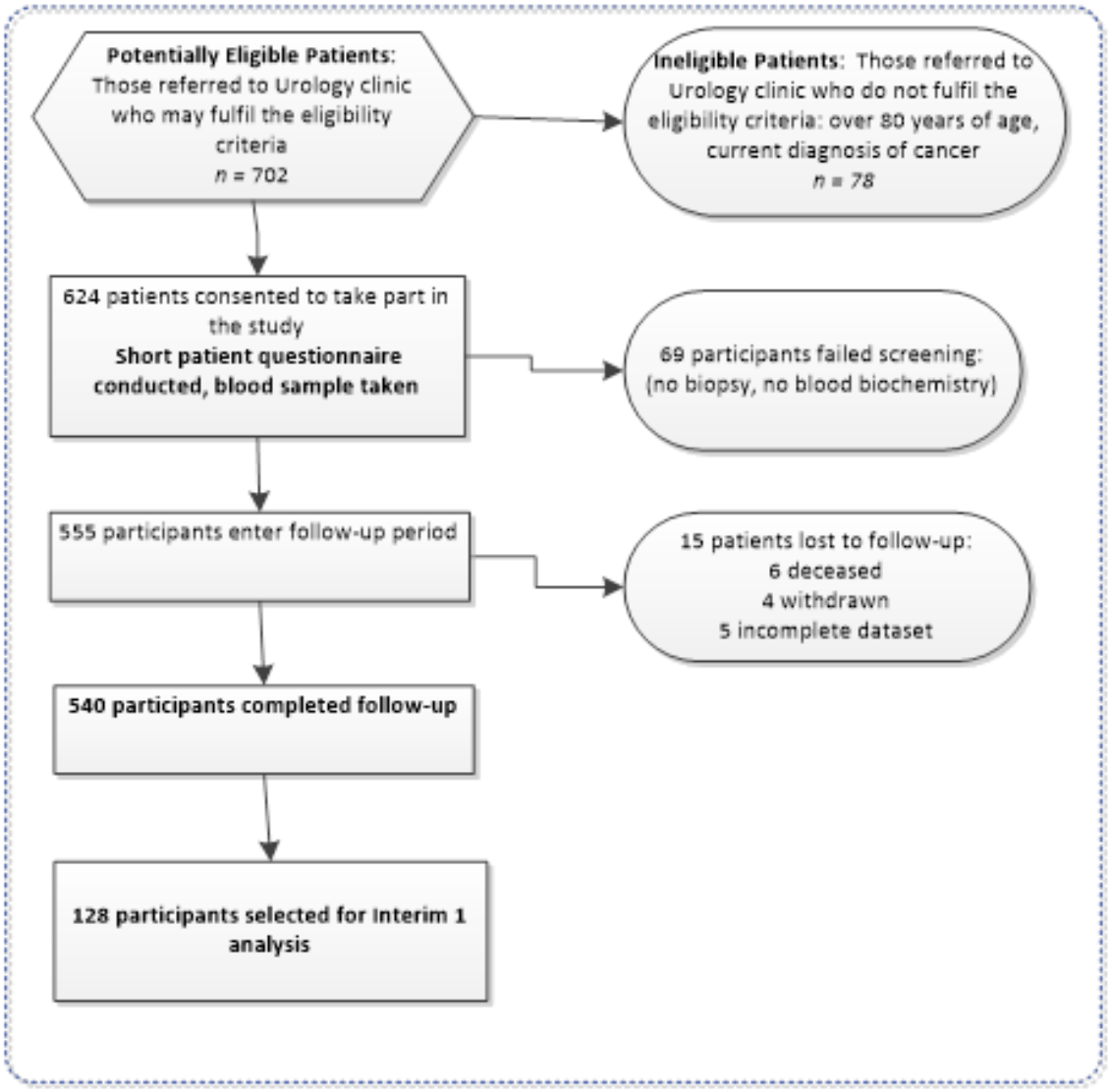
Participant Flow

Participants included in Interim 1 analysis



Baseline Characteristics

A total of 128 male participants were included in the Interim 1 analysis

	Number of participants	Mean	Median	Min, Max
Age at recruitment (years)	128	65.1	65	46, 79
PSA at recruitment (ng/ml)	128	8.03	6.69	2.3, 27.3
Prostate volume at recruitment (cc)	110	44.65	39.7	13, 140

Table 1: Demographic profile and clinical characteristics of the BiopSave participants

DRE findings at recruitment	Number	Percentage	Biopsy derived diagnosis	Number	Percentage
Normal	23	18.3	No abnormality	52	40.6
Small	1	0.8			
Small flat	1	0.8	Prostate cancer	56	43.8
Small benign	21	16.7			
Benign	7	5.6	HG-PIN/ASAP	16	12.5
Firm	4	3.2			
Enlarged benign	22	17.5	BHP	2	1.6
Enlarged	27	21.4			
Slightly enlarged	15	11.9	No Biopsy	2	1.6
Moderately enlarged	4	3.2			
malignant	1	0.8	**Total**	128	100
No DRE performed	2	1.6			
Total	128	100			

Table 2: Clinical characteristics of the BiopSave participants – DRE findings at recruitment

Outcome measures

Primary outcome measure

Model	Mean		% Specificity Quartiles	
	% Sensitivity	% Specificity	1st	3rd
Local PSA	80	21.48	14	27
Prostate BiopSave	80	**60.42**	54.89	66.67
Local PSA	90	11.76	8.33	15
Prostate BiopSave	90	**48.4**	41.67	54.92
Local PSA	95	9.24	6.38	11.67
Prostate BiopSave	95	**40.41**	33.33	47.75
Local PSA	100	5.73	3.33	8.33
Prostate BiopSave	100	**20.02**	8.33	33.33

Table 3: Sensitivity and specificity blind performance bootstrap estimates in the target population for PSA 2.5 to 10 ng/ml

Secondary outcome measures

To be reported following Interim 2 analysis

Adverse Events

There were no adverse events associated with this trial.