Abstract

Background: Most neovascular age-related macular degeneration (nAMD) treatments involve long-term follow-up of disease activity. Home-monitoring would reduce the burden on patients and those they depend on for transport, and release more clinic appointments for other patients. The MONARCH study aimed to evaluate three home-monitoring tests for patients to use to detect active nAMD compared to diagnosis of active nAMD by hospital follow-up.

Objectives:

There were five objectives:

A. Estimate the accuracy of three home-monitoring tests to detect active nAMD.

B. Determine the acceptability of home-monitoring to patients and carers and adherence to home-monitoring.

C. Explore whether inequalities exist in recruitment, participants' ability to self-test, and their adherence to weekly testing during follow-up.

D. Provide pilot data about the accuracy of home monitoring to detect conversion to nAMD in fellow eyes of patients with unilateral nAMD.

E. Describe challenges experienced when implementing the tests.

Design: Diagnostic test accuracy cohort study, stratified by time since starting treatment.

Setting: Six UK Hospital Eye Service (HES) Macular Clinics (Belfast, Liverpool, Moorfields, James Paget, Southampton, Gloucester).

Participants:

Patients with at least one study eye being monitored by hospital follow-up.

Reference standard:

Detection of active nAMD by an ophthalmologist at hospital follow-up.

Index tests:

1. KeepSight Journal (KSJ): paper-based booklet of near vision tests presented as word puzzles.

2. MyVisionTrack® (mVT®): electronic test, viewed on a tablet device.

3. MultiBit (MBT): electronic test, viewed on a tablet device.

Participants provided test scores weekly. Raw scores between hospital follow-ups were summarised as averages.

Results: 297 patients (mean age 74.9 years) took part. At least one hospital follow-up was available for 317 study eyes (1,549 complete visits). Median testing frequency was 3 times per month. Estimated areas under receiver operating curves (AUROCs) were <0.6 for all index tests, and only KSJ summary score was significantly associated with the lesion activity (OR=3.48, 95% confidence interval 1.09-11.13, p=0.036). Older age and worse deprivation for home address were associated with lower participation (chi-squared=50.5 and 24.3 respectively, both p = <0.001) but not ability or adherence to self-testing. Estimated AUROCs were higher for conversion of fellow eyes to nAMD (0.85 for KSJ). Almost half of participants called a study helpline, most often due to inability to test electronically.

Limitations: Pre-specified sample size not met; participants' difficulties using the devices; electronic tests not always available.

Conclusions:

No index test provided adequate test accuracy to identify lesion activity as diagnosed in follow-up clinics. Associations of older age and worse deprivation with study participation highlights the potential for inequities with such interventions. Provision of reliable electronic testing was challenging.

Future work:

Future studies evaluating similar technologies should consider:

(i) Independent monitoring with clear stopping rules based on test performance.

(ii) Deployment of apps on patients own devices since providing devices did not reduce inequalities in participation and complicated home-testing.

(iii) Consider alternative methods to summarise multiple scores over the period preceding a follow-up

Trial registration: ISRCTN79058224

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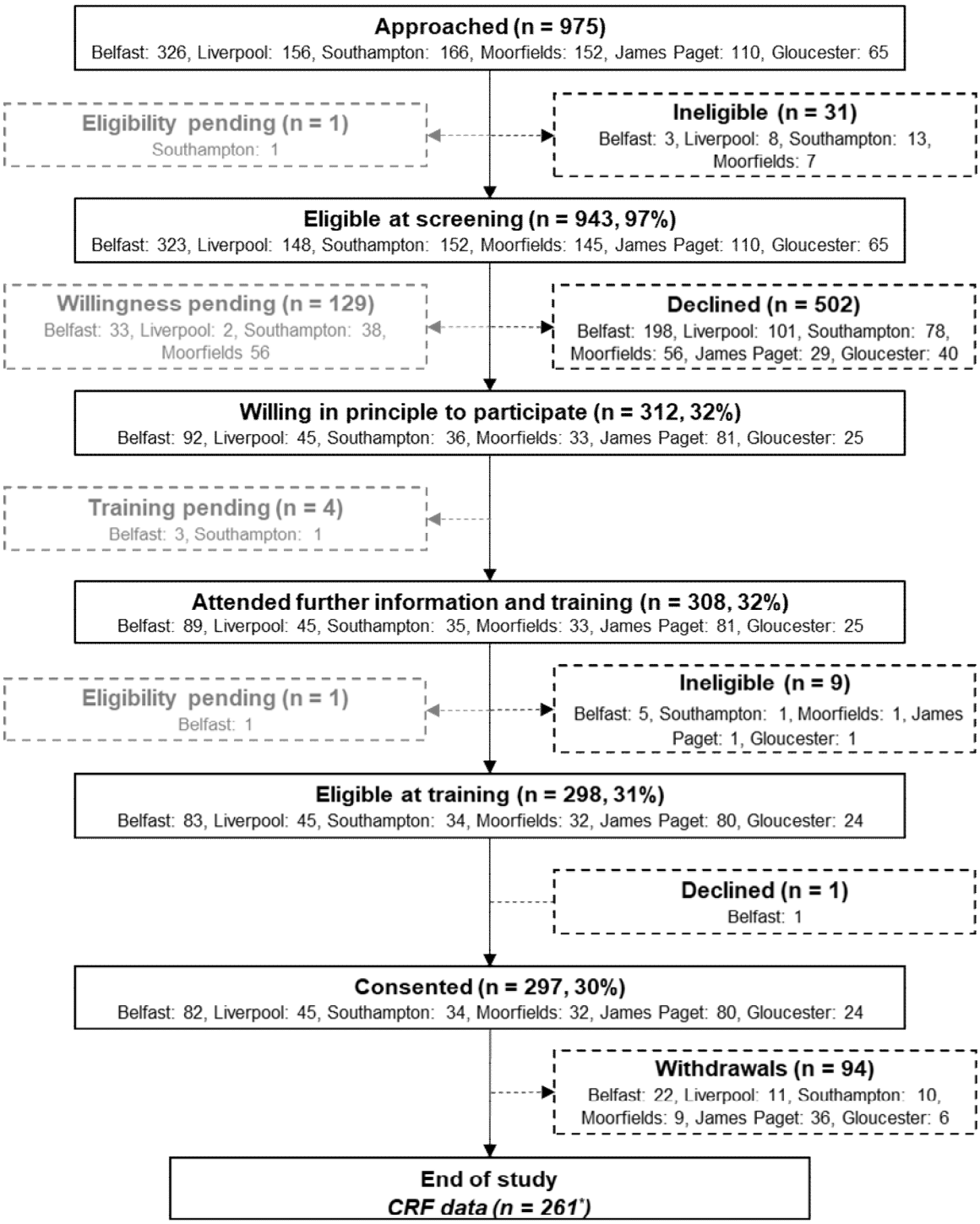
Approached (n = 975)
Belfast: 326, Liverpool: 156, Southampton: 166, Moorfields: 152, James Paget: 110, Gloucester: 65
Eligibility pending (n = 1)
Southampton: 1
Ineligible (n = 31)
Belfast: 3, Liverpool: 8, Southampton: 13, Moorfields: 7
Eligible at screening (n = 943, 97%)
Belfast: 323, Liverpool: 148, Southampton: 152, Moorfields: 145, James Paget: 110, Gloucester: 65
Willingness pending (n = 129)
Belfast: 33, Liverpool: 2, Southampton: 38, Moorfields 56
Declined (n = 502)
Belfast: 198, Liverpool: 101, Southampton: 78, Moorfields: 56, James Paget: 29, Gloucester: 40
Willing in principle to participate (n = 312, 32%)
Belfast: 92, Liverpool: 45, Southampton: 36, Moorfields: 33, James Paget: 81, Gloucester: 25
Training pending (n = 4)
Belfast: 3, Southampton: 1
Attended further information and training (n = 308, 32%)
Belfast: 89, Liverpool: 45, Southampton: 35, Moorfields: 33, James Paget: 81, Gloucester: 25
Eligibility pending (n = 1)
Belfast: 1
Ineligible (n = 9)
Belfast: 5, Southampton: 1, Moorfields: 1, James Paget: 1, Gloucester: 1
Eligible at training (n = 298, 31%)
Belfast: 83, Liverpool: 45, Southampton: 34, Moorfields: 32, James Paget: 80, Gloucester: 24
Declined (n = 1)
Belfast: 1
Consented (n = 297, 30%)
Belfast: 82, Liverpool: 45, Southampton: 34, Moorfields: 32, James Paget: 80, Gloucester: 24
Withdrawals (n = 94)
Belfast: 22, Liverpool: 11, Southampton: 10, Moorfields: 9, James Paget: 36, Gloucester: 6
End of study
CRF data (n = 261*)

Baseline demographic characteristics and exposure to technology of consented participants

		Overall (n = 297)	
		n	%/SD
BASELINE CHARACTERISTIC			
Sex:	Male	123/297	41.4%
	Female	174/297	58.6%
Age	Mean (SD) years	74.9	6.6
Number of study eyes / patient	Mean number per patient (SD)	1.2	0.4
Number of fellow eyes / patient	Mean number per patient (SD)	0.5	0.5
Visual acuity in study eye[1]	Mean (SD) ETDRS	72.9	10.7
Smoking history	Current smoker	30/297	10.1%
	Ex-smoker (> 1 month)	137/297	46.1%
	Never smoked	130/297	43.8%
MEDICAL HISTORY			
Congestive cardiac failure		11/297	3.7%
Myocardial infarction		19/297	6.4%
Peripheral vascular disease		7/297	2.4%
Cerebrovascular disease		21/297	7.1%
Hypertension requiring treatment		158/297	53.2%
Chronic pulmonary disease		28/297	9.4%
Rheumatological disease		53/297	17.8%
Renal disease		25/297	8.4%
Liver disease		7/297	2.4%
Neurological dysfunction		12/297	4.0%
Malignancy		60/297	20.2%
Diabetes - Type 1		7/297	2.4%
Diabetes - Type 2		31/297	10.4%
Other conditions that may affect ability to perform testing		15/297	5.1%
EXPOSURE TO TECHNOLOGY			
Television		294/296	99.3%
Simple mobile phone		130/296	43.9%
Smartphone		197/296	66.6%
Tablet		196/296	66.2%
Laptop/Home Computer		184/296	62.2%
Internet at Home		252/296	85.1%
E-mail		213/296	72.0%
Social Media		97/296	32.8%
TV streaming/On-demand services		146/296	49.3%

1. *For patients with two study eyes, better seeing eye is used*