Appendix 3: Sensitivity Analyses on the primary outcome

Table S1 Negative-binomial GLMM results for an analysis of the primary outcome assuming an intervention-by-time interaction effect (N=1728, 72 sites)

Variable	Rate Ratio	95% Confidence Interval	P-value
Intervention (Reference category: Control condition)	1.04	0.54 to 2.00	0.901
Time since start of study	1.01	0.96 to 1.07	0.630
December/January (Reference: any other month)	0.54	0.284 to 1.03	0.061
Site location in Scotland (Reference: England/Wales)	2.18	1.06 to 4.5	0.034
Time since introduction of Recruitment Review 3-6 months Over 6 months (Reference 0-3 months)	 0.92 0.392	 0.46 to 1.81 0.183 to 0.84	 0.799 0.016

Table S2 Negative-binomial GLMM results for the **per-protocol analysis** of the primary outcome (using actual intervention timings) (N=1248, 52 sites)

Variable	Rate Ratio	95% Confidence Interval	P-value
Intervention (Reference category: Control condition)	1.01	0.50 to 2.04	0.981
Time since start of study	0.97	0.92 to 1.02	0.288
December/January (Reference: any other month)	0.66	0.333 to 1.31	0.233
Site location in Scotland (Reference: England/Wales)	1.81	0.90 to 3.66	0.097

Table S3 Negative-binomial GLMM results for the secondary analysis of the primary outcome excluding data from the pre- and post- rollout periods (N=792, 72 sites)

Appendix 3: Sensitivity Analyses on the primary outcome

Variable	Rate Ratio	95% Confidence Interval	P-value
Intervention (Reference category: Control condition)	1.07	0.54 to 2.13	0.841
Time since start of study	0.94	0.86 to 1.04	0.246
December/January (Reference: any other month)	0.340	0.133 to 0.87	0.024
Site location in Scotland (Reference: England/Wales)	1.89	0.84 to 4.3	0.126
Average number randomised in first 6 months	18.2	2.00 to 166	0.010

Table S4 Intervention effect results from Negative-binomial GLMMs of the primary outcome using different methods of specifying the time trend (N=1728, 72 sites)

Method of specifying time trend	Intervention Effect Rate Ratio	Intervention Effect 95% Confidence Interval	P-value	AIC
Continuous linear term	1.06	0.55 to 2.03	0.870	885.13
Categorical time (categories are months)	1.22	0.63 to 2.34	0.559	904.38
Categorical time (categories in 5 monthly intervals)	1.00	0.52 to 1.92	0.989	889.92
Spline function: B-spline of order 2 with no interior knots	1.06	0.58 to 1.92	0.858	885.13
Spline function: B-spline of order 3 with no interior knots	1.04	0.63 to 1.72	0.870	885.20
Spline function: B-spline of order 3 with 3 interior knots	1.21	0.62 to 2.33	0.578	889.22
Spline function: B-spline of order 4 with 2 interior knots	1.20	0.62 to 2.34	0.582	890.03
Spline function: B-spline of order 4 with 3 interior knots	1.21	0.63 to 2.33	0.574	890.16

AIC, Akaike Information Criterion