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Supplementary appendix

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Outcomes of SARS-CoV-2 Omicron infection in residents of Long-Term Care in England (VIVALDI): a prospective cohort study

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Supplementary Appendix

Additional methods

Cohort selection

Results of PCR or LFD tests that are performed as part of the national testing programme are linked to the individual's unique National Health Service (NHS) number and to the unique identifier of the LTCF, which is allocated to them by the Care Quality Commission (CQC), the national social care regulatory body. Using these results, residents that reside within LTCFs that are taking part in the VIVALDI study can be identified. A unique pseudo-identifier is created for each resident with a test based on their NHS number and enables linkage to other routinely collected pseudonymised datasets.

Blood sampling procedures

Following written informed consent, up to six sequential serum blood samples have been collected from a subset of study participants between June 11, 2020, and January 17, 2022. [1] These samples undergo testing for SARS-CoV-2 anti-nucleocapsid IgG antibody using the Abbott ARCHITECT i-System immunoassay (Abbott, Maidenhead, UK) at the Doctor's Laboratory in London UK. Results are defined as positive if greater than an index value of 1.4 (as recommended by the manufacturer).

Data sources

COVID-19 testing data: Results of SARS-CoV-2 PCR and LFD testing performed as part of the national testing programme within LTCFs and hospitals are stored with demographic details and CQC identifier. Residents who tested positive for SARS-CoV-2 on PCR or LFD between September 1, 2021, and January 17, 2022 were eligible for inclusion. Positive LFD and / or PCR tests occurring within 28 days of each other were excluded and the earliest sample prioritised for inclusion. Only one infection episode per participant was included. Due to national shortages of PCR tests over December 2021 and January 2022, we included both positive LFD and PCR tests to optimise the capture of infections within our population.

Hospital Episode Statistics Admitted Patient Care (HES APC): Maintained by NHS Digital, this dataset details all admissions to NHS hospitals in England. The dataset is updated daily with dates of admission and discharge and monthly with diagnostic codes. [2]

National mortality dataset: Maintained by the Office for National Statistics (ONS), this dataset contains dates and causes of death for people in England as recorded on death certification. It is estimated that there can be a lag of up to two weeks in reporting, collecting and coding deaths.

National Immunisation Management System (NIMS): Maintained by NHS England and used for national reporting of vaccination coverage, demographic details of all individuals registered with a GP in England alongside details of all COID-19 vaccinations administered in England are recorded in this dataset which is updated daily. [3]

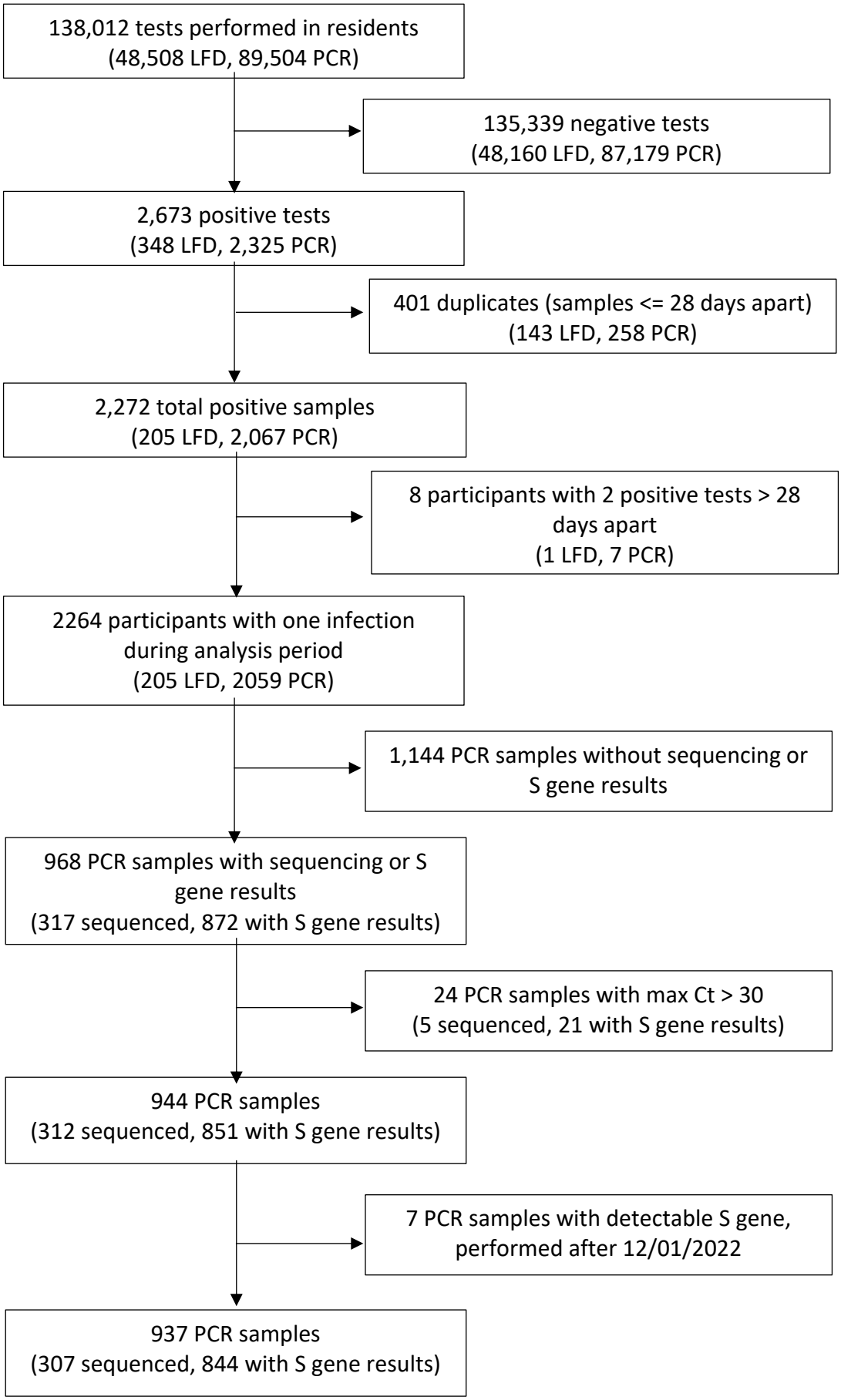
Capacity Tracker: Established by North of England Commissioning Support (NECS) NHS England, this is an online tool that is completed on a daily basis by LTCFs and was established in response to the COVID-19 pandemic to enable LTCFs to report capacity issues. [4]

S-gene results: PCR testing conducted in LTCFs is conducted in a network of accredited laboratories in England, approximately 60% of which use the TaqPath assay (Thermo Fisher Scientific) to detect spike (S), nucleocapsid (N), and open reading frame 1ab (ORF1ab) gene targets. Results are uploaded to the National Pathology exchange (NPEx) database. Using the sample ID number, Cycle threshold (Ct) values were retrieved for positive samples in our cohort. [5]

Sequencing results: As part of the genomic surveillance programme in England, a subset of samples from the national testing programme with detectable SARS-CoV-2 DNA detected on PCR testing are selected for sequencing. Where available, the PANGO lineage assignments for samples included in the study cohort were retrieved from the COG-UK data repository where results are stored. [6]

Additional Figures & Tables

Figure S1: Study flow chart



Pre-Omicron (01 Sept – 12 Dec 2021):

456,301 tests performed in total (226343 (49.6%) LFD, 229958 (50.4%) PCR)
98650 (21.6% of all tests performed) were unlinked of which 26532 (26.9%) LFD and 72118 (73.1%) PCR

During this period there were 26532/226343 (11.72%) unlinked LFD tests and 72118/229958 (31.36%) unlinked PCR tests in residents

Omicron period (13 Dec 2021 – 1 Feb 2022):
338932 tests performed in total (119258 (58.8%) LFD , 139674 (41.2%) PCR)
60434 (17.8% of all tests performed) were unlinked of which 18425 (30.5%) LFD and 42009 (69.5%) PCR

During this period there were 18425/119258 (15.45%) unlinked LFD tests and 42009/139674 (30.08%) unlinked PCR tests in residents

Figure S2: New SARS-CoV-2 cases amongst residents in LTCFs taking part in Vivaldi study between September 1, 2021 and February 1, 2022 according to date of test and variant (where known). The vertical line is set at the date when the first Omicron case was detected in this population (December 13, 2021).

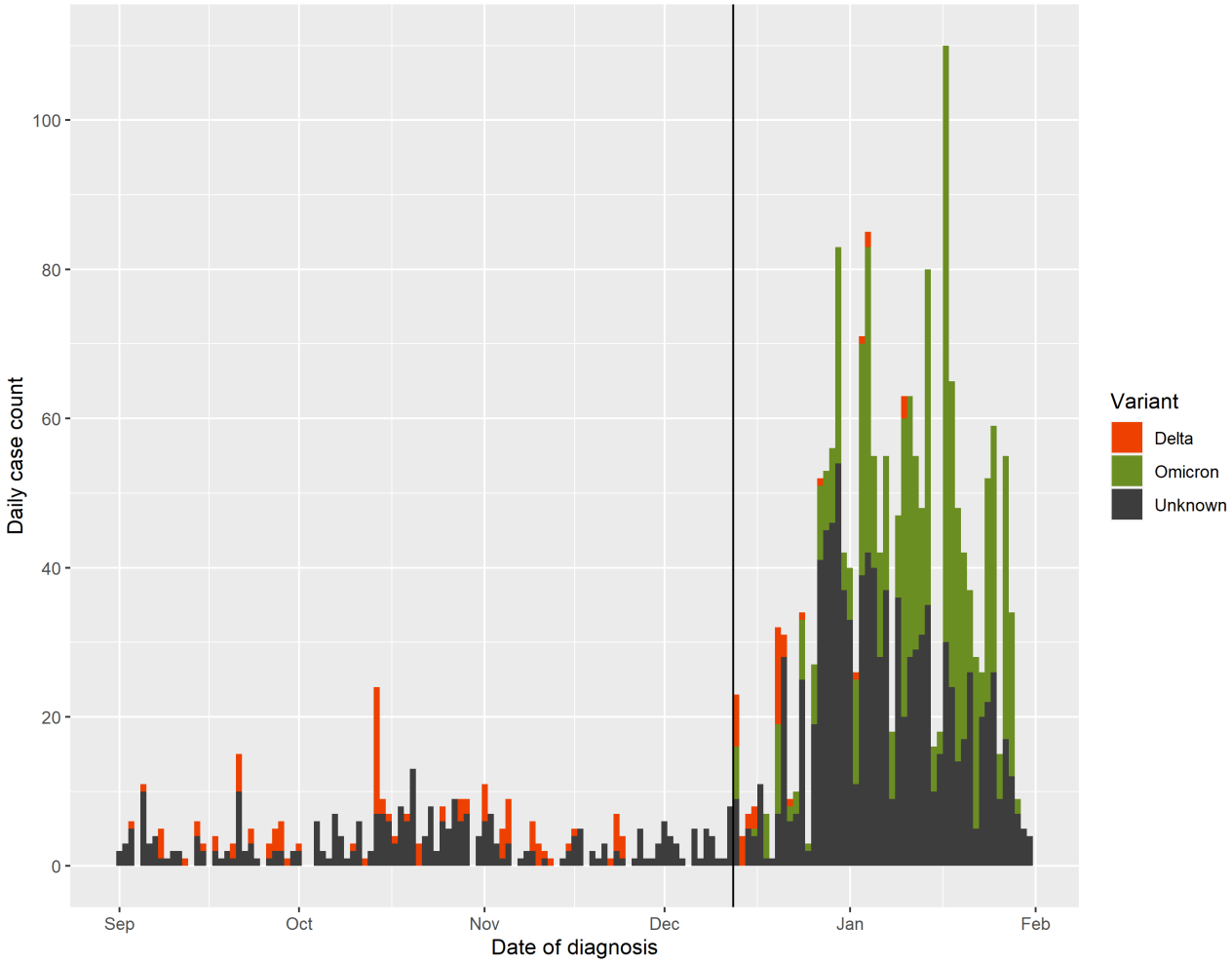


Table S1: Baseline characteristics for care home residents with Omicron versus Delta (based on SGTF or lineage data)

	Delta	**Omicron**	**P value^**
Total	143	794	
Age (IQR, range)	85·1 (77·9-91·6, 66·0-102·8)	85·2 (79·0-90·6, 60·0-104·7)	0.958
Sex			0.347
Female	96 (67·1)	564 (71·0)	
Male	47 (32·9)	230 (29·0)	
Primary vaccine course			0.37
AstraZeneca ChAdOx1	72 (50·3)	422 (53·1)	
Pfizer BNT162b2	41 (28·7)	251 (31·6)	
Not recorded	7 (4·9)	32 (4·0)	
Unvaccinated	23 (16·1)	89 (11·2)	
Booster vaccination status±			
Booster > 1 week before positive test	52 (36·4)	611 (77·0)	<0·0001
Days from booster to positive test (IQR, range)	39 (10-72, 1-89)	90 (72-103, 1-265)	
Infection history			
Any evidence of past infection	4 (2·8)	87 (11·0)	<0·0001
Previous positive PCR or LFD	2 (1·4)	53 (6·7)	0·013
SARS-CoV-2 antibodies	0 (0·0)	0 (0·0)	NA
Prior COVID-19 hospital admission	2 (1·4)	45 (5·7)	0·031
Any Hospital Admission with 14 days of positive test	14 (9·8)	32 (4·0)	<0·0001
COVID-19 deaths#	18 (12·6)	38 (4·8)	<0·0001
Number of care home beds (IQR, range)	59 (44-69, 24-127)	60 (46-80, 23-149)	

#COVID-19 deaths defined as death within 28 days of PCR or COVID-19 recorded on death certificate.
±Booster vaccinations shown for entire study cohort, regardless of primary vaccination status
^ Chi-square for categorical variables and Mann-Whitney test for continuous variables for difference between Omicron and Delta group

Table S2: Comparison of cohorts of participants for whom SGTF / sequencing data are available with those for whom these data were unavailable

	All infections	SGTF / lineage available	SGTF / lineage unavailable	p value ^
Total	2264	885	1379	
Age (IQR, range)	84·5 (77·9-90·0, 53·0-105·0)	85·0 (78·7-90·6, 60·0-104·7)	84·3 (77·2-89·8, 53·0-105·0)	<0·0001
Sex				0·147
Female	1559 (68·9)	625 (70·6)	934 (67·7)	
Male	705 (31(1)	260 (29·4)	445 (32·3)	
Time period of positive test				<0·0001
Pre-Omicron: September 1, 2021 - December 12, 2021	400 (17·7)	102 (11·5)	298 (21·6)	
Omicron: December 13, 2021 - February 1, 2022	1864 (82·3)	783 (88·5)	1081 (78·4)	
Primary vaccine course				0·20
AstraZeneca ChAdOx1	1189 (52·5)	461 (52·1)	728 (52·8)	
Pfizer BNT162b2	676 (29·9)	283 (32·0)	393 (28·5)	
Not recorded	97 (4·3)	35 (4·0)	62 (4·5)	
Unvaccinated	302 (13·3)	106 (12·0)	196 (14·2)	
Booster vaccination status±				
Booster > 7 days before positive test	1468 (64·8)	647 (69·1)	821 (61·9)	<0·0001
Days from booster to positive test (IQR, range)	81 (63-98, 1-182)	87 (69-101, 1-127)	79 (60-95, 1-182)	<0·0001
Infection history				
Any evidence of past infection	253 (11·2)	82 (9·3)	171 (12·4)	0·021
Previous positive PCR or LFD	158 (7·0)	47 (5·3)	111 (8·0)	0·013
SARS-CoV-2 antibodies	27 (1·2)	7 (0·8)	20 (1·5)	0·013
Prior COVID-19 hospital admission	110 (4·9)	42 (4·7)	68 (4·9)	0·84
Hospital Admission with 14 days of positive test				
Any	126 (5·6)	42 (4·7)	84 (6·1)	0.17
Positive test September 1, 2021 - December 12, 2021	42 (10·5)	6 (5·9)	36 (12·1)	0·078
Positive test December 13, 2021 - February 1, 2022	84 (4·5)	36 (4·6)	48 (4·4)	0·87
COVID-19 deaths#				

All	150 (6·6)	56 (6·3)	94 (6·8)	0·65
Positive test September 1, 2021 - December 12, 2021	51 (12·8)	13 (12·7)	38 (12·8)	1·00
Positive test December 13, 2021 - February 1, 2022	99 (5·3)	43 (5·5)	56 (5·2)	0·77
Number of care home beds (IQR, range)	59 (44-80, 17-149)	60 (46-80, 23-149)	59 (44-80, 17-149)	

#COVID-19 deaths defined as death within 28 days of PCR or COVID-19 recorded on death certificate.
^ Chi-square for categorical variables and Mann-Whitney test for continuous variables for difference between "available SGTF/lineage" and "no available SGTF/lineage groups"

Table S3: Cox proportional Hazards models for hospitalisation within 14 days from positive test for SARS-CoV-2 with interaction terms in the full cohort.

Variable	Adjusted HR	95% CI	P value
	Interaction with vaccine type (p=0.0324)		
Sex			
Male	Ref	-	-
Female	0·57	0·40-0·81	<0·0001
Age (per year increase)	1·03	1·01-1·05	0·012
Primary vaccine course			0·47‡
Unvaccinated	Ref†	-	-
AstraZeneca ChAdOx1	0·79†	0·34-1·81	-
Pfizer BNT162b2	1·37†	0·58-3·24	-
Type not known	-‡	-‡	-
Period & primary vaccine course interaction			0·048‡
Omicron vs Delta in unvaccinated group	0·60	0·26-1·41	-
Omicron vs Delta in Pfizer BioNTech group	0·34	0·16-0·72	-
Omicron vs Delta in Oxford AstraZeneca group	0·85	0·46-1·56	-
Omicron vs Delta in unknown vaccine type group	-‡	-‡	-
Booster vaccine status			0·0008
No booster	Ref	-	-
Booster more than 1 week before Dx	0·50	0·31-0·82	<0·0001
Past infection status			
No past infection	Ref	-	-
Past infection	0·22	0·07-0·69	<0·0001

† As reported for pre-Omicron period, but subject to multiplicative interaction term for the Omicron period.
‡ There were no hospital admissions among cases with vaccine 'type not known' in the pre-Omicron period, leading to a perfect prediction problem for model fitting. As such, coefficients cannot be estimated for this group, and the P-values presented are also calculated with omission of these coefficients

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STROBE Checklist

	Item No	Recommendation	Page No
Title and abstract			
	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-6
Participants	6	*a) Cohort study*? Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*? Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross sectional study*? Give the eligibility criteria, and the sources and methods of selection of participants	4-6
		(*b*) *Cohort study*? For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*? For matched studies, give matching criteria and the number of controls per case	n/a

Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5, appendix
Bias	9	Describe any efforts to address potential sources of bias	5, 6
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	6
		(*b*) Describe any methods used to examine subgroups and interactions	6
		(*c*) Explain how missing data were addressed	5-6
		(*d*) *Cohort study*? If applicable, explain how loss to follow-up was addressed *Case-control study*? If applicable, explain how matching of cases and controls was addressed *Cross sectional study*? If applicable, describe analytical methods taking account of sampling strategy	5,6
		(*e*) Describe any sensitivity analyses	4-6
Results			
Participants	13*	(*a*) Report numbers of individuals at each stage of study? eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7, appendix
		(*b*) Give reasons for non-participation at each stage	Appendix
		(*c*) Consider use of a flow diagram	Figure S1 (appendix)
Descriptive data	14*	(*a*)Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7, table 1, table S1
		(*b*) Indicate number of participants with missing data for each variable of interest	n/a
		(*c*) *Cohort study*? Summarise follow-up time (eg average and total amount)	7
Outcome data	15*	*Cohort study*? Report numbers of outcome events or summary measures over time	7, 8
		Case-control study? Report numbers in each exposure category, or summary measures of exposure	
		Cross sectional study? Report numbers of outcome events or summary measures	
Main results	16	(*a*) Report the numbers of individuals at each stage of the study?eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7, 8, figure S1

		(*b*) Give reasons for non-participation at each stage	7, figure S1
		(*c*) Consider use of a flow diagram	Figure S1
Other analyses	17	Report other analyses done?eg analyses of subgroups and interactions, and sensitivity analyses	7, 8
Discussion			
Key results	18	Summarise key results with reference to study objectives	8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9, 10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9, 10
Generalisability	21	Discuss the generalisability (external validity) of the study results	9, 10
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Declaration of funding sources