Effect of a Home Visit–Based Low Vision Rehabilitation Intervention on Visual Function Outcomes: An Exploratory Randomized Controlled Trial

Jennifer H. Acton, Bablin Molik, Helen Court, and Tom H. Margrain

School of Optometry & Vision Sciences, College of Biomedical and Life Sciences, Cardiff University, Cardiff, United Kingdom

Correspondence: Tom H. Margrain, School of Optometry & Vision Sciences, College of Biomedical and Life Sciences, Cardiff University, Maindy Road, Cardiff CF24 4HQ, UK; margrainth@cardiff.ac.uk.

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Purpose. To examine the effect of a home visit-based visual rehabilitation intervention on: (1) self-reported visual function and (2) depression, wellbeing, loneliness, adjustment to visual loss, and generic health-related quality of life.

Methods. In an exploratory, assessor-masked, individually randomized, single-center controlled trial, 67 participants (age: 75.22 ± 16.21 years) with low vision were allocated either to receive the home visit-based visual rehabilitation intervention (n=35) or to a waiting list control arm (n=32). Outcome measures were collected by telephone interview at baseline and 6 months later. The primary outcome measure was the 48-item Veterans Affairs Low Vision Visual Functioning Questionnaire (VA LV VFQ-48). Secondary outcome measures were: the Patient Health Questionnaire; the Warwick-Edinburgh Mental Well-being Scale, the Adjustment to Age-related Visual Loss Scale, the standardized health-related quality of life questionnaire, and the University of California, Los Angeles Loneliness Scale. Questionnaire scores at follow-up were analyzed using analysis of covariance, controlling for the baseline score and the variables, age, number of comorbidities, visual acuity, and baseline wellbeing score.

RESULTS. Visual function (VA LV VFQ-48) improved at follow-up in both groups, with a significantly greater improvement demonstrated by the intervention group (95% confidence interval, 0.33-0.68 logits, P = 0.031), with a moderate effect size (0.55). Secondary outcomes did not indicate any statistically significant differences between groups.

Conclusions. The study provides preliminary evidence that a home visit-based visual rehabilitation intervention has a positive influence on vision-related functional outcomes. A larger trial with an expanded intervention to include a mental health component and cost-effectiveness analysis is needed. (ISRCTN.com number, 44807874.)

Keywords: low vision, visual rehabilitation, quality of life, depression, wellbeing

Low vision is prevalent in society: it affects 25,600 people per million in North and South America¹ and nearly 2 million individuals in the United Kingdom.² Visual rehabilitation services can improve the functional ability of those with sight loss,³ reduce disability,⁴ and improve quality of life.⁵ However, the optimum method of provision of these services is open to debate.

In the United Kingdom, visual rehabilitation encompasses a range of hospital- and community-based services that are provided by both the health care and social care sectors, which offer distinct and complementary services. Health care-based services are often delivered by optometrists and provide individuals with optical and nonoptical low vision aids, advice on lighting and contrast enhancement. Social care services adopts a home visit-based approach that may include home modifications and daily living coping strategies, provision of nonoptical aids, mobility training, and advice on welfare benefits. These home visit-based social care services are often provided by visual rehabilitation officers. In the United Kingdom, visual rehabilitation officers complete 2 or 3 years of full-time training at a higher education institution before working with people with sight loss. Once qualified, their

duties are to promote independence by helping individuals learn new skills or regain lost skills and to rebuild confidence following sight loss.

There is good evidence that the health care-based interventions in the United Kingdom are effective, ⁶ although not as effective as some of the more holistic services provided in North America⁷; this may be explained by differences in the nature and intensity of the services. In contrast to health care-based interventions, there is a distinct lack of evidence to support the effectiveness of the social care element of visual rehabilitation, ⁸ which undermines this element of the service. For example, the visual rehabilitation service in several parts of the United Kingdom, including Wales, has been reduced recently because there are no longer any minimum statutory rehabilitation requirements. ⁹ Furthermore, there is a shortage of visual rehabilitation officers, with an estimated 550 practicing professionals in the United Kingdom¹⁰ and training is now only offered at one UK institution.

A comprehensive review of evidence demonstrates that the low vision service alone improves clinical measures of visual function and activities of daily living.⁸ While there is some evidence for improved health-related quality of life out-

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comes^{5,11} and vision-related quality of life^{4,6,11,12} in response to visual rehabilitation, there is also a lack of evidence exclusively for the social care aspect of visual rehabilitation.¹³

Other studies have demonstrated improved mood and reduced depression following interventions such as a low vision service¹⁴⁻¹⁶ and a vision self-management program.⁵ Yet, in the United Kingdom, there remains a lack of emotional support for individuals with low vision and their family members and the need for development of standardized referral pathways.¹⁷ Therefore, evidence to support the effectiveness of the social care element of visual rehabilitation is needed urgently.

The primary aim of the present study was to examine the effect of a home visit-based visual rehabilitation intervention, delivered by visual rehabilitation officers, on self-reported visual function. The secondary aims were to determine the effect of the intervention on: depression, wellbeing, loneliness, adjustment to visual loss, and generic health-related quality of life.

METHODS

Study Design

The methods for this trial have been described in detail elsewhere.¹⁸ Briefly, this study was an exploratory, assessormasked, individually randomized, single-center controlled trial. Participants were allocated to the intervention or a waiting list arm of the trial in a 1:1 ratio over an 18-month period.

Intervention

A home visit-based visual rehabilitation intervention provided by two experienced visual rehabilitation officers, each with 7 to 8 years of experience, was evaluated. The visual rehabilitation officers were employed by the charitable organization, Sight Cymru, based in Cardiff, United Kingdom. The intervention consisted of 1 to 11 home visits to assess the needs of the individual with low vision in several areas including: functional vision, lighting, emotional difficulties, personal hygiene, medication management, kitchen safety, household tasks, welfare entitlements, orientation and mobility, and communication. Training and support was then tailored within these areas (e.g., support in the use of low vision aids, pill organizer provision, liquid level indicator provision, and long cane training). The number of visits was determined by the visual rehabilitation officer on a case-by-case basis, depending on the needs of the individual. A description of the specific training and support in each area of need is detailed elsewhere.¹⁸

During the trial, all participants had access to hospital- and community-based low vision optometric assessments, such that the control and intervention groups differed only in the receipt of the visual rehabilitation officer intervention. For each participant allocated to the intervention arm, the number and type of intervention items and the number of visits were recorded.

Outcome Measures

The primary outcome measure was the 48-item Veterans Affairs Low Vision Visual Functioning Questionnaire (VA LV VFQ-48), a functional questionnaire that assesses the difficulty in performing daily activities in visually impaired individuals. ¹⁹ This validated unidimensional outcome measure consists of 48 items that reflect activities important to most patients, related to mobility tasks, visual motor tasks, reading tasks, and visual information processing tasks. A difficulty rating is applied to each item, as determined by four response categories: not

difficult, slightly/moderately difficult, extremely difficult, and impossible. Another possible response is that the activity is not performed for nonvisual reasons. Secondary outcome measures were: the Patient Health Questionnaire (PHQ-9), an assessment of depression symptom severity²⁰; the Warwick-Edinburgh Mental Well-being Scale (WEMWBS), a population measure of subjective wellbeing²¹; the Adjustment to Agerelated Visual Loss Scale (AVL-12), a measure of psychological adjustment to vision loss²²; the standardized health-related quality of life questionnaire (EQ-5D-5L)²³; and the University of California Los Angeles (UCLA) Loneliness Scale, a measure of subjective feelings of loneliness.²⁴

Outcome measures were obtained by telephone interview at baseline and repeated after 6 months and were conducted by a trained interviewer who was masked to the group allocation. At the 6-month follow-up interview, after the collection of all outcome measures, the interviewer was unmasked, in order to assess intervention satisfaction. To assess satisfaction, the Manchester Low Vision Questionnaire²⁵ was used, consisting of a question about how helpful participants perceived the intervention to be, as well as two open questions asking about aspects of the service that the participants were satisfied or dissatisfied with.

Sample Size

Although exploratory in nature, a sample size calculation was conducted to guide the study. On the basis of an effect size determined by the VA LV VFQ-48 scores in a previous study, a sample of 30 participants in each group at follow-up was expected to detect a standardized difference of 0.84 logits between those in the intervention and control groups, with 95% power and an alpha level of 0.05 (two-tailed). To allow for individuals who may withdraw from the study, we aimed to recruit over 70 individuals over a period of 12 months.

Inclusion/Exclusion Criteria

Adults who were eligible for the Sight Cymru visual rehabilitation service were included in the study. The Sight Cymru criteria for service provision includes individuals with sight loss that cannot be corrected by glasses and that causes significant difficulties in carrying out daily tasks, regardless of sight registration status. There were no specific acuity or visual field requirements. Those with significant or urgent need were excluded from the study; for example, those with significant risk of injury at home as assessed by screening were allocated to a fast track service.

Exclusion criteria further consisted of: those living outside of geographic catchment area; previous recipients of a comprehensive visual rehabilitation service, since their most recent significant decrease in vision; cognitive impairment determined using a shortened version of the Mini-Mental State Exam; inability to use a telephone (e.g., caused by very poor hearing); inability to understand English; those who were unable to take part in a 6-month study; those who were unable to provide informed consent; and those with planned cataract extraction over the next 6 months.

Study Procedures

Following informed consent, baseline assessments consisted of a medical history and visual acuity measurement (Early Treatment Diabetic Retinopathy Study), at the Cardiff University School of Optometry and Vision Sciences. The baseline telephone-administered interview then took place within 1 week of the initial visit. Randomization was performed 1 week after the baseline interview, by comput-

er-generated schedule, undertaken by one of the authors (JA), to receive the visual rehabilitation officer intervention or to remain on the Sight Cymru waiting list (control) in the ratio 1:1. Participants were stratified by age (older than or younger than 65 years) and baseline visual acuity (better or worse than 1.0 logMAR).

The study adhered to the tenets of the Declaration of Helsinki. The Research Ethics Audit Committee, at the Cardiff University School of Optometry and Vision Sciences, reviewed and approved the study (#1377).

Analysis

All data were recoded such that all items had a consistent valence. Rasch analysis was applied to the VA LV VFQ-48, WEMWBS, and AVL-12 outcomes. Rasch analysis was undertaken according to the Andrich Rating Scale model²⁶ using Winsteps version 3.75.0. Rasch analysis is a probabilistic logistic model, which produces logit values to describe item difficulty and person ability, and provides a scoring key to convert raw scores to interval level scores and confirm instrument unidimensionality and assess reliability of item measures. Standard scoring was used for the remaining secondary outcome measures (PHQ-9, EQ-5D, and UCLA scale) to ensure the results would be directly comparable with previous studies. Scores of EQ-5D were converted to index values.

Questionnaire scores at follow-up were analyzed using analysis of covariance, controlling for the covariates: baseline score, age, number of comorbidities, visual acuity, and baseline wellbeing score. The association between the number of interventions and the outcomes was evaluated by logistic regression. Within-group changes were assessed by paired samples *t*-test (2-tailed).

RESULTS

A total of 255 consecutive cases were screened for eligibility and of these, 136 (53%) individuals met the initial inclusion criteria for the study; of that number, 71 (52.2%) agreed to participate. A total of 67 participants (31 male, age 75.22 ± 16.21 years) successfully adhered to the intervention (i.e., received all visits), as determined by the visual rehabilitation officer and completed both interviews. The remaining four participants were lost to follow-up, as they were unable to be contacted. There were no missing data or protocol violations. Based on self-reported information, five participants (one from the control group and four from the intervention group) were referred to low vision services by the visual rehabilitation officer. None of the participants received any new optical devices from their optometrists during the trial period. However, two of the participants had the strength of their magnifier increased.

The demographic characteristics of the cohort are described in Table 1. The number of comorbidities of the entire cohort ranged from 0 to 4 (mode = 1). Self-reported causes of vision loss included age-related macular degeneration (n = 39); glaucoma (n = 6); diabetic retinopathy (n = 4); and stroke (n = 8). After randomization, the control and visual rehabilitation groups consisted of 32 and 35 participants, respectively. In the visual rehabilitation group, the modal number of intervention items was four, which were carried out over three visits (mode).

The data from the preintervention questionnaires were used to produce item calibration estimates using Rasch analysis. The precision of these estimates was confirmed for all three of the questionnaires by the high-item separation

TABLE 1. Demographic and Questionnaire Data at Baseline

Variable	Control, $n = 32$	Visual Rehabilitation, $n = 35$
Age, y (SD)	76.3 (16.3)	74.2 (16.2)
Sex, M/F	14/18	17/18
VA logMAR (SD)	0.9 (0.8)	1.0 (0.8)
Number of comorbidities, n (SD)	1.5 (1.2)	1.5 (1.0)
Self-reported causes of vision loss		
AMD, n	20	19
Glaucoma, n	3	3
Diabetic retinopathy, n	2	2
Stroke-related, n	5	3
Other (e.g., tumor, congenital conditions), n	2	8

reliability coefficients indicating the stability of the item estimates (VA LV VFQ-48 = 0.95; AVL-12 = 0.86; WEMWBS = 0.96). These estimates were used to generate a scoring key to recode the raw questionnaire scores into continuous data for the purposes of the study.

Rasch analysis fit statistics were used to identify how well each item contributed to the underlying unidimensional measure.²⁷ The analysis provides two χ^2 fit statistics, infit and outfit, which are calculated from the mean square of the residuals, ranging from zero to infinity. Perfectly fitting items are expected to have an infit or outfit value of 1. Linacre²⁸ indicates that items with infits/outfits of up to 1.5 are still productive for measurement (i.e., these items add to the scale in a meaningful way). Overall, the majority of the items for all three questionnaires exhibited satisfactory infit and outfit values. Items 7 and 12 of the AVL-12 had infit/outfit values of >1.5 (item 7: infit 2.0, outfit 1.9; item 12: infit 1.8, outfit 2.0). However, while these items do not exhibit "perfect" fit to the Rasch model, Linacre²⁸ indicates that although items with infits/outfits of 1.5-2.0 produce off-variable noise, they neither construct nor destruct the measurement. For this reason, it was decided to retain these items, as they still provided helpful information about patient functioning.

Outcome Measures at Follow-Up

Scores for the primary and secondary outcomes at baseline and follow-up are shown in Table 2. Visual function as measured by the VA LV VFQ-48 (overall score) improved at follow-up by 0.53 (SD 0.69) and 0.19 (SD 0.68) logits in the intervention and control groups, respectively. The 95% confidence interval (CI) for the effect of the intervention (0.33 to 0.68) indicates a statistically significant, baseline adjusted, difference between groups at the 5% level (P =0.031, partial $\eta^2 = 0.075$). As expected, baseline VA LV VFQ-48 was a significant positive predictor of follow-up score (coefficient = 0.61, P < 0.001). For the overall VA LV VFQ-48 score, the effect size of the intervention (defined as the standardized mean difference, i.e., the difference in the mean changes divided by the pooled standard deviation of the change) was 0.55. The results suggest within group changes between baseline and follow-up for the VA LV VFQ-48 score for the intervention group only.

The improvement at follow-up was not consistent across the domains of the VA LV VFQ-48 (Table 2). The only domain that showed a significant baseline adjusted difference between groups at the 5% level (P = 0.012, partial $\eta^2 = 0.100$) was the visual motor skills domain (95% CI = 0.11-0.88).

TABLE 2. Scores in Each Group of the Trial at Baseline and 6 Months

		Visual Rehabilitation,	Between-Group Effects,
Outcome Measure	Control, $n = 32$	n=35	P value
VA LV VFQ-48, average overall score (logits)			
Mean baseline score, logits (SD)	-0.19 (0.98)	0.07 (0.92)	
Mean score at 6 months, logits (SD)	-0.37 (0.97)	-0.51 (0.93)*	0.031
VA LV VFQ-48: mobility (logits)			
Mean baseline score, logits (SD)	-0.19 (1.00)	0.09 (0.88)	
Mean score at 6 months, logits (SD)	-0.42 (0.89)	-0.35 (0.73)*	0.477
VA LV VFQ-48: visual motor skills (logits)			
Mean baseline score, logits (SD)	-0.04 (1.21)	0.05 (0.90)	
Mean score at 6 months, logits (SD)	-0.33 (1.08)	-0.67 (0.96)*	0.012
VA LV VFQ-48: reading			
Mean baseline score, logits (SD)	-0.40 (1.24)	-0.11 (1.20)	
Mean score at 6 months, logits (SD)	-0.71 (1.15)	-0.79 (1.56)*	0.227
VA LV VFQ-48: visual information processing			
Mean baseline score, logits (SD)	-0.23 (0.97)	0.13 (1.22)	
Mean score at 6 months, logits (SD)	-0.31 (1.03)	-0.32 (1.17)*	0.122
PHQ-9			
Mean baseline score, logits (SD)	6.13 (5.26)	9.00 (5.79)	
Mean score at 6 months, logits (SD)	6.56 (6.00)	8.03 (6.00)	0.764
WEMWBS			
Mean baseline score, logits (SD)	0.60 (1.08)	0.24 (0.74)	
Mean score at 6 months, logits (SD)	0.37 (0.94)	0.20 (0.73)	0.583
UCLA Loneliness Scale			
Mean baseline score, logits (SD)	10.47 (13.81)	13.14 (13.34)	
Mean score at 6 months, logits (SD)	12.81 (14.71)	14.51 (15.19)	0.127
AVL-12			
Mean baseline score, logits (SD)	0.29 (1.10)	0.30 (1.15)	
Mean score at 6 months, logits (SD)	0.15 (0.50)	0.30 (0.74)	0.081
EQ-5D score			
Mean baseline score, logits (SD)	0.60 (0.30)	0.51 (0.31)	
Mean score at 6 months, logits (SD)	0.58 (0.29)	0.52 (0.34)	0.946

Units for VA LV VFQ-48, WEMWBS, and AVL-12 are in logits. More positive scores on the WEMWBS, AVL-12, and EQ-5D indicate greater wellbeing, greater ability, and greater health utility, respectively. More positive scores on the LV VFQ 48, PHQ-9, and UCLA scale indicate greater disability, more depressive symptoms, and more loneliness, respectively.

The remaining outcomes did not indicate any statistically significant differences between groups based on the 95% CI for the effect of the intervention, at the 5% level. Relative to the intervention group, depressive symptoms (PHQ-9) were slightly increased at follow-up in the control group (95% CI = -2.03 to 2.75). Wellbeing scores (WEMWBS) declined slightly in both arms at follow-up, more so in the control group (95% CI = -0.36 to 0.20). Symptoms of loneliness as measured by the UCLA Loneliness Scale increased slightly in both arms at follow-up, by a slightly greater amount in the control group (95% CI = -4.47 to 6.41). Adjustment to visual loss was worse in the control group at follow-up and unchanged in the rehabilitation group (95% CI = -0.42 to 0.03). The health status score (EQ-5D) was essentially unchanged at follow-up in both groups (95% CI = -0.14 to 0.13).

The effect of the number of intervention items on the questionnaire scores was determined by logistic regression, using age, number of comorbidities, and VA as covariates. Questionnaire scores were dichotomized (i.e., an improvement in score or a lack of improvement in score). For the score of VA LV VFQ-48, the model correctly classified 82.9% of cases overall

and reached statistical significance ($\chi^2=12.05$, df=4, P=0.017). The odds ratio was 2.23 (95% CI = 0.96-5.18). Although suggestive of a positive dose-response relationship, the CI just includes 1; therefore, the possibility that there is no relationship between the number of interventions and the improvement in visual function cannot be excluded.

Masking

There were no instances of inadvertent unmasking of the interviewer. The interviewer guessed the group allocation correctly in 59.3% (95% CI = 47%-71%) of cases (i.e., no more successfully than by chance alone).

Adverse Events

Consistent with the protocol, 19 participants (12 from the intervention arm and 7 from the control arm) were referred to their general practitioner for depressive symptoms. One participant was excluded from the study, on the basis of converting to urgent need with respect to visual rehabilitation.

^{*} Significant within-group changes; P < 0.01.

TABLE 3. Qualitative Feedback From Participants About Intervention Satisfaction and Number of Participants Who Received Each Intervention Item

Oualitative Feedback	Visual Rehabilitation Group
	Огоцр
Helpfulness of intervention $(n = 34)$	
Extremely helpful, <i>n</i> (%)	23 (68)
Quite helpful, n (%)	7 (21)
Moderately helpful, n (%)	2 (6)
Not helpful, <i>n</i> (%)	2 (6)
Aspects of intervention ranked as most helpful	
by individuals who received the item	
Kitchen training, n (%)	16 of 28 (57)
Mobility training, n (%)	9 of 19 (47)
Advice on managing medications, n (%)	2 of 4 (50)
Lighting advice, n (%)	2 of 4 (50)
Communications advice, n (%)	6 of 26 (23)
Low vision aid advice, n (%)	6 of 28 (21)
Referral to other agencies, n (%)	5 of 26 (19)

Acceptability of the Intervention

A total of 34 participants responded to questions about their satisfaction with the intervention and one individual, who could not recall the intervention, was unable to respond. Overall, intervention satisfaction was high (see Table 3). Kitchen training was highlighted in qualitative feedback in which participants indicated particular aspects of the intervention that they found to be the most helpful. Two of 34 (6%) participants indicated dissatisfaction with the intervention, because of the appointment waiting times and dissatisfaction with the inability to regain government benefits.

DISCUSSION

The findings of this exploratory study demonstrate a significantly greater improvement in visual function following visual rehabilitation, delivered by visual rehabilitation officers, relative to waiting list controls. The study provides preliminary evidence that a home visit-based visual rehabilitation intervention has a positive influence on vision-specific functioning with moderate effect size.

The present evidence is based on a visual function-related outcome measure and is in agreement with previous studies showing effective rehabilitation by interventions with similar aspects to the present study, using different outcomes. 4-7,11,12,29 The magnitude of the effect size found in the current study (0.55) was smaller than that found in previous studies, which also used the VA LV VFQ-48 (ranging from 1.14-2.51^{7,30}). However, these studies^{7,30} evaluated a Veterans Affairs rehabilitation program, which was much more intensive (40-day inpatient program³⁰ and 5-week outpatient program with 5 hours of homework per week⁷) and holistic relative to that in the current study, and the waiting list control group declined slightly in all aspects of function, 7 unlike the small improvement seen in the present study. Results for the individual domains of the VA LV VFQ-48 demonstrated a significant effect only in visual motor skills (i.e., an improvement in tasks such as getting dressed, grooming, eating, cleaning, cooking, and working on hobbies), unlike previous findings in which the greatest effect was in the reading ability domain.7

The present exploratory findings are not consistent with a previous study by Reeves et al., ¹³ who also examined a home visit-based rehabilitation intervention. That study did not find an effect of visual rehabilitation in a three-arm randomized

controlled trial that compared: standard hospital clinic-based visual rehabilitation; standard hospital-based rehabilitation plus up to three additional home visits by a trained visual rehabilitation officer; and standard hospital-based rehabilitation plus up to three nonrehabilitation home visits from a "community care worker" (with no formal training). However, comparison is confounded given several differences to the design of the current study. In the study by Reeves et al., 13 the cohort only included participants with age-related macular degeneration and the visual rehabilitation officer focused on the use of low vision aids, while participants of the present study had low vision attributed to a range of causes and employed a range of rehabilitation intervention items encompassing several aspects of daily living. This more accurately reflects the work undertaken by visual rehabilitation officers. Additionally, different outcome measures were assessed.

In the present study, secondary outcome measures were not significantly different between the intervention and control groups. Although there was a lack of significant improvement in psychosocial outcomes such as depression, wellbeing, and loneliness, the intervention did not specifically address mental health and psychosocial issues, whereas visual function, as related to daily living tasks, was specifically targeted. While the findings of the present study do not appear to support previous findings of a positive effect of a low vision intervention on depression, 5,14-16 other studies have shown that visual rehabilitation has a greater effect on functional status than on psychological status. 5,7,15,16,29,31-33 This observation suggests an integrated multidisciplinary approach to visual rehabilitation would be appropriate for those with clinically significant depressive symptoms.

The conduct of the current trial was supported by recruitment to target. Barriers to recruitment occurred during or immediately after screening. Typical reasons given for declining to take part in the study included: inability to attend the baseline visit due to poor mobility or being housebound; a lack of interest; an illness; being too busy; having too many health appointments; and feeling that taking part in the study would be too much effort. Therefore, for these groups of individuals, the findings of the study should be interpreted with caution.

The strengths of the study include the robust randomized waiting list controlled trial design, the analysis based on predefined outcomes and the successful masking of the interviewer. The limitations of the study include the modest sample size and the lack of multiple study sites. A larger trial would likely enable more conclusive results relating to the effect of the number of intervention items on the outcomes.

The implication of these findings on future work is the necessity for a larger trial with an expanded intervention to include a mental health component and cost effectiveness analysis. In the United Kingdom, the type of social care provision provided by visual rehabilitation officers, and studied here, has been in decline. Services have been cut and the number of visual rehabilitation officers being trained has reduced steadily over the last 12 years. The findings reported here may persuade policy planners in the United Kingdom to recognize the value of visual rehabilitation officers and halt the decline in service provision. In conclusion, this exploratory study provides evidence that rehabilitation officer input is effective with respect to vision-related functional outcomes and suggests that home visit-based visual rehabilitation may be a useful part of an integrated care pathway.

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