E.7.2 Self monitoring

RQ23a: What strategies and tools are useful for self-monitoring for people with AMD?

Bibliographic reference	**Randomised Trial of a Home Monitoring System for Early Detection of Choroidal Neovascularization Home Monitoring of the Eye (HOME) Study. Chew E Y; Clemons T E; Bressler S B; Elman M J; Danis R P; Domalpally A ; Heier J S; Kim J E; Garfinkel R , Ophthalmology, 121, 535-533, 2014**
Country/ies where the study carried out	USA
Study type	Randomised Controlled Trial
Aim of the study	To determine whether home monitoring with the ForeseeHome device, using macular visual field testing with hyperacuity technique and telemonitoring, results in earlier detection of age-related macular degeneration-associated choroidal neovascularization, reflected in better visual acuity, when compared with standard care.
Study dates	Published 2014 Enrolled between 30/07/2010 and 16/11/2012
Sources of funding	Supported by the National Institutes of Health.
Sample size	1520
Inclusion Criteria	Patients were at risk for developing CNV, with either bilateral large drusen (potentially 2 study eyes) or large drusen in 1 eye (study eye) and advanced AMD in the fellow (nonstudy eye) and best-corrected visual acuity (BCVA) of 20/60 or better in the study eyes.
Exclusion Criteria	Patients with pre-existing significant visual field defect Patients with reliable qualification test Patient did not meet study ocular criteria Patients were seen more frequently than 4 months Patients did not take online device tutorial Patients' media opacities were not sufficient for fundus photographs Patients' study eye did not have BCVA 20/60 or better Evidence of macular or retinal disorder in study eye Patients with no computer experience Patients did not consent to examination by ophthalmologist
Baseline characteristics	

Baseline characteristics	Devise monitoring	Standard care	Total

Bibliographic reference	Randomised Trial of a Home Monitoring System for Early Detection of Choroidal Neovascularization Home Monitoring of the Eye (HOME) Study. Chew E Y; Clemons T E; Bressler S B; Elman M J; Danis R P; Domalpally A ; Heier J S; Kim J E; Garfinkel R , Ophthalmology, 121, 535-533, 2014
	<table><tr><td>Number</td><td>763</td><td>757</td><td>1520</td></tr><tr><td>Female (%)</td><td>444 (58.2)</td><td>451 (59.6)</td><td>895 (58.9)</td></tr><tr><td>Mean age (SD)</td><td>72.6 (7.7)</td><td>72.3 (7.7)</td><td>72.5 (7.7)</td></tr><tr><td>White race (%)</td><td>733 (96.1)</td><td>730 (96.4)</td><td>1463 (96.3)</td></tr><tr><td>AREDS2 participant</td><td>295 (38.7)</td><td>269 (35.5)</td><td>564 (37.1)</td></tr><tr><td>Bilateral large drusen</td><td>642 (84.1)</td><td>608 (80.3)</td><td>1250 (82.2)</td></tr><tr><td>Large druse, advanced AMD</td><td>111 (14.5)</td><td>132 (17.4)</td><td>243 (16.0)</td></tr><tr><td>Mean visual acuity (SD)</td><td>81.5 (7.5)</td><td>81.9 (7.1)</td><td>81.7 (7.3)</td></tr></table>
Study visits and procedures	At baseline, all participants underwent best corrected visual acuity (BCVA) testing and colour fundus photography of 3 stereoscopic field in both eyes. Certified examined used a standardized protocol to obtain visual acuity using the electronic version of the Early Treatment Diabetic Retinopathy Study visual acuity charts.
Intervention	Home monitoring device. In addition to receiving the same standard care instructions, the participants received a home monitoring device, with instructions for installation and use.
Comparator	Standard care. The participants randomised to the standard care only group received instruction that were investigator specific for self-monitoring of vision at home to detect progression of AMD.
Outcomes	Detection of progression to CNV Vision function at the time of CNV detection
Analyses	The Mann-Whitbney U test T-test Fisher exact test was used to compare proportions between 2 groups 2 interim analyses were planned at appropriately 50% and 75% of the total number of CNV events.
Length of follow up	Planned follow-up until 31/05/2014
Results	Progression to Choroidal neovascularization

Bibliographic reference	Randomised Trial of a Home Monitoring System for Early Detection of Choroidal Neovascularization Home Monitoring of the Eye (HOME) Study. Chew E Y; Clemons T E; Bressler S B; Elman M J; Danis R P; Domalpally A ; Heier J S; Kim J E; Garfinkel R , Ophthalmology, 121, 535-533, 2014

82 participants (intention to treat cohort) have progressed to CNV in at least 1 of their study eyes based on investigators' determination including 51 in the device group and 31 in the control group.

Visual acuity at the time of choroidal neovascularization detection

Primary visual acuity outcome at diagnosis of choroidal neovascularization by treatment group

Population	Treatment			
	Device monitoring	Standard care	Total	P value
Intent to treat population				
No. of patients	51	30	81	
VA score at baseline				
Mean (SD)	79.7 (8.0)	80.7 (5.7)	80.1 (7.2)	
Median (IQR)	81.0 (73.0 to 86.0)	82.0 (77.0, 85.0)	81.0 (75.0, 85.0)	
VA score at CNV event				
Mean (SD)	72.3 (13.8)	68.1 (16.1)	70.8 (14.8)	
Median (IQR)	75.0 (70.0, 82.0)	72.0 (64.0, 77.0)	73.0 (67.0, 80.0)	
VA score change from baseline at event				
Mean (SD)	-7.4 (11.4)	-12.6(16.5)	-9.3(13.7)	
Median(IQR)	-4.0(-11.0, -1.0)	-9.0 (-14.0, -4.0)	-7.0 (-12.0, -2.0)	0.021

Secondary visual acuity outcomes at diagnosis of choroidal neovascularization by treatment group

Population	Treatment, no (%)			
	Device monitoring	Standard care	Total	P value

Bibliographic reference	Randomised Trial of a Home Monitoring System for Early Detection of Choroidal Neovascularization Home Monitoring of the Eye (HOME) Study. Chew E Y; Clemons T E; Bressler S B; Elman M J; Danis R P; Domalpally A ; Heier J S; Kim J E; Garfinkel R , Ophthalmology, 121, 535-533, 2014

Intent to treat population				
No. of patients	51	30	81	
Maintained 20/40 or better	40 (87)	18 (62)	58 (77)	0.014
Maintained vision (loss of no more than 5 letters)	27 (53)	12(40)	39(48)	0.185
15+ letter loss from baseline	6 (12)	7(23)	13(16)	0.146
Declined to 20/200 or worse	1 (2)	1 (3)	2 (2)	0.607

Missing data handling/loss to follow up	24 out of a total of 763 participants in device group discontinued in the study 20 out of a total of 757 participants in control group (standard care group) discontinued in the study
Was allocation adequately concealed?	The study was unmasked (participants, investigator, and clinical co-ordinator were aware of the random assignment of the device and control groups)
Was knowledge of the allocated intervention adequately prevented during the study?	Unclear
Was the allocation sequence adequately generated?	Unclear
Was the study apparently free of other problems that could put it at a high risk of bias?	Yes
Were incomplete outcome data adequately addressed?	Yes

Bibliographic reference	Randomised Trial of a Home Monitoring System for Early Detection of Choroidal Neovascularization Home Monitoring of the Eye (HOME) Study. Chew E Y; Clemons T E; Bressler S B; Elman M J; Danis R P; Domalpally A ; Heier J S; Kim J E; Garfinkel R , Ophthalmology, 121, 535-533, 2014
Are reports of the study free of suggestion of selective outcome reporting?	Yes
Other information	All comparison were made in the ITT cohort, which included all participants who had an investigator-confirmed CNV event assigned to the 2 groups regardless of the adherence to the use of the device. Additionally analysis was conducted on the initial per protocol (PPI) population, in which the device group was restricted to those participants who were using the device at the time of CNV detection, regardless of adherence to minimal recommended frequency of monitoring, and on a second per protocol (PP2) population, which further restricted the device group to only those population who met minimum use criteria of 2 tests per week in their study eye(s) before the CNV event.

Bibliographic reference	Improved Adherence to Vision Self-monitoring with the Vision and Memory Stimulating (VMS) Journal for Non-neovascular Age-related Macular Degeneration during a Randomized Controlled Trial. Bittner AK ; Torr-Brown S ; Arnold E ; Nwankwo A ; Beaton P ; Rampat R ; Dagnelie G ; Roser M , Journal of clinical & experimental ophthalmology 5: 320, 2014
Coutry/ies where the study carried out	USA
Study type	Randomised controlled trial
Aim of the study	To determine whether vision self-monitoring frequency and confidence were greater amongst intermediate stage, non-neovascular AMD patients who received the VMS journal compared to those receiving usual care (e.g..Amsler grid or instructions from their eye care provider) To determine whether the VMS journal could help promote adhere to weekly vision self-monitoring over the course of a year.
Study dates	Published 2014 Recruitment between Jan and December 2011.
Sources of funding	Supported by National Institutes of Health Grants
Sample size	198
Inclusion Criteria	Patients with intermediate stage, non-neovascular AMD

<table>
<tr><th>Bibliographic reference</th><th>Improved Adherence to Vision Self-monitoring with the Vision and Memory Stimulating (VMS) Journal for Non-neovascular Age-related Macular Degeneration during a Randomized Controlled Trial. Bittner AK ; Torr-Brown S ; Arnold E ; Nwankwo A ; Beaton P ; Rampat R ; Dagnelie G ; Roser M , Journal of clinical & experimental ophthalmology 5: 320, 2014</th></tr>
<tr><td>Exclusion Criteria</td><td>Patients with vision loss due to ocular pathology other than AMD or cataract were excluded.
Patients had cataract in the last 3 months or capsulotomy in the last 24 hours in either eye
Patients were unable to give informed consent, non-English speaking or unable to complete the required procedures.</td></tr>
<tr><td>Baseline characteristics</td><td>The characteristics of participants in VMS journal and control groups who completed at least one follow-up.
<table>
<tr><td></td><td>VMS journal</td><td>Standard care</td><td>Total</td></tr>
<tr><td>Number</td><td></td><td></td><td>157</td></tr>
<tr><td>Female (%)</td><td>48 (65.8)</td><td>44 (52.4)</td><td>92 (58.6)</td></tr>
<tr><td>Mean age (SD)</td><td>74.0 (8.9)</td><td>76.8 (8.7)</td><td>75.5 (8.9)</td></tr>
<tr><td>Previous NV AMD one eye (%)</td><td>9 (12.3)</td><td>11 (13.1)</td><td>20 (12.7)</td></tr>
<tr><td>Intermediate AMD one eye (%)</td><td>21 (28.8)</td><td>24 (28.6)</td><td>45 (28.7)</td></tr>
<tr><td>Intermediate AMD both eye (%)</td><td>43 (58.9)</td><td>49 (58.3)</td><td>92 (58.6)</td></tr>
<tr><td>Mean VA better eye (logMAR)</td><td>0.15 (0.12)</td><td>0.21 (0.21)</td><td>0.18 (0.18)</td></tr>
<tr><td>Mean VA worse eye (logMAR)</td><td>0.32 (0.30)</td><td>0.45(0.38)</td><td>0.39 (0.35)</td></tr>
</table></td></tr>
<tr><td>Study procedures</td><td>Participant’s ocular disease status and corrected disease visual acuity (VA) were measured by retinal specialists using standard clinical tests.
Participants were randomly allocated to experimental and control groups.
There were 2 follow-up questionnaires which were either completed by phone interviews by researchers or self-completed by the participants via paper questionnaires.</td></tr>
<tr><td>Intervention</td><td>VMS journals were mailed to participants in the experimental group, with no training or education provided by the eye care provider. A <5 minute duration follow-up call occurred 2 weeks after the study materials were mailed to participants to confirm receipt of journal and address questions.</td></tr>
<tr><td>Comparator</td><td>Usual care</td></tr>
<tr><td>Outcomes</td><td>Vision self-monitoring frequency
Confidence in vision self-monitoring
Adherence to weekly vision self-monitoring over the course of a year</td></tr>
</table>

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<tr><td>Analyses</td><td>The relationship between dichotomous variables was assessed by Pearson’s chi-square tests.
Differences in continuous variables among groups were examined by two sample t-tests.
Multiple logistic regression models were used to explore factors that were predicators of weekly vision self-monitoring behaviour and non-confidence in their vision monitoring.
Multiple logistic regression models were used to explore factors that were predicators of weekly vision self-monitoring behaviour and non-confidence in their vision monitoring.</td></tr>
<tr><td>Length of follow up</td><td>12 months</td></tr>
<tr><td>Results</td><td>Vision self-monitoring frequency
At 6 and 12 months, respectively, 29% and 25% of the control subjects (n=22 and 17) indicated that they had not checked their vision in the past 6 months, while 1.5% and 5% (n=1 and 3) of the subjects with the VMS journal reported that they did not check their vision.
There was a statistically significant difference in the proportion of subjects in each group who reported vision monitoring at least weekly at 6 and 12 months, respectively 85% and 80% of the subjects with the VMS journal vs 50% of the control group at both follow-up times (p<0.001).

After adjusting for all other characteristic variable, participants with the VMS journal had statistically significant 7.1 and 4.2 times greater odds of reporting they self-monitor their vision weekly at 6 and 12 month s respectively.
<table>
<tr><td></td><td colspan="3">6 month follow up</td><td colspan="3">12 month follow up</td></tr>
<tr><td>Weekly vision self-monitoring</td><td>OR</td><td>95%CI</td><td>P values</td><td>OR</td><td>95%CI</td><td>P values</td></tr>
<tr><td>VMS group vs Control group</td><td>7.12</td><td>2.68, 18.9</td><td><0.001</td><td>4.18</td><td>1.68, 10.4</td><td>0.002</td></tr>
</table>

Confidence in vision self-monitoring
There was a highly statistically significant difference in the portion of patients who reported that they were not confident that monitoring their vision was helping to take care of their sight when comparing the VMS journal group to the usual care control group: 15% vs 53% at 6 months, and 13% vs 44% a6t 12 months (p<0.001).</td></tr>
</table>

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<tr><td></td><td>After adjusting for all other characteristic variables, participants in the usual care group had statistically significant 6.7 and 5.0 times greater odds of reporting non-confidence at 6 and 12 months respectively.
<table>
<tr><td></td><td colspan="3">6 month follow up</td><td colspan="3">12 month follow up</td></tr>
<tr><td>Weekly vision self-monitoring</td><td>OR</td><td>95%CI</td><td>P values</td><td>OR</td><td>95%CI</td><td>P values</td></tr>
<tr><td>VMS group vs Control group</td><td>0.15</td><td>0.06, 0.38</td><td><0.001</td><td>0.20</td><td>0.07, 0.56</td><td>0.002</td></tr>
</table>

Adherence to weekly vision self-monitoring over the course of a year
72% of patients (N=113, n=53 in VMS group and n=60 controls) completed both the 6 and 12-month questionnaires. The analyses of these 113 patients to evaluate changes in response over time from 6 to 12 months. There was no statistically change in weekly vs less frequent self-monitoring between the groups (p=0.68), with 82% and 80% of the VMS group and control subjects, respectively reporting no change in their frequency between 6 and 12 months.</td></tr>
<tr><td>Missing data handling/loss to follow up</td><td>21 out of a total of 94 who received the VMS journal and 20 out of a total of 104 who were in the control group were lost to follow-up or developed neovascular AMD.
A small proportion of patients in each groups completed the 12-month follow up after missing the 6-month follow-up.</td></tr>
<tr><td>Was allocation adequately concealed?</td><td>Unclear</td></tr>
<tr><td>Was knowledge of the allocated intervention adequately prevented during the study?</td><td>Unclear</td></tr>
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Were incomplete outcome data adequately addressed?	Unclear
Are reports of the study free of suggestion of selective outcome reporting?	Yes