Reviewer ID	
Date	

ADMINISTRATION DETAILS	
Study ID	
Publication status	
Papers this study may link with	
AIM OF THE STUDY	
STUDY DETAILS	
Study design	
Country	
Number of centres	
Sample identification	
Method of recruitment	
Allocation method	
Study dates	
Duration of the study	
Length of follow up	
Eligibility criteria for the study	
Inclusion criteria	
Exclusion criteria	
Interventions and comparators	
Comparisons (Intervention versus comparator)	1. 2.
Settings	
Details of the intervention	
Details of the comparator	

Details of education and training provided	
Details of person involved in the study	
Details of point-of-care tests used for INR monitoring	
Details of laboratory analysers used for INR monitoring	
Type of vitamin K anatagonists used by participants	
Time on anticoagulant therapy	
Primary outcomes reported	
Secondary outcomes reported	
Adverse events reported	
Study power and statististical analysis	
Additional information	
Source of funding	

PARTICIPANTS CHARACTERISTICS			
Number of participants, n (%)	**Total**	**Intervention**	**Comparator**
Screened			
Excluded			
Enrolled			

Excluded			
Randomised			
Excluded			
Analysed			
Excluded			
Discontinued study			
Primary analysis data cut-off date			

Patient baseline characteristics	**Total**	**Intervention**	**Comparator**	**Difference between the groups**
Total participants, n				
Adult, n				
Children, n				
Age (years) (mean/median, SD/range)				
Gender (M/F), n (%)				
Reason for anticoagulation				
Atrial fibrillation, n (%)				
Artificial heart valves, n (%)				
Venous thromboembolism, n(%)				
Other indication, n(%)				
INR target range,n(%)				
2 to 3				
2.5 to 3.5				
□3				
Time on anticoagulant therapy, n(%)				
□3 months				
□6 months				
□12 months				
Receiving treatment with any other blood thinning drugs e,g., clopidogrel, aspirin), n(%)				
Additional information (e.g., comorbidity present, coronary risk factors etc.)				
Feasibility of testing, n (%)				

	Total	Intervention	Comparator	Additional information
Total invited				
Response rate				
Willing to participate				
Provided consent				
Attended training				
Completed training				
Completed intervention				
Reason for the drop-outs, pre randomisation				
Reason for the drop-outs, after randomisation				

OUTCOMES							
Clinical Outcomes/ Adverse events	**Intervention**		**Control**		**Difference between groups**	**p value**	**Additional information**
	Events (n)	**Total (N)**	**Events (n)**	**Total (N)**			
Number of bleeds or blood clots							
Major haemorrhage							
Minor haemorrhage							
Thromboembolic events							
Cerebrovascular events							
Number of deaths							
Number of deaths from INR testing							
Number of deaths from VKA therapy							
Adverse events							
Adverse events from INR testing							

Adverse events from false test results							
Adverse events from VKA therapy and sequelae							

Intermediate Outcomes	specify measures eg mean (SD)	Intervention n=		Control n=		Difference between groups	p value	Additional information
		value	SD, range etc.	value	SD, range, etc.			
Time in therapeutic range for INR (ITT analysis)								
INR values (mean, median/SD, range)								
Test failure rate								
Time to test results								
Patient compliance with testing								
Patient compliance with treatment								
Frequency of testing								
Frequency of visits to primary care clinics								
Frequency of visits to								

secondary care clinics								

Patient reported outcomes	**specify measures eg, mean (SD)**	**Intervention (n=)**		**Control (n=)**		**Difference between groups values (variance)**	**p value**	**Additional information**
		values	**SD, range etc**	**values**	**SD, range etc**			
People anxiety associated with waiting time for results and not knowing their current coagulation status								
Health-related quality of life								
Acceptability of the tests								

Give details of any other outcomes