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Cohort study of Anticoagulation Self-Monitoring (CASM):
a prospective study of its effectiveness in the community

INTRODUCTION
Oral anticoagulation therapy (OAT) substantially reduces thromboembolic events with no increase in major haemorrhagic events.1–5 However, uptake is still affected by the need to maintain the international normalised ratio (INR) in a narrow range, which requires frequent testing and dose adjustment. Reliable and accurate point-of-care devices enable patients to test their INR in their own setting. They can either self-monitor their INR and have their oral anticoagulation dosage managed by a healthcare provider or they can self-manage and adjust their own dosage.

Patients have been found to vary considerably in their ability to self-monitor and self-manage. Results of randomised controlled trials (RCTs) show that only 38% (range 12–59%) of those initially identified as potentially eligible for self-monitoring of OAT actually participated in the trials; in addition, only 78% assigned to the intervention continued self-monitoring until the end of the trial.6

Current guidelines recommend self-monitoring or self-management for patients who have long-term indications, a recognised target INR, and have received appropriate training by a health professional.2,3 The outcomes of the trials for those that participate fully have been positive for both self-monitoring and self-managing OAT,2 but it is not known whether these results translate into routine practice. This study aimed to:

• prospectively estimate the current levels of control and adverse events in patients self-monitoring OAT in the UK;
• explore the factors that predict successful self-monitoring of INR;
• ascertain whether the success of INR self-monitoring and level of side effects reported in RCTs of self-monitoring INR are translated to a non-selected population; and
• estimate the adequacy of existing training and quality-assurance arrangements.

METHOD
Study population and recruitment
The study population consisted of all people who purchased an INR self-monitoring device from the main distributor in the UK. During the study period, this distributor had 99.9% of the market share. All people aged ≥18 years, who were able to give informed consent, comprehend English sufficiently well to be interviewed, and registered with a UK GP were eligible to take part. Recruitment lasted from February 2009 until August 2011. Originally, only those who were new to self-monitoring — defined as self-monitoring for ≤3 months — were recruited. However,
due to low numbers, recruitment was broadened to include people who had been self-monitoring for some time and were purchasing replacement devices.

Sample size
As the primary aim of the study was to obtain an adequate estimate of the rate of successful self-monitoring, the sample size calculation was based on a certain precision around this estimate (equal to 1.96 standard errors, or one side of a 95% confidence interval [CI]). The worse-case scenario in terms of precision, given a rate of 50% (maximum variance) and a 20% attrition, would require 300 participants to achieve a precision of ±6% around the estimate (for example, 95% CI = 44 to 56). A rate of 35% (or 65%) based on the same sample would give a precision of ±5.4%. Rates of <35% (or >65%) would give better precision levels. This sample also allows for the identification of predictive variables with odds of greater than approximately 2.5 — for example, an odds ratio (OR) of 2.3 for an event of 70% in the successful group, versus 50% in the unsuccessful group — with similar confidence.

Baseline telephone interviews and questionnaires
Consenting participants were sent a postal questionnaire and telephoned to complete a baseline interview. Details requested covered:

- basic demographics;
- anticoagulation history;
- self-monitoring training;
- support;
- adverse events;
- quality assurance;
- comorbidity;
- medications;
- attitudes towards self-monitoring of INR;
- confidence about self-monitoring INR;
- psychosocial measures.

How this fits in
Oral anticoagulation therapy (OAT) greatly reduces thromboembolic events without increasing major haemorrhagic events. The outcomes of a number of trials have been positive for both self-monitoring and self-managing oral anticoagulation, but it is not known whether these results translate into routine practice. This study shows that, even without much training, individuals on OAT can self-monitor, and even self-manage, their international normalised ratio (INR) with positive results outside of trial settings. Such patients could be offered self-monitoring and self-management of their OAT with suitable healthcare support. However, it should be noted that participants in this study were highly educated so caution should be taken with regard to generalising the findings to the broader population.

The psychosocial measures comprised the EQ-5D, Conscientiousness scale, Morisky Adherence to Medication Scale, National Institute of Health and Care Excellence [NICE] Depression Screening Tool, State-Trait Anxiety Inventory, Hospital Anxiety and Depression Scale, Brief Illness Perception Questionnaire, an adapted Treatment Self-Regulation Questionnaire including perceived competence/self-efficacy scale and Health Care Climate Questionnaire (based on the theory of self-determination) and the Theory of Planned Behaviour Questionnaire.

Interview schedule
Face-to-face interviews were conducted with a small number of participants. Interviews were semi-structured with open-ended questions to elicit new information; they were recorded using digital audio equipment and transcribed. Questions explored the:

- experiences of self-monitoring, focusing on the barriers and facilitators;
- reasons for not starting, or not continuing, self-monitoring;
- training received; and
- quality assurance.

Follow-up data collection
Participants were contacted by telephone at 3, 6, and 12 months to ascertain whether they were still self-monitoring; a brief questionnaire explored their experiences of doing so. At 12 months, participants were also sent a validated questionnaire to assess their oral anticoagulation knowledge. During follow-up, they recorded their INR data in a log book and posted it to the study coordinator every 3 months. Clinical data for participants for the 12-month study period were ascertained from GP medical records. Two GPs independently classified the reported adverse events using the bleeding severity index; differences were resolved by discussion.
Data analysis

Statistical analyses were performed using SPSS (version 20). Comparisons of descriptive data were conducted using χ² tests for categorical variables and binary logistic regression for continuous variables. The proportion of participants continuing to self-monitor over time was ascertained from the interview data, while the proportion of time in therapeutic range (TTR) was calculated using the INR data. Percentage TTR (%TTR) was calculated using Rosendaal et al’s method in Stata (version 11).

Successful self-monitoring was defined as the proportion of participants:

- continuing to self-monitor for 12 months;
- not experiencing adverse events over the 12 months; and
- achieving >80% TTR.

In the calculation of TTR, the participant’s reported target range was used for analyses; participant-reported INR tests conducted by health professionals were excluded. Duplicate tests carried out on the same day were averaged. The start date was taken as the date of the baseline interview; the end date was 365 days later. Participant INR data was excluded if the submitted test results spanned <90 days in total during the study period. TTR was not interpolated for the missing periods. Data with a reported gap between tests of >12 weeks was treated as intermittent.

Forward stepwise logistic regression was used to establish potential predictors of successful self-monitoring. Only baseline characteristics were included in the model; the addition of whether a participant had experienced a surgical procedure during the 12 months was excepted as this was likely to reduce TTR. Age, sex, condition requiring oral anticoagulation, duration of self-monitoring, surgical procedure during follow-up, and previous oral anticoagulation complications were all entered into a model before the addition of baseline variables with a univariate OR P-value of <0.10.

RESULTS

Of the individuals approached to participate in the study, 299 were eligible, completed the baseline questionnaires, and were recruited. Of these, three participants did not go on to begin self-monitoring (two due to lack of support from their healthcare provider and one for unknown reasons). Of the remaining 296 (from 290 general practices), 15 were lost to follow-up, seven stopped using OAT, and seven stopped self-monitoring; this gave a total of 267 (90.2%) who were still self-monitoring at 12 months (Figure 1). Of those who stopped self-monitoring, four did so due to lack of healthcare provider support, two were unable to use the monitor reliably, and one was for unknown reasons.

Baseline characteristics

The baseline characteristics of the cohort are presented in Table 1. In total, 51.2% were new to self-monitoring. The median target INR was 2.5 (interquartile range [IQR] 2.5–3.2). This varied by condition as follows:

- atrial fibrillation: median INR target of 2.5 (IQR 2.5–2.5);
- mechanical heart valve: median INR target of 3.0 (IQR 3.0–3.5);
Thrombosis: median INR target of 2.5 (IQR 2.5–3.0), and antiphospholipid syndrome: median INR target of 3.5 (IQR 2.5–3.8).

Just under half of participants self-monitored but received assistance with dose adjustment (133/296, 44.9%), while others self-managed and adjusted their own medication (116/296, 39.2%). A smaller number (47/296, 15.9%) did a mixture of both. Those new to self-monitoring were significantly less likely to be self-managing (25.7%, P < 0.001) than those who had been self-monitoring for a longer period of time (53.5%).

Table 2 details participants’ psychosocial characteristics. More than half had problems in one or more dimensions of the EQ-5D (153/292, 52.4%), with the largest percentage being for those experiencing pain (122/296, 41.2%). Those who had been self-monitoring for longer had higher self-efficacy scores (P = 0.003), higher social pressure scores (P = 0.030), felt more in control of their illness (P = 0.016), and thought that their treatment controlled their illness more (P = 0.020). According to the NICE depression screening tool just over one-quarter (26.9%) of the participants were depressed, however, according to their HADS scores they were no more depressed and were slightly less anxious than the general population (Appendix 1).

Training details

Nearly all participants (92.9%) made use of the information book and/or DVD that came with the monitor. However, only 45.9% of participants had received in-person training with a median duration of 35 minutes. Only six of 39 (15.4%) of those new to self-

| Baseline characteristic | n | Total cohort* | n | New to self-monitoring | n | Ongoing self-monitoring | P-valueδ |
|-------------------------|---|--------------|---|------------------------|---|------------------------|---------|
| **Demographic**         |   |              |   |                        |   |                        |         |
| Age, median (IQR)       | 295 | 61.0 (50.0–68.0) | 152 | 59.0 (49.0–66.0) | 143 | 63.0 (52.0–69.0) | 0.031 |
| Male, n (%)             | 296 | 163 (55.1) | 152 | 88 (57.9) | 144 | 75 (52.1) | 0.315 |
| White ethnicity, n (%)  | 294 | 293 (99.7) | 150 | 149 (99.3) | 144 | 144 (100.0) | 1.000 |
| **Highest educational qualification attained** |   |              |   |                        |   |                        |         |
| No qualification, n (%) | 294 | 16 (5.4) | 152 | 10 (6.6) | 143 | 6 (4.2) | 0.582 |
| O-Level or GCSE, n (%)  | 22 (7.5) | 10 (6.6) | 12 (8.4) |
| A-Level, n (%)          | 13 (4.4) | 8 (5.3) | 5 (3.5) |
| Professional qualification, n (%) | 91 (31.0) | 42 (27.8) | 49 (34.3) |
| University degree, n (%) | 152 (51.7) | 81 (53.6) | 71 (49.7) |
| **Condition requiring anticoagulation** |   |              |   |                        |   |                        |         |
| Antiphospholipid syndrome, n (%) | 25 (8.4) | 13 (8.6) | 12 (8.3) |
| Atrial fibrillation, n (%) | 68 (23.0) | 40 (26.3) | 28 (19.4) |
| Mechanical heart valve, n (%) | 97 (32.8) | 44 (28.9) | 53 (36.8) |
| Thrombosis, n (%)       | 106 (35.8) | 55 (36.2) | 51 (35.4) |
| **Oral anticoagulation history** |   |              |   |                        |   |                        |         |
| Target INR, median (IQR) | 295 | 2.5 (2.5–3.2) | 152 | 2.5 (2.5–3.0) | 144 | 3.0 (2.5–3.3) | 0.088 |
| Duration of OAT, months, median (IQR) | 295 | 62.0 (14.0–137.0) | 151 | 21.0 (7.0–74.0) | 144 | 107.0 (56.3–162.5) | <0.001 |
| Previous OAT complication, n (%) | 295 | 101 (34.2) | 152 | 48 (31.6) | 143 | 53 (37.1) | 0.321 |
| Taking OAT other than warfarin, n (%) | 296 | 10 (3.4) | 152 | 4 (2.6) | 144 | 6 (4.2) | 0.469 |
| **Characteristics of self-monitoring** |   |              |   |                        |   |                        |         |
| Duration, months, median (IQR) | 295 | 2.0 (1.0–4.0) | 151 | 1.0 (0.0–1.0) | 144 | 45.0 (8.8–94.5) | <0.001 |
| Received in-person self-monitoring training, n (%) | 296 | 136 (45.9) | 152 | 69 (45.4) | 144 | 67 (44.5) | 0.845 |
| Duration of in-person training for those that received it in minutes, median (IQR) | 129 | 35.0 (20.0–60.0) | 66 | 30.0 (20.0–60.0) | 63 | 45.0 (20.0–80.0) | 0.010 |
| **Other medications** |   |              |   |                        |   |                        |         |
| Total medications, median (IQR) | 296 | 3.0 (1.0–5.0) | 152 | 3.0 (1.0–5.0) | 144 | 3.0 (1.0–6.0) | 0.213 |
| Polypharmacy (total >3), n (%) | 296 | 129 (43.6) | 152 | 62 (40.8) | 144 | 67 (44.5) | 0.320 |
| Taking medication that affects anticoagulation, n (%) | 296 | 167 (54.4) | 152 | 83 (54.6) | 144 | 84 (58.3) | 0.580 |
| **Oral anticoagulation dose management** |   |              |   |                        |   |                        |         |
| Self-testing, n (%) | 133 (44.9) | 79 (52.0) | 54 (37.5) |
| Mixed, n (%) | 47 (15.9) | 34 (22.4) | 13 (9.0) |
| Self-managing, n (%) | 116 (39.2) | 39 (25.7) | 77 (53.5) |

\*n = 296. \*n = 152. \*n = 144. \*P-values calculated using χ² for categorical variables and binary logistic regression for continuous variables. GCSE = General Certificate of Secondary Education. IQR = interquartile range. OAT = oral anticoagulation therapy.
monitoring who were also self-managing had received any in-person training at baseline. Those new to self-monitoring who were self-testing or doing a mixture were more likely to receive training (59.5% and 47.1% respectively). The majority of this training took place in an outpatient hospital setting (62.5%), followed by primary care (36.8%); the remainder received training in both settings. Throughout the study period, 36/267 (13.5%) participants received additional training.

Knowledge of oral anticoagulation
At 12 months, the participants had a high level of knowledge about OAT on the 20-item questionnaire (median score 18.0, IQR 16.0–19.0). There was no difference between those new to self-monitoring and those ongoing with self-monitoring. There was also no association between knowledge score and receiving in-person training (P = 0.658) or >80% TTR (P = 0.370).

Areas where knowledge was lower were:
• diet and supplements;
• additional medication;
• testing frequency; and
• when to seek medical attention.

Adverse events
Reports on adverse events were obtained from the GPs of 255 (86.1%) participants.

| Table 2. Psychosocial factors |
|-------------------------------|
| Psychosocial factors          | n  | Total cohort¹ | New to self-monitoring² | Ongoing self-monitoring³ | P-value³ |
| EQ-5D                         |    |               |                          |                          |         |
| Total score, median (IQR)     | 292| 6.0 (5.0–8.0) | 150                      | 6.0 (5.0–8.0)            | 142      | 5.0 (5.0–7.3) | 0.401 |
| Problem in any dimension, n(%)| 292| 153 (52.4)    | 150                      | 87 (58.0)                | 142      | 66 (46.5)    | 0.049 |
| Mobility problem, n(%)        | 292| 88 (29.7)     | 152                      | 47 (30.9)                | 144      | 41 (28.5)    | 0.645 |
| Self-care problem, n(%)       | 292| 31 (10.5)     | 152                      | 15 (9.9)                 | 144      | 16 (11.1)    | 0.727 |
| Problem with usual activities, n(%)| 292| 92 (31.2) | 152                      | 53 (34.9)                | 143      | 39 (27.3)    | 0.160 |
| Pain, n(%)                    | 292| 122 (41.2)    | 152                      | 67 (44.1)                | 144      | 55 (38.2)    | 0.304 |
| Anxiety problem, n(%)         | 292| 69 (23.5)     | 150                      | 41 (27.3)                | 143      | 28 (19.6)    | 0.119 |
| Visual scale, median (IQR)    | 292| 80.0 (65.0–90.0) | 150                  | 78 (60.0–90.0)           | 142      | 80.0 (69.8–90.0) | 0.156 |

Depression and anxiety
Depressed NICE screening tool, n(%) | 294| 79 (26.9) | 150 | 47 (31.3) | 144 | 32 (22.2) | 0.079 |
Depressed assessed via HADS, n(%) | 295| 46 (15.6) | 152 | 26 (17.1) | 143 | 20 (14.0) | 0.461 |
Anxious assessed via HADS, n(%) | 295| 70 (23.7) | 152 | 34 (22.4) | 143 | 36 (25.2) | 0.571 |
STAI trait anxiety score, median (IQR) | 295| 33.0 (28.0–44.0) | 151 | 32.0 (27.0–44.0) | 144 | 33.0 (29.0–44.0) | 0.878 |

Self-determination theory
Autonomy score, median (IQR) | 295| 4.8 (3.8–5.5) | 151 | 4.8 (4.0–5.5) | 144 | 4.8 (3.8–5.5) | 0.415 |
Control score, median (IQR) | 295| 1.0 (1.0–2.5) | 151 | 1.3 (1.0–2.3) | 144 | 1.0 (1.0–2.5) | 0.680 |
Relative autonomy index, median (IQR) | 295| 3.0 (1.8–4.0) | 151 | 3.0 (2.0–4.3) | 144 | 2.9 (1.5–3.8) | 0.307 |
Self-efficacy maximum marks, n(%) | 296| 220 (84.5) | 152 | 119 (78.3) | 143 | 131 (91.0) | 0.003 |
Health care climate score, median (IQR) | 294| 34.0 (24.0–41.0) | 150 | 33.0 (20.0–41.0) | 144 | 34.0 (27.0–42.0) | 0.185 |

Theory of planned behaviour
Attitude score, median (IQR) | 296| 6.0 (5.5–7.0) | 152 | 6.0 (5.5–7.0) | 144 | 6.0 (5.5–7.0) | 0.309 |
Social pressure score, median (IQR) | 296| 5.0 (4.0–7.0) | 152 | 4.5 (4.0–6.4) | 144 | 5.5 (4.0–7.0) | 0.030 |
Control score, median (IQR) | 296| 7.0 (6.5–7.0) | 152 | 7.0 (6.5–7.0) | 144 | 7.0 (7.0–7.0) | 0.099 |
Intention score, median (IQR) | 296| 7.0 (7.0–7.0) | 152 | 7.0 (7.0–7.0) | 144 | 7.0 (7.0–7.0) | 0.526 |

Illness perception
Consequences, median (IQR) | 295| 3.0 (2.0–7.0) | 152 | 4.5 (2.0–7.0) | 143 | 3.0 (1.0–6.0) | 0.600 |
Timeline, median (IQR) | 295| 10.0 (10.0–10.0) | 152 | 10.0 (10.0–10.0) | 143 | 10.0 (10.0–10.0) | 0.002 |
Personal control, median (IQR) | 294| 6.0 (3.0–8.0) | 152 | 6.0 (3.0–8.0) | 142 | 7.0 (4.0–8.0) | 0.014 |
Treatment control, median (IQR) | 295| 9.0 (8.0–10.0) | 152 | 9.0 (7.0–10.0) | 143 | 9.0 (8.0–10.0) | 0.020 |
Identity, median (IQR) | 295| 3.0 (1.0–6.0) | 152 | 3.0 (1.0–6.0) | 143 | 2.0 (1.0–6.0) | 0.150 |
Concern, median (IQR) | 295| 5.0 (2.0–8.0) | 152 | 6.0 (3.0–8.0) | 143 | 4.0 (2.0–7.0) | 0.008 |
Understanding, median (IQR) | 295| 9.0 (8.0–10.0) | 152 | 9.0 (8.0–10.0) | 143 | 10.0 (8.0–10.0) | 0.719 |
Emotional response, median (IQR) | 294| 3.0 (1.0–6.0) | 151 | 4.0 (1.0–7.0) | 144 | 2.0 (0.0–5.0) | 0.001 |

Other
Requiring social assistance, n(%) | 294| 83 (28.2) | 150 | 44 (29.3) | 144 | 39 (27.1) | 0.668 |
Conscientiousness, median (IQR) | 282| 41.0 (36.0–45.0) | 143 | 42.0 (36.0–46.0) | 139 | 41.0 (36.0–45.0) | 0.878 |
Perfect medication adherence score, n(%) | 288| 176 (61.1) | 149 | 94 (63.1) | 139 | 82 (59.0) | 0.856 |

¹n = 296. ²n = 152. ³n = 144. ⁴P-values calculated using χ² for categorical variables and binary logistic regression for continuous variables. HADS = Hospital Anxiety and Depression Scale. IQR = interquartile range. NICE = National Institute for Health and Care Excellence. STAI = State-Trait Anxiety Inventory.
Six (2.4%) participants experienced a serious adverse event — two deaths (one cause not reported, one from bowel cancer), two major bleeds, one thrombosis, and one transient ischaemic attack (TIA) — two experienced a minor bleed, and 18 experienced bleeds that were adjudicated to be less minor, as defined by the bleeding severity index. There were no significant differences in baseline characteristics between those with \( n = 255 \) and without \( n = 41 \) GP reports.

Twenty-eight participants self-reported adverse events, comprising serious adverse events (one TIA, three major bleeds), minor bleed \( n = 4 \), and sub-minor bleed \( n = 20 \). Of these, one serious adverse event (major bleed while participant was abroad), three minor bleeds, and 15 sub-minor bleeds were not reported by the participant’s GP. There were no significant differences between those new to, and those ongoing with, self-monitoring in terms of adverse events. There were also no differences between those who were self-managing and those who were self-testing.

**Frequency of testing**

Participants reported a median of 10.9 days between tests [IQR 7.2–17.4]. Those who had been self-monitoring for longer tested marginally more frequently [median 11.4 versus 10.5 days]. Frequency of testing varied by condition:

- antiphospholipid syndrome: tested most frequently, median days between tests 8.0 [IQR 4.4–10.8];
- mechanical heart valve: median days between tests 10.8 [IQR 7.0–14.6];
- thrombosis: median days between tests 12.6 [IQR 7.5–18.8]; and
- atrial fibrillation: median days between tests 13.2 [IQR 7.9–18.4].

Those who were only self-testing had the longest time between tests (median days between tests 14.7, IQR 9.7–21.1) and those self-managing the shortest (median days between tests 8.3, IQR 6.0–13.5); those undertaking a mixture were situated in between (median days between tests 9.8, IQR 5.8–15.9).

**Quality assurance**

Nearly two-thirds \( (171/267, 64.0\%) \) had performed an external calibration check of their device during the 12-month period. Of these, 50.8% compared their monitor with another monitor, 43.2% compared it with a venous sample, and 3.5% compared it with both; 2.3% were unknown. The majority \( (n = 117, 68.4\%) \) had been advised to perform quality-assurance checks by their healthcare provider; the remainder used their initiative and coincided a self-monitoring test with a clinic monitoring appointment. The number of quality-assurance checks performed during the 12 months ranged from 1 to 24 (median 2, IQR 1–4).

**Time in therapeutic range**

INR data was received from 273 participants (92.2% of the 296 who started self-monitoring) and was analysed for 269 (90.9%). Median %TTR was 78.5% (IQR 64.9–88.5). Table 3 shows that the older age groups had the highest %TTR. There was little difference in %TTR between those new to self-monitoring (median 76.1%, IQR 65.0–87.0) and those continuing to self-monitor (median 80.1%, IQR 64.8–91.4).

A total of 61 participants reported differing therapeutic ranges over the year. The breadth of INR target ranges started from as low as 0.4; the majority of cases \( (n = 243/296, 82.1\%) \) had a range of 1 and the broadest range was 2. At 12 months, GPs were asked for their patient’s target range. These were compared with the target ranges reported by the participants at either the 12-month telephone interview or the last completed interview; for 80 participants (80/255, 31.4%) target ranges did not match. In 27 instances the participant reported a narrower range and in 25 the GP reported a narrower range; in the remaining 28 cases the breadth was the same but the actual range was different.

The participants’ 12-month mean %TTR (mean 75.3%, standard deviation 16.9) was higher than that achieved by the intervention groups in five \( 21,23,25–27 \) of the seven \( 21–27 \) published RCTs.

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### Table 3. Percentage of time spent in therapeutic range

| Age, years | n  | % TTR, median (IQR) | Range |
|------------|----|---------------------|-------|
| <39        | 23 | 75.0 (64.8–83.1)    | 15.3–100.0 |
| 40–49      | 38 | 71.9 (58.9–86.0)    | 24.9–100.0 |
| 50–59      | 56 | 76.6 (62.4–85.8)    | 26.1–98.4 |
| 60–69      | 100| 78.9 (62.1–90.4)    | 28.4–100.0 |
| 70–79      | 45 | 85.0 (73.4–90.6)    | 23.8–100.0 |
| ≥80        | 7  | 90.7 (77.3–95.9)    | 54.9–100.0 |
| All ages   | 269| 78.5 (64.9–88.5)    | 15.3–100.0 |

IQR = interquartile range. TTR = time in therapeutic range.
Successful self-monitoring

The majority of participants who commenced self-monitoring were still doing so 12 months later (267/296, 90.2%). In addition, the majority of participants did not experience serious adverse events either GP or self-reported. Therefore, the main measure of successful self-monitoring was taken as the percentage of time in therapeutic range (TTR). Those who achieved >80% (n=128/269, 47.5%) of their time during follow-up in therapeutic range were defined as successful. Table 4 shows the logistic regressions, including the fixed variables and the baseline characteristics, that significantly differed at univariate level between those achieving ≤80% TTR and those with >80% TTR over the 12-month study period.

Results show that an increased EQ-5D visual scale was significantly associated with >80% TTR (OR 1.017, 95% CI = 1.001 to 1.034) as well as the forced variables of age and condition requiring oral anticoagulation. As antiphospholipid syndrome causes increased variability in INR the analysis was repeated removing these participants (n = 26). This resulted in the target INR becoming significant rather than the condition requiring anticoagulation, with those conditions with the lowest target ranges resulting in higher %TTR. Again age and a higher EQ-5D visual score were associated with higher %TTR.

DISCUSSION

Summary

These results demonstrate that patients can successfully self-monitor their INR outside trial settings. Successful self-monitoring was defined as having >80% TTR; nearly one-half of participants met this criterion. Increased age, OAT for atrial fibrillation or thrombosis, and having a higher score on the EQ-5D visual scale were all associated with success. When the participants with antiphospholipid syndrome were removed from the model only increased age and EQ-5D visual scale and lower target INR range were associated with success. Of concern is that less than one-half the participants had received in-person training (46%) and, when it was present, this lasted, on average, for <1 hour. Instead, individuals appeared to rely solely on the training information that came with their device when it was purchased. Anticoagulation services varied in the support offered to patients wishing to self-monitor. Some had established systems, including training schemes, in place. In other areas, particularly those in which local GP surgeries were commissioned to provide anticoagulation services for their patients, approval to self-monitor was done on a more ad hoc basis without any dedicated schemes set up. Moreover, only 15% of those new to self-monitoring who were adjusting their own dosage of anticoagulation therapy had received in-person training when they commenced self-monitoring.

This cohort comprised well-educated, professional people, who successfully managed their self-monitoring with relatively little training; they also had a high level of knowledge about oral anticoagulation which was not related to training. Participants were aware of quality assurance and nearly two-thirds had performed an external calibration check of their device over the 12 months. In addition, they were similar to the general population in terms of anxiety and depression. A small number of participants could not commence self-monitoring or dropped out due to lack of healthcare provider support.
Strengths and limitations
To the authors’ knowledge this is the first prospective cohort study of people self-monitoring their INR outside of trial conditions; the modified study design allowed for comparisons between those new to self-monitoring and those who had been self-monitoring for some time.

A limitation of the study is that, due to the fact that self-monitoring INR devices are expensive (approximately £400 in the UK), the participants were those people who were well educated and able to afford the device. This is of concern as the results may, therefore, not be generalisable to the wider population and current provision may be widening inequalities in health care.

Another potential limitation is the fact that the study, in part, relied on participants’ self-reported INR results. However, the accuracy of these have been confirmed in a small sample in which the reported results were compared to those stored in the memory of their monitor.

Comparison with existing literature
The majority of participants were still self-monitoring at 12 months, with a level of control higher than that achieved by the majority of participants in other RCTs.21-27 These results are consistent with the findings of a large retrospective study28 of patient self-testing, which showed a high level of control in males (76%TTR), females (71%TTR), and older patients (>74 years, >73% TTR). In addition, the low number of adverse events compares favourably with rates for those in the intervention arms of the RCTs (7.5%).

Implications for practice
This study reliably shows that participants can effectively self-monitor their own INR, but current provision is limited due to the initial costs of the device and the lack of healthcare provider support.

Even with little training, people on OAT can successfully self-monitor and self-manage their INR; however, the fact that one-third of the participants gave different target INR ranges from the ones provided by their GP at the end of this study suggests that closer monitoring by healthcare providers may be warranted.
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Appendix 1. Baseline self-rated anxiety and depression of the CASM cohort members compared to population data using the Hospital Anxiety and Depression Score^a^  

|                      | Male CASM (n = 162) | Population^b^ | Female CASM (n = 133) | Population^b^ |
|----------------------|---------------------|----------------|------------------------|----------------|
| HADS anxiety score, median (IQR) | 4.0 (2.0–7.0)       | 5.0 (3.0–8.0)   | 5.0 (3.0–8.0)          | 6.0 (4.0–9.0)   |
| HADS depression score, median (IQR) | 3.0 (1.0–5.0)       | 3.0 (1.0–6.0)   | 3.0 (1.0–6.0)          | 3.0 (1.0–6.0)   |

IQR = interquartile range. ^A score of 0–7 is regarded as being normal, ≥8 indicates the presence of anxiety or depression. Population data from: Crawford JR, Henry JD, Crombie C, Taylor EP. Normative data for the HADS from a large non-clinical sample. Br J Clin Psychol. 2001; 40(Pt 4): 429–434.