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Original research

Evaluating the use of proactive surveillance and remote patient monitoring to guide the timing of valve intervention in patients with severe asymptomatic aortic stenosis (APRAISE-AS): results of a pilot randomised controlled trial

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ABSTRACT

Background The insidious nature of aortic stenosis (AS) combined with the advanced age of the affected population results in underreporting of symptoms and underestimation of impact on functional capacity and quality of life. Although guidelines recommend early valve replacement in severe asymptomatic AS when coupled with adverse prognostic features, capacity within healthcare systems may limit translation into clinical practice. The use of remote monitoring and proactive surveillance to inform clinical management of heart valve disease is an underexplored area. APRAISE-AS evaluated the utility of remote monitoring to pre-empt/detect a change in clinical status (incorporating a symptom tracker, frailty assessment and quality of life score) to inform patient management.

Methods 12-month open-label, two-arm, parallel group randomised controlled pilot trial conducted in two tertiary cardiac centres. 38/66 participants (≥18 years) with asymptomatic severe AS were randomly assigned (1:1) to standard care or the APRAISE-AS intervention in addition to standard care. The primary aim of the study was to (1) test the trial protocol, (2) determine acceptability of the APRAISE-AS intervention and (3) inform the most appropriate outcome measure(s) and sample size for a full-scale randomised controlled trial.

Results 38 participants were assigned to standard care (n=19) or to standard care plus the APRAISE-AS intervention (n=19). Adherence rates were high: 81% for the weekly symptom assessments, 91% for the fortnightly timed up and go tests and 93% for the monthly health-related quality of life assessments using the Kansas City Cardiomyopathy Questionnaire (KCCQ). Clinical review and onward referral for valve replacement were triggered by a change from baseline in symptoms and KCCQ scores.

Conclusion Remote monitoring of severe asymptomatic AS can be safely delivered in practice. Although the pilot did not recruit to target, a digitally enabled clinical pathway to optimise the management of asymptomatic severe AS is acceptable to clinicians and patients.

Trial registration number [ISRCTN19413194](https://www.isrctn.com/ISRCTN19413194).

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ In people with asymptomatic severe aortic stenosis (AS), a watchful waiting strategy with 6-month clinic-based review and valve intervention at the point of symptom development has limitations since the slowly progressive nature of AS combined with the advanced age of the affected population predispose to under-reporting of symptoms, which develop insidiously and are mistaken for age-related decline rather than disease progression. Although the evidence base is evolving, the optimal timing of valve intervention in asymptomatic severe AS is yet to be determined; in the interim, however, there are no data exploring the use of digitally enabled solutions to guide management in this high-risk patient cohort.

WHAT THIS STUDY ADDS

⇒ APRAISE-AS is the first UK study evaluating the use of remote monitoring and proactive surveillance in people with asymptomatic severe AS. Longitudinal patient self-reported quantitative/objective (functional capacity) and qualitative/subjective (symptoms and disease-specific quality of life) data provide an opportunity for clinical teams through near-real time surveillance to identify people just as symptoms due to ventricular decompensation start to develop and refer them onward for timely valve intervention. A digitally augmented strategy may well lead to improved use of healthcare resources.

INTRODUCTION

On a global scale, the incidence of calcific aortic valve disease and in particular, aortic stenosis (AS) is significant. Prevalence is increasing with an ageing population, such that the condition is expected to affect approximately one in eight people aged ≥75 years.^{1 2} Without treatment, prognosis is poor and, once symptoms develop, mortality is comparable to that of



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HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings of our pilot study indicate remote monitoring and proactive surveillance of symptoms, functional capacity and quality of life can be safely and effectively delivered. Although used in an older group of people, the digital intervention was acceptable, considered user-friendly with high rates of completion of the tests included. APRAISE-AS describes an innovative solution to enable digital transformation of the clinical management pathway for people with asymptomatic severe AS which can be scaled and deployed within healthcare settings.

many metastatic cancers with 5-year survival being between 15% and 50% for people with severe AS.³ In view of the risks of delayed treatment, prompt intervention (surgical/transcatheter) is mandated.³ In truly asymptomatic people, a 'watchful waiting' strategy with 6-monthly clinic-based review is recommended.⁴ The slowly progressive nature of AS combined with the advanced age of the affected population however, predispose to underreporting and/or underestimation of symptoms.⁵ Symptoms often develop insidiously and may be mistaken for age-related decline rather than disease progression.⁶ Moreover, during this period, structural and functional left ventricular changes, for example, hypertrophy or longitudinal global strain may worsen leading to irreversible myocardial damage, which is associated with poor outcomes following intervention and worse long-term survival.⁷ Additional risks associated with a watchful waiting strategy include sudden cardiac death (with an incidence of 1.5% per year) and death while awaiting valvular intervention.^{8,9} The evidence-base to inform the optimal timing of intervention is rapidly evolving with an indication towards a reduction in unplanned cardiovascular and heart failure hospitalisations with early valve intervention. However, this recommendation is taken from a pooled analysis of significantly different clinical trials composed of a relatively young cohort.^{9–11} Currently ongoing trials will further inform clinical decision making regarding the benefits of early valve replacement in a more high-risk cohort that is often reflective of that seen in practice.⁴ Furthermore, not all patients will want to opt for early intervention, many will be of older age with a focus on quality of life; in addition, there is a need for additional effective monitoring of patients beyond the clinic and hospital, not only in severe AS but also other moderate and severe valve disease.

The APRAISE-AS pilot study was developed to determine safety, utility and practical implementation of a novel digital application to support proactive remote patient monitoring, coupled with near real-time clinician surveillance in people with asymptomatic severe AS.¹² The intervention aimed to facilitate the assessment of symptom development, health-related quality of life (assessed using the Kansas City Cardiomyopathy Questionnaire (KCCQ)) and functional capacity (using the timed up and go (TUG) test as a marker of frailty). If found to be a workable solution, the ultimate aim would be to pinpoint symptom onset, pre-empt potential deterioration and guide the optimal timing of valve replacement. This pilot study aimed to (1) test the trial protocol (2) evaluate acceptability of the APRAISE-AS intervention and (3) inform the selection of outcome measure(s) and sample size for a full-scale randomised controlled trial (RCT).

METHODS**Study design**

APRAISE-AS was a 12-month open-label, two-arm, parallel group randomised controlled pilot trial conducted in two tertiary cardiac centres and was designed to assess the trial protocol and determine recruitment and retention rates, data collection procedures and data completeness. The study also evaluated acceptability of and adherence to the APRAISE-AS intervention. Furthermore, the trial was designed to inform the selection of the most appropriate primary outcome measure for a full-scale RCT and has been conducted as per Consolidated Standards of Reporting Trials (CONSORT) guidance for the delivery of randomised pilot trials.¹³ The trial protocol has been previously published¹² and was reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.¹⁴ Delivery of the trial was overseen by a trial management group and an independent trial oversight committee was responsible for data monitoring and ensuring overall safety.

Participants

Adults (aged ≥ 18 years) with a confirmed diagnosis of severe asymptomatic AS and able to access and use app-based programmes were eligible for enrolment and recruited from two tertiary cardiac centres. Participants were excluded if there was evidence of (1) cognitive decline and/or lack of capacity, (2) moderate or more severe disease of other valves or (3) comorbidities that would preclude successful valve intervention, for example, life expectancy of less than 2 years. A complete list of inclusion and exclusion criteria has been published previously.¹² All participants provided written informed consent.

Recruitment and randomisation

Potential participants were screened by the clinical research team; eligibility was assessed against predefined protocol inclusion/exclusion criteria and following review of the participants' clinical record. Suitable subjects were approached via telephone or during routine clinic visits by the research team and were given a patient information sheet. For those who expressed an interest in taking part in the trial, consent, enrolment and baseline data collection and assessments of symptom status, functional capacity and quality of life were undertaken prior to randomisation.

Participants were randomly assigned in a 1:1 ratio to either standard care (control arm) or standard care supplemented with the APRAISE-AS intervention (intervention arm). Randomisation and treatment allocation was undertaken by Birmingham Clinical Trials Unit using a computer-generated sequence created by a programmer independent to the study team. To ensure balance in the intervention allocations, a minimisation algorithm was applied which took into consideration age ('<50 years' and ' ≥ 50 years'), sex assigned at birth ('male' and 'female') and ethnicity ('white' and 'non-white'). In addition, a random element was incorporated into the randomisation algorithm to reduce the likelihood of the intervention allocation becoming predictable.

Procedures

The trial intervention has been described in detail elsewhere.¹² In brief, the APRAISE-AS intervention consisted of two components; a patient-facing digital application facilitating qualitative/subjective (eg, symptoms and quality of life) and quantitative/objective (functional capacity) data capture of patient self-reported

symptoms, functional capacity and disease-specific health-related quality of life. Data from the patient-facing app were collated and presented via a clinician's portal which allowed for near-real-time surveillance of patient self-reported healthcare data; the aim being to enable clinical prioritisation of patients who demonstrated early warning signs of decompensation or symptom deterioration to allow for escalation of treatment and/or earlier referral for consideration of valve replacement. Over a 12-month period, participants used the app to self-report information relating to:

- Symptoms (assessed using New York Heart Association and Canadian Cardiovascular System classification) dyspnoea/fatigue/palpitations/angina and syncope) on a weekly basis.
- Frailty/functional capacity (TUG test) every 2 weeks (frailty, assessed using gait speed, is known to correlate with major morbidity and mortality after valve surgery and provides a continuous reproducible measure allowing for an assessment of functional status over time).^{15 16}
- Disease specific patient-reported outcome measures (PROMs) using the KCCQ once a month (KCCQ has been studied extensively in the setting of AS and has been found to be a reliable, reproducible and valid measure of symptoms, functional status, quality of life and prognosis).^{17 18}

All participants continued with 6-monthly in-person follow-up appointments; patient self-reported data supplemented clinical reviews during routine follow-up appointments in the valve surveillance service. Participants allocated to standard care were not given access to the digital application. Given the nature of the intervention, it was not possible to blind patients or clinicians to the treatment arm to which participants were allocated.

Outcomes

The primary outcome of this pilot was to assess recruitment and retention, data collection processes, data completeness, adherence to and acceptability of the APRAISE-AS intervention. Secondary outcomes are described in the previously published protocol paper and include collection of data pertaining to KCCQ, TUG, time to valve replacement, in-hospital, 30-day and 1-year mortality, incidence of unplanned hospital admissions and healthcare resource utilisation.¹² The patient-reported outcomes and tests for assessment of functional capacity and symptoms were selected after consultation with patients living with AS in addition to the opinions of clinical experts in the management of AS. A robust body of literature describes the association between functional capacity (determined using gait

speed) and health-related quality of life (assessed using the KCCQ) with clinical outcomes in people diagnosed with AS.^{15 17} The primary and secondary outcomes measures were chosen to inform a proposed full-scale RCT in which the clinical and cost effectiveness of remote monitoring with proactive surveillance/reporting of symptoms, functional capacity and quality of life in the context of earlier detection of a change in clinical status with earlier/timelier referral for intervention can be determined.

Statistical analysis

Since this was a pilot study, a formal sample size calculation was not undertaken. Published recommendations for pilot studies suggest a requirement of 30 patients or more to obtain estimates of the parameters needed to determine sample size.^{19 20} Assuming a loss to follow-up rate of just under 10% over the 12-month follow-up period, this pilot study planned for 33 patients to be randomised to each group, with a total of 66 patients overall. This would allow estimation of recruitment and retention rates with 95% CI maximum widths of 20% and 25%, respectively.

Although not required a-priori for the funding application, a series of thresholds against which to assess trial delivery in relation to overall recruitment, retention and adherence to the intervention are described in [table 1](#). Since a definition of what constitutes adherence to the intervention was not predefined in the trial protocol, the level of engagement with the intervention and completion of the tests were part of the primary outcomes. As such, completion data for the symptom's questionnaire, TUG test and health-related quality of life questionnaire were calculated based on the number tests completed compared with the expected number of tests for each patient.

Recruitment and retention rates were reported as numbers and percentages along with Agresti-Coull method based 95% CIs. For all other outcomes, estimates of differences between groups (ie, mean difference, HR) were presented with two-sided 95% CIs. Participants were analysed in the intervention group to which they were randomised, and all participants were included whether they received the allocated intervention. All primary analyses (primary and secondary outcomes including safety outcomes) were based on the intention-to-treat (ITT) principle.

For secondary outcomes that are continuous and were collected at multiple time-points, difference between group means and associated 95% CI at each time point (ie, 6 and 12 months) were estimated using a repeated measures mixed-effects linear regression model. Parameters allowing for patient, intervention arm, baseline score, time and the randomisation

Table 1 APRAISE-AS proposed outcome targets and achievement

	Red	Amber	Green	Observed percentage (n/N %; 95% CI) Mean (SD)
Recruitment				
Proportion of eligible participants (as assessed by the researchers) meeting eligibility criteria and agreeing to participate	<40%	40–50%	>50%	38/123 31 (23 to 40)
Retention				
Proportion of participants remaining in the study at 12 months	<50%	50–60%	>60%	36/38 95 (82 to 99)
Intervention adherence				
Symptoms test (weekly)	Mean adherence <75%	Mean adherence between 75% and 90%	Mean adherence >90%	81 (18.6)
TUG test (biweekly)	Mean adherence <75%	Mean adherence between 75% and 90%	Mean adherence >90%	91 (10.9)
KCCQ (monthly)	Mean adherence <75%	Mean adherence between 75% and 90%	Mean adherence >90%	93 (8.8)
KCCQ, Kansas City Cardiomyopathy Questionnaire; TUG, timed up and go.				

minimisation variables were included. Time was assumed to be a categorical (fixed) variable; to allow for a varying treatment effect over time, a time by treatment interaction parameter has been included in the model, which was fitted via restricted maximum likelihood. A compound symmetry covariance structure was assumed. Estimates of the least-squares mean differences between groups at each time-point were estimated from the model including this interaction parameter. For any time to event outcomes, the numbers of patients and percentages experiencing the event were summarised over time between groups with estimates of HR and the corresponding 95% CI presented using a Cox-proportional hazards model where appropriate.²¹ Kaplan-Meier survival curves were constructed for visual presentation of any time-to-event data where applicable (online supplemental materials).

Analyses were performed on all available data (without any imputation) using SAS software, V.9.4 (or higher) and Stata software, V.18 (or higher). All model based analyses were adjusted for the minimisation variables and baseline values (where available). Full details regarding the analysis methods are provided in the statistical analysis plan.

Patient and public involvement

Members of a local hospital patient charity which comprised people living with heart disease reviewed the research protocol and gave constructive feedback regarding the research question and study design. A patient advisory group (PAG) was established to inform the development, testing and refinement of the APRAISE-AS app via a process of participatory design. The PAG supported user testing of the app and their input guided the frequency of reporting for the symptoms, TUG and health-related quality of life assessments to ensure acceptability in terms of burden from a patient's perspective. The PAG also reviewed all patient facing materials and will support dissemination of trial findings among relevant patient groups.

RESULTS

Between 19 January 2023 and 26 February 2024, 428 patients were screened for eligibility in two tertiary cardiac centres. 305 (71%) were not considered eligible due to the reasons described in figure 1 which meant 123 (29%, 95% CI 25% to 33%) were eligible. Of the 123 (29%) that were eligible and approached to

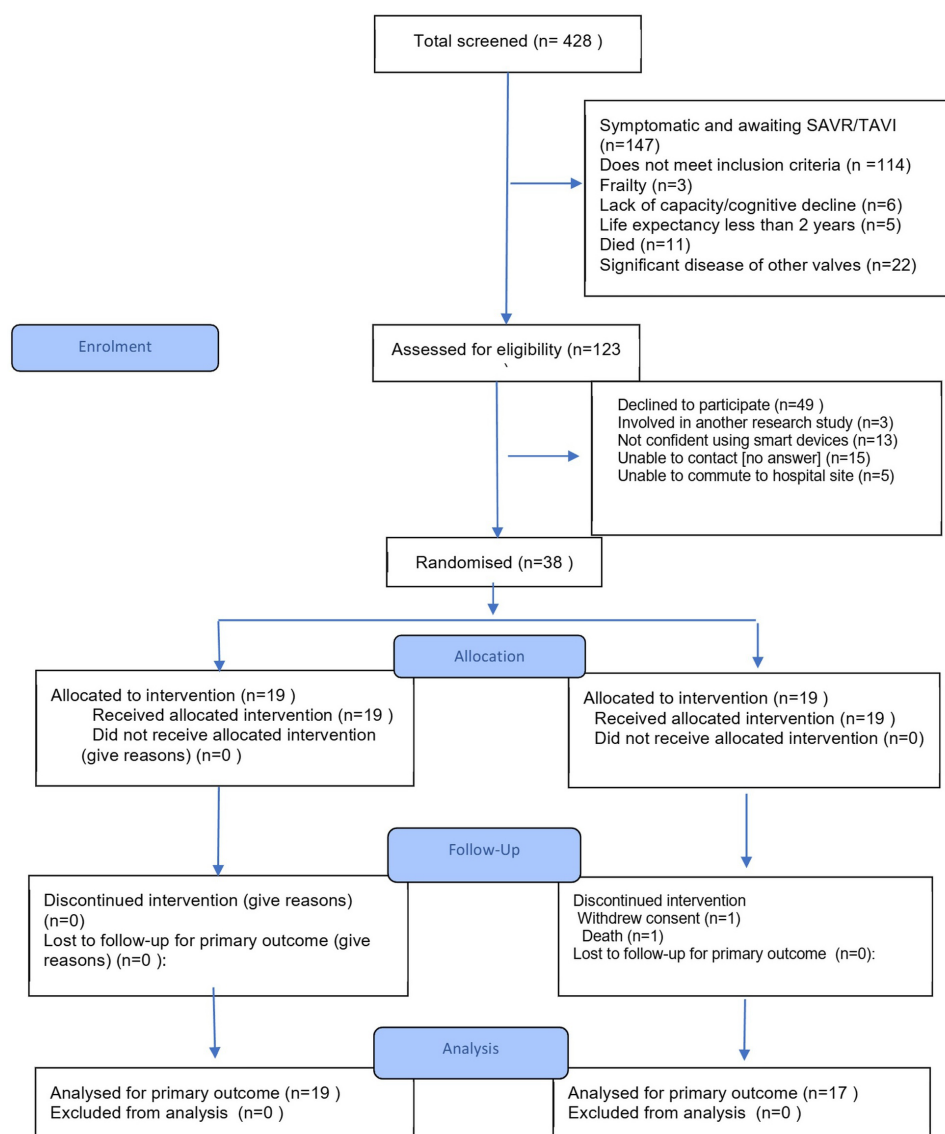


Figure 1 CONSORT 2025 flow diagram. CONSORT, Consolidated Standards of Reporting Trials; IC, inclusion criteria; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

Table 2 Baseline characteristics and demographic data

Baseline characteristics		Intervention (n=19)	Standard care (n=19)	Total (n=38)
Age (years)	Mean (SD)	75.2 (12.9)	75.5 (11.9)	75.4 (12.2)
Sex assigned at birth, n (%)	Male	13 (68)	12 (63)	25 (66)
	Female	6 (32)	7 (37)	13 (34)
Ethnicity, n (%)	White	17 (89)	18 (95)	35 (92)
	Non-white	2 (11)	1 (5)	3 (8)
Height (cm)	Mean (SD)	168.8 (9.2)	167.9 (7.6)	168.3 (8.4)
Weight (kg)	Mean (SD)	77.9 (19.2)	75.3 (14.8)	76.6 (16.9)
BMI (kg/m ²)	Mean (SD)	27.2 (6.0)	26.6 (4.1)	26.9 (5.1)
Systolic BP (mm Hg)	Mean (SD)	142 (20)	144 (19)	143 (19)
Diastolic BP (mm Hg)	Mean (SD)	76 (7)	81 (10)	78 (9)
Heart rate (bpm)	Mean (SD)	76 (11)	77 (16)	76 (14)
Creatinine (micromol/L)	Mean (SD)	80 (26)	81 (25)	80 (25)
eGFR (ml/min)	Mean (SD)	76 (15)	74 (16)	75 (15)
NYHA class-n (%)	Class I	13 (68)	16 (84)	29 (76)
	Class II	6 (32)	3 (16)	9 (24)
Smoking status	Person who has quit smoking	6 (32)	8 (42)	14 (37)
	Person who has never smoked	13 (68)	11 (58)	24 (63)
Echocardiogram data				
LVEF (%)	Mean (SD)	61 (5)	60 (4)	60 (4)
Aortic valve area (cm)	Mean (SD)	0.8 (0.2)	0.7 (0.1)	0.7 (0.2)
Mean pressure gradient	Mean (SD)	43.4 (8.9)	39.9 (11.5)	41.6 (10.3)
Comorbidities				
History of ischaemic heart disease		3 (16%)	6 (32%)	9 (24%)
Previous myocardial infarction		0 (0%)	3 (16%)	3 (8%)
Previous PCI		0 (0%)	2 (11%)	2 (5%)
Previous CABG		2 (11%)	2 (11%)	4 (11%)
Previous stroke/TIA		2 (11%)	2 (11%)	4 (11%)
Atrial fibrillation		4 (21%)	5 (26%)	9 (24%)
Hypertension		10 (53%)	9 (47%)	19 (50%)
Hypercholesterolaemia		8 (42%)	9 (47%)	17 (45%)
Diabetes		4 (21%)	4 (21%)	8 (21%)
Asthma		3 (16%)	1 (5%)	4 (11%)
COPD		0 (0%)	2 (11%)	2 (5%)

BMI, body mass index; BP, blood pressure; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; TIA, transient ischaemic attack.

take part in the pilot study, 38 patients (31%, 95% CI 23% to 40%) consented to participation and underwent baseline assessments prior to randomisation; 19 (50%) were randomised to standard care and 19 (50%) were randomised to standard care plus the APRAISE-AS intervention, as described in figure 1. For those participants who were deemed eligible to take part in the trial and were approached, the main reasons for declining participation were not wanting to take part in research (n=49, 40%) followed by not feeling confident in using a smart device/app based programme (n=13, 11%). Of those patients who consented and were randomised, 36 (95%, 95% CI 82% to 99%) completed the trial. All 38 participants were included in the ITT population.

The two groups were well balanced in terms of baseline characteristics and comorbidities (table 2); the mean (SD) age of all participants was 75.4 (12.2) years demonstrating that older age did not deter from engagement with the intervention. Of the participants recruited to the trial 25 (66%) were male and 35 (92%) participants were white. The mean ejection fraction at baseline was 60% (SD 4.4; range 50–70%).

Primary outcome measures

This pilot study was not powered to detect a difference in outcome measures, but was designed to determine whether there may be any issues with patient recruitment or retention and importantly to ensure processes for data collection were robust, the completion of tests was optimum, all of which in turn will inform the delivery of and the principal outcome measure(s) for the main RCT.

Recruitment and retention

Recruitment to the trial was undertaken in two tertiary cardiac centres; The Royal Wolverhampton NHS Trust and Queen Elizabeth Hospital Birmingham. Although the target sample size was not met, once participants were recruited, they continued with the study until its completion. 38 of 123 eligible participants were recruited; the recruitment rate from those eligible is (38/123)=0.31 with a precision estimate (95% CI) of (0.23 to 0.40). While no participants were lost to follow-up, one participant died during the 12-month follow-up period. One

Table 3 Summary of patient and clinician feedback regarding the APRAISE-AS intervention and suggested improvements

Theme	Comments and/or suggested improvement(s)
Ease of use of the APRAISE-AS intervention	Participant: "The app was easy to use as was access to, completion of and submission of the questionnaires" "Using the app was mostly straightforward and it was very reassuring to be monitored so thoroughly" "Overall, worked well and tests were easy to complete, but the notifications weren't constant" Clinician: "Onboarding to the app is straightforward. Using the portal is easy enough and gives a trend of how the patient is doing in between clinic appointments" "Being able to access patient self-reported information and look at trends in between clinic visits allowed for a more informed discussion at the 6-monthly follow-up appointment"
Patient empowerment	Participant: "The app made me think more clearly about my condition and symptoms, giving me more confidence to keep fit despite my severe condition" "I found it reassuring to know I was being monitored in the background" "Taking part in the study has increased my own awareness of the condition" "The communication of app content with the clinical team was reassuring"
Informing patient care	Participant: "The tests completed on the app gave updates on progress and at the clinic appointment was used to plan care" Clinician: "The severe symptom notifications were helpful, and often when contacting the patient, it didn't warrant any further intervention, but in some people did flag a change which then resulted in a clinical review and subsequent intervention"
Notification reminders	Participant: "the reminders to complete the app didn't always come through, so I set a reminder on my phone" "Notifications were intermittent"
Suggested improvements:	
Log-in	Participant: "The login was complicated, easier login through use of finger/thumb print"
Ease of access	Participant: "It isn't always easy to read the questions on an iPhone and once downloaded the app couldn't be used on another device like a tablet"
Greater clarity regarding the questionnaires	Participant: "The wording of the questions was not easy to follow; these could be made easier to follow" "The questions were long-winded and often the ask is not clear, this isn't good for people with low health literacy. You should consider the average reading age of the population"
Timed up and go test	Participant: "The on-line stopwatch did not seem very responsive potentially over-estimated the time taken to complete the test" "more reliable Start/Stop controls"
Notification reminders	Participant: "Ensure reminders are set up when setting up the app initially"

participant proceeded to valve replacement soon after randomisation to standard care and asked to withdraw from further follow-up. Overall retention of trial participants (36/38, 95%) at 12 months was high, with a precision estimate of 0.82 to 0.99 (95% CI).

Data collection, data completeness, adherence to and acceptability of the APRAISE-AS intervention

Data collection processes were robust as demonstrated by the average adherence to and data completeness described in [table 1](#). Symptoms were reported by participants on a weekly basis with an average adherence/completion rate of 81% (SD 18.6). Functional capacity using TUG was reported by participants on a fortnightly basis with an average adherence/completion rate of 91% (SD 10.9). Health related quality of life, using KCCQ was reported by participants monthly with an average adherence/completion rate of 93% (SD 8.8) (see online supplemental materials).

Analysis of the primary outcome measures demonstrated good engagement and acceptability of the intervention from both participant and clinician perspectives. As described in [table 3](#), participant and clinician feedback regarding their experience of taking part in the trial and in particular use of the APRAISE-AS intervention was positive. Assessment of app utility from a patient's perspective indicates they felt reassured their symptoms, quality of life and levels of activity were being monitored

in between appointments. All participants felt the app was easy to use, however, they would have preferred to be able to access the app on multiple devices rather than just a smartphone. This was not felt to be prohibitive to participation in the trial. The log in process was found to be difficult for some participants, but recording of symptoms, quality of life and functional capacity was relatively quick and easy. Notification reminders to complete the tests, although intermittent, were felt to be helpful. From a clinician's perspective, near real-time surveillance of patient reporting symptoms, functional capacity and quality of life via the clinician's portal was considered straightforward and the data contained within could be used to supplement clinical review appointments.

Secondary outcome measures

Inclusion and collation of the secondary outcome measures was undertaken to determine how readily these data could be collected during the pilot study. In addition, these outcomes will be used to inform selection of the most appropriate outcome measure(s) in addition to informing a sample size calculation when transitioning to a larger scale RCT.

Severe symptoms/red flag notifications and subsequent actions (healthcare resource utilisation) data are described in [tables 4 and 5](#) respectively. Over the duration of the study, a total of 693 symptom tests, 483 TUG tests and 248 health-related quality of life questionnaires were completed by participants randomised

Table 4 Summary of severe symptom notifications (intervention arm)

Symptom	Number of symptoms tests completed using the intervention	Severity				Total number of times reported	Total number of red flag/severe symptom notification generated	Severe symptoms notifications as a proportion of the total number of times reported (n=302)
		Nil (NYHA I/CCS I)	Mild (NYHA II/CCS II)	Moderate (NYHA III/CCS III)	Severe (NYHA IV/CCS IV)			
Dyspnoea		19	55	5	1	80	1	0.3%
Palpitations		14	1	0	0	15	0	0%
Fatigue		31	62	18	1	112	1	0.3%
Dizziness		–	–	–	–	68	68	22.5%
Lower leg/ankle swelling		–	–	–	–	16	16	5.3%
Chest pain		3	2	5	1	11	1	0.3%
Syncope		–	–	–	–	0	–	0%
Total	693					302	87	28.8%

CCS, Canadian Cardiovascular System; NYHA, New York Heart Association.

to the intervention. For those randomised to standard care, these tests were undertaken at baseline, 6-month and 12-month follow-up appointments. Of those allocated to the intervention 13 (68.4%) participants reported a total of 87 severe symptoms relating mainly to dizziness (22.5%), peripheral oedema (5.3%), breathlessness (0.3%) and fatigue (0.3%). One participant reported chest pain (0.3%). Seven notifications for a clinical review were triggered by a >10-point change from baseline for those submitting their health-related quality of life questionnaire (KCCQ). Subsequent healthcare related contacts in response to the symptoms noted and changes in KCCQ were predominantly in the form of a telephone call; 10 contacts resulted in onward referral for aortic valve replacement and 5 contacts resulted in a clinic review.

As described in table 6, the mean (SD) time taken to complete the TUG test in the intervention arm was 11.6 (3.3) s and in the standard care arm was 11.2 (3.9) s at baseline compared with 10.8 (2.8) s in the intervention arm and 13.1 (9.1) s in the standard care arm at 12 months, demonstrating a 3-second difference (95% CI –6.2 to 0.2) between the two arms over the 12-month duration of follow-up. Health related quality of life was assessed using the KCCQ overall summary score (KCCQ-OSS); mean (SD) at baseline in the intervention arm was 92.2 (8.6) and 90.0 (13) at 12 months. In the standard care arm, at baseline KCCQ-OSS was 91.8 (11.7) compared with 87.0 (15.1) at 12 months. The overall difference in KCCQ-OSS at 12 months between groups was 3.2 (95% CI –3.6 to 10.0). Importantly, compared with baseline assessments, quality of life did not change significantly for those participating in the trial, however for those in whom valve replacement was undertaken,

improvement in overall KCCQ score post valve replacement was observed (online supplemental material).

For participants randomised to the intervention arm who reported a severe symptom and/or a clinically meaningful reduction in health-related quality of life, a remote review was undertaken and an in-person clinic appointment arranged if deemed clinically appropriate. In those participants in whom an in-person clinical review was undertaken, seven were referred to the heart team for consideration of aortic valve replacement from the intervention group and the median time from referral to valve replacement was 242 days (IQR 135–302) compared with 175 days (IQR 151–270) in those randomised to standard care (in which group nine were referred for valve replacement).

In-hospital mortality and mortality at 30 days postrandomisation were comparable in both groups; in terms of all-cause mortality at 12 months, one postrandomisation death was noted in the standard care arm, attributed to heart failure with reduced ejection fraction. Left ventricular ejection fraction remained unchanged in both groups. Healthcare resource utilisation data (table 6) indicates that during their 12-month follow-up, a greater proportion of participants randomised to the intervention group required input following a self-report of a severe symptom and/or a deterioration of >10 units from baseline for their KCCQ health related quality of life.

Adverse events and protocol deviations

There were no serious adverse events recorded during the trial. There were two protocol deviations recorded; one relating to an IT/WiFi connectivity issue in which a treatment allocation made was not recorded at the point of randomisation. The second deviation relates to the protocol stipulation regarding the need for an echocardiogram either 7 days prior to or following the 6-month and 12-month review appointments. In many centres, echocardiography access is limited due to workforce/capacity challenges. To avoid increasing workload in an already stretched service, the trial management team agreed that if an echocardiogram could not be undertaken within the window indicated in the trial protocol, this should be considered a protocol deviation. The timing of echocardiograms in relation to follow-up appointments will be reviewed when considering the larger scale RCT.

Table 5 Actions taken following notification of a severe symptom (healthcare resource utilisation)

Nature of contact±outcome	Number
Telephone review only by research/clinical team and no further action	58
Telephone review followed by routine clinic appointment (appointment within next 7 days)	3
Telephone review resulting in expedited clinic appointment	2
Telephone review, referral to heart team and now awaiting AVR	10
Total number of healthcare contacts	73
AVR, aortic valve replacement.	

Table 6 Summary of secondary outcome measures at baseline, 6 months and 12 months

Outcome	Time point	Summary statistic	Intervention (n=19)	Standard care (n=19)	Effect size* (95% CI)
AVR	Within 12 months	N (%)	7 (37)†	9 (47)	0.67 (0.23 to 1.98)‡
		Median (IQR) time to AVR (in days)	242 (135–302)	175 (151–270)	–
		SAVR	2	4	–
		TAVI	5	5	–
		Postvalve replacement events§			–
		Major bleeding (as per VARC clinical outcomes)	0	1	–
		Vascular access site or access related complication	0	1	–
		Acute kidney injury	0	1	–
		Conduction disturbances and/or arrhythmia	2	4	–
LVEF (%)	Baseline	N; Mean (SD)	19; 61 (5)	19; 60 (4)	–
	6 months	N; Mean (SD)	19; 62 (6)	17; 59 (5)	2.6 (–1.1 to 6.2)
	12 months	N; Mean (SD)	19; 61 (8)	17; 58 (5)	2.4 (–1.2 to 6.1)
KCCQ overall score (0–100)¶	Baseline	N; Mean (SD)	19; 92.2 (8.6)	19; 91.8 (11.7)	–
	6 months	N; Mean (SD)	19; 91.7 (8.4)	17; 91.0 (11.7)	0.9 (–5.8 to 7.7)
	12 months	N; Mean (SD)	19; 90.0 (13)	17; 87.0 (15.1)	3.2 (–3.6 to 10.0)
Time-up and go test	Baseline	N; Mean (SD)	18; 11.6 (3.3)	19; 11.2 (3.9)	–
	6 months	N; Mean (SD)	18; 11.5 (4.7)	16; 10.9 (3.5)	–1.9 (–5.1 to 1.3)
	12 months	N; Mean (SD)	18; 10.8 (2.8)	17; 13.1 (9.1)	–3.0 (–6.2 to 0.2)
Unplanned hospital admissions	Within 1 year	N (%)	3 (16)	1 (5)	–
		Total N of hospital unplanned admissions	3	2	–
Death	In-hospital mortality	N (%)	0 (0)	0 (0)	–
	Within 30 days	N (%)	0 (0)	0 (0)	–
	Within 1 year	N (%)	0 (0)	1 (5)	–
Incidence of stroke	Within 1 year	N (%)	0 (0)	1 (5)	–
Incidence of MI	Within 1 year	N (%)	0 (0)	0 (0)	–

*All treatment effects are shown as the mean between-group difference except as marked. All analyses were adjusted for minimisation variables and baseline value (where available). For any outcomes that were continuous data and collected at multiple time points, the time point and treatment according to time interaction were also included in the model.

†One patient had their AVR after their 12 months visit was completed but as this was reported in the trial, we have included this in the analysis.

‡This treatment effect is reported as a HR.

§Not mutually exclusive.

¶0=worst score and 100=best score so higher scores indicating better outcome.

AVR, aortic valve replacement; HR, hazard ratio; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVEF, left ventricular ejection fraction; MI, myocardial infarction; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; VARC, Valve Academic Research Consortium.

DISCUSSION

To our knowledge, this is the first UK study to show that remote monitoring and proactive surveillance of symptoms, functional capacity and quality of life using a mobile app is both feasible and safe in an elderly population of patients with severe asymptomatic AS. Our findings indicate the trial protocol can be delivered and the outcome measures collected will inform the development of a full-scale RCT.

Digital data collection processes were robust and data completeness in the intervention group was high with 81% of symptom tests, 91% of the TUG tests and 93% of the health-related quality of life questionnaires being submitted within the specified time window, despite the elderly population being studied. End user feedback indicated that the study intervention was well received by both participants and clinicians demonstrating proof of concept and safety in delivery of the intervention in people with asymptomatic severe AS. There were, however, improvements suggested to further increase the likelihood of participant engagement, given that a proportion of people did not feel comfortable using a smart device. Specifically, it was recommended that future enhancements of the remote monitoring platform should allow for access on desktop/laptop-based devices in addition to smart devices through use of a URL rather than an app-based front end.

Clinicians were able to use the clinical portal to monitor participants in between clinic appointments and found the notification of severe symptoms helpful to assess whether participants would benefit from an earlier review. Given standard outpatient appointments are on average 6 months apart for people with asymptomatic severe AS, and symptom onset is often insidious and mistaken for age related decline, early detection using remote monitoring allowed for earlier recognition of critical symptom development which acted as the trigger for clinical review and onward referral for valve intervention. Allowing clinicians to respond to a change in clinical status sooner than had the patient been reviewed at their 6 monthly clinical appointment. In addition, it was noted that 6 monthly clinic reviews provide single time point clinical assessments; however, longitudinal data collected over time (as with the intervention) provides insights into steady decline which otherwise would not be appreciated as disease progression/symptom development, particularly when incorporating disease-specific health related quality of life PROMs and frailty measures into the clinical assessment. A schematic describing the flow of information between the patient facing app and clinical portal can be found in [figure 2](#) and online supplemental file 1.

Clinicians involved in the trial recommended a review of which symptoms and when patient self-reporting of a symptom

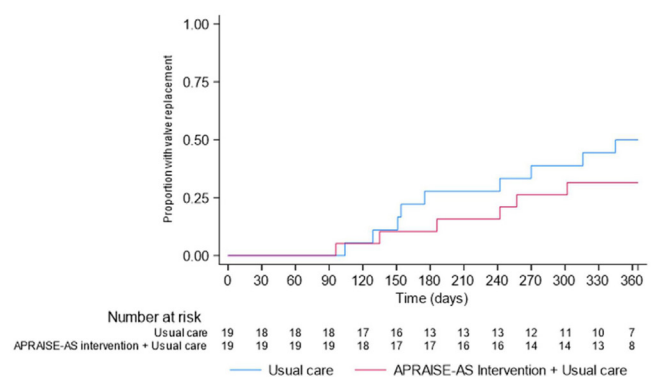


Figure 2 Time to aortic valve replacement.

should trigger a notification to the clinical team. For example, in our trial cohort (particularly in those assigned to intervention arm), dizziness was the most frequent symptom that generated a red flag notification. When reviewed by a clinician however, the dizziness reported was not related to physical exertion and was often a pre-existing/long-standing concern. Dizziness is a relatively common symptom in the older age group included²² and loses sensitivity and specificity if not associated with physical exertion in the context of severe AS.²³ Exertional dizziness was proposed as a symptom against which to review the patient based on clinical consensus from those involved in the design of the trial. Although in clinical practice exertional syncope/presyncope is associated with poor outcomes and warrants immediate referral for valve replacement, most patient contacts in the trial were about dizziness not related to pre-syncope or exertion. Dizziness per se is a symptom that is common in those of median age 75 years, but which the clinicians found non-discriminatory. When transitioning to the main RCT, if dizziness is reported, further clarification will be sought whether this is precipitated by exertion or is associated with syncope. Clinical review will then be warranted if the participant suffers from exertional angina, exertional syncope and/or the development of heart failure, since these are indicative of haemodynamic progression to severe symptomatic AS and are associated with poor outcomes.²⁴

In this pilot of mainly elderly patients, participant retention was high and there were good levels of patient engagement and activation. Patient activation (ie, the knowledge and confidence a person has in managing their health) particularly in older people living with long-term conditions and multi-morbidity, has been associated with improved health-related quality of life.²⁵ KCCQ overall summary score (KCCQ-OSS) is the most common parameter against which health status is assessed prior to and after aortic valve replacement in the interventional AS trials. Our data indicate that participants taking part in the trial had good health related quality of life at the outset and throughout the duration of the study. For those in whom valve replacement was undertaken, KCCQ increased to levels (KCCQ-OSS=100) where participants were no longer troubled by any symptoms or limitations in functional capacity secondary to their AS (see online supplemental materials figure 2). These findings are supported by published data in which PROMs have been associated with prognostic and health-economic value following cardiac intervention.²⁶

The TUG test was used as a surrogate marker for frailty and gait speed was used to assess functional status over time, owing to its association with prognosis in people with AS. Although there are data describing an association between gait speed and

poor outcomes, the TUG test did not generate any red flag alerts in the pilot trial; indicating overall good baseline levels of functional capacity for those participating in the trial as described in table 6. When transitioning to the larger trial, and acknowledging the increasing adoption of wearables, there is an opportunity to incorporate step count to track both activity and inactivity, to allow for the prevention, detection and monitoring of long-term health conditions as described in the National Health Service 10 Year Health Plan.²⁷

Severe AS even in asymptomatic patients can predispose to progressive left ventricular dysfunction, which is associated with poor outcomes following valve intervention.²⁸ Ventricular function may not fully recover even after intervention. Reassuringly, our echocardiography data for participants who underwent valve replacement indicate that despite the development of symptoms and/or reduction in quality of life, the timing of intervention was such that it took place before irreversible myocardial damage occurred.

While the time from a change in clinical status to aortic valve replacement appears to be shorter in the standard care arm, it is highly likely trial participants have increased awareness of clinically important changes in symptoms/functional capacity because of their participation in the trial.

This is not an unusual phenomenon and is known as the participation effect or the Hawthorn effect; where patients in clinical trials, including those in the control arm experience better health outcomes when compared with the intervention arm.²⁹ As such, the standard care cohort in the pilot study is not truly reflective of the watchful waiting cohort encountered in routine clinical practice. For historical controls from one of the recruiting sites, the median time for diagnosis of severe AS to aortic valve replacement was longer, at 325 days (IQR 177–1291).

Patients in both arms had enhanced access to healthcare providers, not needing to go through the usual UK primary/secondary care interface to trigger clinical review or therapy (as is the case in most trials). They could simply contact the research team and speak to a clinical specialist within a matter of days. In addition, clinicians not only had access to patient-initiated contact for those on remote monitoring but also long their longitudinal self-reported data. This meant inevitably that clinicians were more aware of the health status of the participant, as they had more data on which to base judgements regarding the timing of intervention. In this pilot study, this led to a longer time to intervention without an increase in risk from that delay. The additional information from remote monitoring provides enhanced insights into participant health and well-being, leading to safer practice and better timing of intervention. We accept however that we do not have enough proof to exclude unnecessary healthcare utilisation without clinical benefit. The full-scale RCT will collect information in terms of clinical benefit, including procedural complication rates, hospital admissions, heart failure episodes and mortality. Our pilot study has however shown is that remote monitoring is feasible, acceptable and safe.

When considering the primary outcomes measure(s) to determine sample size for the full-scale RCT, KCCQ is a reliable, responsive and reproducible validated health status instrument.¹⁸ However, given the evolving evidence base and guideline recommendations regarding the optimal management strategy in people with severe AS it is likely outcomes relating to a composite of all-cause mortality, unplanned hospitalisations (eg, stroke, heart failure) in addition to a quality of life measure may be appropriate to compare a watchful waiting strategy augmented with remote monitoring and proactive symptom surveillance versus valve intervention.

Further research is needed also to an expanded role for remote monitoring in all types of heart valve disease, and in less than severe categories.

LIMITATIONS

In this current study, the recruitment rate per month was less than predicted. This was largely attributable to the prolonged recovery post-COVID 19 when research staff were still diverted to restoration of clinical services in the two recruiting National Health Service (NHS) organisations. In addition, when reviewing the reasons potential participants gave for not wanting to take part in the trial when deemed eligible (figure 1), a small proportion were not confident in using smart devices (15%). It is noteworthy that the two recruiting sites are in the most deprived integrated care boards in the country, with ethnically and racially diverse populations, with 15.6% having English as a second language. In future, we will add patient facing resources and short videos in appropriate language formats to describe the remote monitoring platform when transitioning to a larger RCT. However, when considered in the context of other RCTs undertaken in this cohort, approximately over half of those participants screened for eligibility were randomised.^{10 11} On scaling to a larger RCT, suboptimal recruitment could be addressed through extending the window over which recruitment takes place, developing access via a URL based platform accessible on computers, tablets and smart devices, producing short videos describing how to use the patient facing app, in addition to targeting participant selection through valve surveillance clinics which are now well established in most NHS hospitals. The APRAISE-AS investigators will make a concerted effort to ensure females and those from ethnic minority under-represented groups in addition to the targeted selection of participants from areas of deprivation so as not to widen health inequalities when developing the full-scale RCT.

Overall, the pilot trial demonstrated that participants were willing to take part in a trial in which the safety and utility of remote patient monitoring in the context of asymptomatic severe AS was used to supplement standard care. Our findings indicate that the intervention can be safely delivered, the design of the app was found by participants to be user-friendly and the high rates of adherence/completion of tests indicate that the frequency of reporting was not onerous. From a patient and clinician perspective the intervention was found to be acceptable and a full-scale RCT is feasible. The APRAISE-AS intervention provides a scalable innovative and effective remote monitoring platform that can be used to support the delivery of care to people diagnosed with severe asymptomatic AS.

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