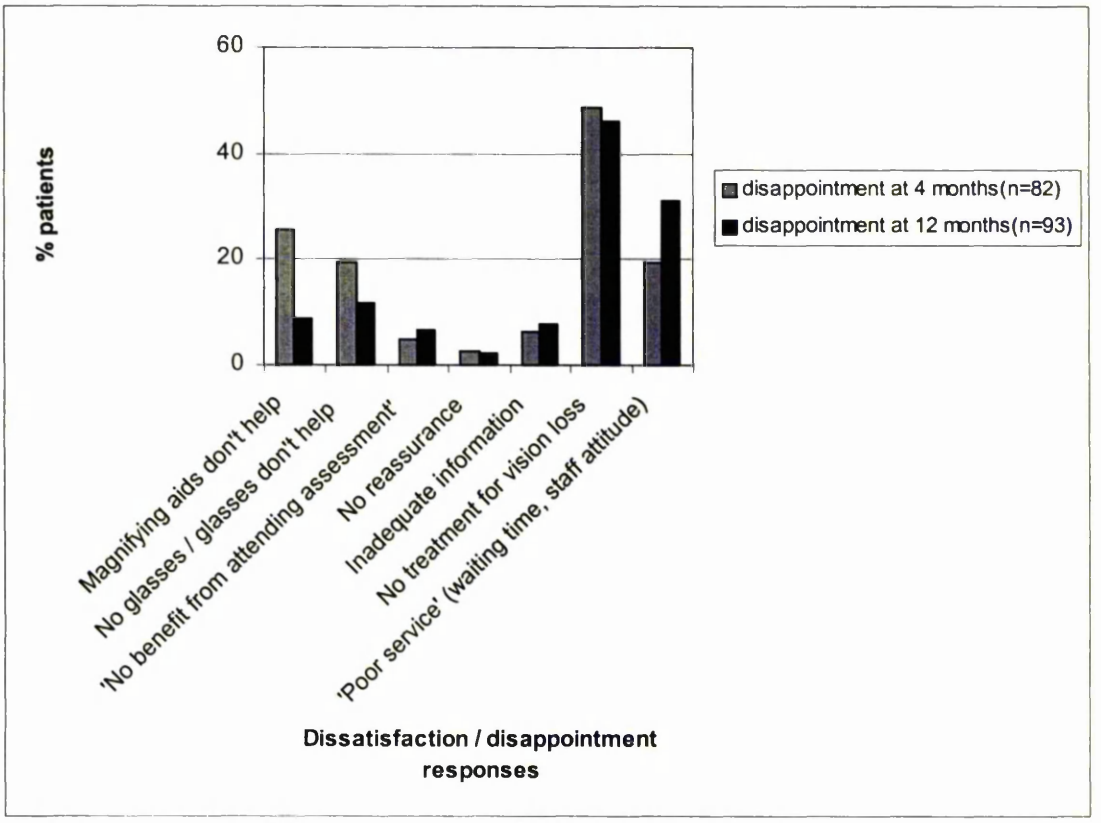


Figure 7.30: Benefits of attending the clinic

(a) Aspects of the clinic service with which patients were most satisfied, reported at 4 months and at 12 months, in comparison to initial expectations at baseline



(b) Aspects of the clinic service with which patients were most disappointed, reported at 4 months and at 12 months



7.5 QoL (SF-36 and VCM1) and psychological (NAS) outcomes at baseline and follow-up

A summary of the main outcomes at baseline and at 12 month follow-up is given below.

7.5.1 SF-36

From the raw data recorded on the questionnaires, scores were computed for each scale and then transformed to summary scores ranging from 0 to 100 (i.e. 'worst' to 'best' states) according to the SF-36 Scoring Manual (Medical Outcomes Trust, 1994). Distributions of the summary scores for each of the 9 dimensions of the SF-36 are shown in table 7.14 and in figure 7.31. Figure 7.31 uses the same sample size (n) values for each dimension as shown in table 7.14. According to Ware *et al* (1993) the use of means and standard deviations to describe SF-36 dimension data, which is commonplace in the literature, can 'camouflage important aspects' of the data such as skewness. Ware *et al* (1993) therefore recommend the use of percentiles in addition to means to describe dimension distributions more clearly and also highlight the importance of breaking down SF-36 data by sub-groups, if appropriate, for the population being studied, (for example, grouping on age intervals, sex, social class etc.). The participants in this trial are an elderly, retired population and therefore sub-group analysis of SF-36 scores is not relevant. However, sub-groups are used in a comparison of the SF-36 data against previously published normative data, described in section 7.6 below.

With the exception of 'change in health' the scores for all of the remaining SF-36 dimensions show some deterioration over time between baseline and follow-up. This finding is not surprising given the age profile of the study population.

In addition to using individual dimension scores, two summary measures, namely the physical component summary (PCS) score, and the mental component summary (MCS) score, were calculated (Jenkinson *et al*, 1996). The developers of the SF-36 suggest that the use of these summary scores lessens the role of chance when conducting analyses which test hypotheses relating to health outcomes. These scores (where low and high scores represent 'worse' and 'better' states respectively as for the individual dimensions) are included in table 7.14 and distributions of these measures are given in

figure 7.32. Not surprisingly, these scores show a deterioration over time in health status in keeping with the findings for the individual dimensions.

Table 7.14: SF-36 dimension scores* at baseline and at 12 month follow-up

SF-36 Dimension	Time	N	mean	SD	min.	max.	25%ile	median	75%ile
Physical functioning	Baseline	226	50.69	28.68	0.0	100.0	25.00	50.00	75.00
	12 mths	194	43.76	30.04	0.0	100.0	15.00	45.00	70.00
Role limitation: physical problems	Baseline	226	65.49	43.95	0.0	100.0	0.00	100.00	100.00
	12 mths	194	55.93	44.70	0.0	100.0	0.00	50.00	100.00
Bodily pain	Baseline	226	55.22	29.46	0.0	100.0	32.00	51.00	84.00
	12 mths	194	50.68	30.29	0.0	100.0	22.00	51.00	72.00
General health perception	Baseline	226	62.22	24.44	0.0	100.0	45.00	67.00	82.00
	12 mths	194	60.63	24.84	0.0	100.0	40.00	62.00	82.00
Energy / vitality	Baseline	226	48.38	22.44	5.0	95.0	30.00	45.00	66.25
	12 mths	194	43.58	20.95	0.0	90.0	25.00	45.00	60.00
Social functioning	Baseline	226	77.71	27.21	0.0	100.0	59.37	87.50	100.00
	12 mths	194	61.08	32.03	0.0	100.0	25.00	75.00	87.50
Role limitation: emotional problems	Baseline	221	82.20	33.41	0.0	100.0	83.34	100.00	100.00
	12 mths	194	79.04	35.37	0.0	100.0	66.67	100.00	100.00
Mental health	Baseline	224	68.52	19.81	8.0	96.0	56.00	72.00	84.00
	12 mths	193	67.03	19.72	8.0	96.0	56.00	72.00	84.00
Change in health	Baseline	226	37.17	24.06	0.0	100.0	25.00	50.00	50.00
	12 mths	194	37.76	22.80	0.0	100.0	25.00	50.00	50.00
PCS score	Baseline	219	44.91	5.01	31.47	54.25	41.26	45.31	48.96
	12 mths	193	43.31	5.83	31.17	53.67	38.55	43.47	48.41
MCS score	Baseline	219	47.64	4.17	35.09	54.40	44.90	48.05	50.94
	12 mths	193	46.30	4.97	33.57	54.15	42.59	47.04	50.81

* Note: 0=worst, 100=best

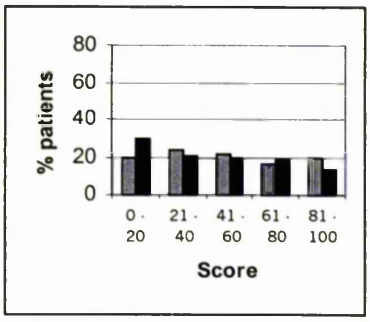
The mean differences over time, and the results of t-tests (paired, two-tailed) carried out to evaluate the statistical significance of change over time are given in table 7.15. With the exception of the physical functioning and social functioning dimensions, and both the physical and mental summary scores, the significant differences on other dimensions are probably not of major functional importance, with relatively small mean differences having been associated with significant p-values due to the large sample size.

Table 7.15: Change over time (from baseline to 12 month follow-up) for SF-36 dimension scores

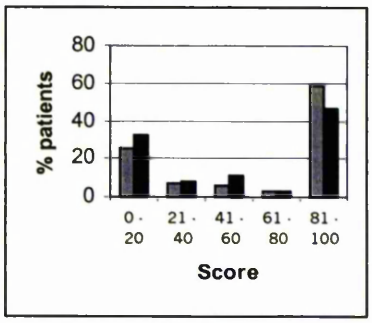
SF-36 Dimension	n	mean difference	(95% confidence interval)	t-value	p-value
Physical functioning	194	8.56	5.84 to 11.28	6.20	0.000****
Role limitation: physical problems	194	12.50	4.60 to 20.40	3.12	0.002**
Bodily pain	194	5.18	0.80 to 9.56	2.34	0.021*
General health perception	194	2.97	-0.38 to 6.32	1.75	0.082
Energy / vitality	194	5.52	2.34 to 8.69	3.43	0.001***
Social functioning	194	17.01	12.53 to 21.49	7.48	0.000****
Role limitation: emotional problems	189	2.29	-4.40 to 8.99	0.68	0.500
Mental health	192	2.21	-0.24 to 4.66	1.78	0.076
Change in health	194	-0.52	-4.51 to 3.48	-0.25	0.799
PCS score	187	1.91	1.23 to 2.59	5.54	0.000****
MCS score	187	1.50	0.86 to 2.14	4.65	0.000****

Significance levels: * $p<0.05$ ** $p<0.01$ *** $p<0.001$ **** $p<0.0001$

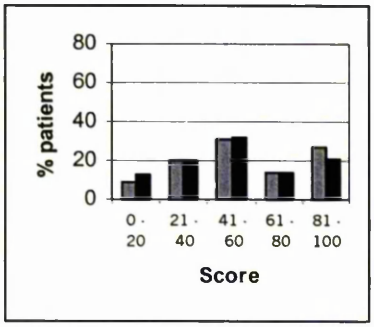
Physical functioning



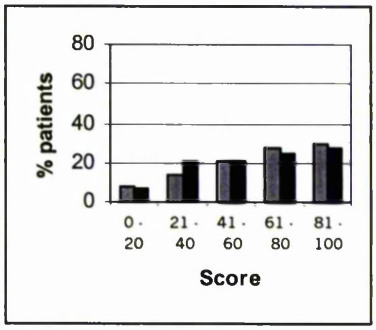
Role limitation: physical problems



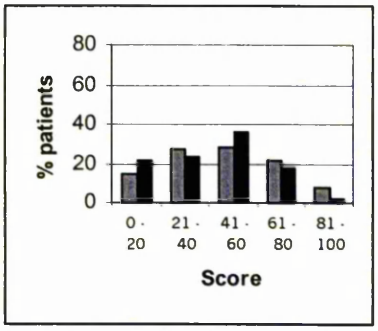
Bodily pain



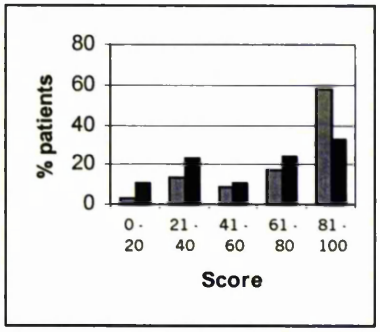
General health perception



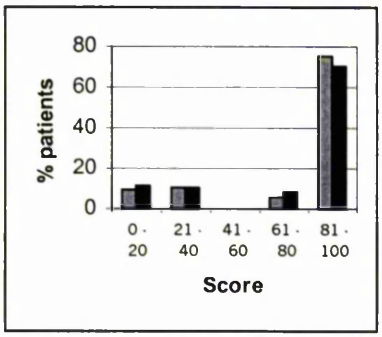
Energy / vitality



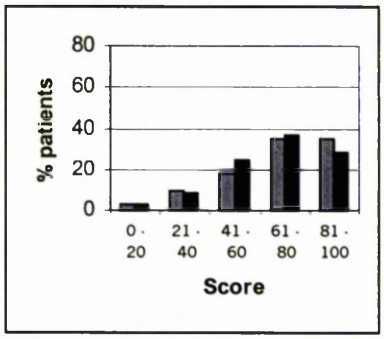
Social functioning



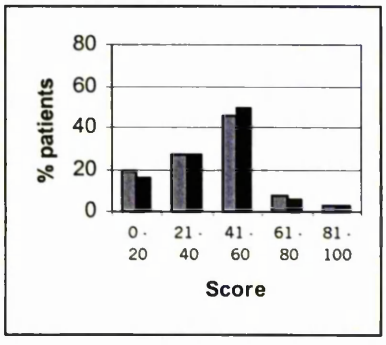
Role limitation: emotional problems



Mental health



Change in health



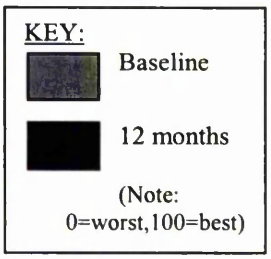
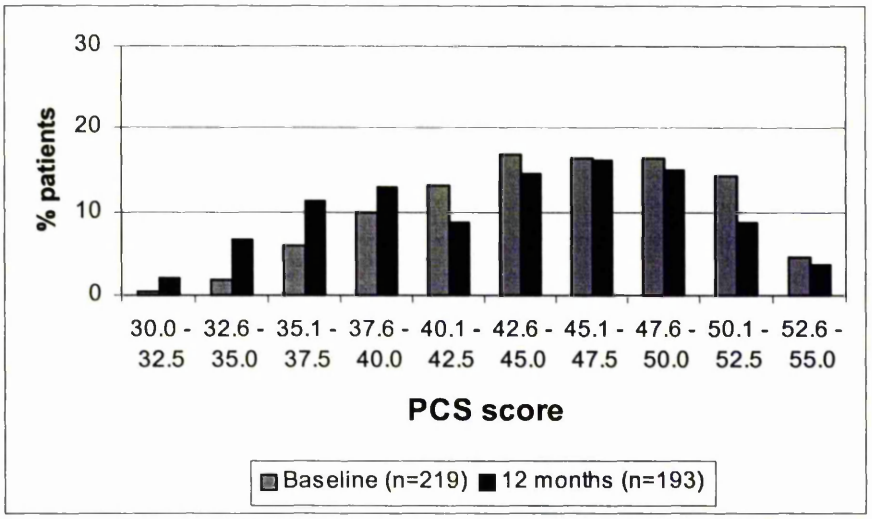


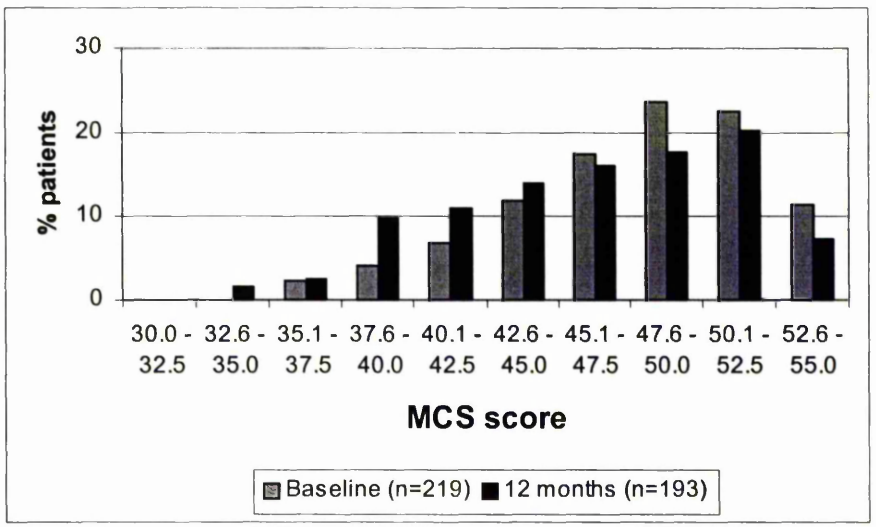
Figure 7.31: Distributions of SF-36 dimension scores at baseline and at 12 month follow-up

Figure 7.32: Distributions of SF-36 summary scores at baseline and at 12 month follow-up

(a) PCS score*



(b) MCS score*



* Note: 0=worst, 100=best

7.5.2 VCM1

Mean values were calculated for each of the ten domains in the VCM1 questionnaire. The domain means (which can range from 0 to 5, representing a good and poor vision-related quality of life respectively) at baseline and 12 month follow-up are given in table 7.16 below.

Table 7.16: VCM1 domain scores* at baseline and at 12 month follow-up

VCM1 domain	Time	N	mean	SD	min.	max.	25%ile	median	75%ile
Embarrassment	Baseline	225	1.72	1.23	0.0	5.0	0.00	2.00	3.00
	12 mths	194	1.91	1.17	0.0	4.0	1.00	2.00	3.00
Frustration / annoyance	Baseline	226	2.85	1.26	0.0	5.0	2.00	3.00	4.00
	12 mths	193	2.97	1.14	0.0	5.0	2.00	3.00	4.00
Loneliness / isolation	Baseline	226	1.14	1.30	0.0	4.0	0.00	1.00	2.00
	12 mths	194	1.44	1.34	0.0	4.0	0.00	1.00	3.00
Sadness / 'feeling low'	Baseline	226	2.11	1.28	0.0	5.0	1.00	2.00	3.00
	12 mths	194	2.18	1.32	0.0	5.0	1.00	2.00	3.00
Worry about eyesight getting worse	Baseline	226	2.30	1.43	0.0	5.0	1.00	2.00	3.00
	12 mths	194	1.91	1.28	0.0	5.0	1.00	2.00	3.00
Concern about safety at home	Baseline	226	0.63	1.05	0.0	4.0	0.00	0.00	1.00
	12 mths	194	0.72	1.03	0.0	4.0	0.00	0.00	1.00
Concern about safety when out of the home	Baseline	226	2.00	1.32	0.0	5.0	1.00	2.00	3.00
	12 mths	194	2.51	1.36	0.0	5.0	1.75	3.00	4.00
Concern about coping with everyday life	Baseline	225	2.23	1.14	0.0	5.0	2.00	2.00	3.00
	12 mths	194	2.64	0.91	0.0	4.0	2.00	3.00	3.00
Eyesight 'stopping you doing the things you want to do'	Baseline	226	3.13	0.88	0.0	5.0	3.00	3.00	4.00
	12 mths	194	3.27	0.97	1.0	5.0	3.00	3.00	4.00
Eyesight interfering with life in general	Baseline	226	2.99	1.14	0.0	5.0	2.00	3.00	4.00
	12 mths	194	3.57	1.11	1.0	5.0	3.00	4.00	4.00

* Note: Low scores=better QoL; high scores=worse QoL

The 10 domain scores were then used to calculate a single composite mean VCM1 score for each patient. Lower scores represent a better visual quality of life. A distribution of the VCM1 scores at baseline and at 12 month follow-up is shown in table 7.17 and in figure 7.33.

Tables 7.16 and 7.17, and figure 7.33 show a deterioration in most of the VCM1 domain scores and in the composite VCM1 score respectively between baseline and follow-up. The mean difference over time, and the results of a t-test (paired, two-tailed) carried out to evaluate the statistical significance of change over time for the VCM1 composite score is given in table 7.18.

Table 7.17: VCM1 composite score* at baseline and at 12 month follow-up

	Time	N	mean	SD	min.	max.	25%ile	median	75%ile
VCM1 score	Baseline	224	2.11	0.81	0.00	4.10	1.60	2.15	2.70
	12 mths	193	2.31	0.83	0.40	4.20	1.60	2.40	3.00

* Note: Low score=better QoL; high score=worse QoL

Figure 7.33: Distributions of the VCM1 score at baseline and at 12 month follow-up

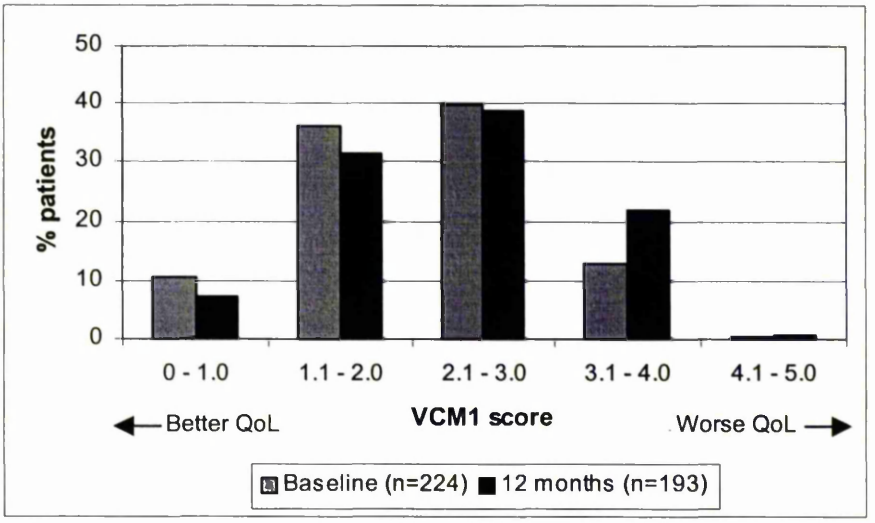


Table 7.18: Change over time (from baseline to 12 month follow-up) for the VCM1 composite score

VCM1 domain	N	mean difference	(95% confidence interval)	t-value	p-value
VCM1 score	192	0.21	0.11 to 0.32	4.14	0.000*

Significance levels: * p<0.0001

7.5.3 NAS

Each of the four dimensions of NAS used in this study (attitude to visual impairment, locus of control, acceptance and self-efficacy) comprises a set of questions with possible responses scored on a five point scale of 1 to 5 (see appendix 9). Seven questions were asked on attitudes to visual impairment, 4 questions deal with locus of control, 9 questions address acceptance and 8 questions explore self-efficacy. In all responses, a high score represents "a desirable state of affairs" (Dodds *et al*, 1991). A dimension score is obtained by summing the individual item scores. The distributions of the dimension scores obtained at baseline and at 12 month follow-up are shown in table 7.19 and in figure 7.34.

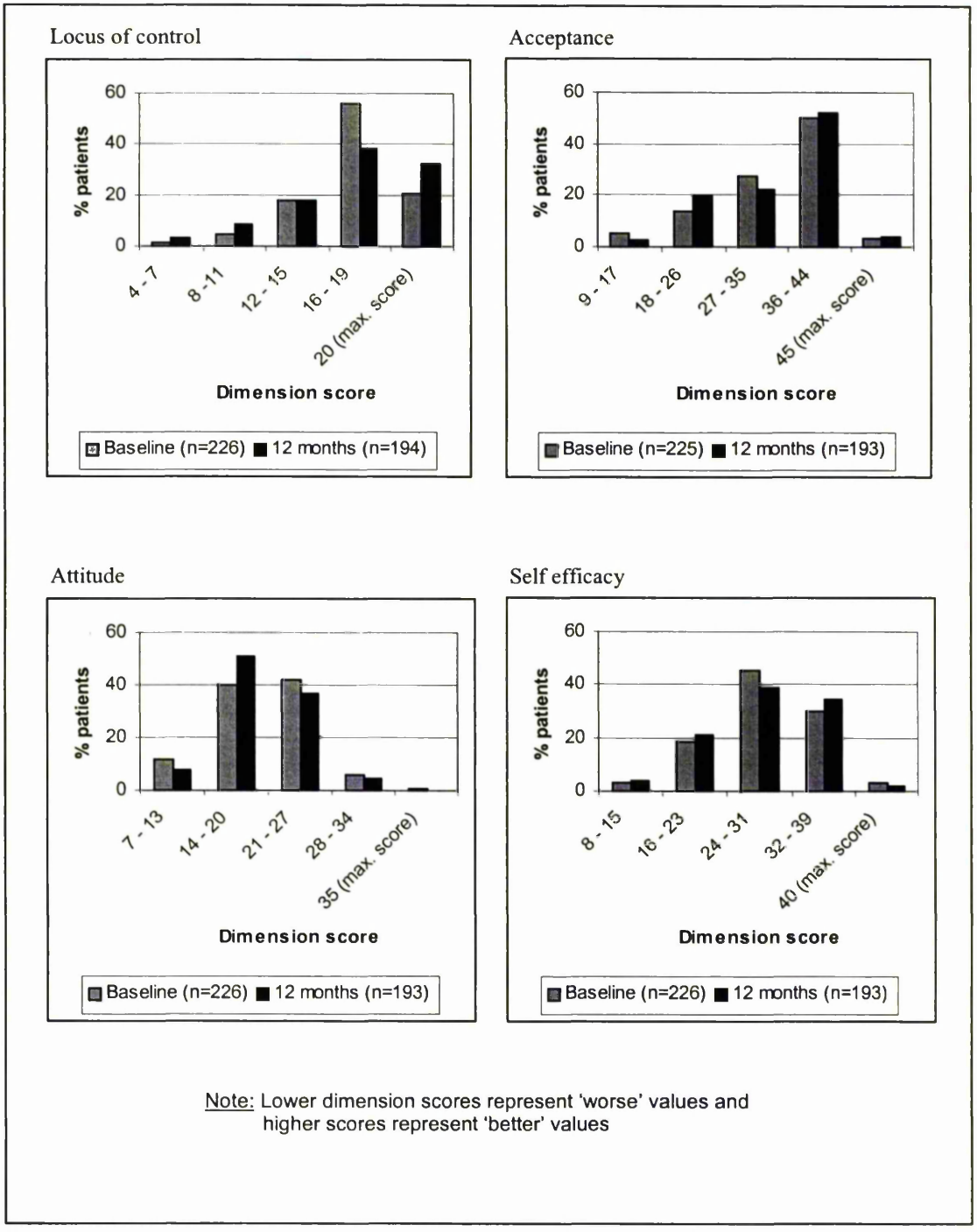
Both table 7.19 and figure 7.34 show little change in the distributions of the NAS dimension scores between baseline and follow-up. There were no significant differences found (paired, two-tailed t-tests) for mean differences over time for these NAS dimensions.

Table 7.19: NAS dimension scores*

NAS Dimension	Time	N	mean	SD	min.	max.	25%ile	median	75%ile
Locus of control	Baseline	226	16.92	2.98	4.0	20.0	16.00	18.00	19.00
(possible score: 4-20)	12 mths	194	16.66	3.72	4.0	20.0	14.00	18.00	20.00
Acceptance	Baseline	225	33.86	8.64	10.0	45.0	29.00	36.00	41.00
(possible score: 9-45)	12 mths	193	34.69	8.37	9.0	45.0	28.50	37.00	41.50
Attitude	Baseline	226	19.87	5.06	8.0	34.0	16.00	20.00	24.00
(possible score: 7-35)	12 mths	193	19.96	4.92	8.0	32.0	16.00	20.00	24.00
Self efficacy	Baseline	226	28.41	6.40	8.0	40.0	24.00	28.00	33.00
(possible score: 8-40)	12 mths	193	27.89	6.92	9.0	40.0	23.00	28.00	33.00

* Note: Low scores=worse state; high scores=better state

Figure 7.34: Distributions of NAS dimension scores at baseline and at 12 month follow-up



Note: Lower dimension scores represent 'worse' values and higher scores represent 'better' values

7.6 Comparisons of trial data against normative data

QoL data for the total study population were compared with previously published normative data. Comparisons are presented for both health-related QoL (SF-36) and vision specific QoL (VCM1). Since comparisons of baseline with 12 month follow-up data for the whole study population are presented in section 7.5 above, showing some deterioration in both SF-36 and VCM1 scores, a comparison against normative data is given for the 12 month study data only.

7.6.1 SF-36 dimensions

The most suitable published normative data for SF-36 dimension scores in elderly people are reported by Lyons *et al* (1994) and Lyons *et al* (1997). The earlier of these two studies explored the suitability of the SF-36 for use with an elderly population. The SF-36 was administered to a random sample of 827 adults in West Glamorgan. This sample contained 216 respondents aged 65 years and older and the analysis of SF-36 dimension scores for this group included breakdowns by factors which may have caused differences in health status, for example the presence of long-standing disability or recent admission to hospital. In a separate study, Lyons *et al* (1997) also administered the SF-36 (as one of three assessment instruments) to 1608 elderly respondents (aged 70 years and over) in order to obtain normative population data on health status and disability of elderly people to use as comparators for research[1]. This research was carried out in three areas, namely West Glamorgan (n=925), Dudley (n=282) and North Staffordshire (n=401). Notwithstanding evidence of variation between the three areas, in the absence of other normative data published for elderly groups separately, their study provided the 'best available' data for comparative purposes with respect to elderly populations. Whilst several other studies have, in recent years, utilised the SF-36 in assessing health status / health-related QoL in elderly populations, there have not been any studies since the research conducted by Lyons *et al* (1997) which have included such a large sample. Furthermore studies which have reported using the SF-36 to measure health status of older people have been concerned with elderly groups with specific health or disease problems, e.g. stroke (Wilkinson *et al*, 1997; Fowler *et* al,

[1] 'Change in health' (a single item which measures change in health with respect to the previous year) has not been included since this item is not used to score any of the other eight health dimensions (see Jenkinson *et al* (1996)).

2000; Bugge *et al*, 2001), coronary artery bypass patients (Kilo *et al*, 2001), or rheumatoid arthritis (Kvien *et al*, 1998).

The 12 month SF-36 dimension scores obtained in this trial are tabulated in comparison with data from Lyons *et al* (1997) in table 7.20. Although Lyons *et al* published SF-36 dimension scores for 3 age groups (70-79, 80-89 and 90-99 years) broken down by sex, only the two younger of these age groups are included for comparison with the trial data due to the relatively small number of cases (n=13) available for the 90-99 year-old age group in the present study. The trend for lower scores with older age and lower scores for women seen in the data from Lyons *et al* can also be observed for the subjects with AMD.

Follow-up SF-36 scores are also compared with the data published by Lyons *et al* (1994) for people with the presence/absence of a limiting long-standing disability. Lyons *et al* demonstrated that the SF-36 distinguished clearly between these two sub-groups by a minimum of 16 points for each dimension. The present data also shows that the SF-36 dimension scores for an elderly population with AMD are at least 11 points lower for each score than the elderly group without long-standing disability. This comparison is given in table 7.21.

Table 7.20: A comparison of study data (SF-36 dimension scores) with normative data for an elderly population.

SF-36 Dimension	Age group (years)	Sex	Mean score for three UK districts* (n for dimension)		AMD RCT mean score (n for dimension)	
Physical functioning	70 – 79	M	64.4	(1530)	52.2	(173)
		F	53.4		52.9	
	80 – 89	M	44.2		48.9	
		F	35.1		31.7	
Role limitation: physical problems	70 – 79	M	68.7	(1527)	55.4	(173)
		F	62.9		54.3	
	80 – 89	M	62.9		75.0	
		F	56.2		49.2	
Role limitation: emotional problems	70 – 79	M	90.8	(1526)	82.6	(173)
		F	82.6		80.1	
	80 – 89	M	87.4		82.8	
		F	86.2		76.4	
Social functioning	70 – 79	M	83.3	(1526)	65.2	(173)
		F	79.2		61.8	
	80 – 89	M	77.8		71.6	
		F	74.0		53.3	
Mental health	70 – 79	M	79.7	(1522)	70.1	(172)
		F	69.3		66.6	
	80 – 89	M	79.6		72.3	
		F	71.4		63.1	
Energy / vitality	70 – 79	M	56.1	(1523)	49.1	(173)
		F	47.2		45.1	
	80 – 89	M	48.7		45.5	
		F	43.8		39.2	
Bodily pain	70 – 79	M	70.2	(1523)	55.7	(173)
		F	62.5		48.5	
	80 – 89	M	68.2		62.3	
		F	60.2		44.7	
General health perception	70 – 79	M	60.7	(1531)	56.1	(173)
		F	56.2		59.6	
	80 – 89	M	55.9		65.2	
		F	54.2		60.3	

* Districts: West Glamorgan, Dudley and North Staffordshire (Lyons *et al.* (1997))

Note: A higher score reflects a better QoL

Table 7.21: A comparison of study data (SF-36 dimension scores) with normative data for an elderly population with and without a long-standing disability

SF-36 Dimension	Mean scores		
	AMD RCT (mean age= 81.0)	**West Glamorgan Survey*** (mean age= 73.9)	
	(n=194)	**Long-standing disability** (n=131)	**No long-standing disability** (n=85)
Physical functioning	43.8	38.8	73.6
Role limitation: physical problems	55.9	37.1	74.6
Role limitation: emotional problems	79.0	68.2	90.7
Social functioning	61.1	59.2	87.8
Mental health	67.0	66.8	83.7
Energy / vitality	43.6	39.7	67.1
Bodily pain	50.7	51.0	80.5
General health perception	60.6	41.6	74.4

* Lyons *et al.* (1994)
Note: A higher score reflects a better QoL

7.6.2 VCM1

The individual domain scores representing the 10 items of the VCM1, together with the composite VCM1 score, are compared against normative data (Frost *et al* 1998). The mean age of this latter sample (n=92) was 72 with a range of 41-91. Although this population is somewhat younger than the study population and included 20 subjects who did not have any eye problems (the remaining subjects having a mixture of ocular pathologies including AMD, cataract and glaucoma), this data has been chosen as the most suitable normative set of data with respect to the VCM1. VCM1 scores are compared against the normative data in table 7.22. Subjects with AMD in the present study have higher scores, i.e. worse vision-related QoL .

Table 7.22: A comparison of study data (VCM1 scores) with normative data

VCM1 domain	**Normative data* mean scores** (n=92)	**AMD RCT mean scores** (n=194)
Life interference	1.5	3.6
Safety outside the home	1.0	2.5
Anger	1.7	3.0**
Depression	0.8	2.2
Coping with everyday life	0.8	2.6
Inability to do activities of choice	1.6	3.3
Fear of deterioration of vision	1.7	1.9
Safety in the home	0.6	0.7
Embarrassment	0.7	1.9
Loneliness	0.4	1.4
VCM1 composite score	1.1	2.3**

* Frost *et al.* (1998)
** n=193
Note: Higher scores reflect worse vision-related QoL

CHAPTER 8: RESULTS II. TWELVE MONTH OUTCOMES ANALYSIS

This chapter presents the results of the main analyses to explore the effectiveness of the interventions delivered in the trial. Prior to these main results, results of baseline equivalence tests are presented.

8.1 Baseline comparability across intervention arms for key variables

Baseline data for outcome measures and other patient characteristics were compared across the three arms of the trial (see Chapter 5, section 5.5.3 for statistical methods). The level of significance used to indicate differences between arms at baseline was $p<0.2$ to ensure that potential important covariates were not excluded from consideration in subsequent analyses. These variables are identified below.

8.1.1 Socio-demographic characteristics

Most of the socio-demographic variables collected at baseline did not show significant differences between the three arms. An ANOVA for age, the only socio-demographic variable on a continuous scale, showed a significant difference at the 0.2 level (df [2, 223], F=1.85, p=0.16). The oldest subjects were those in arm 3 and t-tests showed significant differences between arms 1 and 3 (2-tailed, unpaired, p=0.093), and similarly between arms 2 and 3 (2-tailed, unpaired, p=0.097). Of the category variables only residential status showed a significant difference between arms (Pearson chi-square=19.39, p=0.001). Therefore, equivalence across arms with respect to this group of variables has been largely achieved. A distribution of key socio-demographic variables (age, sex, residential and educational status), by arm, at baseline is given in tables 8.1 (a) and (b). Although the level of education achieved by subjects was recorded in terms of primary, secondary and tertiary levels, the frequencies of responses for some categories by arm were very low, therefore these data were collapsed into a dichotomous variable based on the age at which subjects left full-time education. This

procedure was carried out in order to facilitate statistical power in testing for differences between the three arms[†].

Additional background variables are given in tables 8.2 and 8.3. Table 8.2 includes dichotomous or category variables which represent whether subjects were regularly receiving assistance in terms of social/health care at baseline. Partial sight and blind registration data were also compared between arms retrospectively[‡] and this comparison is shown in appendix 21. There were no significant differences found between arms at baseline for the registration data. Table 8.3 includes variables relating to leisure and social activities. These data include responses to whether subjects were still able to enjoy a certain number of their favourite leisure activities, the extent of social contact (i.e. with family and/or friends), the regular use of public transport[1] and whether or not subjects did their own shopping on a regular basis[2], and finally whether they had attended a place of worship in the fortnight prior to their baseline home visit. Although many subjects who did their own shopping were usually accompanied by a relative or friend (see 7.1), subjects who shopped on their own and those who were accompanied were pooled together since in both scenarios subjects were able to leave their home and take part in shopping activities, thus involving some level of social interaction. With respect to the last variable included in table 8.3, although subjects' religion had been noted, the question of whether a place of worship had been recently attended was considered to be a more useful value, combining social interaction outside the home with a source of personal comfort and possible support gained through religious beliefs. Appendix 7 shows the questionnaire used to gather socio-demographic information and section 6.9.1 discusses the data excluded from analysis.

[†] This was possible due to the availability of a 'convenient' and meaningful cut-off so that there was no risk that dichotomising might obscure a difference.

[‡] The data were readily available from hospital records for 185 patients but for the remaining patients there were problems regarding the availability of medical records.

[1] Regular use of public transport included responses of 'daily', 'at least weekly' and 'at least monthly'; therefore subjects who did not use public transport on a regular basis will have included responses of 'hardly ever' and 'never'.

[2] Shopping regularly was defined as 'doing own shopping all of the time' or 'most of the time'; therefore subjects who did not fall into this category included responses of 'sometimes', rarely' and 'never'.

Table 8.1: Comparison of key socio-demographic continuous variables, by arm, at baseline

(a) Age

Socio-demographic characteristic *(continuous variables)*	n	Arm 1			Arm 2			Arm 3		
		mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3
Age ‡	226	81.04 (76)	6.10	77.53 – 84.81	81.07 (75)	6.16	76.93 – 85.14	82.75 (75)	5.83	79.05 – 86.62

‡ ANOVA: df [2, 223], F=1.85, p=0.16
t-test (2-tailed, unpaired) arms 1 and 3: p=0.093
t-test (2-tailed, unpaired) arms 2 and 3: p=0.097

(b) Other key socio-demographic category variables

Socio-demographic characteristic *(category variables)*	n	Category responses	Arm 1		Arm 2		Arm 3		All
			Frequency	% (in arm)	Frequency	% (in arm)	Frequency	% (in arm)	Total frequency (%)
Sex	226	male	28	36.8	27	36.0	21	28.0	76 (33.6)
		female	48	63.2	48	64.0	54	72.0	150 (66.4)
Residential status †	226	living alone	32	42.1	39	52.0	45	60.0	116 (51.3)
		with spouse	40	52.6	21	28.0	26	34.7	87 (38.5)
		with family	4	5.3	15	20.0	4	5.3	23 (10.2)
Age when left education	226	14yrs & younger	57	75.0	57	66.7	53	70.7	160 (70.8)
		15yrs & older	19	25.0	25	33.3	22	29.3	66 (29.2)

† significant difference between arms (Pearson chi-square=19.39, p=0.001)

Table 8.2: Comparison of additional background category variables relating to existing health and social care, by arm, at baseline *

Socio-demographic characteristic *(category variables)*	N	Category responses	Arm 1		Arm 2		Arm 3		All
			Frequency	% (in arm)	Frequency	% (in arm)	Frequency	% (in arm)	Total frequency (%)
Any regular health/social care	226	yes	31	40.8	32	42.7	29	38.7	92 (40.7)
		no	45	59.2	43	57.3	46	61.3	134 (59.3)
Home help	224	yes	11	14.7	13	17.3	14	18.9	38 (17.0)
		no	64	85.3	62	82.7	60	81.1	186 (83.0)
'Meals on wheels'	224	yes	4	5.3	3	4.0	3	4.1	10 (4.5)
		no	71	94.7	72	96.0	71	95.9	214 (95.5)
Mobility assistance	224	yes	7	9.3	5	6.7	6	8.1	18 (8.0)
		no	68	90.7	70	93.3	68	91.9	206 (92.0)
Personal care	224	yes	5	6.7	8	10.7	5	6.8	18 (8.0)
		no	70	93.3	67	89.3	69	93.2	206 (92.0)
Use of hearing aid	224	yes	14	18.9	13	17.3	19	25.3	46 (20.5)
		no	60	81.1	62	82.7	56	74.7	178 (79.5)

* no 'significant' differences between arms (i.e. $p>0.2$).

Table 8.3: Comparison of additional socio-demographic category variables relating to social contact, by arm, at baseline *

Socio-demographic characteristic *(category variables)*	n	Category responses	Arm 1		Arm 2		Arm 3		All
			Frequency	% (in arm)	Frequency	% (in arm)	Frequency	% (in arm)	Total frequency (%)
No. of leisure activities still enjoyed	226	3 or less	57	75.0	57	76.0	53	70.7	167 (73.9)
		4 or more	19	25.0	18	24.0	22	29.3	59 (26.1)
Visits to family	226	at least weekly	17	22.4	16	21.3	19	25.3	52 (23.0)
		at least monthly	18	23.7	8	10.7	16	21.3	42 (18.6)
		hardly ever	33	43.4	41	54.7	29	38.7	103 (45.6)
		never	8	10.5	10	13.3	11	14.7	29 (12.8)
Visits by family	226	at least weekly	50	65.8	45	60.0	54	72.0	149 (65.9)
		at least monthly	9	11.8	14	18.7	6	8.0	29 (12.8)
		hardly ever	16	21.1	12	16.0	12	16.0	40 (17.7)
		never	1	1.3	4	5.3	3	4.0	8 (3.5)
Visits to friends	226	at least weekly	28	36.8	28	37.3	37	49.3	93 (41.2)
		at least monthly	8	10.5	16	21.3	13	17.3	37 (16.4)
		hardly ever	24	31.6	17	22.7	13	17.3	54 (23.9)
		never	16	21.1	14	18.7	12	16.0	42 (18.6)
Visits by friends	226	at least weekly	36	47.4	34	45.3	40	53.3	110 (48.7)
		at least monthly	8	10.5	13	17.3	10	13.3	31 (13.7)
		hardly ever	22	28.9	16	21.3	14	18.7	52 (23.0)
		never	10	13.2	12	16.0	11	14.7	33 (14.6)
Extent of social contact (combining family & friends)	226	regular - family and friend	31	40.8	25	33.3	38	50.7	94 (41.6)
		regular – family or friend	32	42.1	39	52.0	30	40.0	101 (44.7)
		no regular contact	13	17.1	11	14.7	7	9.3	31 (13.7)
Regular use of public transport	226	yes	39	51.3	34	45.3	36	48.0	109 (48.2)
		no	37	48.7	41	54.7	39	52.0	117 (51.8)
Does own shopping regularly	226	yes	53	69.7	44	58.7	48	64.0	145 (64.2)
		no	23	30.3	31	41.3	27	36.0	81 (35.8)
Attended place of worship recently	226	yes	17	22.4	17	22.7	15	20.0	49 (21.7)
		no	59	77.6	58	77.3	60	80.0	177 (78.3)

* no 'significant' differences between arms (i.e. p>0.2)

8.1.2 Visual function outcomes and task restriction

ANOVAs for both near visual acuity (df [2, 206], F=5.07, p=0.0071) and distance visual acuity (df [2, 213], F=1.84, p=0.16) in the better eye showed a significant difference between arms (using a 0.2 level cut-off for significance). Further analysis showed that near visual acuity was best in arm 3 and worst in arm 2, with a significant difference between arms 1 and 3 (2-tailed, unpaired t-test, p=0.029) and between arms 2 and 3 (2-tailed, unpaired t-test, p=0.002). Distance visual acuity was again best in arm 3 and worst in arm 2, with a significant difference between arms 2 and 3 (2-tailed, unpaired t-test, p=0.07). No significant difference was found between arms for best eye contrast sensitivity.

Average restriction in activities and average reading restriction scores (see 7.3.3 for the derivation of these scores) were also tested for baseline comparability. An ANOVA for average restriction in activities showed a difference between arms (df [2, 202], F=2.99, p=0.0524). Average restriction in activities was worst (i.e. had the highest mean score) in arm 1 and best in arm 3. A t-test showed significant differences between arms 1 and 3 (2-tailed, unpaired, p=0.014), and less so between arms 1 and 2 (2-tailed, unpaired, p=0.199). No arm differences were observed for average reading restriction scores.

Table 8.4 gives a comparison of visual functions and task restriction scores, by arm, at baseline.

Table 8.4: Comparison of visual function and task restriction variables, by arm, at baseline

Visual functions	n	Arm 1			Arm 2			Arm 3		
		mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3
Best eye distance acuity (with correction) (logMAR) †	216	0.77 (72)	0.34	0.47 - 1.01	0.84 (73)	0.39	0.54 - 1.08	0.73 (71)	0.36	0.44 - 1.00
Best eye near acuity (with correction) (M units +4.00 Add.) ‡	209	2.80 (72)	2.10	1.08 - 4.00	3.20 (68)	2.38	1.00 - 5.00	2.09 (69)	1.70	0.90 - 2.50
Best eye contrast sensitivity (logCS)	175	0.83 (56)	0.33	0.60 - 1.05	0.78 (58)	0.34	0.45 - 1.05	0.86 (61)	0.34	0.60 - 1.05
Task restriction										
Average task restriction score ±	205	0.54 (70)	0.24	0.32 - 0.74	0.49 (69)	0.25	0.32 - 0.71	0.44 (66)	0.24	0.24 - 0.63
Average reading restriction score	146	0.67 (44)	0.32	0.40 - 1.00	0.63 (50)	0.31	0.40 - 0.88	0.58 (52)	0.36	0.18 - 0.96

† ANOVA: df [2, 213], F=1.84, p=0.16
t-test (2-tailed, unpaired) arms 2 and 3: p=0.07

‡ ANOVA: df [2, 206], F=5.07, p=0.0071
t-test (2-tailed, unpaired) arms 1 and 3: p=0.029
t-test (2-tailed, unpaired) arms 2 and 3: p=0.002

± ANOVA: df [2, 202], F=2.99, p=0.0524
t-test (2-tailed, unpaired) arms 1 and 2: p=0.199
t-test (2-tailed, unpaired) arms 1 and 3: p=0.014

8.1.3 SF-36 dimension scores

Most of the SF-36 dimension scores did not show significant differences between arms. However, ANOVAs for 'role limitation due to emotional problems' (df [2, 218], F=3.45, p=0.0335), mental health (df [2, 221], F=2.52, p=0.0829), and the mental component summary measure (see section 7.5.1) derived from the SF-36 (df [2, 216], F=2.29, p=0.1042) showed a difference between arms according to the cut-off level of significance ($p<0.2$) used to test for comparability. Subjects in arm 2 experienced less role limitation due to emotional problems than those in the other arms. T-tests showed significant differences between arms 1 and 2 (2-tailed, unpaired, p=0.015) and between arms 2 and 3 (2-tailed, unpaired, p=0.028). Similarly, subjects in arm 2 had significantly better mental health scores than those in arm 1 (2-tailed, unpaired t-test, p=0.033). Not surprisingly therefore, subjects in arm 2 had a higher (i.e. better) mean mental component summary score than those in both arms 1 and 3. T-tests confirmed a significant difference for this score between arms 1 and 2 (2-tailed, unpaired, p=0.046) and less so between arms 2 and 3 (2-tailed, unpaired, p=0.086). Table 8.5 gives a comparison of the SF-36 dimension scores and the physical and mental component summary scores, by arm, at baseline.

8.1.4 VCM1 scores

An ANOVA for the composite VCM1 score (a continuous variable) did not show any significant difference between arms. Two of the ten mean domain scores (see 7.5.2) showed significant differences (using $p<0.2$) between arms when ANOVAs were carried out. These two domains were 'loneliness/isolation due to eyesight' experienced by the subjects (df [2, 223], F=5.67, p=0.004), and eyesight 'stopping you doing what you want to do' (df [2, 223], F=2.14, p=0.12). The sense of loneliness was greatest (i.e. scored worst) in arm 1 subjects and least in arm 3. T-tests for this variable were therefore most significantly different between arms 1 and 3 (2-tailed, unpaired, p=0.001), with smaller differences between arms 2 and 3 (2-tailed, unpaired, p=0.083) and arms 1 and 2 (2-tailed, unpaired, p=0.109). The interference of eyesight with respect to subjects' ability to carry out their activities of choice was again greatest (i.e. 'worst') among subjects in arm 1, with little difference in the mean scores for this variable between arms 2 and 3. A t-test therefore showed a significant difference between arms 1 and 2 (2-tailed, unpaired, p=0.063) and arms 1 and 3 (2-tailed,

unpaired, p=0.092). Table 8.6 shows a comparison of domain scores (using the median, minimum and maximum values) and the VCM1 score, by arm, at baseline.

Table 8.5: Comparison of SF-36 dimension scores, by arm, at baseline

SF-36 dimensions	N	Arm 1			Arm 2			Arm 3		
		mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3
Physical functioning	226	54.01 (76)	28.87	30.0 - 80.0	49.80 (75)	28.44	25.0 - 75.0	48.20 (75)	28.79	25.0 - 75.0
Role limitation: physical problems	226	60.86 (76)	44.97	0.0 - 100.0	72.00 (75)	41.50	25.0 - 100.0	63.67 (75)	45.08	0.0 - 100.0
Bodily pain	226	57.29 (76)	32.95	34.25 - 96.0	55.84 (75)	27.45	32.0 - 72.0	52.51 (75)	27.78	32.0 - 74.0
General health perception	226	61.53 (76)	24.38	42.75 - 82.0	64.85 (75)	21.67	45.0 - 82.0	60.29 (75)	27.08	40.0 - 82.0
Energy / vitality	226	47.24 (76)	23.70	25.0 - 68.75	51.93 (75)	20.99	35.0 - 70.0	46.00 (75)	22.39	30.0 - 65.0
Social functioning	226	75.99 (76)	28.85	50.0 - 100.0	79.67 (75)	26.14	62.5 - 100.0	77.50 (75)	26.79	50.0 - 100.0
Role limitation: emotional problems †	221	77.03 (74)	37.80	33.33 - 100.0	90.41 (73)	26.92	100.0 - 100.0	79.28 (74)	33.43	66.67 - 100.0
Mental health ‡	224	64.87 (75)	23.94	44.0 - 84.0	72.11 (74)	16.26	63.0 - 84.0	68.64 (75)	17.97	60.0 - 84.0
Change in health	226	38.16 (76)	24.66	25.0 - 50.0	39.00 (75)	25.08	25.0 - 50.0	34.33 (75)	22.43	25.0 - 50.0
Physical component summary score	219	44.88 (73)	5.51	40.72 - 49.80	45.29 (72)	4.61	42.52 - 48.66	44.55 (74)	4.92	40.44 - 48.64
Mental component summary score ±	219	47.06 (73)	4.82	43.67 - 51.17	48.47 (72)	3.49	45.53 - 51.32	47.39 (74)	4.02	44.71 - 50.29

† ANOVA: df [2, 218], F=3.45, p=0.0335
t-test (2-tailed, unpaired) arms 1 and 2: p=0.015; t-test (2-tailed, unpaired) arms 2 and 3: p=0.028

‡ ANOVA: df [2, 221], F=2.52, p=0.0829
t-test (2-tailed, unpaired) arms 1 and 2: p=0.033

± ANOVA: df [2, 216], F=2.29, p=0.1042
t-test (2-tailed, unpaired) arms 1 and 2: p=0.046; t-test (2-tailed, unpaired) arms 2 and 3: p=0.086

Table 8.6: Comparison of VCM1 domains and the overall VCM1 score, by arm, at baseline

VCM1 score and domains	n	Arm 1			Arm 2			Arm 3		
		mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3
VCM1 score	224	2.21 (76)	0.83	1.70 - 2.80	2.10 (74)	0.81	1.50 - 2.70	2.03 (74)	0.79	1.38 - 2.70
Embarrassment	225	1.58 (76)	1.30	0.0 - 2.75	1.88 (74)	1.16	1.0 - 3.0	1.71 (75)	1.24	1.0 - 2.0
Frustration / annoyance	226	2.96 (76)	1.15	2.0 - 4.0	2.80 (75)	1.20	2.0 - 4.0	2.79 (75)	1.42	2.0 - 4.0
Loneliness / isolation †	226	1.49 (76)	1.39	0.0 - 3.0	1.13 (75)	1.30	0.0 - 2.0	0.79 (75)	1.13	0.0 - 2.0
Sadness / 'feeling low'	226	2.20 (76)	1.39	1.0 - 3.0	2.16 (75)	1.16	2.0 - 3.0	1.97 (75)	1.28	1.0 - 3.0
Worry about eyesight getting worse	226	2.36 (76)	1.52	1.0 - 4.0	2.25 (75)	1.43	1.0 - 3.0	2.29 (75)	1.34	1.0 - 3.0
Concern about safety at home	226	0.70 (76)	1.05	0.0 - 1.0	0.56 (75)	1.02	0.0 - 1.0	0.64 (75)	1.09	0.0 - 1.0
Concern about safety when out of the home	226	2.05 (76)	1.25	1.0 - 3.0	2.00 (75)	1.19	1.0 - 3.0	1.95 (75)	1.51	0.0 - 3.0
Concern about coping with everyday life	225	2.32 (76)	1.13	2.0 - 3.0	2.17 (75)	1.19	1.0 - 3.0	2.19 (74)	1.11	2.0 - 3.0
Eyesight 'stopping you doing the things you want to do' ‡	226	3.30 (76)	0.89	3.0 - 4.0	3.04 (75)	0.83	3.0 - 4.0	3.05 (75)	0.91	3.0 - 4.0
Eyesight interfering with life in general	226	3.16 (76)	1.13	2.0 - 4.0	2.93 (75)	1.03	2.0 - 3.0	2.88 (75)	1.24	2.0 - 4.0

† ANOVA: df [2, 223], F=5.67, p=0.004
t-test (2-tailed, unpaired) arms 1 and 3: p=0.001
t-test (2-tailed, unpaired) arms 2 and 3: p=0.083
t-test (2-tailed, unpaired) arms 1 and 2: p=0.109

‡ ANOVA: df [2, 223], F=2.14, p=0.12
t-test (2-tailed, unpaired) arms 1 and 2: p=0.063
t-test (2-tailed, unpaired) arms 1 and 3: p=0.092

8.1.5 NAS dimension scores

Of the four NAS dimensions (see 7.5.3), only locus of control, showed a significant difference between arms (using $p<0.2$) when an ANOVA was carried out (df [2, 223], F=2.14, p=0.1199). The mean locus of control score was highest (i.e. best) for arm 3 subjects. A t-test (2-tailed, unpaired) showed a significant difference between arms 1 and 3 (p=0.056) and between arms 1 and 2 (p=0.133). Table 8.7 shows a comparison of the four NAS dimensions, by arm, at baseline.

Table 8.7: Comparison of NAS dimension scores, by arm, at baseline

NAS dimensions	n	Arm 1			Arm 2			Arm 3		
		mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3
Locus of control † *(possible score: 4-20)*	226	16.36 (76)	3.29	15.0 - 19.0	17.12 (75)	2.92	16.0 - 19.0	17.29 (75)	2.66	16.0 - 20.0
Acceptance *(possible score: 9-45)*	225	32.57 (76)	9.72	27.0 - 40.0	34.43 (74)	7.81	29.0 - 41.0	34.61 (75)	8.22	30.0 - 41.0
Attitude *(possible score: 7-35)*	226	19.55 (76)	5.39	15.25 - 24.0	20.15 (75)	5.02	17.0 - 24.0	19.91 (75)	4.81	17.0 - 23.0
Self efficacy *(possible score: 8-40)*	226	27.62 (76)	6.38	24.0 - 33.0	29.32 (75)	6.21	25.0 - 34.0	28.31 (75)	6.58	23.0 - 34.0

† ANOVA: df [2, 223], F=2.14, p=0.1199
t-test (2-tailed, unpaired) arms 1 and 2: p=0.133
t-test (2-tailed, unpaired) arms 1 and 3: p=0.056

8.1.6 Duration of low vision assessments

ANOVAs of the duration of low vision assessments at the initial low vision appointment (df [2, 171], F=3.63, p=0.0287), and the second appointment, i.e. which took place at approximately 4 months into the trial, (df [2, 144], F=3.71, p=0.0268) showed significant differences (using p<0.2) between arms. The duration of the initial assessments was longest for subjects in arm1 and shortest in arm 3. T-tests of duration between arms 1 and 3 showed a significant difference (p=0.005), and a less significant difference between arms 2 and 3 (p=0.149). The duration of the second assessments was again longest for subjects in arm 1 and shortest for those in arm 3. T-tests of this assessment duration showed significant differences between arms 1 and 3 (p=0.011) and between arms 1 and 2 (p=0.054). Table 8.8 shows a comparison of the two assessment durations, by arm, at baseline. These data are also described in more detail in 6.5.2.

Table 8.8: Comparison of low vision assessment durations (minutes), by arm, at baseline

Low vision assessment	n	Arm 1			Arm 2			Arm 3		
		mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3
Initial assessment duration †	174	66.04 (53)	17.19	55.0 - 75.0	62.16 (58)	17.22	50.0 - 71.25	58.25 (63)	12.02	50.0 - 60.0
Second assessment duration ‡	147	47.71 (51)	16.46	38.0 - 60.0	41.22 (45)	15.96	30.0 - 50.0	40.20 (51)	12.37	30.0 - 45.0

† ANOVA: df [2, 171], F=3.63, p=0.0287
t-test (2-tailed, unpaired) arms 1 and 3: p=0.005
t-test (2-tailed, unpaired) arms 2 and 3: p=0.149

‡ ANOVA: df [2, 144], F=3.71, p=0.0268
t-test (2-tailed, unpaired) arms 1 and 2: p=0.054
t-test (2-tailed, unpaired) arms 1 and 3: p=0.011

8.1.7 Subject expectations of the initial low vision assessment

The seven most frequently cited expectations of the initial low vision appointment which subjects had at the baseline interview (i.e. prior to their first clinic appointment) were tested for differences between arms. None of these dichotomous variables (i.e. whether or not each expectation had been stated) showed a significant difference between arms using the chi-square test. These data are described in more detail in section 7.1 for the whole study population.

Table 8.9 shows a comparison of subject expectations prior to the initial low vision assessment, by arm, at baseline.

Table 8.9: Comparison of expectations of the initial low vision assessment cited by subjects, by arm, at baseline *

Expectation cited	n	Category responses	Arm 1		Arm 2		Arm 3		All
			Frequency	% (in arm)	Frequency	% (in arm)	Frequency	% (in arm)	Total frequency (%)
'Ability to carry out tasks'	226	yes	31	40.8	37	49.3	38	50.7	106 (46.9)
		no	45	59.2	38	50.7	37	49.3	120 (53.1)
To obtain a magnifying aid(s) *(specific reference to LVAs)*	226	yes	23	30.3	25	33.3	30	40.0	78 (34.5)
		no	53	69.7	50	66.7	45	60.0	148 (65.5)
To obtain glasses	226	yes	18	23.7	22	29.3	13	17.3	53 (23.5)
		no	58	76.3	53	70.7	62	82.7	173 (76.5)
'An improvement in vision'	226	yes	15	19.7	17	22.7	19	25.3	51 (22.6)
		no	61	80.3	58	77.3	56	74.7	175 (77.4)
Information	226	yes	14	18.4	8	10.7	9	12.0	31 (13.7)
		no	62	81.6	67	89.3	66	88.0	195 (86.3)
Reassurance / comfort	226	yes	9	11.8	7	9.3	9	12.0	25 (11.1)
		no	67	88.2	68	90.7	66	88.0	201 (88.9)
'To be able to see'	226	yes	8	10.5	8	10.7	5	6.7	21 (9.3)
		no	68	89.5	67	89.3	70	93.3	205 (90.7)

* no significant differences between arms (i.e. p>0.2)

8.1.8 Subject motivation

Subject motivation (rated by optometrists using a three point scale) with respect to the use of LVAs loaned during the initial low vision assessment (see 7.3.2) was tested for differences between arms. No statistical difference was found using the chi-square test at baseline and at the second clinic assessment (at approximately 4 months) and there was also no significant difference between arms for these data.

The extent of diary completion (see 6.7) was explored as a proxy form of 'motivation', i.e. subjects who completed their diaries more fully during their 12 month participation in the trial might be argued to be more motivated generally in their use of LVAs. Also, diary completion could be argued as being linked to visual acuity and possibly task restriction. Therefore the extent of diary completion (measured as the number of partially or fully completed diaries returned) was also tested for differences (using the Chi-square test) between arms. No statistical difference was found.

Table 8.10 shows a comparison of measures of subject motivation by arm.

Table 8.10: Comparison of subject motivation variables by arm *

Measure of motivation	n	Category responses	Arm 1		Arm 2		Arm 3		All	
			Frequency	% (in arm)	Frequency	% (in arm)	Frequency	% (in arm)	Total frequency	(%)
Optometrist rating of patient motivation at initial low vision assessment	178	High	28	49.1	28	45.2	34	57.6	90	(50.6)
		Moderate	23	40.4	30	48.4	23	39.0	76	(42.7)
		Low	6	10.5	4	6.5	2	3.4	12	(6.7)
Optometrist rating of patient motivation at second low vision assessment (at approx. 4 mths)	155	High	21	37.5	18	37.5	19	37.3	58	(37.4)
		Moderate	29	51.8	25	52.1	28	54.9	82	(52.9)
		Low	6	10.7	5	10.4	4	7.8	15	(9.7)
Extent of diary completion (either partial or fully completed diaries)	226	0 diaries	27	35.5	22	29.3	22	29.3	71	(31.4)
		1 diary	25	32.9	14	18.7	18	24.0	57	(25.2)
		2 diaries	4	5.3	6	8.0	9	12.0	19	(8.4)
		3 diaries	4	5.3	8	10.7	7	9.3	19	(8.4)
		4 diaries	16	21.1	25	33.3	19	25.3	60	(26.5)

* no significant differences between arms (i.e. p>0.2)

8.2 Comparability of drop-outs versus non drop-outs

Baseline outcome measures and other patient characteristics were compared for subjects who had dropped out of the study against the baseline data for subjects who completed the trial. Although the number of drop-outs was relatively small compared to the number of subjects remaining in the study (32/226), this analysis was carried out to check whether the subjects who dropped out were a 'distinct' group by comparison with the remaining participants, and therefore would potentially influence the extent of generalisability of the study.

Appendix 18 contains the results of the comparisons presented as a set of tables representing several groups of variables. T-tests were used to test for significant differences between drop-outs and non drop-outs for continuous variables, and chi-square tests were used for discrete data. The p values obtained for some of the chi-square tests may not be very accurate due to more than 20% of expected cell frequencies being less than 5 for some of the variables (where this has occurred a footnote has been added to the table).

Significant differences (using $p<0.05$) were found between the two groups (i.e. drop-outs and non drop-outs) for several socio-demographic characteristics. The percentage of subjects who were receiving additional social care (i.e. the services of a home help ($p=0.02$), 'meals on wheels' ($p=0.001$) and personal care ($p=0.016$)) was higher among the drop-outs. Furthermore, the percentage of subjects who used public transport regularly (see 8.1.1 for the definition of this variable) was lower among drop-outs ($p=0.038$).

No significant differences between groups were found for visual functions and task restriction variables.

Three of the SF-36 dimensions, namely, physical functioning ($p=0.035$), role limitation due to physical problems ($p=0.013$) and general health perception ($p=0.035$) showed significant differences. The mean scores were at least 9.8 points lower for each of these dimensions among the drop-out group. Therefore, not surprisingly, the physical component summary score for the SF-36 was also lower for drop-outs and showed a significant difference ($p=0.045$).

The VCM1 showed significant differences for two of the domains, i.e. sadness/'feeling low' (p=0.044) and concern about safety when out of the home (p=0.043). However, whilst the mean score for the former domain was worse for drop-outs, the mean score was better for the drop-out group for the latter domain. The composite VCM1 score did not show a significant difference between the two groups.

Only one of the four NAS dimensions showed a difference between groups. The mean score for locus of control was lower, i.e. worse, for drop-outs with a borderline 'significance' of p=0.059.

The duration of the initial low vision assessment was compared for the two groups with no significant difference found. The duration of the second assessment was not compared since some subjects had already dropped out of the study by this time. However, since all of the drop-outs had attended the initial assessment, expectations of this assessment were compared for drop-outs and non drop-outs. A significant difference was found for three out of seven expectations, namely 'an improvement in vision' (p=0.029), 'information' (p=0.045), and 'to be able to see' (p=0.008). A higher proportion of subjects in the drop-out group had stated each of the three responses. Subject motivation with respect to the use of LVAs, as rated by optometrists, was compared for the initial low vision assessment. No significant difference was found for motivation between the two groups.

These results indicate that the drop-outs were perhaps a more frail group overall than the subjects who remained in the trial. This is evidenced by poorer scores on several physical dimensions of the SF-36, and by higher uptake of social care at home. The drop-out group also used public transport less and therefore the fact that this group were less concerned about their safety when out of the home can be explained by their likelihood of being more housebound. These findings may also explain why the drop-out group scored worse on both the 'sadness' domain of the VCM1 and on the 'locus of control' dimension of the NAS. These results are in keeping with the leading explanations for drop-outs which were death and ill-health preventing the collection of final outcomes.

8.3 Effectiveness of the interventions

Analysis of final outcome measures by arm to determine the effectiveness of the interventions in the trial followed a staged approach involving 5 statistical steps (as described in section 5.5.4). Initially analyses which were unadjusted for baseline measures were carried out on the outcome variables. This process involved two stages, namely analyses of variance to test for differences between arms and regression analyses to test for specific contrasts if differences were found. The results are given in 8.3.1 below. Analyses were then conducted, this time adjusting for corresponding baseline values, again using ANOVAs to test for differences between arms and regressions to test for specific contrasts. The findings for the two stages of adjusted analyses are given in 8.3.2. Finally in the last stage, outcome differences between arms were analysed by regression modelling, adjusting for baseline measures and covariates. The results are given in 8.3.3 below. The usual level of statistical significance, $p<0.05$, was used for these analyses.

8.3.1 Unadjusted analysis

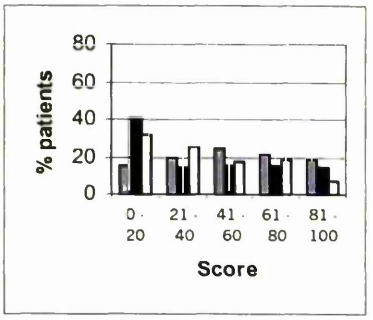
8.3.1.1 Analysis of variance

Simple univariate ANOVAs of 12 month continuous outcome variables, by arm, were carried out to test for differences between arms. For ordinal outcome scales, a simple univariate nonparametric ANOVA for rank order data (the Kruskal-Wallis test) was used. Category outcome variables were analysed using the chi-square test. Distributions of these outcome variables, by arm, are also presented in this section.

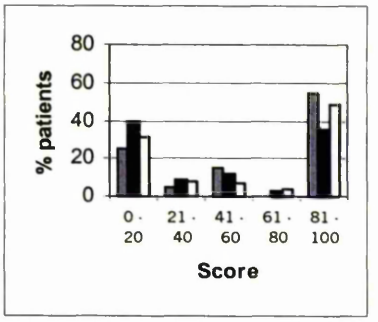
SF-36 dimension scores

The results of ANOVAs of the SF-36 dimensions are shown in table 8.11. Only two of the SF-36 dimensions indicated any difference between arms, namely physical functioning and energy / vitality (with best scores for arm 1 for each dimension). The physical component summary score also showed a difference between arms. Figure 8.1 shows a comparison of the distributions of the SF-36 dimensions at 12 months, by arm (the sample size values for n for each dimension are the same as those given in table 8.11). A comparison of the PCS and MCS scores are shown in figure 8.2.

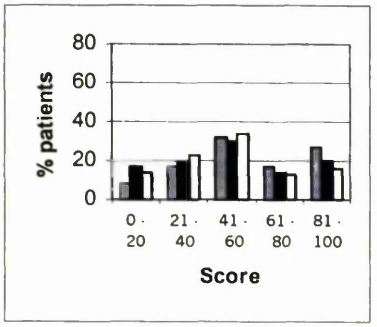
Physical functioning



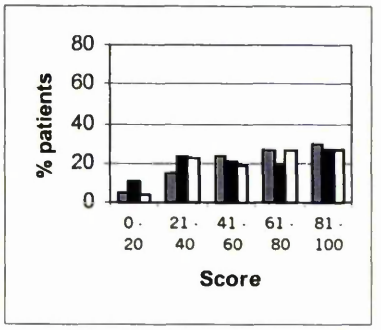
Role limitation: physical problems



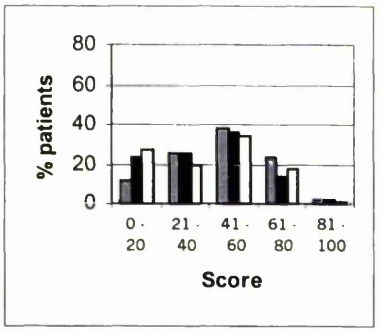
Bodily pain



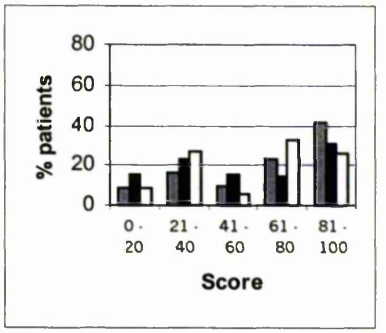
General health perception



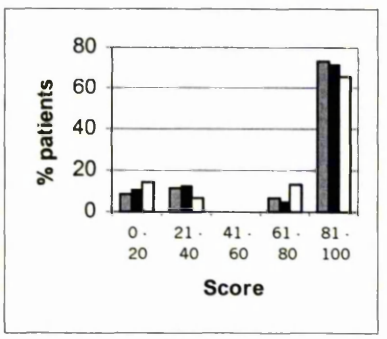
Energy / vitality



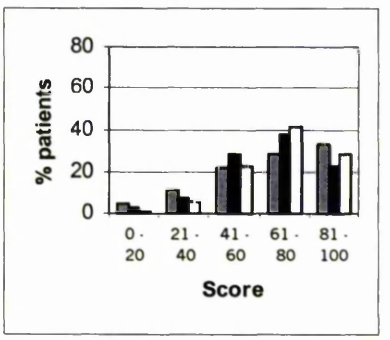
Social functioning



Role limitation: emotional problems



Mental health



Change in health

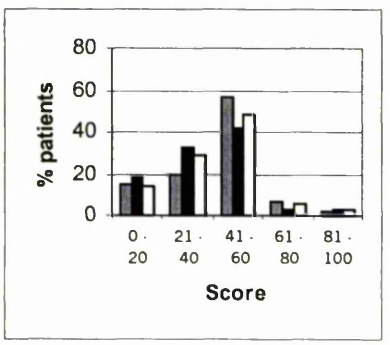
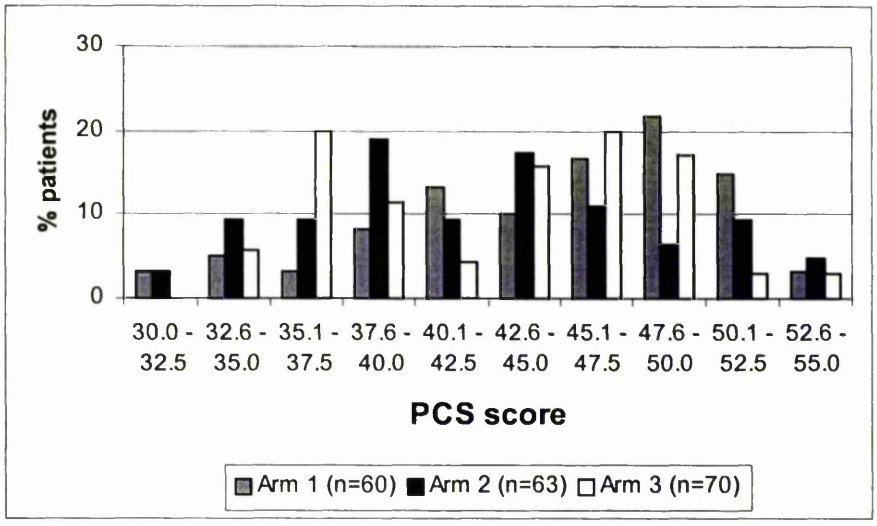


Figure 8.1: Distributions of the SF-36 dimensions at 12 months, by arm

Figure 8.2: Distributions of the SF-36 summary scores at 12 months, by arm

(a) PCS score



(b) MCS score

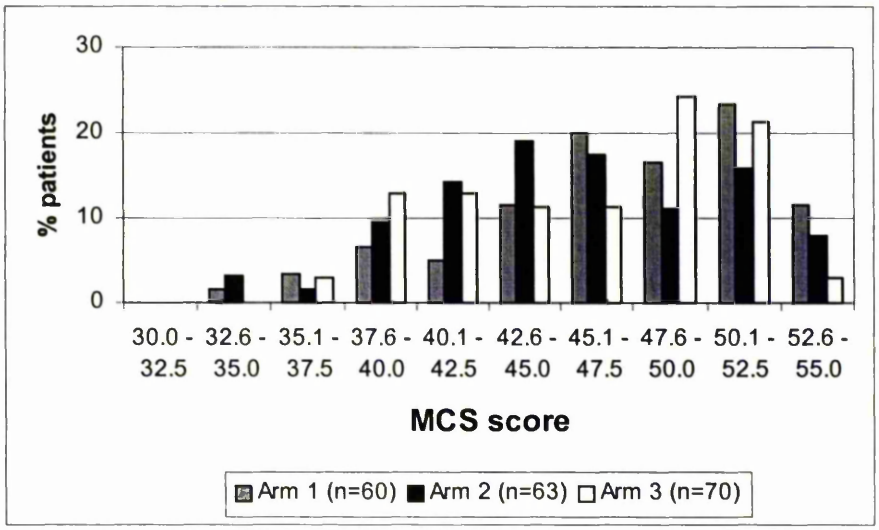


Table 8.11: Unadjusted analysis of variance of SF-36 dimension scores at 12 months

SF-36 Dimension	n	Arm 1 mean dimension score	Arm 2 mean dimension score	Arm 3 mean dimension score	F- statistic (df)	p value
Physical functioning	194	52.33	40.23	39.64	3.64 (2, 191)	0.0282**
Role limitation: physical problems	194	63.75	46.88	57.50	2.30 (2, 191)	0.1025
Bodily pain	194	56.60	49.27	46.89	1.78 (2, 191)	0.1716
General health perception	194	63.78	56.92	61.33	1.23 (2, 191)	0.2955
Energy / vitality	194	48.67	41.02	41.57	2.61 (2, 191)	0.0760*
Social functioning	194	67.50	55.47	60.71	2.22 (2, 191)	0.1115
Role limitation: emotional problems	194	81.67	79.17	76.67	0.32 (2, 191)	0.7257
Mental health	193	66.53	65.84	68.53	0.33 (2, 190)	0.7165
Physical component summary score	193	44.78	42.28	42.96	3.09 (2, 190)	0.0478**
Mental component summary score	193	47.15	45.59	46.21	1.53 (2, 190)	0.2201

df=degrees of freedom

* $p<0.1$ ** $p<0.05$

VCM1 scores

The results of this analysis are given in table 8.12. The only individual domain of the VCM1 which showed any difference between arms was the subjects' response with respect to the extent that eyesight interfered with life in general. The overall VCM1 score did not show any difference between arms. Figure 8.3 shows a comparison of the distribution of the overall VCM1 score, by arm, at 12 months.

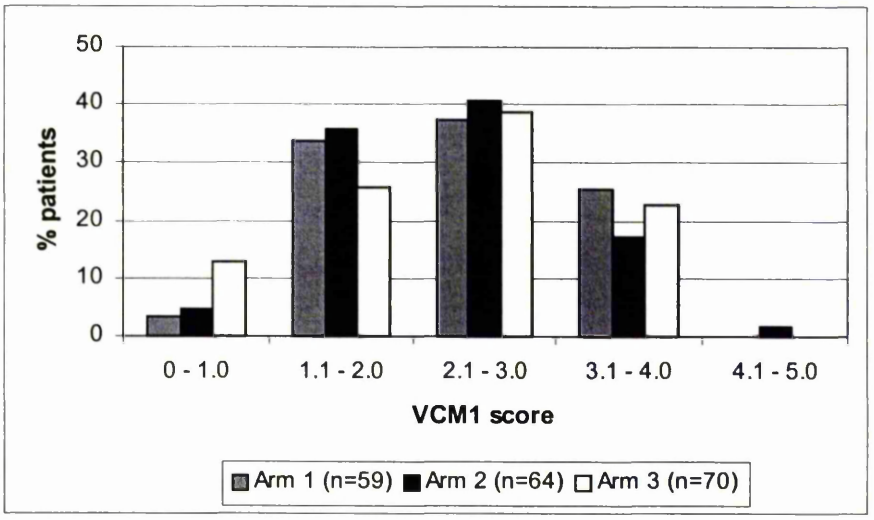
Table 8.12: Unadjusted analysis of variance of VCM1 scores at 12 months

VCM1 domain	n	Arm 1 mean domain score	Arm 2 mean domain score	Arm 3 mean domain score	F- statistic (df)	p value
Embarrassment	194	1.97	2.03	1.76	1.01 (2, 191)	0.3676
Frustration / annoyance	193	3.03	3.03	2.86	0.52 (2, 190)	0.5926
Loneliness / isolation	194	1.43	1.59	1.30	0.80 (2, 191)	0.4511
Sadness / 'feeling low'	194	2.22	2.30	2.03	0.74 (2, 191)	0.4802
Worry about eyesight getting worse	194	1.97	1.84	1.93	0.15 (2, 191)	0.8603
Concern about safety at home	194	0.72	0.80	0.64	0.37 (2, 191)	0.6886
Concern about safety when out of the home	194	2.67	2.48	2.40	0.64 (2, 191)	0.5281
Concern about coping with everyday life	194	2.75	2.63	2.57	0.64 (2, 191)	0.5291
Eyesight 'stopping you doing the things you want to do'	194	3.43	3.23	3.17	1.27 (2, 191)	0.2846
Eyesight interfering with life in general	194	3.83	3.52	3.39	2.76 (2, 191)	0.0660*
VCM1 score	193	2.40	2.35	2.20	0.97 (2, 190)	0.3828

df=degrees of freedom

* $p<0.1$

Figure 8.3: Distribution of the overall VCM1 score, by arm, at 12 months.



NAS dimension scores

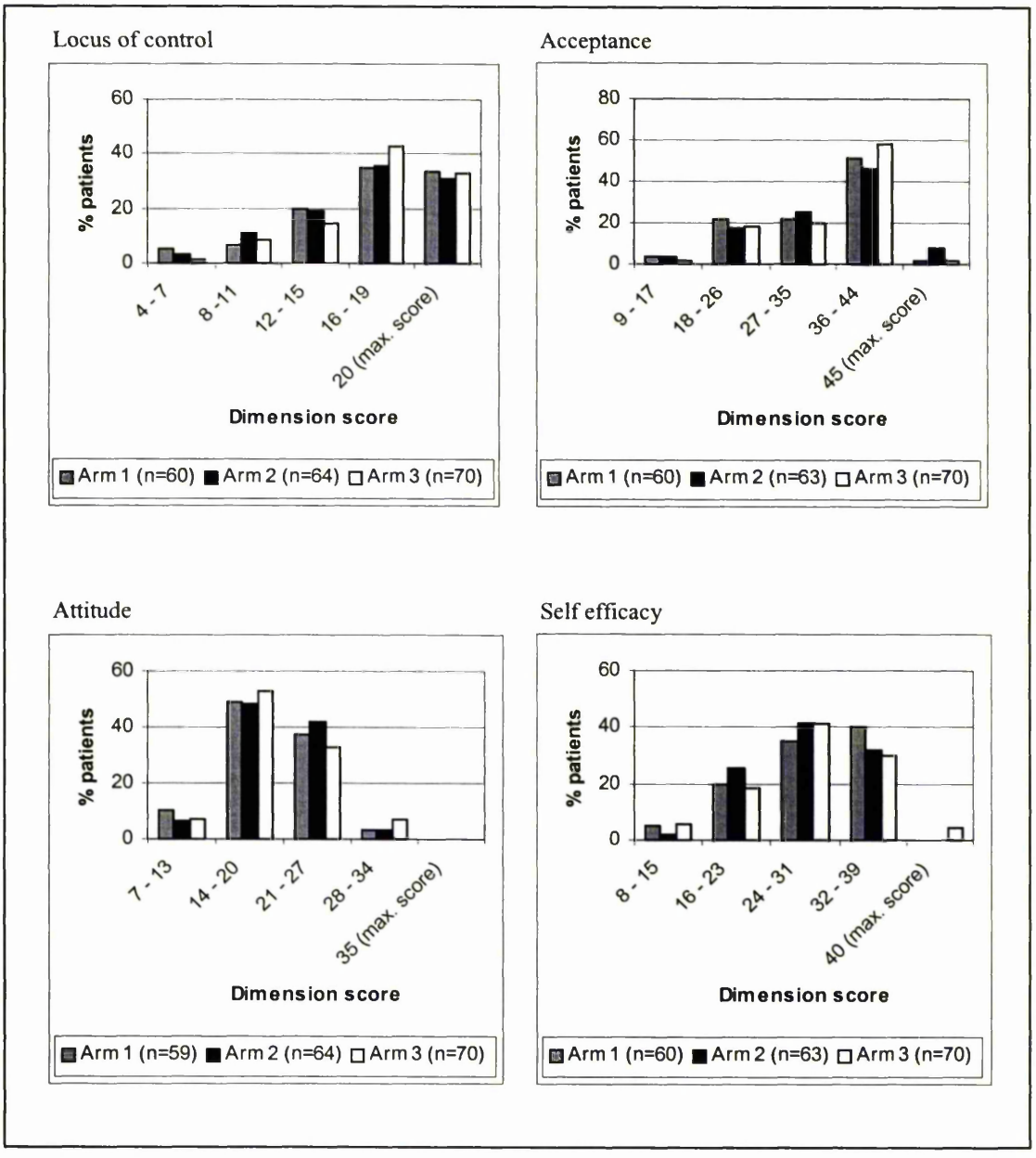
The results of ANOVAs for the NAS dimensions are given in table 8.13. None of the four dimensions showed any difference between arms. Figure 8.4 gives comparisons of distributions of the four NAS dimensions, by arm, at 12 months.

Table 8.13: Unadjusted analysis of variance of NAS dimensions at 12 months

NAS Dimension	n	Arm 1 mean dimension score (n)	Arm 2 mean dimension score (n)	Arm 3 mean dimension score (n)	F- statistic (df)	P value
Locus of control *(possible score: 4-20)*	194	16.47 (60)	16.52 (64)	16.96 (70)	0.35 (2, 191)	0.7049
Acceptance *(possible score: 9-45)*	193	34.05 (60)	34.57 (63)	35.34 (70)	0.39 (2, 190)	0.6763
Attitude *(possible score: 7-35)*	193	19.56 (59)	20.16 (64)	20.13 (70)	0.29 (2, 190)	0.7518
Self efficacy *(possible score: 8-40)*	193	27.57 (60)	27.78 (63)	28.26 (70)	0.17 (2, 190)	0.8429

df=degrees of freedom

Figure 8.4: Distributions of the four NAS dimensions, by arm, at 12 months



Note: High scores represent the better state.

Self-rated task restriction scores and measured task performance

Neither the overall average task restriction score nor the average reading restriction score showed any difference between arms.

Measured task performance percentage scores calculated for a set of reading tasks, i.e. based on reading grocery labels, medicine instructions and items on a shopping list (see 7.3.3 for the derivation of these values), were analysed using two different outcome groupings. A dichotomous variable representing subjects who scored more than 50% or less than or equal to 50% was generated. A second dichotomous variable using a higher cut-off value was generated for subjects scoring more than 75%. The different cut-offs were used to ensure that differences would not be missed.

Similarly, three different outcome groupings were established for the task of reading use-by-dates on grocery labels. A dichotomous variable was created which represented the subject's ability to read at least one of two use-by-dates on two separate grocery labels versus not managing to read any. A second dichotomous variable represented subjects who could read the use-by-dates on both of the labels versus only one or none. A third variable was generated with three ordinal categories, being able to read both use-by-dates, being able to read only one date, and not being able to read either dates.

Finally, three different outcome groupings were constructed for the multi-component task of reading the instructions on a medicine bottle (i.e. the name of the medicine and the dosage). A dichotomous variable divided subjects into those who could read either the name or the dosage of the medicine and those who could not identify either. Another dichotomous variable was created to distinguish subjects who could read both the name and the dosage of the medicine and those who could only read part or none of the information required. A third variable with three ordinal categories was used to identify subjects who could read both the name and dosage of the medicine, those who could read the name of the medicine only, and those who could not read either part of the medicine instructions.

There was some marginal statistical difference indicated between arms for the grocery label and medicine instruction tasks. There was some suggestion that subjects in arm 3 were managing to perform slightly better than those in arms 1 and 2 with respect to

reading both of the use-by-dates. Subjects in arm 3 also performed slightly better in managing to read both the name and dosage in the medicine instructions task.

Table 8.14 (a) gives the results of the analysis of self-rated task restriction for arm differences, and table 8.14 (b) shows the findings for measured task performance. Figure 8.5 (a) and (b) shows the distributions of the average task restriction score and the average reading restriction score respectively by arm, at 12 months.

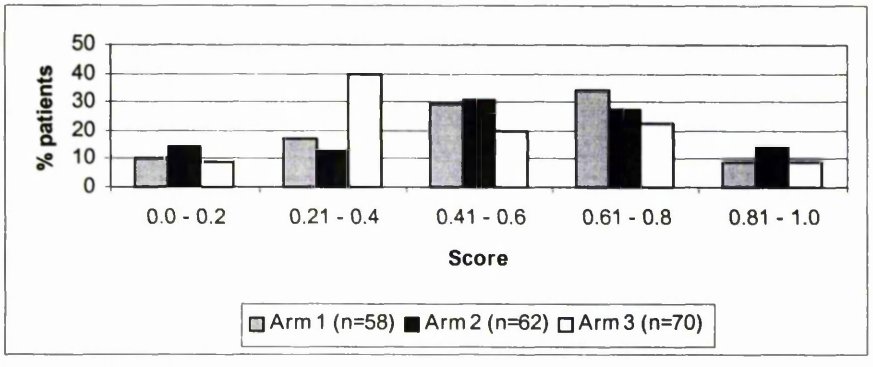
Table 8.14 (a): Unadjusted analysis of variance of average task restriction scores at 12 months

Restriction score	n	Arm 1 mean dimension score	Arm 2 mean dimension score	Arm 3 mean dimension score	F- statistic (df)	p value
Average general task restriction score	190	0.53	0.53	0.46	1.98 (2, 187)	0.1414
Average reading restriction score	91	0.55	0.65	0.50	1.43 (2, 88)	0.245

df=degrees of freedom (Note: lower scores = less task restriction)

Figure 8.5: Distributions of task restriction scores

(a) Average general task restriction score



(b) Average reading restriction score

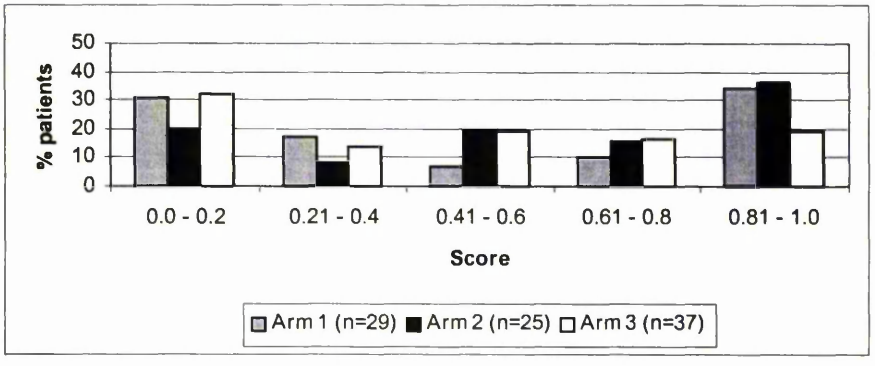


Table 8.14 (b): Chi-square analysis of arm differences for task performance outcomes at 12 months

Restriction score	n (all)	Arm 1 % frequency	Arm 2 % frequency	Arm 3 % frequency	χ^2	p value
Task performance percentage score groups for reading tasks:		(n=58)	(n=63)	(n=70)		
<=50% scored		44.8	55.6	38.6	3.902	0.142
>50% scored	191	55.2	44.4	61.4		
<=75% scored		53.4	63.5	44.3	4.915	0.086*
>75% scored		46.6	36.5	55.7		
Task performance outcome category groups for reading 2 grocery label 'use-by-dates':		(n=59)	(n=63)	(n=70)		
None read		33.9	38.1	22.9		
One read		32.2	38.1	28.6	9.337	0.053*
Both read	192	33.9	23.8	48.6		
None read		33.9	38.1	22.9	3.862	0.145
At least one read		66.1	61.9	77.1		
None or one read		66.1	76.2	51.4	8.985	0.011**
Both read		33.9	23.8	48.6		
Task performance outcome category groups for reading medicine (name & dose) instructions:		(n=58)	(n=64)	(n=70)		
None read		44.8	53.1	38.6		
Name only read		6.9	9.4	4.3	5.542	0.236
Name & dose read	192	48.2	37.5	57.1		
None or dose only read		44.8	53.1	38.6	2.866	0.239
Name (or name+dose) read		55.2	46.9	61.4		
None or dose only read		51.7	62.5	42.9	5.173	0.075*
Name & dose read		48.3	37.5	57.1		

* p<0.1 ** p<0.05

Patterns of LVA use

The results of a simple univariate nonparametric ANOVA for rank order data (the Kruskal-Wallis test) used to look for arm differences in respect to patterns of LVA use, are given in table 8.15. Each of these three variables used a five-point scale. The three variables included in the analysis were the frequency of use of the primary LVA loaned to / owned by the subjects (see 7.3.4 which describes the process which was used to identify a primary LVA for each subject at 12 month follow-up), the average duration of use, and the longest duration of use of the primary LVA. None of these three measures showed any arm difference. Figure 8.6 (a), (b) and (c) shows distributions of the three process measures for LVA use, by arm, at 12 months. (A similar analysis of secondary aids (see 7.3.4) also failed to show any arm difference).

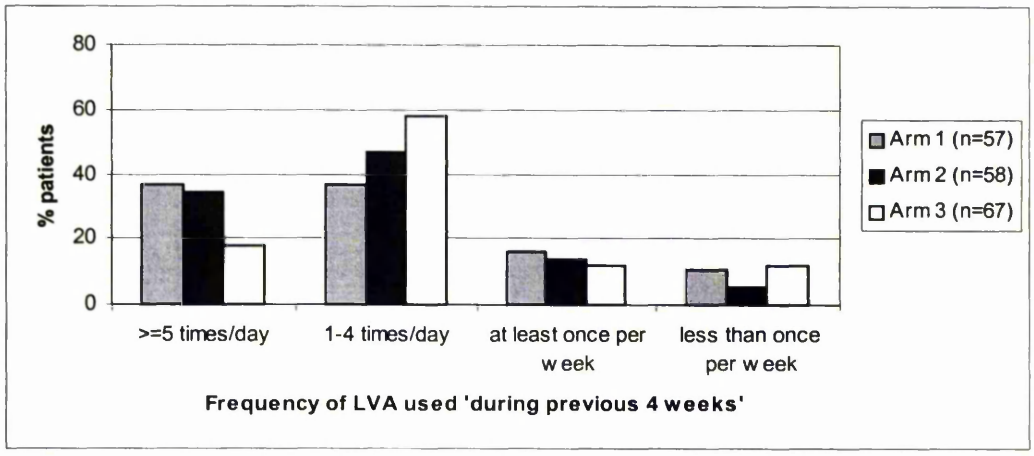
Table 8.15: Kruskal-Wallis nonparametric ANOVA for arm differences for LVA use process measures

Process measures for primary LVA	**n (all)**	**Arm 1 % frequency**	**Arm 2 % frequency**	**Arm 3 % frequency**	**χ^2 with ties (df)**	**p value**
Frequency of use		(n=57)	(n=58)	(n=67)		
Less than once per week		10.5	5.1	12.0		
At least once per week	182	15.8	13.8	11.9	3.549	0.1696
1-4 times per day		36.8	46.6	58.2	(2)	
>=5 times per day		36.8	34.5	17.9		
Average duration of use		(n=53)	(n=56)	(n=63)		
< 1 minute		1.9	1.8	0.0		
1-4 minutes	172	64.2	58.9	74.6	2.209	0.3314
5-14 minutes		26.4	28.6	20.6	(2)	
15-29 minutes		5.7	7.1	0.0		
>=30 minutes		1.9	3.6	4.8		
Longest duration of use		(n=53)	(n=56)	(n=63)		
1-4 minutes		58.5	44.6	57.1		
5-14 minutes	172	11.3	30.4	30.2	2.251	0.3245
15-29 minutes		9.4	14.3	4.8	(2)	
>=30 minutes		20.8	10.7	7.9		

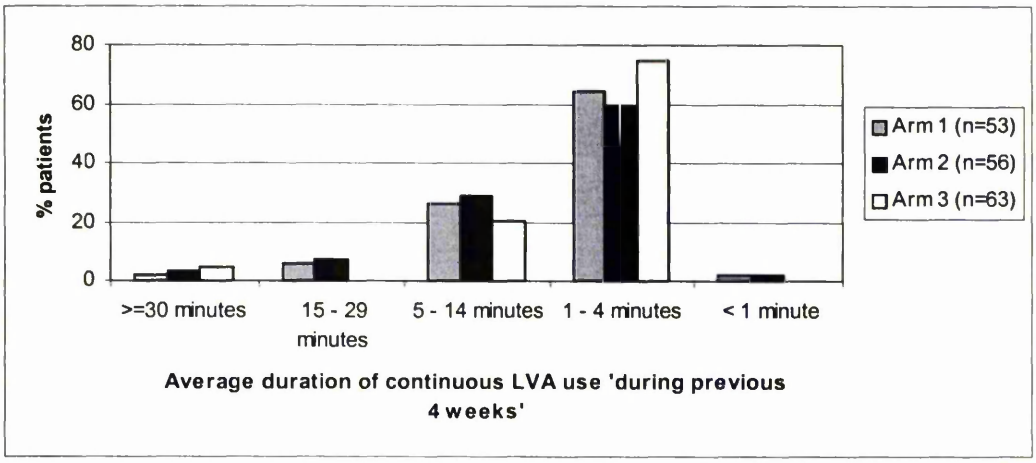
df=degrees of freedom

Figure 8.6: Patterns of use of the primary LVA, by arm, at 12 months

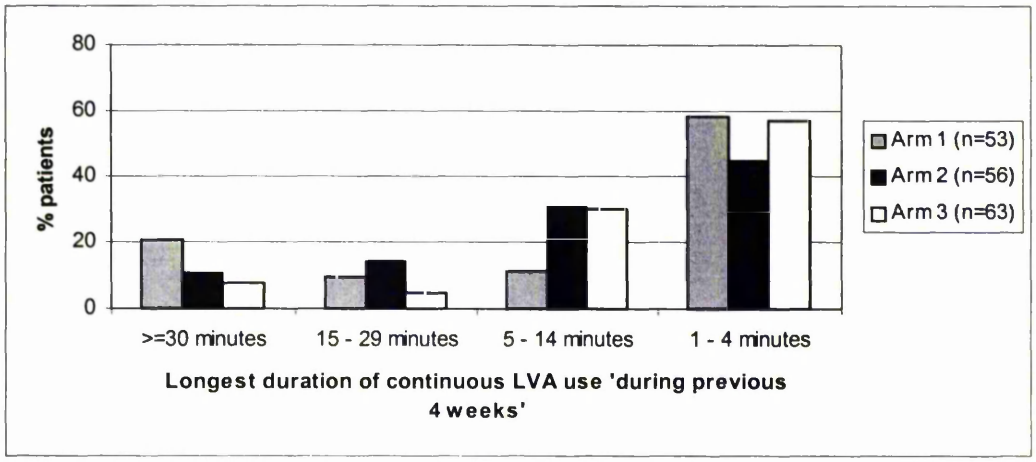
(a) Frequency of use (reported for the 'previous 4 weeks')



(b) Average duration of continuous use (reported for the 'previous 4 weeks')



(c) Longest duration of continuous use (reported for the 'previous 4 weeks')



Knowledge about use of residual vision in AMD

The responses to three questions concerning subjects' understanding of the use of their residual vision (see 7.4.1) were transformed into dichotomous variables for outcome analysis. Each variable divided subjects into those who correctly offered 'agreement' or 'strong agreement' (or conversely disagreement where appropriate) versus those who were uncertain of the correct response or who disagreed incorrectly. Simple univariate cross-tabulations by arm did not show any significant differences between arms for any of the knowledge questions. The results are given in table 8.16. Figure 8.7 (a), (b) and (c) shows the distribution of the actual responses for each of the three questions regarding the use of residual vision, by arm, at 12 months.

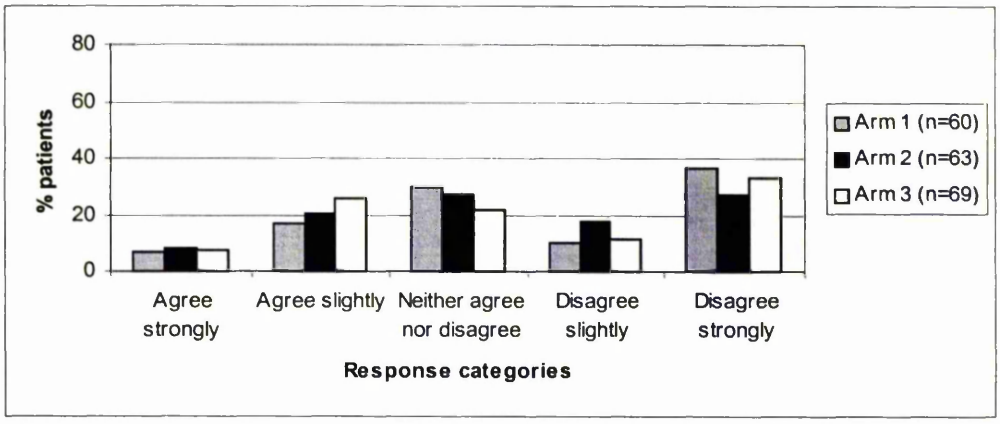
Table 8.16: Chi-square analysis of arm differences for questions assessing subject understanding of the use of residual vision, at 12 months

Statement used to assess understanding of the use of residual vision	**n (all)**	**Arm 1 % frequency**	**Arm 2 % frequency**	**Arm 3 % frequency**	χ^2	**p value**
"Using your eyes too much will make your remaining vision worse"	192	(n=60)	(n=63)	(n=69)		
Correctly disagreed		46.67	44.44	44.93	0.0677	0.967
Agreed / uncertain		53.33	55.56	55.07		
"Sitting too close to the TV causes your eyesight to worsen"	192	(n=60)	(n=62)	(n=70)		
Correctly disagreed		63.33	61.29	55.71	0.8549	0.652
Agreed / uncertain		36.67	38.71	44.29		
"When you are reading, more light will improve your ability to see"	193	(n=60)	(n=63)	(n=70)		
Correctly agreed		85.00	92.06	92.86	2.6309	0.268
Disagreed / uncertain		15.00	7.94	7.14		

Figure 8.7: Distributions of subject responses to each of three questions regarding the use of residual vision, by arm, at 12 months.

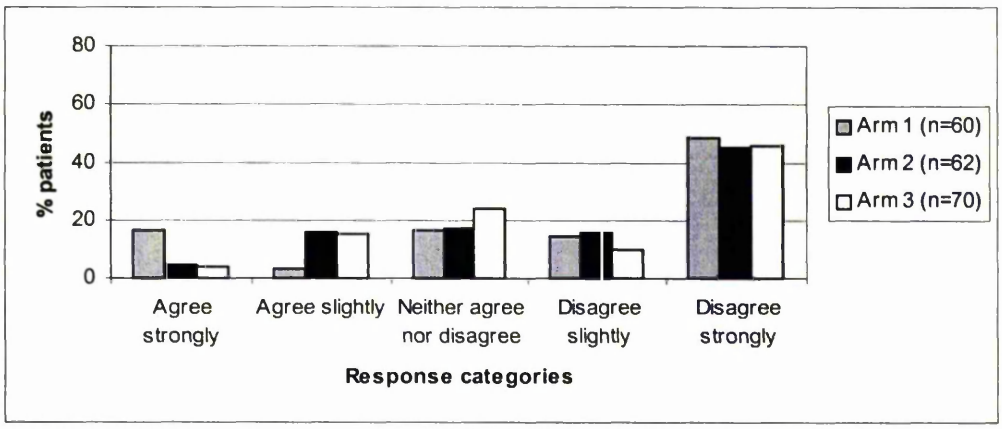
(a) Responses to the statement:

"Using your eyes too much will make your remaining vision worse"



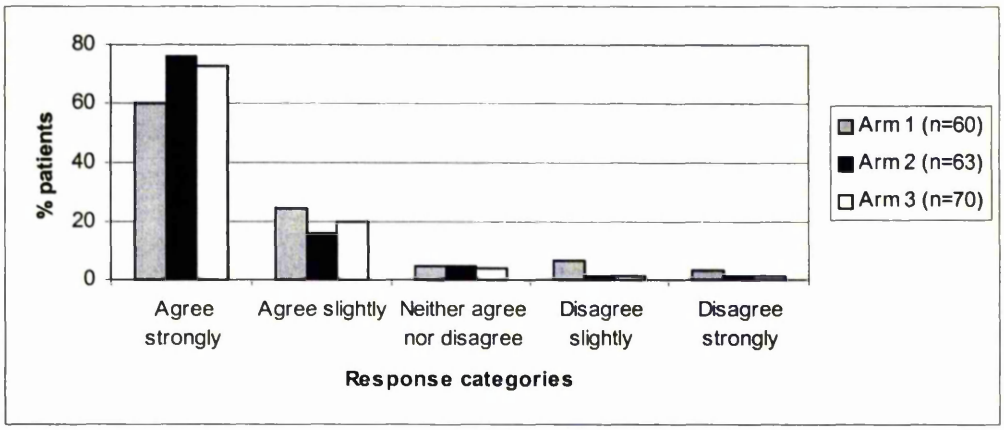
(b) Responses to the statement:

"Sitting too close to the TV causes your eyesight to worsen"



(c) Responses to the statement:

"When you are reading, more light will improve your ability to see"



8.3.1.2 Contrasts between arms

In the second stage of unadjusted analysis, regressions were carried out to test for specific differences, i.e. 'contrasts', between arms, to see whether there was any indication that arm 2 outcomes were better than outcomes in arms 1 and 3, as hypothesised at the outset (see 5.5.4 and 5.5.6). Arm 2 was therefore assigned as the base category for this analysis, and two dummy variables were generated to represent the remaining arms. The regression equation modelled therefore was:

$$Outcome = \beta_2 arm1 + \beta_1 arm3 + \beta_0$$

where: β_0 is the mean of the outcome for arm 2

β_1 is the difference between the mean for arm 3 and arm 2

β_2 is the difference between the mean for arm 1 and arm 2

(β symbolises the regression coefficients)

Strictly speaking only the outcome variables which had indicated statistically significant differences between arms in the first stage of unadjusted analysis of variance (8.3.1.1 above) needed to be included in this stage. However, for completeness, other key outcome variables which had not shown arm differences in the first stage were also included in this analysis (these were the overall VCM1 score, the four NAS dimension scores and task restriction scores). Logistic regression was used for the task performance variables (since these variables are dichotomous) which had shown some arm differences. However, patterns of LVA use and understanding of residual vision, which had not shown any arm differences at all in the first stage of analysis, were excluded from this stage. The results of linear regressions are presented in table 8.17. Table 8.18 gives the results of the logistic regressions used for measured task performance variables.

Table 8.17: Unadjusted linear regression analysis of key outcome variables by randomisation arms 1 and 3, against arm 2

Outcome variable	n	Differences between means							
		Arm 1				Arm 3			
		Coef.	95% CI	t	p value	Coef.	95% CI	t	p value
SF-36 scores:									
Physical functioning	194	12.099	1.593 - 22.605	2.27	0.024*	-0.591	-10.703 - 9.520	-0.12	0.908
Energy / vitality	194	7.651	0.285 – 15.017	2.05	0.042*	0.556	-6.533 - 7.645	0.15	0.877
Physical component summary score	193	2.505	0.452 – 4.559	2.41	0.017*	0.685	-1.292 – 2.662	0.68	0.495
VCM1 domain & score:									
Vision interfering with life in general	194	0.318	-0.074 – 0.709	1.60	0.111	-0.130	-0.507 – 0.247	-0.68	0.497
VCM1 overall score	193	0.055	-0.242 – 0.351	0.36	0.716	-0.141	-0.425 – 0.143	-0.98	0.329
NAS scores:									
Locus of control score	194	-0.049	-1.372 – 1.274	-0.07	0.942	0.442	-0.831 – 1.715	0.68	0.495
Acceptance	193	-0.521	-3.510 – 2.467	-0.34	0.731	0.771	-2.106 – 3.648	0.53	0.597
Attitude	193	-0.597	-2.354 – 1.160	-0.67	0.504	-0.028	-1.711 – 1.656	-0.03	0.974
Self efficacy	193	-0.211	-2.682 – 2.260	-0.17	0.866	0.479	-1.900 – 2.859	0.40	0.691
Average task restriction scores:									
General restriction	190	-0.006	-0.089 – 0.077	-0.14	0.889	-0.072	-0.151 – 0.008	-1.78	0.077
Reading restriction	91	-0.103	-0.293 – 0.087	-1.08	0.285	-0.153	-0.333 – 0.028	-1.68	0.096

CI = confidence interval

* $p<0.05$

Table 8.18: Unadjusted logistic regression analysis of key outcome variables by randomisation arms 1 and 3, against arm 2

Task performance assessment outcome variable	n	Arm 1				Arm 3			
		OR	95% CI	z	p value	OR	95% CI	z	p value
Percentage score for reading tasks:									
Score > 50%	191	1.538	0.751 – 3.153	1.18	0.239	1.991	0.997 – 3.976	1.95	0.051
Score > 75%	191	1.515	0.732 – 3.135	1.12	0.263	2.188	1.090 – 4.392	2.20	0.028*
Reading 2 'use-by-dates':									
At least one 'use-by-date' read	192	1.200	0.572 – 2.518	0.48	0.630	2.077	0.976 – 4.418	1.90	0.058
Both 'use-by-dates' read	192	1.641	0.744 – 3.622	1.23	0.220	3.022	1.434 – 6.370	2.91	0.004**
Reading medicine instructions:									
At least name of medicine read	192	1.395	0.684 – 2.847	0.91	0.360	1.805	0.908 – 3.590	1.68	0.092
Name and dose of medicine read	192	1.556	0.756 - 3.202	1.20	0.230	2.222	1.111 – 4.444	2.26	0.024*

OR = Odds ratio

CI = Confidence interval

* $p<0.05$ ** $p<0.01$

SF-36 dimension scores

Two SF-36 dimensions, namely physical functioning and energy / vitality which had shown arm differences were included, as was the physical component summary score. Table 8.17 shows that whilst arms 2 and 3 are essentially similar, arm1 appears to be better (i.e. scores are higher) for these two dimensions and for the physical component summary score, without adjusting for baseline.

VCM1 scores

There was no evidence of any arm effect for the overall VCM1 score or even for the domain score representing the extent to which eyesight had 'interfered with life in general' which had initially shown some difference between arms.

NAS dimension scores

There was no evidence of any arm effect for each of the NAS dimensions with coefficients for arms 1 and 3 being close to zero.

Self-rated task restriction scores and measured task performance

Although the average task restriction score did not show a difference between arms for a simple unadjusted ANOVA, this outcome score showed a possible arm effect in favour of arm 2, which appeared to be slightly better than arm 3. However, the coefficient for arm 1 was close to zero, i.e. the same as arm 2. The evidence for a possible arm effect in favour of arm 2 with respect to arm 3 was again marginal for the average reading restriction score, but again arms 1 and 2 were reasonably similar (although the coefficient for arm 1 was not close to zero).

Task performance outcomes which had shown some marginal arm differences between arms (using the chi-square test) were analysed using logistic regression (as stated above). The results indicate that subjects in arm 3 are more able to perform reading tasks (see table 8.18).

8.3.2 Analysis adjusting for corresponding baseline measurements

8.3.2.1 Analysis of variance

In this third stage of analysis, univariate ANOVAs of 12 month scores, adjusting for baseline outcomes, by arm were carried out to test for differences between arms. Where possible, outcome variables analysed in the first stage (8.3.1 above) were included. However some outcome variables could not be included in analyses adjusting for baseline measures due to the unavailability of the latter. For example, patterns of LVA use could not be included here since primary LVAs could not be identified at the start of the trial. Similarly, measured task performance was not assessed at baseline and is therefore excluded from analyses adjusting for baseline. Outcome measures representing subject understanding about the use of residual vision, are excluded from this stage (since it was not appropriate to adjust for baseline), but included in the fourth stage of regression analysis (see 8.3.4) below. The findings are presented below.

SF-36 dimension scores

The results of the ANOVAs for the individual SF-36 dimensions and for the physical and mental component summary scores, after adjustment for baseline, are given in table 8.19. Four of the dimensions, i.e. role limitation due to physical problems, social functioning, energy / vitality and general health perception, indicate some overall difference between arms. Both the physical and mental component summary scores also show arm differences.

VCM1 scores

Neither individual VCM1 domains nor the overall VCM1 composite score showed any difference between arms having adjusted for baseline values. The results are given in table 8.20.

Table 8.19: Analysis of variance of SF-36 dimension scores at 12 months, adjusted for corresponding baseline measures

SF-36 Dimension	n	F- statistic (df)	p value
Physical functioning	194	2.21 (3, 190)	0.1125
Role limitation: physical problems	194	3.72 (3, 190)	0.0259*
Bodily pain	194	1.16 (3, 190)	0.3165
General health perception	194	2.69 (3, 190)	0.0706
Energy / vitality	194	5.29 (3, 190)	0.0058**
Social functioning	194	4.60 (3, 190)	0.0112*
Role limitation: emotional problems	189	0.33 (3, 185)	0.7211
Mental health	192	2.29 (3, 188)	0.1037
Physical component summary score	187	6.85 (3, 183)	0.0014**
Mental component summary score	187	7.26 (3, 183)	0.0009***

df=degrees of freedom

* $p<0.05$ ** $p<0.01$ *** $p<0.001$

Table 8.20: Analysis of variance of VCM1 scores at 12 months, adjusted for corresponding baseline measures

VCM1 domain	n	F- statistic (df)	p value
Embarrassment	193	1.20 (7, 185)	0.3029
Frustration / annoyance	193	0.72 (7, 185)	0.4866
Loneliness / isolation	194	2.11 (6, 187)	0.1237
Sadness / 'feeling low'	194	0.42 (7,186)	0.6573
Worry about eyesight getting worse	194	0.25 (7,186)	0.7816
Concern about safety at home	194	0.39 (6,187)	0.6790
Concern about safety when out of the home	194	0.28 (7,186)	0.7593
Concern about coping with everyday life	194	0.27 (7,186)	0.7632
Eyesight 'stopping you doing the things you want to do'	194	0.29 (7,186)	0.7495
Eyesight interfering with life in general	194	1.23 (7,186)	0.2954
VCM1 score	192	0.52 (3,188)	0.5961

df=degrees of freedom

NAS dimension scores

The results of ANOVAs with adjustment for corresponding baseline scores are given in table 8.21. As for the unadjusted analyses of variance, none of the dimensions showed a difference between arms after adjustment for baseline.

Table 8.21: Analysis of variance of NAS dimension scores at 12 months, adjusted for corresponding baseline measures

NAS Dimension	n	F- statistic (df)	P value
Locus of control	194	0.32 (3, 190)	0.7258
Acceptance	192	0.16 (3, 188)	0.8560
Attitude	193	0.06 (3, 189)	0.9424
Self efficacy	193	0.28 (3, 189)	0.7553

df=degrees of freedom

Self-rated task restriction scores

There were no arm differences for either the overall average task restriction score or the average reading restriction score when ANOVAs were carried out with adjustment for baseline. The results are shown in table 8.22.

Table 8.22: Analysis of variance of average task restriction scores at 12 months, adjusted for corresponding baseline measures

Restriction score	n	F- statistic (df)	p value
Average general task restriction score	172	1.33 (3, 168)	0.268
Average reading restriction score	69	1.63 (3, 65)	0.204

df=degrees of freedom

8.3.2.2 Contrasts between arms using regression analysis adjusted for baseline

As for the second stage of analysis (8.3.2 above), regressions were carried out to test for specific 'contrasts' between arms, also adjusting for corresponding outcome measures at baseline. Again, in keeping with the main hypothesis, arm 2 versus arm 1, and arm 2 versus arm 3, were explored. For this fourth stage of analysis, outcome measures which had demonstrated arm differences at the third stage, i.e. for univariate ANOVAs adjusting for baseline, were all included. Although strictly unnecessary, other key outcome measures which had not shown arm differences were also included for completeness and to corroborate the findings for these variables at the previous stage of analysis. As for the third stage of analysis requiring adjustment for baseline, patterns of LVA use and measured task performance outcomes were excluded from this analysis due to the unavailability of baseline outcomes. Regression analysis results are given in table 8.23.

SF-36 dimension scores

The four dimensions which had indicated some overall arm differences after adjusting for baseline, i.e. role limitation due to physical problems, social functioning, energy / vitality, and general health perception, and both the physical and mental component summary scores were included in the regression analysis with baseline adjustment. The results show that arms 2 and 3 are essentially the same for the first three dimensions, but arm 1 appears to be better for these outcomes. For the general health perception dimension, both arms 1 and 3 are slightly better, but with marginal significance, than arm 2. Both arms 1 and 3 were better (arm 1 more so than arm 3) than arm 2 for each of the physical and mental component summary scores. The findings for the component summary measures are consistent with the results for individual SF-36 dimensions, but are more sensitive because the former are aggregated scores.

VCM1 scores

There was no evidence of any arm effect for the overall VCM1 score or for the VCM1 domain scores after adjusting for baseline values, with the possible exception of the domain score for loneliness / isolation. This domain analysis indicated that arm 1 was slightly better than arm 2 on this domain (but with marginal statistical significance).

Table 8.23: Linear regression analysis of key outcome variables by randomisation arms 1 and 3, against arm 2, adjusted for baseline measures

Outcome variable	n	Differences between means							
		Arm 1				Arm 3			
		Coef.	95% CI	t	p value	Coef.	95% CI	t	p value
SF-36 scores:									
Role limitation: physical problems	194	21.080	5.469 – 36.692	2.66	0.008**	14.302	-0.685 – 29.290	1.88	0.061
Social functioning	194	15.483	5.413 – 25.553	3.03	0.003**	7.563	-2.106 – 17.233	1.54	0.125
Energy / vitality	194	10.649	4.149 – 17.149	3.23	0.001***	4.271	-2.013 – 10.556	1.34	0.182
General health perception	194	7.548	0.102 – 14.993	2.00	0.047*	7.366	0.171 – 14.561	2.02	0.045*
Physical component summary score	187	2.986	1.371 – 4.601	3.65	0.000****	1.898	0.343 – 3.453	2.41	0.017*
Mental component summary score	187	2.881	1.376 – 4.386	3.78	0.000****	1.753	0.317 – 3.189	2.41	0.017*
VCM1:									
VCM1 overall score	192	-0.061	-0.297 – 0.174	-0.52	0.607	-0.116	-0.342 – 0.109	-1.02	0.310
NAS scores:									
Locus of control score	194	0.421	-0.834 – 1.677	0.66	0.509	0.437	-0.759 – 1.633	0.72	0.472
Acceptance	192	0.362	-2.319 – 3.043	0.27	0.790	0.726	-1.841 – 3.293	0.56	0.578
Attitude	193	-0.215	-1.765 – 1.335	-0.27	0.785	0.033	-1.449 – 1.516	0.04	0.965
Self efficacy	193	0.442	-1.996 – 2.880	0.36	0.721	0.885	-1.445 – 3.214	0.75	0.455
Average task restriction scores:									
General restriction	172	-0.044	-0.106 – 0.019	-1.37	0.172	-0.044	-0.105 – 0.017	-1.44	0.153
Reading restriction	69	-0.144	-0.316 – 0.028	-1.68	0.099	-0.115	-0.271 – 0.042	-1.46	0.148

CI = confidence interval

* p<0.05 **p<0.01 ***p<0.001 ****p<0.0001

NAS dimension scores

There was no evidence of any arm effect for each of the NAS dimensions after adjusting for baseline.

Self-rated task restriction scores

There was no evidence of any arm effect on the general average task restriction score, with both coefficients for arms 1 and 3 close to zero. There was also no evidence of an arm effect on the average reading restriction score after adjustment for baseline.

Knowledge about the use of residual vision

Logistic regression analyses with adjustment for baseline values were carried out on the three outcome variables representing subjects' understanding of the use of residual vision. The results of these analyses are given in table 8.24 and show no evidence of arm effects.

Table 8.24: Logistic regression analysis of key outcome variables by randomisation arms 1 and 3, against arm 2, adjusted for baseline measures

Outcome variables representing subject understanding of the use of residual vision	**n**	**Arm 1**				**Arm 3**			
		OR	**95% CI**	**z**	**p value**	**OR**	**95% CI**	**z**	**P value**
Response to *"Using your eyes too much will make your remaining vision worse"*:									
Correctly answered	191	1.027	0.501 – 2.103	0.07	0.943	0.966	0.483 – 1.932	-0.10	0.923
Response to *"Sitting too close to the TV causes your eyesight to worsen"*:									
Correctly answered	191	1.017	0.478 – 2.165	0.04	0.964	0.756	0.369 – 1.549	-0.76	0.445
Response to: *"When you are reading, more light will improve your ability to see"*:									
Correctly answered	193	0.585	0.177 – 1.931	-0.88	0.379	1.398	0.370 – 5.287	0.49	0.621

OR = Odds ratio

CI = Confidence interval

8.3.3 Multivariate regression analysis of outcomes, adjusting for baseline and covariates, by arm

In the final stage of analysis, outcome differences between arms at 12 months were analysed by regression modelling, adjusting for baseline measures and covariates. This required multiple linear regression for continuous outcome measures, and logistic regression for ordinal data (see also 5.5.4). Before conducting the multiple regressions, analyses of variance were once again used to check for arm differences.

Initially, a 'full' regression model was fitted to include various prognostic or confounding factors. These covariates included variables which showed differences between arms at baseline for tests of baseline equivalence (using $p<0.2$) (see 8.1 above). Consequently the regression model, used for each outcome measure, initially included the following eleven covariates: age, residential status, best eye distance visual acuity, best eye near visual acuity, average (overall) task restriction score, duration of the initial low vision assessment, duration of the second low vision assessment, locus of control (NAS dimension), role limitation due to emotional problems (SF-36 dimension), mental health (SF-36 dimension), and the mental component summary score (SF-36). The model was then altered to exclude the duration of low vision assessments, since the inclusion of these two variables in the models reduced the overall sample size by approximately half due to the extent of missing data. The resulting model failed to show any major arm effects, with the adjustment for covariates making little difference to the results described above for the regression analysis adjusting for baseline only. However, the number of variables included in this revised model (i.e. the 'full' model excluding low vision assessment durations) meant that too many degrees of freedom were being lost and introduced the risk that some of the predictor variables may have been strongly correlated with others. Therefore, a reduced model was fitted for all outcome variables using fewer predictor variables. The reduced models using fewer covariates did not give appreciably different results from the full models fitted before. However, collinearity between covariates was also investigated by generating a correlation matrix for continuous variables, and by using t-tests to look for associations between the only category variable in the list of covariates used (i.e. residential status) with the other covariates. Several pairs of continuous variables had correlation coefficients greater than 0.4 as indicated in the matrix. Significant differences were found for age between the residential status groups representing subjects living with spouse and subjects living with family (t-test, 2-tailed, unpaired, $p=0.0008$), and between residential status groups

representing subjects living alone and living with spouse (t-test, 2-tailed, unpaired, p=0.0000). A borderline significant difference was also found for the locus of control dimension of the NAS between subjects living alone and those living with family (t-test, 2-tailed, unpaired, p=0.0529). Models containing pairs of covariates with correlation coefficients greater than 0.4 (i.e. in either a positive or negative direction) were changed to exclude one of the covariates of such pairs in turn to determine whether the arm effects would then differ. Reducing some of the models further (when appropriate) did not change the findings. Therefore it was concluded that there were no analysis problems introduced by including both variables of a correlated pair of covariates in some of the models. Thus, the original choice of reduced model was retained in these instances. A correlation matrix for covariates (i.e. continuous variables) is given in figure 8.8 below.

The results of the final reduced models, adjusting for baseline measures and selected covariates, are given in the tables below under separate headings for the different 'groupings' of outcome measures i.e. SF-36 dimensions, VCM1 scores, NAS dimensions, self-rated task restriction and measured task performance, and knowledge about the use of residual vision.

Figure 8.8: Correlation matrix of the continuous variables selected as covariates in regression modelling

Covariates	Role limitation (emotional) (SF-36)	Mental health (SF-36)	MCS score (SF-36)	Locus of control (NAS)	Near visual acuity (best eye)	Distance visual acuity (best eye)	Task restriction (MLVQ)	Age
Role limitation (emotional) (SF-36)	1.000							
Mental health (SF-36)	0.412 *	1.000						
MCS score (SF-36)	0.626 *	0.702 *	1.000					
Locus of control (NAS)	0.288	0.388	0.456 *	1.000				
Near visual acuity (best eye)	-0.092	-0.055	-0.015	-0.065	1.000			
Distance visual acuity (best eye)	-0.007	-0.039	-0.000	-0.002	0.731 *	1.000		
Task restriction (MLVQ)	-0.149	-0.296	-0.276	-0.168	0.486 *	0.507 *	1.000	
Age	0.152	0.106	0.021	0.006	-0.070	0.037	0.083	1.000

* correlation co-efficient > 0.4

SF-36 dimension scores

The results for the individual dimensions are given in table 8.25. After adjustment for baseline measures and covariates, the reduced models show that adjusting for covariates has not altered previous findings. Arm 1 appears to be performing best for selected dimensions, and arm 3 is similar to arm 1. The results for the physical and mental component summary scores, presented separately in table 8.26, indicate that these outcomes are best for arm 1, and next best for arm 3.

Table 8.25: Regression analysis of SF-36 dimension scores by randomisation arms 1 and 3, against arm 2, adjusted for baseline measures and covariates

SF-36 dimension scores	Covariates	n	ANOVA	Regression analysis							
				Arm 1				Arm 3			
				Coef.	95% CI	t	p value	Coef.	95% CI	T	p value
Physical functioning	Task restriction, locus of control	175	df (5,169), F=2.55, p=0.081	8.040	0.876 – 15.205	2.22	0.028*	2.108	-4.761 – 8.976	0.61	0.545
Role limitation: physical problems	Task restriction, MCS, role limitation (emotional)	169	df (6,162), F=3.48, p=0.033*	20.328	4.839 – 35.816	2.59	0.010**	13.160	-1.796 – 28.116	1.74	0.084
Social functioning	Near visual acuity, distance visual acuity, task restriction, MCS, role limitation (emotional)	160	df (8,151), F=6.00, p=0.003**	18.373	7.864 – 28.881	3.45	0.001***	10.555	0.212 – 20.899	2.02	0.046*
Mental health	Task restriction, MCS, role limitation (emotional)	169	df (6,162), F=2.69, p=0.071	6.560	0.721 – 12.399	2.22	0.028*	4.854	-0.804 – 10.512	1.69	0.092
Energy / vitality	Residential status, task restriction, locus of control, MCS, role limitation (emotional)	169	df (9,159), F=3.98, p=0.021*	3.463	2.684 – 16.363	2.75	0.007**	2.679	-3.925 – 9.283	0.80	0.424
General health perception	Age, MCS, role limitation (emotional)	188	df (6,181), F=2.95, p=0.055	8.436	1.372 – 15.499	2.36	0.020*	5.944	-0.827 – 12.714	1.73	0.085

CI = confidence interval; df = degrees of freedom; * p<0.05 **p<0.01 ***p<0.001 ****p<0.0001

Note: MCS = mental component summary score (SF-36); near and distance visual acuities are for 'best eye'.

Excluded outcome variables: Role limitation: emotional problems, n=188, ANOVA: df (4,183), F=0.48, p=0.619; Bodily pain, n=161, ANOVA: df (10,150), F=1.63, p=0.200

Table 8.26: Regression analysis of SF-36 component summary scores by randomisation arms 1 and 3, against arm 2, adjusted for baseline measures and covariates

SF-36 scores	Covariates	n	ANOVA	Regression analysis							
				Arm 1				Arm 3			
				Coef.	95% CI	t	p-value	Coef.	95% CI	t	p-value
Physical component summary score	Near visual acuity, task restriction, locus of control, MCS, mental health	161	df (8,152), F=5.47, p=0.005**	2.961	1.185 – 4.736	3.29	0.001***	1.692	-0.043 – 3.427	1.93	0.056
Mental component summary score	Near visual acuity, task restriction, locus of control, role limitation (emotional)	161	df (7,153), F=6.37, p=0.002**	2.760	1.227 – 4.293	3.56	0.000****	1.595	0.082 – 3.108	2.08	0.039*

CI = confidence interval; df = degrees of freedom; * p<0.05 **p<0.01 ***p<0.001 ****p<0.0001

Note: MCS = mental component summary score (SF-36); near visual acuity is for 'best eye'.

VCM1 scores

The results for the overall VCM1 score are given in table 8.27. After adjustment for baseline measures and covariates, the reduced model shows that adjusting for covariates has not changed previous findings, in that there is still no evidence of any arm effect. The table does not include regression results for the individual domains, as none of these showed any significant differences between arms for either the full or reduced models. The smallest p-value obtained was for the domain representing 'loneliness / isolation' (p=0.179), in favour of arm 1, thus reinforcing the lack of evidence for arm differences in the earlier stages of analysis. The table of results for the overall VCM1 score is included to show the absence of any arm effects.

NAS dimension scores

The reduced model shows that adjusting for covariates has not changed previous findings in that there is still no evidence of any arm effect. Table 8.28 gives the results for each of the four NAS dimensions. No differences between arms can be seen.

Self-rated task restriction scores

The reduced model shows that adjusting for covariates has not changed previous findings in that there is still no convincing evidence of any arm effects. However, there is some evidence, which is barely significant, that arm 1 may be 'better' (i.e. shows slightly less restriction) on the reading score than arm 2. Table 8.29 gives the results for both the overall and reading restriction scores.

Measured task performance

The logistic regression model used for this data shows that adjusting for covariates (baseline data were unavailable for task performance assessments), has resulted in arm effects essentially disappearing when compared with the unadjusted analysis (which had shown that subjects in arm 3 were better able to perform reading tasks, see 8.3.1.2). This finding is explained by the fact that reading tasks are highly dependent on near vision and arm 3 subjects had better near vision at baseline (see 8.1.2). Table 8.30 gives the results of this analysis

Table 8.27: Regression analysis of the VCM1 score by randomisation arms 1 and 3, against arm 2, adjusted for baseline measures and covariates

VCM1	Covariates	n	ANOVA	Regression analysis							
				Arm 1				Arm 3			
				Coef.	95% CI	t	P value	Coef.	95% CI	t	P value
Overall score	Distance visual acuity, locus of control, mental health	188	df (6,181), F=0.21, p=0.811	-0.008	-0.243 – 0.227	-0.07	0.946	-0.067	-0.290 – 0.157	-0.59	0.558

CI = confidence interval; df = degrees of freedom

Note: MCS = mental component summary score (SF-36); near and distance visual acuities are for 'best eye'.

Excluded outcome variables:

Embarrassment (covariates: mental health) :	ANOVA: n=192, df (4,187), F=1.05, p=0.352
Frustration/annoyance (covariates: MCS)	ANOVA: n=188, df (4,183), F=0.48, p=0.622
Loneliness/isolation (covariates: distance visual acuity, locus of control, mental health)	ANOVA: n=190, df (6,183), F=0.92, p=0.400
Sadness/'feeling low' (covariates: age, distance visual acuity, locus of control, MCS, mental health)	ANOVA: n=185, df (8,176), F=0.69, p=0.505
Worry about eyesight getting worse (covariates: role limitation (emotional), mental health)	ANOVA: n=188, df (5,182), F=0.28, p=0.757
Concern about safety at home (covariates: age, residential status, locus of control, MCS)	ANOVA: n=188, df (8,179), F=0.91, p=0.404
Concern about safety out of the home (covariates: distance visual acuity, locus of control, mental health)	ANOVA: n=190, df (6,183), F=0.27, p=0.761
Concern about coping with everyday life (covariates: near visual acuity, locus of control, MCS)	ANOVA: n=180, df (6,173), F=0.13, p=0.881
Eyesight 'stopping you doing the things you want to do' (covariates: distance visual acuity, locus of control, MCS)	ANOVA: n=185, df (6,178), F=0.70, p=0.497
Eyesight interfering with life in general (covariates: task restriction, locus of control, MCS, Role limitation (emotional), mental health)	ANOVA: n=169, df (8,160), F=1.88, p=0.157

Table 8.28: Regression analysis of NAS dimension scores by randomisation arms 1 and 3, against arm 2, adjusted for baseline measures and covariates

NAS dimension scores	Covariates	n	ANOVA	Regression analysis							
				Arm 1				Arm 3			
				Coef.	95% CI	t	p-value	Coef.	95% CI	t	p-value
Locus of control	Age, residential status, task restriction, mental health	174	df (8,165), F=0.57, p=0.569	0.673	-0.575 –1.921	1.06	0.289	0.313	-0.910 –1.536	0.50	0.614
Acceptance	Age, task restriction, MCS	168	df (6,161), F=0.36, p=0.696	0.338	-2.335 – 3.011	0.25	0.803	1.113	-1.536 – 3.761	0.83	0.408
Attitude	Distance visual acuity, MCS, age, task restriction	165	df (7,157), F=0.03, p=0.970	0.205	-1.446 – 1.855	0.25	0.807	0.077	-1.532 – 1.687	0.09	0.924
Self efficacy	Age, residential status, task restriction, locus of control, MCS	168	df (9, 167), F=0.18, p=0.832	0.057	-2.359 –2.474	0.05	0.963	0.657	-1.716 – 3.029	0.547	0.585

CI = confidence interval; df = degrees of freedom

Note: MCS = mental component summary score (SF-36); distance visual acuity is for 'best eye'.

Table 8.29: Regression analysis of self-rated task restriction scores by randomisation arms 1 and 3, against arm 2, adjusted for baseline measures and covariates

Task restriction scores	Covariates	n	ANOVA	Regression analysis							
				Arm 1				Arm 3			
				Coef.	95% CI	t	p-value	Coef.	95% CI	T	p-value
General task restriction score	Age, near visual acuity, locus of control	163	df (6,156), F=0.78, p=0.458	-0.033	-0.099 – 0.032	-1.01	0.312	-0.037	-0.102 – 0.027	-1.15	0.250
Reading restriction score	Age, near visual acuity, locus of control	68	df (6,61), F=1.84, p=0.167	-0.167	-0.343 – 0.008	-1.90	0.061	-0.095	-0.253 – 0.062	-1.21	0.232

CI = confidence interval; df = degrees of freedom

Note: near visual acuity is for 'best eye'.

Table 8.30: Logistic regression analysis of measured task performance outcomes by randomisation arms 1 and 3, against arm 2, adjusted for covariates

Task performance assessment outcome variable	Covariates	n	Arm 1				Arm 3			
			OR	95% CI	z	p value	OR	95% CI	Z	p value
Percentage score for reading tasks:										
Score > 50%	Age, near visual acuity, locus of control	182	1.706	0.727 – 4.007	1.23	0.220	1.603	0.697 – 3.686	1.11	0.267
Score > 75%	Age, near visual acuity, locus of control, MCS, mental health	177	1.749	0.740 – 4.135	1.28	0.203	1.883	0.820 – 4.327	1.49	0.136
Reading 2 'use-by-dates':										
At least one 'use-by-date' read	Age, near visual acuity, locus of control	183	1.033	0.438 – 2.433	0.10	0.941	1.371	0.566 – 3.321	0.70	0.485
Both 'use-by-dates' read	Age, residential status, near visual acuity, locus of control, MCS, mental health	178	2.058	0.775 – 5.469	1.45	0.148	2.713	1.078 – 6.827	2.12	0.034*
Reading medicine instructions:										
At least name of medicine read	Age, near visual acuity, locus of control	183	1.494	0.651 – 3.430	0.95	0.344	1.454	0.645 – 3.280	0.90	0.367
Name and dose of medicine read	Age, residential status, near visual acuity, locus of control, MCS, mental health	178	2.282	0.897 – 5.805	1.74	0.083	2.030	0.839 – 4.908	1.57	0.116

OR = Odds ratio CI = Confidence interval *p<0.05

Note: MCS = mental component summary score (SF-36); near visual acuity is for 'best eye'.

Patterns of LVA use

Although the data for these outcome measures is of an ordinal nature, multiple linear regression was used for illustrative purposes to gauge whether an adjustment for covariates (there were no corresponding baseline values) would indicate any differences between arms. Although strictly speaking, the coefficients should not be interpreted in a quantitative manner, this regression was carried out to test whether there were any substantial changes. Table 8.31 gives the results of this analysis and shows very little evidence of any arm effect, although there is possibly some indication that whilst arm 3 was 'poorer' than arm 2 with respect to LVA use, there was no appreciable difference between arms 1 and 2.

Knowledge about the use of residual vision

Logistic regression analysis adjusting for baseline values and covariates did not show any arm effect. The results are given in table 8.32.

Table 8.31: Regression analysis of patterns of LVA use outcomes by randomisation arms 1 and 3, against arm 2, adjusted for covariates

Process measures (for primary LVA)	Covariates	n	Regression analysis							
			Arm 1				Arm 3			
			Coef.	95% CI	t	p-value	Coef.	95% CI	t	p-value
Frequency of LVA use	Age, residential status, near visual acuity, distance visual acuity, locus of control, MCS, role limitation (emotional)	170	0.050	-0.347 – 0.447	0.25	0.805	-0.356	-0.736 – 0.024	-1.85	0.066
Average duration of continuous LVA use	Age, near visual acuity, task restriction, locus of control, MCS	146	-0.103	-0.380 – 0.173	-0.74	0.461	-0.156	-0.435 – 0.123	-1.11	0.270
Longest duration of continuous LVA use	Residential status, task restriction, locus of control, MCS	151	-0.035	-0.425 – 0.355	-0.18	0.860	-0.313	-0.690 – 0.063	-1.64	0.102

CI = confidence interval

Note: MCS = mental component summary score (SF-36); near and distance visual acuities are for 'best eye'.

Table 8.32: Logistic regression analysis of AMD knowledge (use of residual vision) outcomes by randomisation arms 1 and 3, against arm 2, adjusted for baseline and covariates

Statement used to assess understanding of the use of residual vision	Covariates	n	Arm 1				Arm 3			
			OR	95% CI	z	p value	OR	95% CI	Z	p value
Disagreed with: ***"Using your eyes too much will make your remaining vision worse"***	Locus of control, MCS, role limitation (emotional)	185	1.205	0.537 – 2.702	0.45	0.651	1.131	0.528 – 2.420	0.32	0.752
Disagreed with: ***"Sitting too close to the TV causes your eyesight to worsen"***	Age, residential status, near visual acuity, distance visual acuity, locus of control, MCS, role limitation (emotional), mental health	176	1.209	0.496 – 2.951	0.42	0.68	1.016	0.428 – 2.410	0.04	0.971
Agreed with: ***"When you are reading, more light will improve your ability to see"***	Near visual acuity, distance visual acuity, MCS	178	1.324	0.288 – 6.095	0.36	0.718	1.381	0.300 – 6.366	0.41	0.679

OR = Odds ratio CI = Confidence interval Note: MCS = mental component summary score (SF-36); near and distance visual acuities are for 'best eye'.

8.3.4 Key findings of the analysis of the effectiveness of interventions

The results of the final stage of analysis, i.e. adjusting for baseline measures and important covariates, show that the subjects allocated to arm 2 of the trial did not have significantly better outcomes, for any of the measures investigated at 12 months follow-up, when compared with subjects allocated to arms 1 and 3. The results also show evidence of some better outcomes for subjects in arm1 when compared to those in arm 2. These differences in favour of arm 1 were demonstrated, at varying levels of statistical significance, for six of the eight SF-36 dimensions, the two SF-36 component (i.e. physical and mental) summary scores, and (marginally) for self-rated restriction in reading. Social functioning (SF-36) was significantly different at the 0.001 level; role limitation due to physical problems (SF-36) and energy/vitality (SF-36) were both significantly different at the 0.01 level. The SF-36 MCS and PCS scores were significant at the 0.0001 and 0.001 levels respectively, which is not surprising given that these measures are more sensitive because they are aggregated scores. The remaining SF-36 outcomes which showed a difference (physical functioning, mental health and general health perception), and self-rated reading restriction were significant at (or near to for the latter) the 0.05 level.

Measured task performance, on the other hand, was better (for one of the four reading tasks assessed) among arm 3 subjects versus those in arm 2. However, subjects in arm 3 had better near visual acuity at baseline than subjects in the other arms which may have influenced this finding (see 8.1.2 and 8.3.3). Similarly, the frequency of use of LVAs shows a borderline significant difference for subjects in arm 3, who used their devices less often, when compared against LVA use in arm 2 (note caution given above with respect to the use of linear regression for patterns of LVA usage).

No arm differences were found for the VCM1 score or for the NAS dimensions. Subjects' understanding of the use of residual vision also did not show any significant differences between arms at 12 months.

CHAPTER 9: DISCUSSION

9.1 Discussion overview

This thesis has described two of the four key objectives of this trial (see 4.3). The main objective was to determine the effectiveness of an enhanced versus a traditional optometric low vision rehabilitation service by conducting a comparison between arms for a range of outcomes. The other objective within the scope of this thesis was to report on longitudinal data for a large sample of patients with AMD with respect to their pathway through a low vision service. Data included socio-demographic characteristics, visual functions, self-rated task restrictions, measured task performance, use of LVAs, knowledge of AMD / residual vision, generic health-related QoL, vision-related QoL, and psychological adjustment to visual impairment. Firstly, this chapter will revisit the rationale for the study and examine how successfully the trial was implemented. Secondly, a summary will be provided for the main findings for each objective. Wider issues arising from the results will then be explored, limitations of the study will be discussed and generalisability will be considered. In conclusion, implications for service development will be addressed together with indications for future research.

9.2 Summary of the trial profile

The present RCT was conducted in response to the lack of high quality evidence about the effectiveness and cost-effectiveness of alternative forms of low vision care for subjects with AMD (Russell *et al*, 2001). The author is not aware of any previously published trials that have evaluated alternative forms of low vision care, although others are at a planning or early recruitment stage (Harper, 2003, personal communication; Raasch, 2002). The present study has also provided a unique opportunity for describing and monitoring over time a large sample of elderly patients with AMD, with respect to a wide range of parameters used as outcome measures for comparative purposes vis-à-vis the main trial hypothesis (see 5.5.6).

The proportion of patients who completed the trial for non-clinical outcomes was high (194/226). Some drop-outs had been anticipated due to mortalities and 13/226 (5.75%) patients died before their final home visit. The other main reasons for drop-outs included patients moving away from the study area or being too ill to receive a home visit. Only a relatively small proportion of patients dropped out due to reluctance to participate, for example, on account of their disappointment and unmet expectations with respect to treatment or improvement in vision. Overall, patients were very willing to participate. This factor may reflect the strong desire for help that low vision patients present with. Even though interviews were sometimes long and tiring for patients, this did not deter the majority from agreeing to a follow-up interview a year after the collection of baseline outcomes.

9.3 RCT results

9.3.1 Analysis of the effectiveness of optometric versus enhanced interventions

The findings presented in chapter 8 suggest that the main hypothesis of the trial should be rejected (see 5.5.6). The results of the final stage of analysis, i.e. adjusting for baseline measures and important covariates, show that the subjects allocated to arm 2 of the trial did not have significantly better outcomes for any of the measures investigated at 12 months follow-up, when compared with subjects allocated to arms 1 and 3. Indeed, the results show some evidence for better outcomes for subjects in arm 1 on selected outcomes, when compared to those in arm 2. It is important to note that whilst outcomes for arm 2 appeared to be worse during the staged approach of the analysis this effect was reduced when the analysis was adjusted for covariates in the final stage. Differences in favour of arm 1 were demonstrated (at varying levels of statistical significance) for six of the eight SF-36 dimensions, the two SF-36 component (i.e. physical and mental) summary scores, and (marginally) for self-rated restriction in reading. In contrast, measured reading task performance was better among arm 3 subjects versus those in arm 2, even after adjusting for the better near visual acuity at baseline in arm 3. The only positive finding for arm 2 (albeit showing borderline statistical significance) was an increase in LVA use when compared with arm 3 subjects. In broad terms, taking all outcomes into consideration there were no substantial differences in outcomes between all three arms of the trial.

No arm differences were observed for the VCM1 composite score or for the NAS dimensions. Similarly, there was no difference shown for subject understanding of the use of residual vision, which was surprising given the extra input from the rehabilitation officer in arm 2.

9.3.2 AMD study population characteristics

The socio-demographic characteristics of the study sample as a whole are in keeping with expected findings. The higher proportion of females, ethnic characteristics, and significantly, the age distribution, all reflect the epidemiology of AMD in a Western society (Hyman, 1992; O'Shea, 1998; Arnold and Sarks, 2000).

Other findings are also in keeping with the age group included in the trial, such as marital status (and thus residential status) and the high proportion of those retired from employment. Years of education achieved are typical of the birth cohorts (including the decades between 1900 and 1940). Analysis of the extent of social integration shows that 13.7% of the subjects in the study reported that they did not have any regular contact with either family members of friends. This latter finding may reflect the fact that the study population is elderly and more susceptible to chronic disease, and that a low level of social integration (determined by the extent of contact with family, friends and participation in community activities) has been linked in other surveys to poorer health in general (Blaxter, 1990).

9.3.3 Impairment, disability and quality of life measures: a longitudinal analysis

The longitudinal analysis of variables showed some interesting findings (these results are presented in chapter 7). Perhaps unsurprisingly in AMD, there was a significant deterioration in the visual functions (distance and near visual acuity and contrast sensitivity) over time. For example, the drop for distance visual acuity was of the order of 2 lines on a logMAR chart, a change that would be regarded as clinically important. Despite this deterioration, however, restriction in activity was slightly reduced over time, (though this was not statistically significant), presumably on account of the impact of the low vision interventions and/or the subjects adapting to their visual impairment. It might be argued, however, that a limitation with respect to this study was that baseline re-assessment for subjects who had experienced substantial deterioration in vision during the course of the trial was not carried out. Such deterioration may have been a

factor that could have affected QoL and the inclusion of the subjects concerned may have reduced the possibility of detecting favourable changes in QoL.

There was a statistically significant difference in the VCM1 score (representing vision-related QoL) at 12 months with a mean difference in VCM1 scores between baseline and follow-up of 0.21 (with 95% confidence intervals of 0.11 to 0.32) on a scoring scale which has a range of 5, i.e. possible values between 0 and 5 (with higher scores representing worse QoL). The mean difference found therefore represents a reduction of 4.2% on the VCM1 scoring scale. Test-retest reliability is considered to be good for the VCM1 and the VCM1 has shown significant correlation with visual acuity "in the expected direction" (Frost *et al*, 1998; Massof and Rubin, 2001). However, the interpretation of the mean difference obtained over time in this study is open to some debate with respect to functional significance. For example, the deterioration in mean vision-related QoL, while being of statistical significance, should be regarded as 'no change', since a change of 0.2 in the VCM1 score falls within a single SD of test-retest differences (Frost *et al*, 1998). Interestingly, the results from VCM1 consistently show that the individual domain of least concern to patients both at baseline and at follow-up was that of 'safety at home'; the two VCM1 domains of greatest concern to the patients at baseline and 12 months later were the prevention by poor eyesight of 'doing the things you want to do', and 'eyesight interfering with life in general'. This latter finding is somewhat at odds with the decrease (though small) in restriction derived from the MLVQ data.

Several dimensions of the SF-36 demonstrated a statistically significant change over time. The social functioning and physical functioning dimensions each showed a significant deterioration at the $p<0.0001$ level, as did both the PCS and MCS scores. Other statistically significant deteriorations in dimensions included energy/vitality, role limitation due to physical problems and bodily pain. There is clearly more evidence in support of a greater deterioration for dimensions of a physical nature than those which represent mental aspects of health. However, it should be noted that, as suggested above for vision-related QoL, with the exception of the social functioning and physical functioning dimensions, these findings represent small differences in terms of the SF-36 dimension scales, and the changes are therefore unlikely to be predictive of important functional change. Some decline in generic health status was expected in an elderly

population who are susceptible to an increase in chronic conditions over a twelve month period. None of the NAS dimensions showed any significant change over time, with before and after scores being very comparable.

The results obtained for the comparison of SF-36 scores and the VCM1 domain scores against normative data suggest that QoL in AMD subjects is characterised by worse scores than those obtained for elderly people without long-standing disability (SF-36) (Lyons *et al*, 1994), and similarly by worse scores than those for a sample of people with a variety of ophthalmic conditions (VCM1) (Frost *et al*, 1998).

Subject knowledge of the use of residual vision improved for the sample overall over time, although the extent of change was disappointing in view of the emphasis placed on educational aspects in the low vision assessment process. These results support the findings from a small pilot study describing the development of the MLVQ (Harper *et al*, 1999).

During baseline interviews patients were asked what expectations they had of their forthcoming low vision assessments. Not surprisingly, many patients were hoping that they would be assisted in improving their ability to carry out daily tasks. Over a third of all patients were aware of the availability of magnifying aids and were hoping to receive suitable devices. Approximately a quarter of patients were also keen to obtain glasses. About a quarter were expecting to benefit from an improvement in their vision.

The requirements identified by patients during their assessments also typically reflected the types of needs identified in other studies, with reading (in relation to various tasks including reading ordinary as well as large print, correspondence, shop prices etc.) being noted most often (e.g. Elliot *et al*, 1997; Watson *et al*, 1997(a); Watson *et al*, 1997(b)). LVAs loaned at the initial assessment were mostly the more simple types of devices, namely stand magnifiers (loaned most often, and usually illuminated), and hand magnifiers. This result also reflects the findings of other studies (Leat and Rumney, 1990; Leat *et al*, 1994; Shuttleworth *et al*, 1995). The majority of patients in the trial reported using at least one LVA (94.5% of subjects of the 182/194 (93.8%) who had at least one LVA at home at 12 months). It was possible to identify a primary aid for 172 subjects of the 194 who completed the trial and a secondary aid which was

reported as being used for 101 subjects. Amongst these patients, most used both their primary and secondary aids between 1-4 times daily and for a duration of continuous use lasting between 1-4 minutes (see 7.3.4). While these very high usage rates for LVAs differ from the findings reported in two UK hospitals (Humphry and Thompson, 1986; McIlwaine *et al*, 1991), the present findings are comparable to other results on LVA use reported elsewhere, for example by Virtanen and Laatikainen (1991) in Finland, Watson *et al*, (1997(a)) in the USA, and Leat *et al*, (1994), Shuttleworth *et al*, (1995) and Harper *et al*, (1999) in the UK. The duration of use figures further emphasise the significance of spot reading tasks versus extended leisure reading, a point made previously by Leat *et al* (1994). It is of interest that high usage rates for reading related tasks do not appear to have led to significant improvements in RTS over time nor to a 'better' result for the vision-related QoL measure, albeit a measure not developed with low vision rehabilitation in mind (see next section).

9.4 Why did the trial find no evidence in favour of the enhanced model of low vision care?

The main hypothesis of the trial is underpinned by the argument that additional vision-specific training and the enhanced model of care in arm 2 would reduce restrictions in activities more effectively than in the other arms, thereby promoting better adjustment to vision loss. Therefore, it was reasonable to expect some relative enhancement in vision-related QoL in arm 2 subjects, an improvement that may have led to a possible effect on generic health-related QoL (i.e. by showing no, or a lesser, decline in health status in this group given that the population is elderly and that a general decline in health status would be expected over 12 months for the study population as a whole). In contrast, however, the findings have not shown better outcomes, however measured, for subjects in arm 2.

The remainder of this section will try to consider the factors that may have influenced the findings of this RCT. Several different perspectives need to be considered, including the extent to which the study protocol was adhered to, the key aspects of the intervention delivered in arm 2, and the suitability of outcomes. Firstly, arguments will be presented to suggest that there is no reason to question the validity of the trial, and

therefore secondly, a number of possible reasons for the ineffectiveness of the intervention will be explored.

9.4.1 Validity of the study

As has been stated previously (see 1.2) an RCT is the best method of comparing effectiveness of different interventions in health research (Altman, 1996). This trial complied with the CONSORT criteria as recommended by the CONSORT group guidelines (Altman, 1996; Moher *et* al, 2001) (see 5.5.1, 6.1 and appendix 16). Randomisation ensured that baseline equivalence had been achieved across arms for most variables. Despite a median age of 82 years, 72% (226/314) of eligible people agreed to take part. Of the 226 subjects recruited, 194 (86%) completed the trial, an excellent completion rate given the elderly study population. These statistics suggest that the findings are likely to be highly applicable and also illustrated that trials involving the elderly are feasible. In addition, the desired sample size was obtained and so the study was sufficiently powered to detect any significant difference in outcome between arms post-intervention (see 5.2.4 and 5.3). The timings of 'events' e.g. clinic assessments, specific arm interventions and visits to collect baseline and final outcomes have, overall, been adhered to in the study schedule as originally envisaged. Furthermore, the use of an 'intention-to-treat' analysis in comparing outcomes across arms (Bland, 1995) contributes to the generalisability of this study.

Whilst randomisation was concealed to rule out selection bias, there is some evidence that broken blinding occurred during the trial. The extent of broken blinding was explored once data collection had ceased (see 6.8). Although the researcher who measured outcomes was blinded, some patients became unmasked during the assessment (at 12 months, the researcher correctly 'guessed' arm allocation for 51% of participants compared to 33% expected by chance). Unmasking could have introduced information bias although such bias would have been expected to lead to an exaggerated effect rather than no effect. It is important to note also that the researcher was not responsible for the delivery of interventions and had no vested interest in the planning of services. The researcher adhered to a standardized protocol throughout the trial and furthermore, the majority of data were based on closed questions with less risk of bias arising than with open questions (Patton, 1987; Bryman, 1988). Since this trial did not

find the differences that had been expected, other issues, in terms of the intervention and the outcomes used, need to be considered.

9.4.2 Elements of the intervention

It is important to consider the content of the intervention in arm 2 and whether critical elements were included. For example, was the scope and intensity of the input in arm 2 sufficiently extensive to yield benefits? Trial data demonstrates that the rehabilitation officer regularly exchanged devices for subjects in arm 2 and addressed a variety of training issues with respect to the handling of LVAs, and other factors such as lighting and posture, as well as supplying additional information about AMD and relevant support services. The benefits of such training in the use of LVAs have long been argued to be of considerable positive value in low vision outcomes (Nilsson, 1990; McIlwaine *et al*, 1991; Warren, 1995; Watson *et al*, 1997(b)). A possible explanation may be that the intervention in arm 2 essentially reinforced the training already provided by the optometrists in the low vision clinic, a factor reinforced by the equivalent (and high) usage rates of LVAs by subjects in all arms of the trial. While the reinforcement of this type of training in the home could have advantages by taking into account the subject's environment (Muirhead, 1994; Stoll *et al*, 1995), there are additional aspects of training which might have extended the intervention in arm 2 into a more substantive approach. For example, this substantive approach could have included training in formal viewing strategies such as eccentric viewing and steady eye strategy (e.g. Nilsson and Nilsson, 1986; Goodrich and Mehr, 1986; Nilsson, 1990), i.e. training that would have been additional to the training in device handling provided in the HES. However, since there is no recognized protocol with proven effectiveness for such additional training, uncertainty remains regarding the type of approach that would be most appropriate. There is also the question of whether the intervention should have been delivered more frequently and/or over a longer period of time in order to provide a more sustained model of low vision management. In designing this trial, however, it was considered important to be realistic about what type of service delivery may have been possible, while utilizing evidence about ineffective services and device training from previous work.

This trial was not designed to assess the effects of established activities in low vision rehabilitation alone, but was intended to determine the benefits of an enhanced model of care which included home-based training. While the benefits of low vision training including the use of LVAs and other strategies to maximize the use of residual vision have been researched (e.g. Nilsson, 1990; Culham *et al*, 1990; Leat *et al*, 1994; Warren, 1995; Shuttleworth *et al*, 1995; Watson *et al*, 1997(a); Harper *et al*, 1999), there has not been an RCT of low vision rehabilitation versus no low vision rehabilitation. At the outset of this trial it was not considered appropriate to have a 'no intervention' arm for ethical reasons. In addition to the ethical dilemma, having a 'no intervention' arm (in contrast to, for example, a trial investigating medical treatment or surgical treatment) is likely to involve contamination, whereby subjects may access alternative statutory or voluntary services. An RCT of low vision rehabilitation versus no rehabilitation is currently under way in the United States where the researchers have addressed these ethical concerns by delaying the intervention (Raasch, 2002; Harper, 2002, personal communication). Whilst the evidence for the benefit of low vision rehabilitation is emerging (Scott *et al*, 1999; Wolffsohn and Cochrane, 2000; Russell *et al*, 2001), what is less clear is the effectiveness of different forms of service delivery. It is also important to note that since this trial did not compare low vision rehabilitation with no rehabilitation, the quality of evidence of the benefits of rehabilitation cannot be shown to be better or worse than that obtained from previous studies. The evidence generated by this trial is only relevant to the different types of intervention delivered during the trial.

9.4.3 Conventional low vision rehabilitation

The delivery of low vision care at MREH during the study was, arguably, representative of low vision management within the HES, and as described above, the high usage rates of LVAs demonstrated in this trial are in keeping with the findings of other studies (e.g. Leat *et al*, 1994) against which the MREH service also demonstrates certain similarities. The MREH low vision service reflects a 'standard HES model' which involves a large number of optometrists with a range of experience, and was provided in this trial in accordance with current NHS clinical activities (i.e. it was not provided as a specific research strategy). This service was a component of care delivered to all patients in the trial. Although there were no clear benefits in measured outcomes demonstrated in relation to the different arms of this trial, this study provides evidence that subjects

receiving low vision rehabilitation services do experience benefits from low vision rehabilitation activities. This benefit is best reflected in this trial by the high usage rates of LVAs for tasks rated as important by subjects, but also by the increased satisfaction with magnifiers over time and by the fact that the majority of subjects chose to attempt assessed reading tasks at 12 months with the use of a magnifier. Arguably, people would not choose to use a device that is awkward or challenging to use to assist them in, for example, reading, if the device provided no benefit to them. It may be argued that the HES had "learnt it's lesson" from studies which had been critical of low vision services (e.g. Humphry and Thompson, 1986; McIlwaine *et al*, 1991) and therefore HES input by optometrists now includes more emphasis on the provision of training in LVA use. However, there is no direct evidence from this trial to support the suggestion that the benefits from the training already provided in the low vision clinic may have resulted in a less demonstrable effect than expected with respect to the supplementary training given to arm 2 subjects.

9.4.4 Outcome measures

A broad range of outcome measures was chosen for this trial, in part, to ensure that the different study objectives could be met (see Chapter 4), but also due to the complexity of the concept of QoL (as described in 3.3). During the design phase of the study, there was debate concerning the choice of outcomes which would be most suitable and most responsive to detecting differences in QoL among a population with visual impairment over time. There was recognition at the outset that a generic health status instrument was likely to be much less sensitive to change following low vision rehabilitation than a vision-specific questionnaire (for example, as reported for patients with cataract, (Damiano *et al*, 1995)). However, the SF-36 was included to ensure that generic QoL could be investigated alongside vision-specific QoL. Moreover, the SF-36 is commonly recommended to complement disease-specific instruments in clinical trials and health care research (Fletcher *et al*, 1992). The SF-36 itself was chosen on the basis that this instrument is a well-validated questionnaire which had already been widely used in health research (Ware, 1993), including studies involving older people (see 7.6.1). The SF-36 had been evaluated for it's suitability of use with an elderly population and had been recommended as being an appropriate choice in such contexts (Hayes *et al*, 1995). This factor would facilitate comparison of the outcomes from this trial with results from other future research studies. Although the SF-36 has been extensively evaluated in

terms of validity and reliability (Jenkinson *et al*, 1996; McHorney, 1996), the suitability of the SF-36 has also been questioned for several reasons. For example, the instrument may fail to distinguish between the many factors which can impact on an elderly individual's QoL, including external support structures, chronic illness, and low education levels (McHorney, 1996). A recent qualitative study in the North West of England involving 56 subjects aged between 65 and 89 years, all with chronic health problems and referrals to community rehabilitation programmes, has also demonstrated problems concerning the ability of elderly respondents in interpreting questions included in the SF-36 during interviewer administration (Mallinson, 2002). This latter study had not been published until after the present trial had ended. In terms of the responsiveness of the instrument, there have been concerns documented in relation to floor and ceiling effects in the context of research involving elderly participants. Ceiling effects have been shown to be a problem when using the SF-36 with elderly subjects and floor effects have been more common with older subjects than, say, with the ill or disadvantaged (McHorney, 1996; Bowling, 2001). This issue makes it difficult to measure decline in health over time for those at the "floor", and improvement in health for those at the "ceiling". It is also important to note that McHorney states that such effects are not unique to the SF-36, and that problematic score distributions are often found on measures of activities of daily living. However, other authors suggest that commonly used generic health status dimensions (such as those which constitute the SF-36) in longitudinal research amongst the elderly are responsive to indicators of worsening health, such as hospitalization or deterioration in chronic disease (Wagner *et al*, 1993).

With respect to vision-related QoL, the results obtained also show no difference between arms, both for individual domains and for the overall VCM1 score. At the time of designing the present RCT, the choice of potential instruments which could be used to measure vision-related QoL was very limited. Other instruments have since been published which not only address vision-related QoL, but also focus more on restrictions in task performance. Massof and Rubin (2001) have highlighted that in the field of rehabilitation there is much reliance placed on the use of various 'functional assessment instruments to serve as surrogates for quality of life instruments'. This trend is evidenced by the recent development of several questionnaires which place a greater focus on task performance and activities of daily living. These include, for example, the

National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) (Mangione *et al*, 1998), the Activities of Daily Vision Scale (ADVS) (Mangione *et al*, 1992), the Low Vision Quality-of-Life Questionnaire (LVQOL) (Wolffsohn and Cochrane, 2000), and the Melbourne Low-Vision ADL Index (MLVAI) (Haymes *et al*, 2001). The VCM1, unlike the questionnaires listed above which use task based parameters as proxy indicators for QoL, focuses on factors linked to mental health and psychological adjustment to low vision, such as depression and concern about vision deterioration. Arguably the low vision intervention, at least as delivered by the optometrists in the HES, is mainly striving to reduce restriction in activities, and as such should arguably lead to better vision-specific QoL. Whilst the present study, when viewed overall, showed no improvement in vision-related QoL at 12 months and a marginal reduction in restriction in activities, research by Scott *et al*, (1999) (using the NEI-VFQ) and also by Wolffsohn and Cochrane (2000) (using the LVQOL), implies that there are small gains in the short-term post low vision rehabilitation, although this research did not provide information regarding longer term benefits. In addition, the functional significance of statistically significant changes in NEI-VFQ and LVQOL scores needs further investigation.

Similarly, in terms of psychological outcomes, the NAS also failed to show an arm effect. The NAS was developed for use among visually impaired adults of working age (i.e. less than 65 years of age) and was piloted on a group of people who had attended a rehabilitation centre for a year (Dodds *et al*, 1991; Dodds *et al*, 1993). This pilot group is described as having 'suffered a severe loss of sight' prior to arrival at the rehabilitation centre. Thus the instrument's suitability for use on an elderly population, including subjects with less severe visual impairment (in keeping with the profile of the subjects included in the present RCT), had not been estimated. The difficulties observed by the researcher with regard to the administration of the NAS, in view of the complex questions included (see 6.9.3), may have also contributed to a reduced responsiveness in the use of this instrument with elderly subjects. The importance of the use of questions which 'people can understand and answer' is an important consideration in the choice of suitable outcome measures (Lessler, 1995; Mallinson 2002).

Another consideration which must be taken into account is the nature of the model of care delivered to arm 2 subjects. As previously stated in this discussion, the rehabilitation strategy in arm 2 focused on dealing with task restriction and the practical/handling factors (for example, ergonomics and lighting) relating to the use of LVAs. Therefore outcomes such as the dimensions of the SF36, the VCM1 and NAS may not have been as responsive as for example more 'restrictions-based' questionnaires such as the NEIVFQ and others mentioned above. Although the MLVQ was used in this trial to record self-rated restriction in activities both at baseline and at 12 months, this resulted in unclear benefits. Some reservations relating to this instrument are explored below.

There is, arguably, a contradiction in the findings, in that although high LVA usage had been observed in the trial overall (in particular for reading), there was only slight improvement in self-rated task restriction scores for all subjects in the trial over time. This suggests that people still feel restricted if they need to use a device to perform simple but important tasks. Since the improvement which had been expected in task restriction over time, and especially in reading restriction, was not observed, the question of whether the restriction measures used were sensitive enough to demonstrate change should also be asked. However, at the time that data was being collected for this study alternative validated instruments, for example, the MLVAI (Haymes *et al*, 2001) and the LVQOL (Wolffsohn and Cochrane, 2000), had not yet been published. There is also the question of whether restriction should be self-rated or measured. Recent research suggests that there may be differences in these approaches. Tejeria *et al* (2002) found little correlation between self-rated restriction in face recognition and measured task performance in face recognition. There is, therefore, a clear need for further research to inform the suitability of outcomes relating to task restriction in low vision trials.

A further factor to consider in relation to outcome measures is the timing of the data collection for final outcomes, i.e. at 12 months. It might be argued that this timescale may have been too long after interventions. For example, outcomes at 12 months may not capture an earlier intervention effect, say at 3 months post-intervention. However, measurement of outcomes at 12 months would still be justifiable in order to test how well any effects, which might have been evident earlier, had been retained. More

frequent measurement of outcomes, possibly over a longer period of time, may have detected changes more readily. For example, Wolffsohn and Cochrane (2000), in reporting the development of a QoL instrument (the LVQOL) for use in low vision rehabilitation, state that an interval of 1 month allowed the detection of changes over time in vision-related QoL. However, it must be noted that the LVQOL was tailored specifically to the evaluation of low vision rehabilitation in a clinical setting. In another study which demonstrated QoL benefits, the NEIVFQ was used to measure outcomes after 3 months (Scott *et al*, 1999). In view of the wide range of outcomes and the number of instruments used, and the lengthy interviews conducted for this trial, it would not have been appropriate to measure the same range of outcomes with greater frequency. Future trials could consider addressing outcome measures at shorter times post intervention, however, since it is crucial that desired outcomes should be sustained, the measurement of outcomes at 12 months as well as, say, at 3 months, could be a valid approach.

9.4.5 Delivery of arm 2 intervention

There was a high compliance rate with respect to intervention delivery in arm 2 (see 6.6). It might be argued that the involvement of just one rehabilitation officer to deliver arm 2 intervention to all of the subjects is a major limitation, in that this approach would not reflect 'reality', were this model of enhanced care to be implemented as a standard service. It was not considered to be feasible, however, to engage the services of several rehabilitation officers for this trial. It should be noted (as stated earlier in 5.4.4) that the trained rehabilitation officer involved in this study also had the benefit of additional low vision training including attendance at MREH. He had previously undertaken a full-time course in, and obtained a certificate of, Higher Education in Rehabilitation Work with Visually Impaired People. Prior to his involvement in the trial he had 4 years experience working as a visual rehabilitation officer. He ensured regular contact with optometrists at MREH by means of frequent visits to the low vision clinic and the provision of reports to the clinic after each home visit had been made. He was extremely systematic in the approach he adopted as evidenced by his documentation of the specific interventions he provided for each participant and his excellent compliance with the trial protocol. To counter the possible limitation arising from the involvement of one rehabilitation officer, it is worth highlighting the high rate of subject compliance in arm 2 (81% of subjects received all three of the scheduled home visits, and 92% had at least

one visit), and the proactive and enthusiastic contribution of the rehabilitation officer in his role, which are factors that may have been an additional advantage in the delivery of arm 2 intervention. However, the excellent compliance among subjects in arm 2 may have also been influenced by their needs for vision-specific help and or reassurance concerning their vision loss. Although reports were exchanged regularly between the rehabilitation officer in arm 2 and the optometrists in the low vision clinic, a possible limitation of arm 2 is that the professionals involved in this type of integrated approach worked from different sites. This, therefore, did not have the advantage of verbal face-to-face exchange between the professionals involved with respect to patient rehabilitation issues. On the other hand, while having a range of professionals providing a model of low vision care which facilitates an exchange of patient information from the same site may prove to be successful in an urban setting (for example, as in low vision services such as those provided at 'Birmingham Focus' in the UK, or the Kooyong Clinic in Australia (Wolffsohn and Cochrane, 2000)), it is difficult to see that such models of care would be feasible in suburban or rural settings.

9.4.6 Arm 3 intervention

The purpose of the intervention in arm 3 was that of a control for the contact time provided to subjects in arm 2, and to assist in any interpretation of between arm comparisons. Since the results show no real differences between arms there is no special requirement to consider the arm 3 input further. However, it is of some interest to consider why the uptake of arm 3 visits was considerably lower. Perhaps the most important reason for this finding was that this intervention was not vision-specific and not integrated with the hospital service. It is also possible that the generic workers were less conscientious and/or motivated in persuading patients to accept their offer of a home visit. It is also conceivable that some subjects may have associated the offer of a home visit by a community worker from Age Concern with being labeled 'old and helpless'. Research on health and ageing has demonstrated that elderly people consider a positive self-image, self-esteem and exercising control over their lives as being of great importance during the ageing process (Heathcote, 2000). Furthermore, other studies have shown the importance of self-reliance amongst patient groups who may either be recovering from, or who may have acquired a disabling illness which subsequently necessitates a variety of coping strategies. For example, self-reliance was identified as one of the most common coping strategies observed amongst survivors of

acute myocardial infarction in Australia, and was also shown to be the most prevalent coping mechanism amongst patients with multiple sclerosis (Daly *et al*, 2000; Buelow, 1991). Other research in Dublin has illustrated that amongst women of 65 years and older living in private accommodation there is a steadfast tendency of 'service refusal' with respect to both statutory and voluntary agencies (Hurley *et al*, 2000). In the context of low vision, a variety of both positive and negative adaptation strategies have been identified, including maintaining independence in order to cultivate a sense of 'self-worth' by not having to ask others for help (Lindö and Nordholm, 1999). It is therefore likely that some subjects in arm 3 may have declined home visits for similar reasons.

9.4.7 Impact of task restriction on QoL

The ability of people with AMD to carry out everyday activities with an LVA may not be as relevant to their QoL as has been assumed in the main hypothesis of this trial. Other researchers have shown that AMD results in a deterioration in QoL (for example, Brenner *et al*, 1993; Scott *et al*, 1994; Brown *et al*, 2000) and the baseline SF-36 data show that this was also true for the study population in this trial (Harper *et al*, 2001). QoL of the subjects did not improve during follow-up despite high, and increasing, use of LVAs. If QoL is not strongly linked to restriction in everyday activities, one might not predict any differences between arms. This explanation might be potentially very important. One explanation may be that the QoL of people with AMD is primarily determined by grief for lost sources of pleasure and relaxation, such as reading, watching television or enjoying social pursuits, rather than by the ability to perform essential activities in a constrained way. Therefore, it might be argued that if the intervention in arm 2 had included components such as counselling and/or an integrated model of care with social services input, significant differences in outcomes such as the VCM1 and the psychosocial dimensions of NAS may have been demonstrated. A recent study in India concluded that a comprehensive multidisciplinary approach which includes a counselling service alongside LVA distribution, training (including formal viewing strategies) and education was of great importance in the management of AMD patients (Khan *et al*, 2002). Khan *et al* describe the particular emphasis that was given to counselling to encourage patients to develop coping strategies with respect to vision loss and to address emotional problems such as depression. Earlier studies have also suggested the need to include counselling, offered not only to the visually impaired

client but also to the family members of the client (Radochoński, 1988; Dodds *et al*, 1994).

9.5 Implications for service development and indications for future research

There is no clear evidence from this study to support recommendations for an enhanced model of care incorporating the form of supplementary input provided to subjects in arm 2 of this trial. Patients receiving low vision care appear to make considerable use of low vision devices for tasks they consider to be important, but the impact of this usage on vision-related QoL and restriction needs further investigation. Although an economic evaluation of different strategies of low vision rehabilitation is outside the scope of this thesis, a formal economic evaluation in relation to this trial is actually no longer necessary on the basis of the results found. Given that the enhanced model of care used in this trial would be more costly to deliver, a balanced view would need to be exercised in the future in terms of cost effectiveness versus potential benefits in the planning of integrated services.

Further work on this dataset will concentrate on: (i) an investigation of the relationships between visual impairment, disability and QoL in AMD, and the identification of a minimum outcome dataset to characterise the dimensions relevant to subjects with AMD; and (ii) an exploration of the total study population to determine which factors are predictive of more successful outcomes, e.g. in terms of vision-related QoL or reduced restriction in activities.

There is still much to be done to inform the debate about strategies for low vision rehabilitation. In the future, a meta-analysis to include these results and other RCT findings may inform the true nature of the effectiveness in low vision rehabilitation. For example, there is recent evidence arising from a meta-analysis of 15 RCTs which explored the effectiveness of health care services requiring preventive home visits to elderly people, to suggest that on balance there are many benefits with respect to mortality and admission to long term institutional care, thereby allowing older people to maintain independence in their own homes (Elkan et al, 2001). The individual trials

themselves showed different outcomes, leading to contradiction in the literature. The small impact of low vision rehabilitation on QoL in studies by Wolffsohn and Cochrane (2000), by Scott et al (1999), and the present trial appear to indicate that low vision rehabilitation may need to be evaluated along similar lines. Further consideration will also need to be given to the nature of interventions in terms of scope and intensity. For example, a research team at the Royal Victoria Hospital in Belfast (in collaboration with Queens University, Belfast) has recently started an RCT which will include an integrated model of care as an intervention arm, extending the training which was offered in arm 2 of this RCT to incorporate the training in viewing strategies described above (Harper, 2003, personal communication).

It might be argued, however, that while the available body of evidence about low vision interventions would have supported the need to conduct the present trial, more pre-trial primary research will need to be carried out to establish the plausibility of any interventions used. In terms of the present RCT, a pragmatic approach of building on existing literature was adopted, rather than including an exploratory pilot phase to inform the content of the trial inputs. The literature illustrates that there are a number of different approaches and models for the delivery of low vision services. At the time when this study was designed it was felt to be extremely worthwhile to investigate the benefits of an enhanced form of low vision care involving specialist input at home, and arm 2 input had good 'face validity'.

Whilst the enhanced model of low vision care delivered in this trial did not match the multi-disciplinary model proposed by the Low Vision Consensus Group (1999), it nevertheless offered a low vision rehabilitation service which linked the information gathered by optometrists in the HES consulting room with the activities carried out by a rehabilitation worker, and in turn with other care providers via referral. The supporting premise with respect to this enhanced model of care is that information such as visual function measurements recorded by optometrists can positively inform the rehabilitation process (Karas and Crossland, 2002). However, no evidence was found to indicate better outcomes across a range of measures for patients receiving this enhanced model of care. Although the Low Vision Consensus Group recommendations also have good 'face validity', it remains to be seen whether their particular recommendations would give rise to better outcomes.

It is important both for the patient and the health care system to be clear about what an intervention is aiming to achieve and for researchers to choose outcome measures that quantify whatever it is that the intervention is designed to improve. Further primary research is needed to determine which interventions might exert the most favourable influence on the measures that are of most importance to patients. Further work should address the health and welfare profile of people with AMD over time. It would be useful from societal perspective to compare the characteristics of individuals with AMD who manage to retain greater independence and sustain QoL versus those who lose independence and/or show a reduction in QoL. This information would provide a broader picture which would be important to informing and guiding the development of low vision rehabilitation services.

This trial has raised several issues surrounding the choice of outcomes. The outcomes chosen in this trial predominantly addressed psychosocial dimensions whereas the intervention was oriented towards the ability to perform tasks and to sustaining this ability. It is therefore important to tease apart the complex relationships between restriction in activities and QoL measures in an elderly population in order to identify how best to quantify the effectiveness of low vision rehabilitation. In terms of dealing with restrictions, a more substantial level of input (i.e. in terms of frequency and duration) with more emphasis placed on training methods such as eccentric viewing could also be investigated. Earlier research (e.g. Hall *et al,* 1987; McIlwaine *et al,* 1991; Shuttleworth *et al,* 1995) has suggested that many LVAs loaned to patients attending low vision rehabilitation services remain unused. Whilst the low vision service at MREH is largely concerned with the provision of LVAs, and basic training in their handling is delivered by the optometrists during clinic assessments, there was a strong argument in favour of exploring the benefits of a model of care which is enhanced by the reinforcement of such training in the home environment, where correct use of devices and lighting may be problematic for many people. Therefore this study has essentially explored the merits of an enhanced ophthalmic service rather than a model of care which may have included other components. Such components could include for example, the aforementioned additional training (i.e. formal viewing strategies), more formal integration with the activities of social services, or counselling. Other researchers (Radochoński, 1988; Dodds et al, 1994; Khan et al, 2002) have identified psychosocial issues as important determinants of QoL of people with AMD. Indeed

separate analyses on the trial dataset, not reported in this thesis, have shown that psychosocial issues weigh heavily on the QoL of people with AMD (Harper *et al*, 2001). This issue highlights a pressing need for effective counselling interventions that can address the emotional and behavioural factors which exert a profound influence on QoL.

It is widely accepted that the RCT is the 'gold standard' methodology for generating evidence about the effectiveness of new forms of low vision care. However, given the findings of the present trial, before designing and conducting such trials researchers should place a greater emphasis on primary research to determine the components of effective low vision intervention.

Manchester Royal Eye Hospital
Oxford Road
Manchester
M13 9WH
Tel. xxxx-xxx-xxxx (to leave a message)
xxxx-xxxxxx (direct line)

Dear

Your consultant has asked us to send you an appointment to attend the low vision clinic at the Eye Hospital and this will be posted to you shortly. The purpose of this letter is to ask you if you would consider taking part in a study about low vision rehabilitation which we are carrying out at the Hospital. You are under no obligation to take part in the study and your clinical care at the Eye Hospital will not be affected in any way should you decide not to take part.

Please read the following information carefully so that you can decide whether or not you would like to take part.

Yours sincerely

Mrs W.B. Russell
Research Officer (Low Vision)

PATIENT INFORMATION SHEET

Project: The effectiveness of low vision rehabilitation care

Research Officer: Mrs Russell
Research Team: Dr Harper, Dr Reeves, Dr Waterman, Prof McLeod, Dr Henson
Manchester Royal Eye Hospital, Oxford Road, Manchester, M13 9WH

What is low vision rehabilitation?
The purpose of low vision rehabilitation is to allow you to make the best possible use of your remaining vision and to allow you to adapt to your loss of vision (e.g. by providing you with a special magnifier or another device to allow you to do something you now find difficult).

What normally happens at the low vision clinic?
You attend the low vision clinic for an initial assessment of your vision by an optometrist (ophthalmic optician). They will discuss with you your vision problems and the various tasks which you may now find difficult to see to do, test your vision and show you various magnifying devices, some of which may help. These low vision magnifying aids can then be loaned to you. The optometrist will then see you for a second follow-up visit about two months later to re-check your vision and see how you are getting on with the low vision aid(s).

What is the purpose of the study?
The aim of the study is to find out the best way to provide a low vision rehabilitation service to patients who suffer from age-related macular degeneration. To do this we need to compare the effectiveness of different approaches to low vision care by seeing how well people do one year after they have been assessed at the Eye Hospital.

What will happen if I take part in the research study?
You will be seen as usual in the low vision clinic by the optometrist as described above but you will also be visited at home on two separate occasions by a member of the research team. She will need to ask you a number of questions about your general health, your vision loss and the use of your magnifiers. These questions will be asked just before your first assessment and then 12 months later. The research officer will also check your vision at home. Lastly, you will need to attend the Eye Hospital for a final check on your vision by the optometrist 12 months

after your first appointment. Because we want to know the best way in which to provide low vision rehabilitation, some patients may need to attend the hospital once more than usual and also be visited at home on three additional occasions by a member of the research team.

What risks are involved in taking part in the research study?
There are no risks to your health from taking part in the study.

What will happen to all the information about my eye health and vision?
Personal information will be kept confidential.

Am I entitled to any travel costs to attend for appointments?
Your normal visits to the low vision clinic form part of the standard low vision care at this hospital and travel costs cannot be reimbursed for these, but we will pay your travel expenses for any additional visits that are necessary for the study.

What will happen if I decide not to take part in the research study?
You do not have to take part in the study if you do not wish to. We will see you in the low vision clinic as planned and your management at the Eye Hospital will continue in the normal way. Similarly, if you change your mind about taking part, you have the right to leave the study at any stage without this affecting your management at the Eye Hospital.

What should I do if I want to know more about the research study?
You are welcome to ask any questions you like about the study at any stage. You can contact us if you wish, by telephoning Mrs Wanda Russell on xxxx-xxxxxx (direct line) or on xxxx-xxx-xxxx (to leave a brief message and to have your call returned). A member of the research team will be contacting you shortly by telephone to ask you if you are prepared to take part in the study and he/she will be happy to answer any questions you may have.

Patient

(1) Please read this form very carefully.

(2) If there is anything that you don't understand about the information sheet or you wish to ask any questions please speak to the investigator named on this form.

(3) Please check that all the information on the patient consent form overleaf is correct. If it is and you understand the explanation then please sign the form below. Please return this form in the prepaid envelope enclosed.

YES

I have been given a written or taped explanation of the study by the investigator named on this form. It includes full details of any potential risks, my rights as a patient and what is to be done to me. I have been given the opportunity to ask questions.

I have had enough time to think about the study, talk to relatives and friends about it and to decide without pressure if I want to take part.

I understand the decision is up to me and that I can change my mind without it affecting how I am treated in the future.

I have been assured that all information collected in the study will be held in confidence and if presented my personal details will be removed.

I agree that the researcher may withdraw me from the study in the interest of my health or welfare.

I have been informed of any compensation arrangements that have been made.

I therefore agree that I will take part in this study.

Signed ..... **Date** .....

Address .....

.....

Patient Consent Form

Project: Randomised controlled trial of an optometric *versus* an integrated low vision rehabilitation service for patients with age-related macular degeneration.

Manchester Royal Eye Hospital
Oxford Road
Manchester
M13 9WH
Tel: xxxx-xxx-xxxx / xxxx-xxxxxx

Patient's surname ..... Other names .....

Hospital number ..... Date of birth .....

Sex (please tick): Male Female

Age .....

Investigator .....

Department of Ophthalmology, Manchester Royal Eye Hospital

The trial is designed to establish the effectiveness of different approaches to the management of patients with low vision due to age-related macular degeneration. There is no health risk to patients who take part.

I confirm that I have explained the clinical trial and supplied the subject with an information sheet and a leaflet explaining the subject's rights in clinical trials in terms which in my judgement are suited to their understanding.

Signature: ..... Date: .....

Manchester Royal Eye Hospital
Oxford Road
Manchester
M13 9WH
Tel. xxxx-xxx-xxxx (to leave a message)
xxxx-xxxxxx (direct line)

Dear

I wrote to you recently inviting you to take part in a study about low vision rehabilitation which we are carrying out at the Hospital. You should also have received your appointment to attend the low vision clinic at the Eye Hospital. If you would like to take part in the study I would need to visit you at home before you attend the low vision clinic. Therefore it is important that if you are willing to take part in the study you must send the enclosed consent form back to me in the envelope provided by return of post or contact me on the phone number above. I enclose a copy of the information sheet about the study. You are under no obligation to take part in the study and your clinical care at the Eye Hospital will not be affected in any way should you decide not to take part.

Please read the following information carefully so that you can decide whether or not you would like to take part. If you would like to join the study please contact me as soon as possible.

Yours sincerely

Mrs W.B. Russell
Research Officer (Low Vision)

APPENDIX 3:
Reasons given for non-consent to participate in the trial

Table A3: Reasons for non-consent

Reason for refusal to participate in the trial	**Number of eligible patients contacted (n=46)**
No specific reason given	20
Patient was too ill to be interviewed	11
Patient's partner was very ill	3
No convenient time available	5
Patient had severe hearing problems	3
Patient did not wish to have any home visits	2
Patient was about to move house	1
Patient was concerned about being part of a research study	1
Total refusals	46

APPENDIX 4:
The inter-relationship between the different acuity notations

(a) Distance acuity

MAR (min arc)	logMAR	Snellen (6m)	Snellen (20ft)	Decimal notation	Keeler A
100	2.0	6/600	20/2000	0.01	
79	1.9	6/480	20/1600	0.0125	20*
63	1.8	6/380	20/1250	0.016	19*
50	1.7	6/300	20/1000	0.02	18*
40	1.6	6/240	20/800	0.025	17*
32	1.5	6/190	20/630	0.032	16*
25	1.4	6/150	20/500	0.04	15*
20	1.3	6/120	20/400	0.05	14*
15.8	1.2	6/95	20/320	0.063	13*
12.5	1.1	6/75	20/250	0.08	12
10.0	1.0	6/60	20/200	0.1	11
8.0	0.9	6/48	20/160	0.125	10
6.3	0.8	6/38	20/125	0.16	9
5.0	0.7	6/30	20/100	0.2	8
4.0	0.6	6/24	20/80	0.25	7
3.2	0.5	6/19	20/63	0.32	6
2.5	0.4	6/15	20/50	0.4	5
2.0	0.3	6/12	20/40	0.5	4
1.58	0.2	6/9.5	20/32	0.63	3
1.25	0.1	6/7.5	20/25	0.8	2
1.0	0.0	6/6	20/20	1	1
0.8	-0.1	6/4.8	20/16	1.25	
0.63	-0.2	6/3.8	20/12.5	1.6	
0.5	-0.3	6/3	20/10	2.0	

* Notations are slightly smaller than equivalent logMAR sizes.

Source: Dickinson, 1998.

The inter-relationship between the different acuity notations

(b) Near acuity

Letter size (lower case) (mm)	Sloan M-notation	Point system	Keeler A	Equivalent Snellen acuity for letters viewed at 25 cm
0.36	0.25	2	1	6/6
0.45	0.32	2.6	2	
0.55	0.4	3.2	3	
0.71	0.5	4	4	6/12
0.83	0.6	4.8		
0.89	0.63	5	5	6/15
1.06	0.75	6		6/18
1.1	0.8	6.4	6	
1.4 newsprint	1.0	8	7	6/24
1.6	1.1	9		
1.75	1.25	10	8	
2.15	1.5	12	9	
2.5	1.75	14		
2.7	1.9	15.4	10	
2.8	2.0	16		
3.2	2.3	18		
3.4	2.4	19.3	11	
3.5	2.5	20		6/60
4.2	3.0	24	12	
5.3	3.8	30	13	
5.6	4.0	32		
6.4	4.5	36		
6.6	4.7	37.5	14	
7.1	5.0	40		6/120
8.3	5.9	47	15	
8.5	6.0	48		6/150
9.7	7.0	56		
10.3	7.3	58.4	16	
11.1	8.0	64		
12.5	9.0	72		
12.9	9.1	73	17	
13.9	10.0	80		6/240
16.1	11.5	92	18	
20.2	14.5	116	19	6/350
25.2	18	143	20	

Source: Dickinson, 1998.

APPENDIX 5:

Data capture sheets for initial and follow-up low vision assessments

ARMD Study: Low Vision First Assessment Data Sheet

Patient identification:	
Surname _____	Hospital No. _____
First name(s) _____	Study No. [ ][ ][ ]
Clinic Visit No. [1]	Date [ ][ ][ ][ ][ ][ ]

Primary Diagnosis:	**Co-morbidity:**	

Visual requirements: *(please tick)*					
Read ordinary print		Read time on watch		Hobbies, interests	
Read large print		Identify money		Reading bus nos., signs	
Read correspondence		Write letters, cards		Other distance tasks	
Read shop prices, labels		Watch TV		Other	

Visions (unaided):	**RE**	**LE**
Distance (logMAR)		
Near (M units)	**M** at cm	**M** at cm

Existing devices (if brought):						
Make	Code No.	Power (D)	Mag. rating	Class e.g. HM(I)	Optimal VA logMAR~DV, M units~NV	Eye RE/LE/ both
1.					*M at cm	
2.					*M at cm	
3.					*M at cm	
4.					*M at cm	

Refraction:	**RE**	**LE**
Distance		

Continued overleaf....

Visual acuity with correction:	RE	LE
Distance (logMAR)		
Near (M units) with +4.00 Add	M at cm	M at cm

Contrast sensitivity (log CS):	RE	LE

Devices loaned:

Make	Code No.	Power (D)	Mag. rating	Class e.g. HM(I)	Optimal VA logMAR / DV, M units / NVA	Eye RE/LE/ both
1.					*M at cm	
2.					*M at cm	
3.					*M at cm	
4.					*M at cm	

Optometrist's assessment of patient motivation for using LVA(s) - *please tick*	High motivation	
	Moderate motivation	
	Low motivation	

Additional comments:

OPTOMETRIST:	Duration of assessment	
	Name	
	Signed	

NB: Please check that all relevant fields have been completed.

ARMD Study: Low Vision Second Assessment Data Sheet

Patient identification:	
Surname _____	Hospital No. _____
First name(s) _____	Study No. ☐☐☐
Clinic Visit No. 2	Date ☐☐☐☐☐☐

New Co-morbidity:		

Optimal entering acuities (with or without Rx):	**RE**	**LE**
Distance (logMAR)		
Near (M units)	M at cm	M at cm

Own non-hospital devices (if brought):

Make	Code No.	Power (D)	Mag. rating	Class e.g. HM (1)	Optimal VA logMAR, DV, M units, NV?	Eye RE/LE/ both
1.					*M at cm	
2.					*M at cm	
3.					*M at cm	
4.					*M at cm	

Devices retained:

Make	Code No.	Power (D)	Mag. rating	Class e.g. HM (1)	Optimal VA logMAR, DV, M units, NV?	Eye RE/LE/ both
1.					*M at cm	
2.					*M at cm	
3.					*M at cm	
4.					*M at cm	

Continued overleaf....

New devices loaned:						
Make	Code No.	Power (D)	Mag. rating	Class e.g. HM (I)	Optimal VA logMAR DV M units NV*	Eye RE/LE/ both
1.					*M at cm	
2.					*M at cm	
3.					*M at cm	
4.					*M at cm	

Devices returned:				
Make	Code No.	Power (D)	Mag. rating	Class e.g. HM (I)
1.				
2.				
3.				
4.				

Optometrist's assessment of patient motivation for using LVA(s): *(please tick)*		
	High motivation	
	Moderate motivation	
	Low motivation	

Additional comments:

OPTOMETRIST:	Duration of assessment	
	Name	
	Signed	

NB: Please check that all relevant fields have been completed.

ARMD Study: Low Vision Third Assessment Data Sheet

Patient identification:	
Surname _____	Hospital No. _____
First name(s) _____	Study No.
Clinic Visit No. 3	Date

NB: Please ensure that all relevant fields are completed.

New Co-morbidity:		

Optimal entering acuities (with or without Rx):	RE	LE
Distance (logMAR)		
Near (M units)	M at cm	M at cm

Contrast sensitivity (log CS)	RE	LE

Own non-hospital devices (if brought):						
Make	Code No.	Power (D)	Mag. rating	Class e.g. HM (I)	Optimal VA logMAR - DV, Munits - NV	Eye RE/LE/ both
1.					*M at cm	
2.					*M at cm	
3.					*M at cm	
4.					*M at cm	

Continued overleaf....

Devices retained:						
Make	Code No.	Power (D)	Mag. rating	Class e.g. HM (I)	Optimal VA logMAR / DV; M units / NV*	Eye RE/LE/ both
1.					*M at cm	
2.					*M at cm	
3.					*M at cm	
4.					*M at cm	

New devices loaned:						
Make	Code No.	Power (D)	Mag. rating	Class e.g. HM (I)	Optimal VA logMAR / DV; M units / NV*	Eye RE/LE/ both
1.					*M at cm	
2.					*M at cm	
3.					*M at cm	
4.					*M at cm	

Devices returned:				
Make	Code No.	Power (D)	Mag. rating	Class e.g. HM (I)
1.				
2.				
3.				
4.				

Additional comments:

OPTOMETRIST:	Duration of assessment:	
	Name:	
	Signed:	

ARMD Study: Low Vision Extra Assessment Data Sheet

Patient identification:	
Surname _____	Hospital No. _____
First name(s) _____	Study No. ☐☐☐
Clinic Visit No. ☐	Date ☐☐☐☐☐☐

NB: Please ensure that all relevant fields are completed.

New Co-morbidity:		

Optimal entering acuities (with or without Rx):	RE	LE
Distance (logMAR)		
Near (M units)	M at cm	M at cm

Contrast sensitivity (log CS)	RE	LE

Own non-hospital devices (if brought):						
Make	Code No.	Power (D)	Mag rating	Class ≥ HM (1)	Optimal VA logMAR / DV Munits / NV*	Eye RE/LE/ both
1.					*M at cm	
2.					*M at cm	
3.					*M at cm	
4.					*M at cm	

Continued overleaf....

Devices retained:						
Make	Code No.	Power (D)	Mag rating	Class e.g. HM (I)	Optimal VA logMAR - DV, M units - NV*	Eye RE/LE/ both
1.					*M at cm	
2.					*M at cm	
3.					*M at cm	
4.					*M at cm	

New devices loaned:						
Make	Code No.	Power (D)	Mag rating	Class e.g. HM (I)	Optimal VA logMAR - DV, M units - NV*	Eye RE/LE/ both
1.					*M at cm	
2.					*M at cm	
3.					*M at cm	
4.					*M at cm	

Devices returned:				
Make	Code No.	Power (D)	Mag rating	Class e.g. HM (I)
1.				
2.				
3.				
4.				

Additional comments:

OPTOMETRIST:	Duration of assessment	
	Name	
	Signed	

APPENDIX 6:
Task performance data capture sheet

ARMD Study: Task Performance Questionnaire

Patient identification:

Surname _____

First name(s) _____

Hospital No. _____

Study No. ☐☐☐

Date ☐☐☐☐☐☐

- *Inform the patient that he/she will be asked to carry out a few simple tasks. Reassure him/her that none of the tasks is a 'test' but that they form an important part of the research that the patient is helping with .*
- *Suggest that if the patient feels that a magnifier would be helpful they should use one.*

Task No. 1: 'Use-by' & 'Best before' dates

Use-by date correctly identified for **meat** item? Y ☐1 N ☐2 N(no attempt made) ☐3

Magnifier used? Y ☐1 N ☐2 If YES, state main type of magnifier used: _____

Best before date correctly identified for **bakery** item? Y ☐1 N ☐2 N(no attempt made) ☐3

Magnifier used? Y ☐1 N ☐2 If YES, state main type of magnifier used: _____

Task No. 2: Completion of 'Manchester Talking Books & Magazines' application form:

	Y	N	N(no attempt made)
Completed name?	☐1	☐2	☐3
Completed telephone no.?	☐1	☐2	☐3
Stated age group correctly?	☐1	☐2	☐3
Ticked request/refusal for books or magazines?	☐1	☐2	☐3

Magnifier used? Y ☐1 N ☐2 If YES, state main type of magnifier used: _____

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Task No. 3: Medicine bottle

	Y	N	N(no attempt made)
Name of medicine correctly identified? *('Paracetamol')*	☐1	☐2	☐3
Dosage of medicine correctly identified? *('1 or 2 ... every 4 to 6 hrs')*	☐1	☐2	☐3

	Y	N	
Magnifier used?	☐1	☐2	If YES, state main type of magnifier used: _____

Task No. 4: Shopping list

- *Advise the patient that this exercise will be timed but reassure as before that this won't be a test, therefore:*
- *Instruct the patient that they must not stop until they have finished reading the whole list.*
- *As for the tasks above, suggest that if the patient feels that a magnifier would be helpful they should use one.*

	Y	N
Shopping list attempted?	☐1	☐2

Tick each shopping item identified:

	Y	N
Bread	☐1	☐2
Apples	☐1	☐2
Tomatoes	☐1	☐2
Half dozen large eggs	☐1	☐2
Biscuits	☐1	☐2
Orange juice	☐1	☐2
Milk	☐1	☐2
Tin of baked beans	☐1	☐2
Light bulbs	☐1	☐2
Batteries	☐1	☐2
Washing-up liquid	☐1	☐2
Toilet roll	☐1	☐2

Time taken ☐☐ min. ☐☐ sec.

	Y	N	
Magnifier used?	☐1	☐2	If YES, state main type of magnifier used: _____

APPENDIX 7:

Background information questionnaire used (a) at baseline, and (b) at follow-up

ARMD Study: Background Information Questionnaire

Patient identification:

Surname _____ Hospital No. _____

First name(s) _____ Study No. ☐☐☐

Address _____

_____ Post code _____

Home tel. no. _____ Work tel. no. _____

Alternative contact tel. no. & name _____

Sex: M ☐1 F ☐2 DOB ☐☐☐☐☐☐

Ethnic Origin:

Afro-Caribbean ☐1 African ☐2 Asian ☐3 White European ☐4 Chinese ☐5 Other ☐6

Religion _____ Date of first low vision assessment: ☐☐☐☐☐☐

General background information:

Residential status: Lives alone ☐1
Lives with partner ☐2
With family/friends ☐3
Other ☐4
→ *Specify* _____

Working?: Full-time ☐1
Part-time ☐2
Retired/stopped ☐3
Never worked ☐4
→ *When retired:* ☐☐ yrs / ☐☐ mths ago

Involved in regular voluntary work? YES ☐1 NO ☐2 Hours per week : ☐☐

Level of education achieved: Primary ☐1
Secondary ☐2
Tertiary or higher ☐3

Age when left education: ☐☐ yrs

Main hobbies/interests: (* indicate if still does)
1. _____ 2. _____
3. _____ 4. _____
5. _____ 6. _____

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Housing information: At current address: < 1 year ☐1
1-5 years ☐2
> 5 years ☐3

General health:

Are you currently taking any medicines prescribed by your GP which you have been taking for a long time? YES ☐1 NO ☐2

Please state why you are taking these medicines (i.e. the illnesses they are being used for):

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

Currently attending hospital / health centre clinic for a health problem other than vision?
YES ☐1 NO ☐2

If YES, specify health problem(s):

1. _____ 2. _____

3. _____ 4. _____

Any other disabilities? YES ☐1 NO ☐2

If YES, specify disability(ies):

1. _____ 2. _____

Receiving regular assistance with daily living activities from social services / community nurse?
YES ☐1 NO ☐2

If YES, specify type(s) of regular assistance:

Home help: YES ☐1 NO ☐2 Meals on wheels: YES ☐1 NO ☐2
Mobility assistance: YES ☐1 NO ☐2 Personal care: YES ☐1 NO ☐2
Other: YES ☐1 NO ☐2
If OTHER, specify:

1. _____ 2. _____

Do you need to use a hearing aid(s) most of the time? YES ☐1 NO ☐2

Family & social activities:

Visits **to family**:	at least weekly	☐ 1	Visits **by family**:	at least weekly	☐ 1
	at least monthly	☐ 2		at least monthly	☐ 2
	few times a year / special occasions	☐ 3		few times a year /special occasions	☐ 3
	hardly ever	☐ 4		hardly ever	☐ 4
	never	☐ 5		never	☐ 5
Visits **to friends**:	at least weekly	☐ 1	Visits **by friends**:	at least weekly	☐ 1
	at least monthly	☐ 2		at least monthly	☐ 2
	few times a year / special occasions	☐ 3		few times a year /special occasions	☐ 3
	hardly ever	☐ 4		hardly ever	☐ 4
	never	☐ 5		never	☐ 5

Do any close friends or relatives have low vision? YES ☐ 1 NO ☐ 2

Involved in any community or social activity in past fortnight? YES ☐ 1 NO ☐ 2

Attended place of worship in past fortnight? YES ☐ 1 NO ☐ 2

Use of public transport:	daily	☐ 1	Does own shopping:	all of the time	☐ 1
	at least weekly	☐ 2	(food & other	mostly	☐ 2
	at least monthly	☐ 3	daily necessities)	sometimes	☐ 3
	hardly ever	☐ 4		rarely	☐ 4
	never	☐ 5		never	☐ 5

Does a relative, friend or an organisation usually provide car transport when you need to make a journey which is too far to walk? YES ☐ 1 NO ☐ 2

What expectations do you have of your appointment at the low vision clinic? *(Tick each response offered - give prompts only when necessary)*

Being able to see	☐	Ability to carry out tasks	☐
Improvement in vision	☐	Reassurance or comfort	☐
Information	☐	Other *(please state)*	☐
Support	☐	_____	
		_____	

ARMD Study: Follow-up Background Information Questionnaire

Patient identification :

Date: ☐☐☐☐☐☐

Surname _____

First name(s) _____

Hospital No. _____

Study No. ☐☐☐

Address _____

_____

Post code _____

Home tel. no. _____

Work tel. no. _____

Alternative contact tel. no. & name _____

Sex: M ☐1 F ☐2

DOB ☐☐☐☐☐☐

General background information:

Residential status:
- Lives alone ☐1
- Lives with partner ☐2
- With family/friends ☐3
- Other ☐4
  - *Specify* _____

Involved in any regular or voluntary work? YES ☐1 NO ☐2 Hours per week : ☐☐

Main hobbies/interests: (* indicate if still does)
1. _____ 2. _____
3. _____ 4. _____
5. _____ 6. _____

Housing information:

At current address:
- < 1 year ☐1
- 1-5 years ☐2
- > 5 years ☐3

General health:

Are you currently taking any medicines prescribed by your GP which you have been taking for a long time? YES ☐1 NO ☐2

Please state why you are taking these medicines (i.e. the illnesses they are being used for):

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

Currently attending hospital / health centre clinic for a health problem other than vision?
YES ☐1 NO ☐2

If YES, specify health problem(s):

1. _____ 2. _____

3. _____ 4. _____

Any other disabilities? YES ☐1 NO ☐2

If YES, specify disability(ies):

1. _____ 2. _____

Receiving regular assistance with daily living activities from social services / community nurse?
YES ☐1 NO ☐2

If YES, specify type(s) of regular assistance:

Home help: YES ☐1 NO ☐2 Meals on wheels: YES ☐1 NO ☐2

Mobility assistance: YES ☐1 NO ☐2 Personal care: YES ☐1 NO ☐2

Other: YES ☐1 NO ☐2

If OTHER, specify:

1. _____ 2. _____

Do you need to use a hearing aid(s) most of the time? YES ☐1 NO ☐2

Family & social activities:

Visits to family:	at least weekly	☐1	Visits by family:	at least weekly	☐1
	at least monthly	☐2		at least monthly	☐2
	few times a year / special occasions	☐3		few times a year /special occasions	☐3
	hardly ever	☐4		hardly ever	☐4
	never	☐5		never	☐5
Visits to friends:	at least weekly	☐1	Visits by friends:	at least weekly	☐1
	at least monthly	☐2		at least monthly	☐2
	few times a year / special occasions	☐3		few times a year /special occasions	☐3
	hardly ever	☐4		hardly ever	☐4
	never	☐5		never	☐5

Do any close friends or relatives have low vision? YES ☐1 NO ☐2

Involved in any community or social activity in past fortnight? YES ☐1 NO ☐2

Attended place of worship in past fortnight? YES ☐1 NO ☐2

Use of public transport:	daily	☐1	Does own shopping:	all of the time	☐1
	at least weekly	☐2	(food & other	mostly	☐2
	at least monthly	☐3	daily necessities)	sometimes	☐3
	hardly ever	☐4		rarely	☐4
	never	☐5		never	☐5

Does a relative, friend or an organisation usually provide car transport when you need to make a journey which is too far to walk? YES ☐1 NO ☐2

APPENDIX 8:
The UK Short-Form 36 Health Survey Questionnaire (SF-36)

ARMD Study: SF36 Questionnaire*

Patient identification:	
Surname _____	Hospital No. _____
First name(s) _____	Study No. ☐☐☐
Visit No. ☐	Date ☐☐☐☐☐☐

- *This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.*
- *If you are unsure about how to answer a question, please give the best answer you can.*

1. In general, would you say your health is?

Excellent	☐1
Very good	☐2
Good	☐3
Fair	☐4
Poor	☐5

2. **Compared to one year ago,** how would you rate your health in general **now?**

Much better now than one year ago	☐1
Somewhat better now than one year ago	☐2
About the same as one year ago	☐3
Somewhat worse now than one year ago	☐4
Much worse now than one year ago	☐5

3. The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

ACTIVITIES	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. **Strenuous activities,** such as heavy work around the house, making a bed, moving a table, gardening			
b. **Moderate activities,** such as pushing a vacuum cleaner or light work around the house			
c. Lifting or carrying groceries			
d. Climbing **several** flights of stairs			
e. Climbing **one** flight of stairs			
f. Bending, kneeling, or stooping			
g. Walking **one hundred yards**			
h. Walking **half a mile**			
i. Walking **more than a mile**			
j. Bathing or dressing yourself			

*Standard U.K. Version 1.0 modified according to Hayes, V. *et al.*

4.	During the **past 4 weeks**, have you had any of the following problems with your regular daily activities (or work) **as a result of your physical health?**		
		YES	NO
a.	Cut down on the **amount of time** you spent on activities or work		
b.	**Accomplished less** than you would like		
c.	Were limited in the **kind** of activities or work		
d.	Had **difficulty** performing the activities or work (for example, it took extra effort)		

5.	During the **past 4 weeks**, have you had any of the following problems with your regular daily activities (or work) **as a result of any emotional problems** (such as feeling depressed or anxious)?		
		YES	NO
a.	Cut down on the **amount of time** you spent on activities or work		
b.	**Accomplished less** than you would like		
c.	Didn't do activities or work as **carefully** as usual		

6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

- Not at all ☐1
- Slightly ☐2
- Moderately ☐3
- Quite a bit ☐4
- Extremely ☐5

7. How much **bodily** pain have you had during the **past 4 weeks?**

- None ☐1
- Very mild ☐2
- Mild ☐3
- Moderate ☐4
- Severe ☐5
- Very severe ☐6

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

- Not at all ☐1
- A little bit ☐2
- Moderately ☐3
- Quite a bit ☐4
- Extremely ☐5

*Standard U.K. Version 1.0 modified according to Hayes, V. *et al.*

9.	These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks:**						
		All of the Time	**Most of the Time**	**A Good Bit of the Time**	**Some of the Time**	**A little of the Time**	**None of the Time**
a.	Did you feel full of life?						
b.	Have you been a very nervous person?						
c.	Have you felt so down in the dumps that nothing could cheer you up?						
d.	Have you felt calm and peaceful?						
e.	Did you have a lot of energy?						
f.	Have you felt downhearted and low?						
g.	Did you feel worn out?						
h.	Have you been a happy person?						
i.	Did you feel tired?						

10. During the **past 4 weeks,** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives etc.)?

All of the time ☐1
Most of the time ☐2
Some of the time ☐3
A little of the time ☐4
None of the time ☐5

11.	How **TRUE** or **FALSE** is **each** of the following statements for you?					
		Definitely True	**Mostly True**	**Don't Know**	**Mostly False**	**Definitely False**
a.	I seem to get ill more easily than other people					
b.	I am as healthy as anybody I know					
c.	I expect my health to get worse					
d.	My health is excellent					

*Standard U.K. Version 1.0 modified according to Hayes, V. *et al.*

APPENDIX 9:
The Nottingham Adjustment Scale (NAS)

ARMD Study: NAS Questionnaire*

Patient identification:

Surname _____ Hospital No. _____

First name(s) _____ Study No. ☐☐☐

Visit No. ☐ Date ☐☐☐☐☐☐

C. Attitudes. *Client must agree/disagree with the following statements.*

	Strongly agree	Agree	Don't know	Disagree	Strongly disagree
1. Visually impaired people are used to failing at most things they do.	1	2	3	4	5
2. Most visually impaired people are constantly worried about what might happen to them.	1	2	3	4	5
3. Most visually impaired people keep a lot of things to themselves.	1	2	3	4	5
4. Most visually impaired people feel that they are worthless.	1	2	3	4	5
5. Visually impaired people are generally more easily upset than sighted people.	1	2	3	4	5
6. Most visually impaired people are dissatisfied with themselves.	1	2	3	4	5
7. Most visually impaired people believe that sight loss is the worst thing that could happen to them.	1	2	3	4	5

D. Locus of control. *Client must agree/disagree with the following statements.*

	Strongly agree	Agree	Don't know	Disagree	Strongly disagree
1. It's what I can do to help myself that's really going to make all the difference.	5	4	3	2	1
2. It's up to me to make sure I make the best of my future in these circumstances.	5	4	3	2	1
3. My own contribution to my rehabilitation doesn't amount to much.	1	2	3	4	5
4. I have little or no control over my progress from now on.	1	2	3	4	5

*Nottingham Adjustment Scale, University of Nottingham

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E. Acceptance. ***Client must agree/disagree with the following statements.***

	Strongly agree	Agree	Don't know	Disagree	Strongly disagree
1. Because of my eye problems, I feel miserable most of the time.	1	2	3	4	5
2. It makes me feel very bad to see all the things sighted people can do which I cannot.	1	2	3	4	5
3. Because of my eye problem, I have little to offer other people.	1	2	3	4	5
4. Because of my eye problem, other people's lives have more meaning than my own.	1	2	3	4	5
5. I feel satisfied with my abilities, and my eye problem doesn't bother me too much.	5	4	3	2	1
6. Almost every area of life is closed to me because of my eye problem.	1	2	3	4	5
7. My eye problem prevents me doing just about everything I really want to do and from being the kind of person I really want to be.	1	2	3	4	5
8. In just about everything, my eye problem is so annoying that I can't enjoy anything.	1	2	3	4	5
9. Often there are times when I think about my eye problem, and it upsets me so much that I am unable to think of or do anything else.	1	2	3	4	5

F. Self-efficacy. ***Client must agree/disagree with the following statements.***

	Strongly agree	Agree	Don't know	Disagree	Strongly disagree
1. I give up on things before completing them.	1	2	3	4	5
2. If something looks too complicated, I will not even bother to try.	1	2	3	4	5
3. When I decide to do something, I go right to work on it.	5	4	3	2	1
4. When trying to learn something new, I soon give up if I am not initially successful.	1	2	3	4	5
5. I avoid trying to learn new things when they look too difficult for me.	1	2	3	4	5
6. Failure just makes me try harder.	5	4	3	2	1
7. I give up easily.	1	2	3	4	5
8. I do not seem capable of dealing with most problems that come up in life.	1	2	3	4	5

*Nottingham Adjustment Scale, University of Nottingham

APPENDIX 10:
A Vision Related Quality of Life Questionnaire (VCM1)

ARMD Study: Eyesight Questionnaire*

Patient identification:

Surname _____ Hospital No. _____

First name(s) _____ Study No. ☐☐☐

Visit No. ☐ Date ☐☐☐☐☐☐

- *Please think about your **eyesight** in the **past month**.*
- *If you use **glasses, contact lenses or magnifiers** for some activities, please answer according to how you can see **when using them.***
- ***Please ask for help** if the questions are not clear.*

Have you had an eye operation, an eyesight test, a change of glasses or a sudden change in the eyesight **in the past month?**

Yes ☐1 No ☐2

Specify:

Think about how your eyesight has made you feel in the past month

Have you felt **embarrassed because of your eyesight?**		Have you felt **frustrated** or **annoyed because of your eyesight?**	
Not at all	☐0	Not at all	☐0
Very rarely	☐1	Very rarely	☐1
A little of the time	☐2	A little of the time	☐2
A fair amount of the time	☐3	A fair amount of the time	☐3
A lot of the time	☐4	A lot of the time	☐4
All the time	☐5	All the time	☐5
Have you felt **lonely** or **isolated because of your eyesight?**		Have you felt **sad** or **low because of your eyesight?**	
Not at all	☐0	Not at all	☐0
Very rarely	☐1	Very rarely	☐1
A little of the time	☐2	A little of the time	☐2
A fair amount of the time	☐3	A fair amount of the time	☐3
A lot of the time	☐4	A lot of the time	☐4
All the time	☐5	All the time	☐5

*University of Bristol, 1996

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In the past month, **how often** have you worried about your **eyesight getting worse?**

- Not at all ☐0
- Very rarely ☐1
- A little of the time ☐2
- A fair amount of the time ☐3
- A lot of the time ☐4
- All the time ☐5

In the past month, how often has your **eyesight** made you **concerned or worried** about the following:

Your general **safety at home?**

- Not at all ☐0
- Very rarely ☐1
- A little of the time ☐2
- A fair amount of the time ☐3
- A lot of the time ☐4
- All the time ☐5

Your general **safety when out** of your home?

- Not at all ☐0
- Very rarely ☐1
- A little of the time ☐2
- A fair amount of the time ☐3
- A lot of the time ☐4
- All the time ☐5

Coping with everyday life?

- Not at all ☐0
- Very rarely ☐1
- A little of the time ☐2
- A fair amount of the time ☐3
- A lot of the time ☐4
- All the time ☐5

In the past month, **how often** has your **eyesight** stopped you doing the things you **want** to do?

- Not at all ☐0
- Hardly at all ☐1
- A little ☐2
- A fair amount ☐3
- A lot ☐4
- An extremely large amount ☐5

In the past month, **how much** has your **eyesight** interfered with your **life in general?**

- Not at all ☐0
- Hardly at all ☐1
- A little ☐2
- A fair amount ☐3
- A lot ☐4
- An extremely large amount ☐5

*University of Bristol, 1996

APPENDIX 11:

The Manchester Low Vision Questionnaire (MLVQ): baseline, follow-up, and abbreviated

ARMD Study: Manchester Low Vision Questionnaire

Patient identification:

Surname _____ Hospital No. _____

First name(s) _____ Study No. ☐☐☐

Visit No. ☐ Date ☐☐☐☐☐☐

Aids identification: Type: MREH=1, Other=2 Form code:

_____ ☐ 1

_____ ☐ 2

_____ ☐ 3

_____ ☐ 4

Tasks and use of low vision aid(s) – *NB Complete columns I, II & III only if no LVA is:*

Task	I) Do you need or want to do this? 1 A lot 2 A bit 3 No	II) Can you do this with or without an LVA? Yes/No/DK	III) Usually who does? 1 You do 2 You, but with help 3 Partner / someone else 4 No one	IV) Have you tried this using an LVA in the last 4 weeks? Yes/No	V) Have you needed an LVA to do this more often than not during the last 4 weeks? Yes/No
Reading letters/cards/other correspondence					
Reading instructions (packets, tins, bottles, medicines etc.)					
Reading 'ordinary' print books/newsprint/magazines					
Reading telephone directory to check numbers					
Reading markings on dials (cooker, radio/Hi-Fi, washer etc.)					
Reading shop prices/labels					
'Read' the time on your watch					
Identifying money					
Reading large print books/newspapers					
Writing own letters, cards etc.					
Signing your own name					
Reading own writing					
Filling in cheques, forms etc.					
Watching TV					
Special hobby (e.g. stamps, models, painting, music)					
DIY/repair/fixing task					
Sewing/knitting/needlework/mending					
Reading street signs/bus numbers/ directions etc.					
Watching an event/trip/theatre					
Games (e.g. cards, board games, bingo)					
Other					

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For each question and for each LVA tick appropriate response:				
How OFTEN have you used your magnifier in the last 4 weeks?	**LVA 1**	**LVA 2**	**LVA 3**	**LVA 4**
Many times (≥ 5) each day				
Several times (1-4) each day				
Weekly (< 1 daily but at least ≥ 1 per week)				
Occasionally (< 1 per week)				
Never (not used at all in last 4 weeks)				
What is the AVERAGE LENGTH OF TIME you have used your magnifier in the last 4 weeks?	**LVA 1**	**LVA 2**	**LVA 3**	**LVA 4**
Specify duration (minutes) if possible else choose a category:				
≥ 30 minutes				
≥ 15 minutes and < 30 minutes				
≥ 5 minutes and < 15 minutes				
≥ 1 minute and < 5 minutes				
< 1 minute				
And what is the LONGEST TIME you have used your magnifier (on any one occasion) in the last 4 weeks?	**LVA 1**	**LVA 2**	**LVA 3**	**LVA 4**
Specify duration (minutes) if possible else choose a category:				
≥ 30 minutes				
≥ 15 minutes and < 30 minutes				
≥ 5 minutes and < 15 minutes				
≥ 1 minute and < 5 minutes				
< 1 minute				
Which of the following statements is most appropriate for you about HOW EASY OR DIFFICULT your magnifier is to use?	**LVA 1**	**LVA 2**	**LVA 3**	**LVA 4**
I have had no difficulty at all				
I have had a little bit of difficulty				
I have had some difficulty				
I have had much difficulty				
I cannot use the magnifier				
Why did you have DIFFICULTY using the magnifier? ***(Ask as an open question and tick all responses given)***	**LVA 1**	**LVA 2**	**LVA 3**	**LVA 4**
Small field of view				
Depth of field				
Working distance				
Handling/dexterity				
Cosmetic appearance				
Making letters into words and/or words into sentences				
Reading across the page/along lines				
Portability				
Focusing on moving objects				
Faulty (bulb, flicker etc.)				
Others, **Specify:**				

Benefits of attending the clinic:

How satisfactory was the explanation you received on the use of magnifiers from the staff at the low vision clinic?

- Entirely satisfactory ☐1
- Fairly satisfactory ☐2
- Neither satisfactory / unsatisfactory ☐3
- Fairly unsatisfactory ☐4
- Entirely unsatisfactory ☐5

Overall, how helpful were your visits to the low vision clinic?

- Extremely helpful ☐1
- Quite a bit helpful ☐2
- Moderately helpful ☐3
- Slightly helpful ☐4
- Not at all helpful ☐5

What were you most satisfied or pleased with?

_____

_____

_____

What were you disappointed with?

_____

_____

Knowledge and views on eye conditions and low vision:

This is not a 'test' and you should not be concerned if you are unsure of the answers, but please give the best answer you can.

Which of the following is the medical name for the <u>main cause</u> of your low vision?
(Do not offer 'uncertain' option.)

- Cataract ☐1
- Macular degeneration ☐2
- Glaucoma ☐3
- Diabetic retinopathy ☐4
- Uncertain ☐5

Which part of the eye does your eye condition effect?
(Do not offer 'uncertain' option.)

- The cornea at the front of the eye ☐1
- The lens inside the eye ☐2
- The nerve at the back of the eye ☐3
- Central part of the retina at back of eye ☐4
- Uncertain ☐5

How much do you agree or disagree with the following statement?
(1=agree strongly, 2=agree slightly, 3=neither agree nor disagree, 4=disagree slightly, 5=disagree strongly)

"Using your eyes too much will make your remaining vision worse."	
"Sitting too close to the TV causes your eyesight to worsen."	
"When you are reading, more light will improve your ability to see."	

Other comments:

Do you wish to make any comments yourself about the service you received from the hospital?

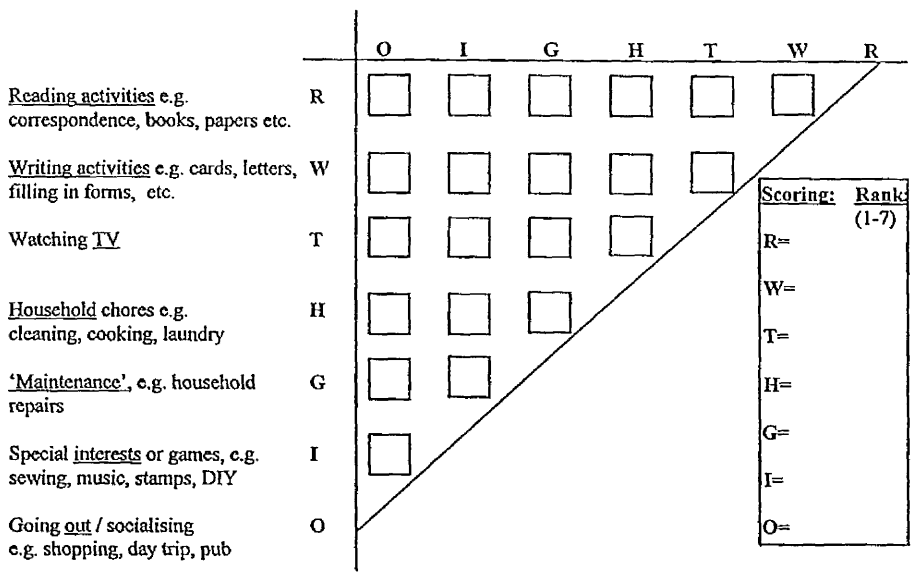
Yes ☐[1] No ☐[2]

PRIORITY RANKING MATRIX FOR TASKS AND DAILY ACTIVITIES

Ask the respondent to rate the importance of each 'task group' over other categories of tasks. For example, by working down the groups ask whether being able to read is considered to be more important than 'going out'; then is being able to read more important than being able to do favourite hobbies; then is being able to read more important than being able to do gardening or DIY; then is being able to read more important than being able to do household chores; and so on. Repeat the process by asking whether being able to write is more important than being able to go out etc.

Scoring: If the respondent considers that being able to read is more important to them than being able to watch TV then enter 'R' in the R/T box.

Finally add up how many times each letter occurs in the matrix in order to work out a priority ranking of the importance of being able to carry out various types of tasks.



Additional comments:

ARMD Study: Manchester Low Vision Questionnaire - Follow-Up

Patient identification:

Surname _____ Hospital No. _____

First name(s) _____ Study No. ☐☐☐

Visit No. 2 Date ☐☐☐☐☐☐

Aids identification:

Main 4 types used:	Where obtained:	Form code:
_____	☐	1
_____	☐	2
_____	☐	3
_____	☐	4

Other types:	Where obtained:	Ever used? Y	N
_____	☐	☐1	☐2
_____	☐	☐1	☐2
_____	☐	☐1	☐2
_____	☐	☐1	☐2

'Where obtained' codes:

1 = **MREH**
2 = **Social services**
3 = **UMIST**
4 = **Other hospital**
5 = **Special centre, e.g. Henshaws**
6 = **Opticians**
7 = **Family / friends / local shop**
8 = **Other (specify)**
9 = **Unsure**

Tasks and use of low vision aid(s) *NB Complete columns I, II & III only if no LVA's*					
Task	I) Do you need or want to do this? 1 A lot 2 A bit 3 No	II) Can you do this with or without an LVA? Yes/No/DK	III) Usually who does? 1 You do 2 You, but with help 3 Partner / someone else 4 No one	IV) Have you tried this using an LVA in the last 4 weeks? Yes/No	V) Have you needed an LVA to do this more often than not during the last 4 weeks? Yes/No
Reading letters/cards/other correspondence					
Reading instructions (packets, tins, bottles, medicines etc.)					
Reading 'ordinary' print books/newsprint/magazines					
Reading telephone directory to check numbers					
Reading markings on dials (cooker, radio/Hi-Fi, washer etc.)					
Reading shop prices/labels					
'Read' the time on your watch					
Identifying money					
Reading large print books/newspapers					
Writing own letters, cards etc.					
Signing your own name					
Reading own writing					
Filling in cheques, forms etc.					
Watching TV					
Special hobby (e.g. stamps, models, painting, music)					
DIY/repair/fixing task					
Sewing/knitting/needlework/ mending					
Reading street signs/bus numbers/ directions etc.					
Watching an event/trip/theatre					
Games (e.g. cards, board games, bingo)					
Other					

For each question and for each LVA tick appropriate response.				
How OFTEN have you used your magnifier in the last 4 weeks?	**LVA 1**	**LVA 2**	**LVA 3**	**LVA 4**
Many times (≥ 5) each day				
Several times (1-4) each day				
Weekly (< 1 daily but at least ≥ 1 per week)				
Occasionally (< 1 per week)				
Never (not used at all in last 4 weeks)				
What is the AVERAGE LENGTH OF TIME you have used your magnifier in the last 4 weeks?	**LVA 1**	**LVA 2**	**LVA 3**	**LVA 4**
Specify duration (minutes) if possible else choose a category:				
≥ 30 minutes				
≥ 15 minutes and < 30 minutes				
≥ 5 minutes and < 15 minutes				
≥ 1 minute and < 5 minutes				
< 1 minute				
And what is the LONGEST TIME you have used your magnifier (on any one occasion) in the last 4 weeks?	**LVA 1**	**LVA 2**	**LVA 3**	**LVA 4**
Specify duration (minutes) if possible else choose a category:				
≥ 30 minutes				
≥ 15 minutes and < 30 minutes				
≥ 5 minutes and < 15 minutes				
≥ 1 minute and < 5 minutes				
< 1 minute				
Which of the following statements is most appropriate for you about HOW EASY OR DIFFICULT your magnifier is to use?	**LVA 1**	**LVA 2**	**LVA 3**	**LVA 4**
I have had no difficulty at all				
I have had a little bit of difficulty				
I have had some difficulty				
I have had much difficulty				
I cannot use the magnifier				
Why did you have DIFFICULTY using the magnifier? ***(Ask as an open question and tick all responses given)***	**LVA 1**	**LVA 2**	**LVA 3**	**LVA 4**
Small field of view				
Depth of field				
Working distance				
Handling/dexterity				
Cosmetic appearance				
Making letters into words and/or words into sentences				
Reading across the page/along lines				
Portability				
Focusing on moving objects				
Faulty (bulb, flicker etc.)				
Others, **Specify:**				

Benefits of attending the clinic:

How satisfactory was the explanation you received on the use of magnifiers from the staff at the low vision clinic?

- Entirely satisfactory ☐1
- Fairly satisfactory ☐2
- Neither satisfactory / unsatisfactory ☐3
- Fairly unsatisfactory ☐4
- Entirely unsatisfactory ☐5

Overall, how helpful were your visits to the low vision clinic?

- Extremely helpful ☐1
- Quite a bit helpful ☐2
- Moderately helpful ☐3
- Slightly helpful ☐4
- Not at all helpful ☐5

What were you most satisfied or pleased with?

_____

_____

_____

What were you disappointed with?

_____

_____

Knowledge and views on eye conditions and low vision:

This is not a 'test' and you should not be concerned if you are unsure of the answers, but please give the best answer you can.

Which of the following is the medical name for the <u>main cause</u> of your low vision?
(Do not offer 'uncertain' option.)

- Cataract ☐1
- Macular degeneration ☐2
- Glaucoma ☐3
- Diabetic retinopathy ☐4
- Uncertain ☐5

Which part of the eye does your eye condition effect?
(Do not offer 'uncertain' option.)

- The cornea at the front of the eye ☐1
- The lens inside the eye ☐2
- The nerve at the back of the eye ☐3
- Central part of the retina at back of eye ☐4
- Uncertain ☐5

How much do you agree or disagree with the following statement?
(1=agree strongly, 2=agree slightly, 3=neither agree nor disagree, 4=disagree slightly, 5=disagree strongly)

"Using your eyes too much will make your remaining vision worse."	
"Sitting too close to the TV causes your eyesight to worsen."	
"When you are reading, more light will improve your ability to see."	

Other comments: **Do you wish to make any comments yourself about the service you received from the hospital?**

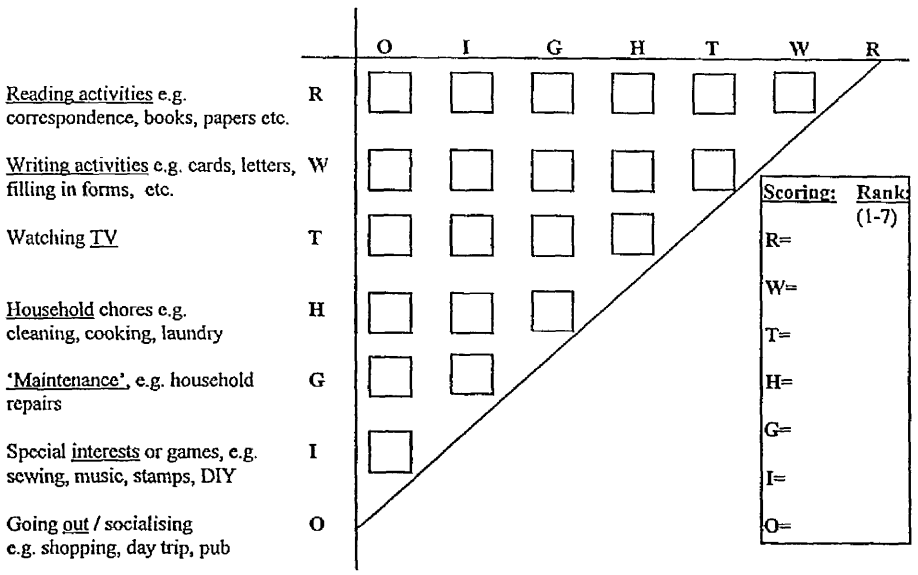
Yes ☐[1] No ☐[2]

PRIORITY RANKING MATRIX FOR TASKS AND DAILY ACTIVITIES

Ask the respondent to rate the importance of each 'task group' over other categories of tasks. For example, by working down the groups ask whether being able to read is considered to be more important than 'going out'; then is being able to read more important than being able to do favourite hobbies; then is being able to read more important than being able to do gardening or DIY; then is being able to read more important than being able to do household chores; and so on. Repeat the process by asking whether being able to write is more important than being able to go out etc.

Scoring: If the respondent considers that being able to read is more important to them than being able to watch TV then enter 'R' in the R/T box.

Finally add up how many times each letter occurs in the matrix in order to work out a priority ranking of the importance of being able to carry out various types of tasks.



Additional comments:

ARMD Study: Short MLVQ

Patient identification:

Surname _____ Hospital No. _____

First name(s) _____ Study No. | | | |

Phone date | | | | | | |

How many magnifiers have you used at all during the last 4 weeks? _____

What tasks have you attempted with a (i.e. any) magnifier during the last 4 weeks?

1. _____ 2. _____

3. _____ 4. _____

5. _____ 6. _____

For each question tick response given:

How OFTEN have you used your magnifier(s) in the last 4 weeks?

Many times (≥ 5) each day	
Several times (1-4) each day	
Weekly (< 1 daily but at least ≥ 1 per week)	
Occasionally (< 1 per week)	
Never (not used at all in last 4 weeks)	

What do you most frequently use a magnifier to do?

And what is the LONGEST TIME you have used a magnifier (at any one time) in the last 4 weeks?

Specify duration (minutes) if possible else choose a category:	
≥ 30 minutes	
≥ 15 minutes and < 30 minutes	
≥ 5 minutes and < 15 minutes	
≥ 1 minute and < 5 minutes	
< 1 minute	

What did you use your magnifier to do on this occasion?

Any other comments given about magnifiers:

Benefits of attending the clinic:

How satisfactory was the explanation you received on the use of magnifiers from the staff at the low vision clinic?

- Entirely satisfactory ☐1
- Fairly satisfactory ☐2
- Neither satisfactory / unsatisfactory ☐3
- Fairly unsatisfactory ☐4
- Entirely unsatisfactory ☐5

Overall, how helpful were your visits to the low vision clinic?

- Extremely helpful ☐1
- Quite a bit helpful ☐2
- Moderately helpful ☐3
- Slightly helpful ☐4
- Not at all helpful ☐5

What were you most satisfied or pleased with?

_____

_____

What were you disappointed with?

_____

_____

Any other comments:

APPENDIX 12:
Rehabilitation Officer input data capture sheet

ARMD STUDY: REHABILITATION OFFICER SHEET

Patient Study No. Hospital No.	Surname	First Name	
Address			
Visit No. Visit date	Visitor's Name	Visitor's signature	
Time arrived at patient's home	Time left patient's home	Duration of visit	
VISION DIFFICULTIES	(Please tick (✓) if yes in appropriate columns / boxes and give comments if applicable in space provided)		
What do you use your magnifier for?	(i) (iv)	(ii) (v)	(iii) (vi)
What has/have your magnifier(s) helped with? ☐ Other, *specify:*	☐ Reading ordinary print ☐ Reading shop prices, labels ☐ Writing letters, cards ☐ Hobbies, interests	☐ Reading large print ☐ Reading time on watch ☐ Signing your name ☐ Bus numbers, signs etc.	☐ Reading correspondence ☐ Identifying money ☐ Watching TV ☐ Other distance tasks
What would you like to use it for?	(i)	(ii)	(iii)

USE OF LVA	Discussed	Problems raised?	Advice given?	Action taken?	Describe briefly problem(s) mentioned, advice given and/or action taken (e.g. repairs, demonstration etc)
How often do you use it?					
Any difficulties using the LVA?					
Other problems / anything else to discuss *Specify:*					
PATIENT IS ASKED TO USE LVA					
Seating / position in room					
Posture					
Lighting					
Handling of the LVA					
Working distance					
Batteries (if applicable)					
ALSO: Suitability of other magnifiers					
Access to other equipment					
Other techniques & training					

OTHER INPUT	(Please tick (✓) for each type of additional input if given and give additional comments if applicable in space provided)	
Information pack about ARMD, range of services including Henshaws etc.		
Referral to Social Services & invitation to information day at Henshaw's		
Information of equipment entitlements through Social Services		
Other e.g. assistance in home safety		

W.Russell, Manchester Royal Eye Hospital, Form 9 (4 Oct 97) p.1

Please give overleaf any other comments about the visit not covered above (e.g. other topics discussed, advice sought or given, or any actions taken).

New devices loaned:

Make	Code No.	Power (D)	Mag. rating	Class e.g. HM (I)

Devices returned:

Make	Code No.	Power (D)	Mag. rating	Class e.g. HM (I)

ADDITIONAL COMMENTS FOR OPTOMETRIST:

ANY OTHER COMMENTS:

APPENDIX 13:

Age Concern Visitor input data capture sheet

ARMD Study: Age Concern Visitor Sheet

Patient Study No.	Hospital No.	Surname	First Name
Address			
Visit No.	Visit date	Visitor's Name	Visitor's signature
Time arrived at patient's home		Time left patient's home	Duration of visit

"HOW ARE YOU COPING WITH YOUR DAILY ACTIVITIES?" (Please tick (✓) if 'yes' in appropriate columns)

Activity	Discussed	Patient clearly raises problems	Advice given?	Any action? (e.g. repairs, demo, etc.)	Describe briefly problem(s) mentioned, advice given and/or action taken
Cleaning					
Cooking					
Shopping					
Personal care					
Other (please state): (i)					
(ii)					
(iii)					

"AND HOW ABOUT YOUR LEISURE ACTIVITIES?" (Please tick (✓) if 'yes' in appropriate columns)

State activities: (i)					
(ii)					
(iii)					

"DO YOU HAVE ANY OTHER PROBLEMS OR DO YOU HAVE ANYTHING ELSE YOU'D LIKE TO DISCUSS?" (Please tick (✓) if 'yes' in appropriate columns)

Low vision					
Reading/writing problems					
General health					
Family issues					
Friends					
Housing/environmental					
Money matters					
Support/advice issues					•
Other - please state: (i)					
(ii)					

Please give overleaf any other comments about the visit not covered above (e.g. other topics discussed, advice sought or given, or any actions taken).

W Russell, Manchester Royal Eye Hospital, Form 10 (25 Sep 97) p.1

ADDITIONAL COMMENTS:

Manchester Royal Eye Hospital

Low Vision Rehabilitation Study

Patient's Diary

Patient's Name:

Instructions for completion are given on the next page. Please read these very carefully before you start to write in this diary.

Study No ☐☐☐

W.Russell, Department of Ophthalmology, Manchester Royal Eye Hospital / Form 11 (20 Jan 98)

Instructions for completing your Diary.

- Please complete the diary as often as you can. Try to complete the diary at least weekly to make sure you don't forget to write down the things which may have happened. If you prefer, fill in the diary every day.

- The diary consists of two sections:

Section 1 asks you to state who you have seen on a daily basis, for example a relative or friend, or perhaps your doctor or a community nurse. Read through the list of different people named, and below each day of the week, write the number of times you have seen the named person in the box provided. If you haven't seen a person in the list on a particular day, please write **'0'** - do not leave the space in the box empty.

Section 2 asks you to write down your comments in response to a few questions. These questions are about the previous week, so you may like to complete this section on a weekly basis. Please feel free to write down anything you would like to say in answer to these questions.

- If you have any problems completing the diary, please telephone Mrs Wanda Russell, the Low Vision Research Officer, on xxxx-xxxxxx (direct

Continued overleaf...

line) or xxxx-xxx-xxxx to leave a message for your call to be returned.

- You have been given a booklet containing 15 weekly diary sheets. This booklet should last 3 months. A week or two before the diary is complete (in about 10 weeks time) you will receive a new booklet through the post which you will need to complete for the **following** 3 months. You will also receive a large pre-paid, addressed envelope in which you are asked to return this diary, once completed, to the Research Officer at Manchester Royal Eye Hospital.

Important:

Please send this diary back as soon as you have completed it.

- In total, you will be asked to complete 4 diary booklets, which amounts to completing the diary for one year.

- All the information which you give in the Patient's Diary will be kept confidential together with any other information you provide at any time of the study in which you are taking part.

- Thank you for your help in completing the Patient's Diary which will make an important contribution to the research study.

W.Russell, Department of Ophthalmology, Manchester Royal Eye Hospital / Form 11 (20 Jan 98)

SECTION 1

Study No. ☐☐☐

Please fill in the date: **Week ending Sunday,** ☐☐☐☐☐☐

Please tick below if you have been to see or been visited at home by the following people. Complete for each day, starting with Monday, during the last week. Write down the total number of times you have seen a particular person. Write 0 if none.							
DAY:	MON	TUE	WED	THU	FRI	SAT	SUN
Your doctor							
A community nurse or health visitor							
Other health worker (state who):							
A home help							
A volunteer							
Family or friends							
Someone else (state who):							

Continued overleaf ...

SECTION 2

Please make any other comments below about your vision and how it has affected you throughout the last week.
Please make any other comments below about how your health in general has been throughout the last week.
Please describe briefly any events which have occurred during the last week which may have affected your health or how you have been feeling (for example a piece of happy or sad news).
Please give any other comments.

Manchester Royal Eye Hospital
Oxford Road
Manchester
M13 9WH
Tel. xxxx-xxx-xxxx (to leave a message)
xxxx-xxxxxx (direct line)

Dear

Thank you for completing your **Patient's Diary** which I left with you when I visited you about three months ago. Please could you return the diary to me in the stamped, addressed envelope enclosed. If you have not completed the diary on a regular basis please return the whole diary including any blank sections or pages. Any information you have filled in will be very useful for the purposes of the research study about the effectiveness of low vision rehabilitation care in which you are taking part.

I have also enclosed a new diary for the next three months and I would be very grateful if you could continue to complete this diary as before. I shall be contacting you soon to answer any questions you may have about the diary.

Yours sincerely

Mrs W.B. Russell
Research Officer (Low Vision)

Manchester Royal Eye Hospital
Oxford Road
Manchester
M13 9WH
Tel. xxxx-xxx-xxxx (to leave a message)
xxxx-xxxxxx (direct line)

Dear

Thank you for completing your **Patient's Diary.** Please could you return the diary to me in the stamped, addressed envelope enclosed. If you have not completed the diary on a regular basis please return the whole diary including any blank sections or pages. Any information you have filled in will be very useful for the purposes of the research study about the effectiveness of low vision rehabilitation care in which you are taking part.

I have also enclosed a new diary for the next three months and I would be very grateful if you could continue to complete this diary as before. I shall be contacting you soon to answer any questions you may have about the diary.

Yours sincerely

Mrs W.B. Russell
Research Officer (Low Vision)

Manchester Royal Eye Hospital
Oxford Road
Manchester
M13 9WH
Tel. xxxx-xxx-xxxx (to leave a message)
xxxx-xxxxxx (direct line)

Dear

Thank you for completing your **Patient's Diary.** Please could you return the diary to me in the stamped, addressed envelope enclosed. If you have not completed the diary on a regular basis please return the whole diary including any blank sections or pages. Any information you have filled in will be very useful for the purposes of the research study about the effectiveness of low vision rehabilitation care in which you are taking part.

I have also enclosed a new diary for the next three months and I would be very grateful if you could continue to complete this diary as before. This is the last diary you will be asked to complete. I shall be contacting you soon to answer any questions you may have about the diary.

Yours sincerely

Mrs W.B. Russell
Research Officer (Low Vision)

Manchester Royal Eye Hospital
Oxford Road
Manchester
M13 9WH
Tel. xxxx-xxx-xxxx (to leave a message)
xxxx-xxxxxx (direct line)

Dear

Thank you for your help with the **Patient's Diary**. Please could you return the diary to me in the stamped, addressed envelope enclosed. Please return the whole diary including any blank sections or pages. Any information which you have filled in will be very useful for the purposes of the research study about the effectiveness of low vision rehabilitation care in which you are taking part.

I shall be contacting you again to arrange a convenient time for a final visit to your home. I shall telephone you a few weeks before this visit is due, which will be in:

If you have any queries please telephone me on the number given above.

Yours sincerely

Mrs W.B. Russell
Research Officer (Low Vision)

Manchester Royal Eye Hospital
Oxford Road
Manchester
M13 9WH
Tel. xxxx-xxx-xxxx (to leave a message)
xxxx-xxxxxx (direct line)

Dear

Thank you for taking part in the research study about the effectiveness of low vision rehabilitation care. Your contribution to the research by taking part in interviews and completing a Patient's Diary has been important and very helpful.

As it will soon be a year since the initial assessment of your vision at the Low Vision Clinic an appointment has been booked for you for a final assessment to be done. Your appointment details are enclosed with this letter. It is very important for you to keep this appointment as this will allow us to see how things have changed for you since you first attended the clinic. If the date you have been given is not convenient, please contact the clinic without delay to change your appointment to a suitable time.

I will also be contacting you soon by phone to arrange a convenient time to visit you for a final interview and to check your vision at home.

Yours sincerely

Mrs W.B. Russell
Research Officer (Low Vision)

APPENDIX 16:

The CONSORT statement checklist of items to include when reporting a randomised trial

PAPER SECTION And topic	Item	Description	Reported on section # / Chapter #
TITLE & ABSTRACT	1	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned").	5.3
INTRODUCTION Background	2	Scientific background and explanation of rationale.	1.2
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	5.2; 5.2.1
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	5.4.3; 5.4.4; 5.4.5
Objectives	5	Specific objectives and hypotheses.	4.3; 5.5.6
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).	5.4.1; 5.4.2
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	5.2.4
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (*e.g.*, blocking, stratification).	5.3
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	5.3
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	5.2.2; 5.3
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.	5.3
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	5.5
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	5.1; 6.1; 6.3; 6.5.1; 6.6.1
Recruitment	14	Dates defining the periods of recruitment and follow-up.	6.2

Baseline data	15	Baseline demographic and clinical characteristics of each group.	7.1; 7.2
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat" . State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).	5.1
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval).	Chapter 7; Chapter 8
Ancilliary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	Chapter 8
Adverse events	19	All important adverse events or side effects in each intervention group.	N/A
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	9.3
Generalizability	21	Generalizability (external validity) of the trial findings.	9.4
Overall evidence	22	General interpretation of the results in the context of current evidence.	9.3; 9.5

APPENDIX 17:

Leisure activities which patients stated that they either could do, or would like to be able to enjoy, at baseline

Table A17: Leisure activities at baseline

Leisure activity	**Examples of specific activities included in or in addition to the leisure activity stated**	**Frequency** (no. times 'could do')†	
'Reading activities'	*Newspapers, books (incl. large print)*	**194**	(51)
Television	*Watching sport, quiz shows*	**157**	(143)
Needlework	*Crochet, sewing, embroidery, knitting, rug-making, tapestry*	**155**	(7)
Gardening	*Allotment, houseplants*	**107**	(57)
'Listening activities'	*Radio (incl. news), listening to music, learning languages, talking books, talking newspapers*	**89**	(87)
'Walking activities'	*Hiking, rambling, walking the dog*	**83**	(38)
Board and card games	*Chess, dominoes, jigsaws, whist, bridge*	**51**	(21)
Sports	*Badminton, climbing, golf, cycling, darts, football, riding, swimming, table tennis, tennis*	**48**	(10)
Dancing	*'Keep fit'*	**47**	(13)
DIY / repairs / mechanics	*Woodwork, household repairs, cycle/car repairs, decorating, marquetry*	**44**	(8)
'Social activities'	*Social clubs, going to pub, family get-togethers, voluntary visiting/work*	**44**	(28)
Cookery	*Baking, jam-making*	**44**	(22)
Crosswords and puzzles	*i.e. activities which involve both reading and writing*	**42**	(18)
Bingo	*(including 1 frequency of bingo calling)*	**41**	(13)
Day trips	*Trips to the countryside, places of interest generally, visiting markets*	**36**	(23)
Travelling and holidays	*Caravan holidays, traveling abroad*	**34**	(18)
Theatre and concerts	*Amateur dramatics, cinema, opera, shows*	**32**	(9)
Driving	*(Especially for day trips)*	**24**	(0)
Bowling	*Bowls, ten pin bowling*	**16**	(2)
'Music making'	*Playing musical instruments, singing*	**15**	(10)
'Writing activities'	*Writing letters, writing poetry, calligraphy*	**15**	(7)
Painting and drawing	*Sign writing, china & pottery painting*	**13**	(0)
Pets	*Budgies, cats, dogs, donkey adoption*	**8**	(8)
Flower arranging	*Bonsai*	**5**	(1)
Bird watching	*Feeding garden birds*	**4**	(3)
Fishing	*Local angling*	**4**	(0)
Shopping	*Car boot sales, window browsing*	**3**	(2)
Scouting and Guiding	*Includes organizing activities*	**3**	(1)
Eating out	*Includes locally and on holidays*	**3**	(2)
Computing related	*Typewriting*	**3**	(2)
Stamps and coins		**3**	(0)
Betting	*General sports betting*	**2**	(1)
Boating and sailing		**2**	(1)
Camping		**2**	(1)
Going to football matches		**2**	(0)
Pottery		**1**	(0)

† A total of 1376 leisure activities were stated by 226 patients; a total of 607 of these activities could still be carried out.

APPENDIX 18:
Comparability of drop-out data with data for subjects who completed the trial

Table A18.1: Comparison of key socio-demographic continuous variables at baseline, for drop-outs versus non drop-outs

(a) Age

Socio-demographic characteristic *(continuous variable)*	n	Drop-outs			Non drop-outs		
		mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3
Age	226	81.16 (32)	6.30	75.25 - 85.75	81.04 (194)	6.03	78.00 - 85.00

no significant difference between groups

(b) Other key socio-demographic category variables

Socio-demographic characteristic *(category variables)*	n	Category responses	Drop-outs		Non drop-outs		All
			Frequency	% (in gp.)	Frequency	% (in gp.)	Total frequency (%)
Sex	226	male	15	46.9	61	31.4	76 (33.6)
		female	17	53.1	133	68.6	150 (66.4)
Residential status	226	living alone	18	56.3	98	50.5	116 (51.3)
		with spouse	13	40.6	74	38.1	87 (38.5)
		with family	1	3.1	22	11.3	23 (10.2)
Age when left education	226	14yrs & younger	21	65.6	139	71.6	160 (70.8)
		15yrs & older	11	34.4	55	28.4	66 (29.2)

no significant difference between groups

Table A18.2: Comparison of additional background category variables relating to existing health and social care at baseline, for drop-outs versus non drop-outs

Socio-demographic characteristic *(category variables)*	n	Category responses	Drop-outs		Non drop-outs		All
			Frequency	% (in gp.)	Frequency	% (in gp.)	Total frequency (%)
Any regular health/social care	226	yes	15	46.9	77	39.7	92 (40.7)
		no	17	53.1	117	60.3	134 (59.3)
Home help †	224	yes	10	31.3	28	14.6	38 (17.0)
		no	22	68.8	164	85.4	186 (83.0)
'Meals on wheels' ‡	224	yes	5	15.6	5	2.6	10 (4.5)
		no	27	84.4	187	97.5	214 (95.5)
Mobility assistance	224	yes	1	3.1	17	8.9	18 (8.0)
		no	31	96.9	175	91.1	206 (92.0)
Personal care ±	224	yes	6	18.8	12	6.3	18 (8.0)
		no	26	81.2	180	93.8	206 (92.0)
Use of hearing aid	224	yes	5	15.6	41	21.4	46 (20.5)
		no	27	84.4	151	78.6	178 (79.5)

† significant difference (Pearson chi-square=5.409, p=0.02)

‡ significant difference (Pearson chi-square=10.903, p=0.001; N.B. 25% cells have expected count less than 5)

± significant difference (Pearson chi-square=5.799, p=0.016; N.B. 25% cells have expected count less than 5)

Table A18.3: Comparison of additional socio-demographic category variables relating to social contact, at baseline, for drop-outs versus non drop-outs

Socio-demographic characteristic *(category variables)*	n	Category responses	Drop-outs		Non drop-outs		All
			Frequency	% (in gp.)	Frequency	% (in gp.)	Total frequency (%)
No. of leisure activities still enjoyed	226	3 or less	27	84.4	140	72.2	167 (73.9)
		4 or more	5	15.6	54	27.8	59 (26.1)
Visits to family	226	at least weekly	9	28.1	43	22.2	52 (23.0)
		at least monthly	5	15.6	37	19.1	42 (18.6)
		hardly ever	15	46.9	88	45.4	103 (45.6)
		never	3	9.4	26	13.4	29 (12.8)
Visits by family	226	at least weekly	25	78.1	124	63.9	149 (65.9)
		at least monthly	2	6.3	27	13.9	29 (12.8)
		hardly ever	5	15.6	35	18.0	40 (17.7)
		never	0	0.0	8	4.1	8 (3.5)
Visits to friends	226	at least weekly	9	28.1	84	43.3	93 (41.2)
		at least monthly	6	18.8	31	16.0	37 (16.4)
		hardly ever	8	25.0	46	23.7	54 (23.9)
		never	9	28.1	33	17.0	42 (18.6)
Visits by friends	226	at least weekly	12	37.5	98	50.5	110 (48.7)
		at least monthly	7	21.9	24	12.4	31 (13.7)
		hardly ever	7	21.9	45	23.2	52 (23.0)
		never	6	18.8	27	13.9	33 (14.6)
Extent of social contact (combining family & friends)	226	regular - family and friend	13	40.6	81	41.8	94 (41.6)
		regular – family or friend	14	43.8	87	44.8	101 (44.7)
		no regular contact	5	15.6	26	13.4	31 (13.7)
Regular use of public transport †	226	yes	10	31.3	99	51.0	109 (48.2)
		no	22	68.8	95	49.0	117 (51.8)
Does own shopping regularly	226	yes	19	59.4	126	64.9	145 (64.2)
		no	13	40.6	68	35.1	81 (35.8)
Attended place of worship recently	226	yes	7	21.9	42	21.6	49 (21.7)
		no	25	78.1	152	78.4	177 (78.3)

† significant difference (Pearson chi-square=4.305, p=0.038)

Table A18.4: Comparison of visual function and task restriction variables at baseline, for drop-outs versus non drop-outs

Visual functions	n	Drop-outs			Non drop-outs		
		mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3
Best eye distance (with correction) (logMAR)	216	0.82 (25)	0.39	0.45 - 1.10	0.78 (191)	0.36	0.46 - 1.00
Best eye near (with correction) (M units +4.00 Add.)	209	2.35 (24)	1.67	0.80 - 4.00	2.74 (185)	2.16	1.00 - 4.00
Best eye contrast sensitivity (logCS)	175	0.89 (18)	0.37	0.45 - 1.20	0.82 (157)	0.33	0.53 - 1.05
Task restriction							
Average task restriction score	205	0.52 (30)	0.25	0.33 - 0.73	0.49 (175)	0.24	0.29 - 0.69
Average reading restriction score	146	0.56 (19)	0.36	0.33 - 1.00	0.63 (127)	0.32	0.40 - 1.00

no significant difference between groups

Table A18.5: Comparison of SF-36 dimension scores at baseline, for drop-outs versus non drop-outs

SF-36 dimensions	n	Drop-outs			Non drop-outs		
		mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3
Physical functioning †	226	40.78 (32)	29.30	15.0 - 55.0	52.32 (194)	28.32	28.75 - 80.0
Role limitation: physical problems ‡	226	47.66 (32)	47.25	0.0 - 100.0	68.43 (194)	42.80	25.0 - 100.0
Bodily pain	226	51.38 (32)	30.26	24.0 - 73.50	55.86 (194)	29.35	32.0 - 84.0
General health perception ±	226	53.81 (32)	27.44	30.0 - 79.25	63.61 (194)	23.70	45.0 - 82.0
Energy / vitality	226	44.06 (32)	23.26	25.0 - 65.0	49.10 (194)	22.28	30.0 - 70.0
Social functioning	226	75.39 (32)	25.89	53.13 - 100.0	78.09 (194)	27.47	59.38 - 100.0
Role limitation: emotional problems	221	88.54 (32)	28.85	100.0 - 100.0	81.13 (189)	34.07	66.67 - 100.0
Mental health	224	64.65 (31)	21.14	52.0 - 84.0	69.15 (193)	19.58	58.0 - 84.0
Change in health	226	36.72 (32)	30.44	0.0 - 50.0	37.24 (194)	22.94	25.0 - 50.0
Physical component summary score *	219	43.24 (31)	5.37	38.29 - 46.78	45.18 (188)	4.91	41.41 - 49.02
Mental component summary score	219	46.79 (31)	4.38	44.28 - 49.79	47.77 (188)	4.13	45.02 - 51.01

† t-test (2-tailed, unpaired) p=0.035

‡ t-test (2-tailed, unpaired) p=0.013

± t-test (2-tailed, unpaired) p=0.035

* t-test (2-tailed, unpaired) p=0.045

Table A18.6: Comparison of the overall VCM1 score and VCM1 domains at baseline, for drop-outs versus non drop-outs

VCM1 score and domains	n	Drop-outs			Non drop-outs		
		mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3
VCM1 score	224	2.18 (31)	0.84	1.80 - 2.80	2.10 (193)	0.80	1.55 - 2.70
Embarrassment	225	1.66 (32)	1.23	0.0 - 3.0	1.73 (193)	1.24	0.50 - 3.0
Frustration / annoyance	226	3.00 (32)	1.24	2.0 - 4.0	2.82 (194)	1.26	2.0 - 4.0
Loneliness / isolation	226	1.38 (32)	1.43	0.0 - 3.0	1.10 (194)	1.28	0.0 - 2.0
Sadness / 'feeling low' †	226	2.53 (32)	1.22	2.0 - 3.75	2.04 (194)	1.28	1.0 - 3.0
Worry about eyesight getting worse	226	2.69 (32)	1.28	1.0 - 4.0	2.24 (194)	1.45	1.0 - 3.0
Concern about safety at home	226	0.53 (32)	0.95	0.0 - 1.0	0.65 (194)	1.06	0.0 - 1.0
Concern about safety when out of the home ‡	226	1.56 (32)	1.37	0.0 - 2.75	2.07 (194)	1.30	1.0 - 3.0
Concern about coping with everyday life	225	2.16 (31)	1.16	2.0 - 3.0	2.24 (194)	1.14	2.0 - 3.0
Eyesight 'stopping you doing the things you want to do'	226	3.06 (32)	0.95	3.0 - 4.0	3.14 (194)	0.88	3.0 - 4.0
Eyesight interfering with life in general	226	3.03 (32)	1.15	3.0 - 4.0	2.98 (194)	1.14	2.0 - 4.0

† t-test (2-tailed, unpaired) p=0.044

‡ t-test (2-tailed, unpaired) p=0.043

Table A18.7: Comparison of NAS dimension scores at baseline, for drop-outs versus non drop-outs

NAS dimensions	n	Drop-outs			Non drop-outs		
		mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3
Locus of control † *(possible score: 4-20)*	226	16.00 (32)	3.29	13.25 - 18.75	17.07 (194)	2.91	16.0 - 19.0
Acceptance *(possible score: 9-45)*	225	31.88 (32)	9.47	22.5 - 40.5	34.19 (193)	8.48	29.5 - 41.0
Attitude *(possible score: 7-35)*	226	19.09 (32)	5.60	15.0 - 21.75	19.99 (194)	4.97	17.0 - 24.0
Self efficacy *(possible score: 8-40)*	226	26.75 (32)	7.50	22.25 - 31.75	28.69 (194)	6.18	24.0 - 34.0

† borderline significance: t-test (2-tailed, unpaired) p=0.059

Table A18.8: Comparison of initial low vision assessment durations (minutes) at baseline, for drop-outs versus non drop-outs

Low vision assessment	n	Drop-outs			Non drop-outs		
		mean (n)	SD	Q1 – Q3	mean (n)	SD	Q1 – Q3
Initial assessment duration	174	59.55 (22)	22.46	45.0 - 63.75	62.27 (152)	14.61	50.0 - 70.0

no significant difference between groups

Table A18.9: Comparison of expectations of the initial low vision assessment cited by subjects at baseline, for drop-outs versus non drop-outs

Expectation cited	n	Category responses	Drop-outs		Non drop-outs		All	
			Frequency	% (in gp.)	Frequency	% (in gp.)	Total frequency	(%)
'Ability to carry out tasks'	226	yes	12	37.5	94	48.5	106	(46.9)
		no	20	62.5	100	51.5	120	(53.1)
To obtain a magnifying aid(s) *(specific reference to LVAs)*	226	yes	6	18.8	72	37.1	78	(34.5)
		no	26	81.3	122	62.9	148	(65.5)
To obtain glasses	226	yes	4	12.5	49	25.3	53	(23.5)
		no	28	87.5	145	74.7	173	(76.5)
'An improvement in vision' †	226	yes	12	37.5	39	20.1	51	(22.6)
		no	20	62.5	155	79.9	175	(77.4)
Information ‡	226	yes	8	25.0	23	11.9	31	(13.7)
		no	24	75.0	171	88.1	195	(86.3)
Reassurance / comfort	226	yes	3	9.4	22	11.3	25	(11.1)
		no	29	90.6	172	88.7	201	(88.9)
'To be able to see' ±	226	yes	7	21.9	14	6.7	21	(9.3)
		no	25	78.1	180	93.3	205	(90.7)

† significant difference (Pearson chi-square=4.758, p=0.029)

‡ significant difference (Pearson chi-square=4.010, p=0.045; N.B. 25% cells have expected count less than 5)

± significant difference (Pearson chi-square=7.003, p=0.008; N.B. 25% cells have expected count less than 5)

Table A18.10: Comparison of subject motivation at baseline, for drop-outs versus non drop-outs

Measure of motivation	n	Category responses	Drop-outs		Non drop-outs		All	
			Frequency	% (in gp.)	Frequency	% (in gp.)	Total frequency	(%)
Optometrist rating of patient motivation at initial low vision assessment	178	High	6	33.3	84	52.5	90	(50.6)
		Moderate	11	61.1	65	40.6	76	(42.7)
		Low	1	5.6	11	6.9	12	(6.7)

no significant differences between groups

APPENDIX 19:
Supporting publications

Russell, W.B., Harper, R.A, Reeves, B.C, Waterman, H.A, McLeod, D., Henson, D.B. (1997) Randomised controlled trial of an integrated versus an optometric low vision rehabilitation service for patients with age-related macular degeneration. *Optom. Vis. Sci.*, **74 (12s)**, 126.

Russell, W.B., Harper, R.A, Reeves, B.C, Waterman, H.A, McLeod, D., Henson, D.B. (1998) Quality of life in age-related macular degeneration. *Optom. Vis. Sci.*, **75 (12s)**, 27.

Harper, R.A., Russell, W.B., Reeves, B.C., Waterman, H., McLeod, D., Henson, D. (1999) Visual function and quality of life in age-related macular degeneration. In: *Proceedings of Vision '99*, The International Low Vision Conference: 189-190.

Russell, W., Harper, R., Reeves, B., Waterman, H., Henson, D., McLeod, D. (2000) Randomised controlled trial of an integrated versus an optometric low vision rehabilitation service for patients with age-related macular degeneration: study design and methodology. *Ophthal. Physiol. Opt.*, **21 (1)**, 36-44.

Harper, R., Reeves, B., Russell, W. (2001) Visual impairment, disability and quality of life in AMD: A longitudinal study. *Ophthalmic Research*, **33 (S1)**, 102.

Harper, R., Russell, W., Reeves, B., Waterman, H., Henson, D., McLeod, D. (2001) Measures of visual impairment and dimensions of quality of life in age-related macular degeneration. *Invest. Ophthalmol. Vis. Sci.*, **42** (Suppl), 722.

Harper, R.A., Russell, W., Reeves, B. (2002) Longitudinal evaluation of visual function and low vision device use in people with AMD: a randomized controlled trial. In: 'Activity and Participation', proceedings of the 7th International Conference on Low Vision, Sweden, 2002, p.27.

Presentations at Conferences

- Graduate Student Research Symposium, Medical School, University of Manchester, June 1999. Talk: "Effectiveness of Low Vision Rehabilitation: A Randomised Controlled Trial".
- Association of Optometrists 24th Hospital Optometrists Annual Meeting, University of Bradford, September 1998. Poster: "Quality of life in age-related macular degeneration: Preliminary Findings". *(Awarded Poster Prize).*
- Regional Postgraduate Ophthalmic Teaching Programme, Manchester Royal Eye Hospital, Central Manchester Healthcare Trust, Summer, 1998. Talk: "Outcomes of Low Vision Rehabilitation".

APPENDIX 20:

Testing and scoring procedures for distance visual acuity, near visual acuity and contrast sensitivity

Distance visual acuity

Following refraction, distance visual acuity was measured using a Lighthouse ETDRS logMAR chart that was internally illuminated. An attempt was made to ensure that all subjects had the opportunity of reading at least 10 letters on the chart (i.e. 2 lines) by varying the test distance between 4m and 1m. After making an appropriate adjustment for the test distance, visual acuity was scored using the interpolated method whereby individual letters on the chart are assigned a logMAR value of 0.02.

Near visual acuity

Reading acuity at 25cm (following refraction and use of a +4.00D reading addition) was recorded using externally illuminated MNREAD charts (the luminance of the white background of the chart was ~100cd/m^2). Subjects read the sentences aloud, starting from a supra-threshold text size, with threshold reading acuity being determined in M units as the smallest print size at which the patient could read the entire sentence without making significant errors (i.e. acuity measured to the nearest 0.1 logMAR).

Contrast sensitivity

Low contrast letter sensitivity was measured using the Pelli-Robson chart at 1m, with a +0.75D addition to supplement the optimal distance refraction. The threshold (logCS) was determined as the last triplet on which at least 2 of the 3 letters were correctly recognised, although miscalling the letter 'C' an 'O', or vice-versa' was permitted, since this method has been shown to improve test reliability (Elliott *et al*, 1991).

12 months follow-up measures

The same visual functions were measured as those measured during the initial assessment with the subject using their habitual spectacle correction.

APPENDIX 21:
Partial sight and blind registration data at baseline and follow-up

Table A21.1: Summary of registration data at baseline and at follow-up, collected retrospectively from available hospital patient records post RCT

Type of registration	Baseline (prior to initial clinic assessment)		Follow-up (at the time of the final 12 month clinic assessment)	
	No. of patients	%	No. of patients	%
Blind	29	15.7	55	29.7
Partial sight	57	30.8	70	37.8
Not registered	99	53.5	60	32.4
Total	185	100.0	185	100.0

Table A21.2: Comparison of registration data, by arm, at baseline *

Type of registration	Arm 1		Arm 2		Arm 3		All
	Frequency	% (in arm)	Frequency	% (in arm)	Frequency	% (in arm)	Total frequency (%)
Blind	15	23.1	9	15.5	5	8.1	29 (15.7)
Partial sight	21	32.3	17	29.3	19	30.6	57 (30.8)
Not registered	29	44.6	32	55.2	38	61.3	99 (53.5)
Total	65	100.0	58	100.0	62	100.0	185 (100.0)

* no significant differences between arms at the 0.05 level (p=0.18)

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