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Original Research

Evaluation of the UK's COVID-19 public health policy "Shielding: Results of a linked data matched cohort study

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ABSTRACT

Objective: To assess outcomes associated with shielding, introduced during the COVID-19 pandemic across the UK to protect those at highest risk of harm.
Study design: Linked data and questionnaires in matched cohorts from the population of Wales, UK.
Methods: We compared individual-level linked routine and self-reported outcomes between people identified for shielding (n = 123,293) and comparators (n = 120,997) matched by age, sex, and previous health service utilisation. We sent questionnaires to 1500 randomly sampled people in each cohort.
Results: At one year 6·1 % of shielded people had contracted SARS-CoV-2 compared to 6·2 % in the matched cohort (Adjusted Odds Ratio [AOR] 0·970; 95 % confidence interval [CI] 0·937 to 1·004). Suspected healthcare associated infections were more likely in shielded people (1·1 % vs 0·6 %; AOR 1·678; 95 % CI 1·529 to 1·842). All-cause and COVID-19 related deaths were higher in the shielded cohort (7·0 % vs 3·5 %; AOR 2·280; 95 % CI 2·190 to 2·374; and 1·1 % vs 0·8 %; AOR 1·430; 95 % CI 1·308 to 1·563, respectively).
About 1/3 completed questionnaires (n = 1015), with linkage possible in 752 cases (shielded: n = 411; matched: n = 341). Shielded respondents reported lower physical and mental health (SF12 PCS difference: −3·752; 95 % CI -4·823 to −2·682; SF12 MCS difference: −1·217; 95 % CI -2·580 to 0·145). They were more likely to have strictly avoided contact; stayed at home; felt scared to go outside; and were less likely to have gone out for shopping, leisure or travel.
Conclusion: We found no evidence of a protective effect of shielding on SARS-CoV-2 infections or COVID-19 related mortality, an increased rate of hospital acquired infections and increased self-isolation. Shielding during a future pandemic should only be considered alongside effective measures to reduce healthcare associated infections.

1. Introduction

A key element of the public health response to the COVID-19 pandemic in the UK was to introduce an intervention known as "shielding" for people identified as clinically extremely vulnerable (CEV). Shielding was introduced on the 22nd March 2020, just before wider lockdown measures.[1] CEV individuals were identified through algorithms applied to central NHS datasets, and by primary and secondary care clinicians who were able to add people at local level.[2–4] People were then contacted by letter from the Chief Medical Officers of the four UK nations, with strong advice to strictly self-isolate - including from family members within the home - for an initial period of 12 weeks. Local authorities sent a further letter offering delivery of food parcels, prescribed medications and other local services. The intervention was

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extended several times, with letters sent over the following year, finally ending in April 2021. This targeted intervention to protect the vulnerable during the COVID-19 pandemic was almost unique, internationally, with only the Republic of Ireland implementing a similar policy named "cocooning".[5–7] Approximately 1·9 million people were advised to strictly self-isolate across the UK, with more than 130,000 in Wales (4 % of the population). The rationale for the shielding policy was to protect those at the highest risk of death or serious harm should they be infected with SARS-CoV-2.[8] There was no prior evidence of effectiveness.

There has been concern that the shielding policy had adverse mental and physical effects on those shielding without a clear reduction in COVID-19 infection rates.[9–11] A modelling study reported that implementing the shielding policy while allowing COVID-19 to spread in the general population would not be effective even with strict adherence.[12]

We evaluated the shielding policy intervention in Wales.[13] We published Phase 1 results of routinely available health outcomes in those who were identified for shielding and all others in Wales in 2020[9] a logic model for the intervention based on interviews with policy makers,[14] and costs of implementation of the policy in Wales.[15] We now publish results of our Phase 2 evaluation, using a matched cohort study design with linked routine health and self-reported outcomes.

1.1. Aim

To evaluate the shielding policy to protect those at serious risk of harm from COVID-19 infection in Wales.

1.2. Objectives

To assess outcomes associated with shielding.

1. Routinely available health outcomes: SARS-CoV-2 tests and infections, including hospital acquired infections; deaths and COVID-19 related deaths; unplanned healthcare utilisation; vaccinations
2. Self-reported health status: quality of life, depression, anxiety; safety concerns; behaviours and activities related to isolation

2. Methods

2.1. Study design

2.1.1. Routinely collected health data

We undertook a retrospective comparative analysis of SARS-CoV-2 tests and results, including nosocomial infections; deaths and COVID-19 related deaths; unplanned healthcare resource utilisation; and vaccinations between people identified for shielding and a matched cohort in Wales. We report routine outcomes for all other people in Wales as context.

We accessed and analysed data via the Secure Anonymised Information Linkage (SAIL) databank (www.saildatabank.com), a remotely accessible, privacy-protecting Trusted Research Environment (TRE), accredited under the Digital Economy Act.[16,17]

We used the C20 Cohort, a population-wide electronic data resource created in response to the outbreak of COVID-19 to facilitate research on the COVID-19 pandemic in Wales.[18] We included C20 Cohort members living in Wales on 23 March 2020, and allocated those identified for shielding between 23 March 2020 and 31 December 2020 to the shielded cohort. We created a similar sized comparator cohort of individuals from the rest of the population, seeking 1-1 matches by age (banded), sex, and healthcare utilisation (banded, based on Emergency Department attendances, emergency admissions to hospital and Critical Care admissions) in the year to March 2020. All other individuals formed a third, general population, cohort. We further partitioned the shielded cohort into four sub-cohorts (severe respiratory conditions; immune-suppression therapy; cancer; others), reflecting information on individuals' inclusion in the shielded cohort.

To preserve anonymity, the matching cohort and questionnaire distribution lists were created within Digital Health and Care Wales (DHCW, within NHS Wales). Cohorts created by DHCW were then transferred to the SAIL databank, for linkage to individual-level data held within SAIL.

Health outcomes for all three cohorts were derived from routinely collected electronic health record data sources, including: Annual District Death Daily; Annual District Death Extract; the Consolidated Death Data Source; the COVID-19 Vaccination Data; the COVID-19 Pathology Data; the Emergency Department Data Set; the Patient Episode Database for Wales; the Critical Care Data Set; and the Welsh Longitudinal General Practice Dataset.

Health records were extracted for dates starting at 23 March 2020 for non-shielded individuals, and from the earliest shielding data recorded (up to 31 December 2020) for the shielded cohort. All individuals were followed up for events up to one year from recruitment.

Routine health outcomes.

1. SARS-CoV-2 infection tests
2. Positive SARS-CoV-2 infection tests
3. Nosocomial SARS-CoV-2 infections
4. All-cause and COVID-19 related deaths
5. Emergency Department (ED) attendances
6. Emergency hospital admissions
7. Critical Care admissions
8. Vaccinations

We assessed the first phase of the mass vaccination programme, from December 2020 to the end of the first year of the pandemic. We included prior vaccinations, arising from initial clinical trials and testing, and those administered abroad. We compared vaccination rates and times to vaccination (in days) for those in the study at the start of the mass vaccination programme.

2.1.2. Self-reported behaviours, activities and outcomes

We randomly sampled 1500 people each from the shielded and comparator cohorts, and NHS Shared Services (responsible for national distribution of letters to shielded people during 2020/2021) posted questionnaires to these individuals in February 2022, 9 months after the end of the shielding period. NHS Shared Services sent a reminder letter with a further questionnaire to non-responders after two weeks. Questionnaires were sent with a prepaid envelope for return direct to Swansea University; a link was also included for online response.

We designed the questionnaire to cover: Health Related Quality of Life (SF-12)[19] and mental health (Patient Health Questionnaire-9 [PHQ-9][20] and Generalised Anxiety Disorder Assessment [GAD-7])[21] safety concerns; behaviours and activities relating to self-isolation. The SF-12, PHQ-9 and GAD-7 all related to the weeks immediately before receipt of questionnaire. Behaviours and activities related to self-isolation measures advised for those included in the shielded cohort were assessed at two time points - at the outbreak of the pandemic in March 2020, and within the most recent two weeks - using a five-point Likert scale (Never/Rarely/Sometimes/Very often/Always).

Questionnaire responses from those not opting out of data linkage were uploaded to the SAIL Databank, allowing linkage to respondent-level routine data.

2.2. Statistical methods

Comparisons of all outcomes in shielded and matched cohorts are summarised by Odds Ratios (OR; binary & ordinal data); Hazard Ratios (HR; times to event) and Differences (D; measurements), from fitted models in which sex (M/F); age (in years) and Welsh Index of Multiple Deprivation (WIMD)[22] (quintile) were also included as explanatory factors and covariates.

Two explanatory variables (sex and age) were used in creating the

matched cohort; however, while matching used age bands, our statistical models included individual-level age (in years) and in linear and quadratic terms, thereby accommodating scenarios in where the exposure of young/old people is different from that for those in between these extremes. We also allowed age to vary by sex, thereby accommodating any systematic difference in its role in responses between males and females. Models, fitted using SPSS, retained all independent variables; estimates are given along with 95 % confidence intervals and p-values.

2.3. Patient and public involvement

The research team included public contributors alongside clinical, policy, academic and methodological members. All research team members had equal responsibility in decisions to develop, manage and deliver and disseminate results from this study. Two public contributors (LB, LD) were co-applicants with input throughout all stages of the study. They worked with six more public contributors via a Patient Advisory Panel set up for this study. An independent Study Steering Committee included two further public contributors. Our public contributors were directly or indirectly affected by the implementation of the shielding policy.

3. Results

3.1. Routine data

Study cohorts: We identified 3,103,276 people resident in Wales at the start of the study period, with 123,293 included in the shielded cohort, which further sub-divided into four sub-cohorts of varying size (Supplemental Figure). Our matching processes allocated a further 120,977 to the comparator cohort; the small difference in cohort sizes arises from a combination of changes to the shielding list over the study period, inconsistencies in coding, and restrictions preventing data linkage for some individuals. The remaining 2,858,986 people formed the general population cohort.

Age and sex data were complete for all people. A WIMD category was not recorded for approximately 6.1 % of people; an ethnicity category was not recorded for approximately 6.5 % of people. Frailty data were available in 85·5 % of cases, consistent with the proportion of general practices (GPs) in Wales contributing source data to the SAIL Databank.

The shielded and matched cohorts had similar sex and age profiles, with higher proportions of women and older people than the general population (Table 1).

Those in the shielded cohort were more likely to live in more deprived areas of Wales than the matched or general population cohorts. There was no evidence of differences in ethnicity profiles of the shielded and matched cohorts although both included a smaller proportion of ethnic minorities than the general population. The proportion of shielded and matched cohorts living in care homes was low (1·1 % and 1·5 %, respectively), but higher than the general population (0·4 %). Those in the shielded cohort were frailer than matched cohort counterparts, with both cohorts frailer than the general population.

Outcomes: People in the shielded cohort were more likely to have been tested for SARS-CoV-2 than counterparts in the matched cohort (38·6 % versus 32·9 %; OR 1·300; 95 % CI 1·278 to 1·323), with both rates higher than in the general population cohort (Table 2).

The proportions tested varied across shielded sub-cohorts, ranging from 34·3 % (immunosuppression therapy) to 42·2 % (cancer). There was no difference in the proportion of people with a positive SARS-CoV-2 test (6·1 % versus 6·2 %; OR 0·970; 95 % CI 0·937 to 1·004); again, these rates are higher than in the general population, with some variation within shielded sub-cohorts. Hospital and suspected hospital onset of COVID-19 were significantly higher in the shielded cohort than the

Table 1
Baseline characteristics of the three study cohorts: shielded; matched; others (general population).

Characteristic	Shielded cohort [n = 123,293]		Matched cohort [n = 120,997]		*Others [n = 2,858,986]*	
Sex						
Female: n (%)	65,713	(53·3 %)	64,858	(53·6 %)	*1,423,024*	*(49·8 %)*
Age (years)						
Mean (sd)	61·8	(18·4)	60·3	(20·9)	*40·9*	*(23·2)*
Median (lq, uq)	66·0	(53·0, 75·0)	65·0	(52·0, 75·0)	*40·0*	*(22·0, 59·0)*
Age group (years)						
0–17	4206	(3·4 %)	7147	(5·9 %)	*572,462*	*(20·0 %)*
18–39	11,280	(9·1 %)	13,110	(10·8 %)	*823,211*	*(28·8 %)*
40–65	45,807	(37·2 %)	41,288	(34·1 %)	*971,734*	*(34·0 %)*
66+	62,000	(50·3 %)	59,452	(49·1 %)	*491,579*	*(17·2 %)*
WIMD quintile[a,b]						
1	26,014	(22·2 %)	21,364	(18·7 %)	*551,801*	*(20·6 %)*
2	24,734	(21·1 %)	22,603	(19·8 %)	*537,481*	*(20·1 %)*
3	23,218	(19·8 %)	22,732	(19·9 %)	*530,842*	*(19·8 %)*
4	22,113	(18·8 %)	23,607	(20·6 %)	*528,288*	*(19·7 %)*
5	21,256	(18·1 %)	24,067	(21·0 %)	*534,873*	*(19·9 %)*
Missing[c]	5958	(4·8 %)	6624	(5·5 %)	*175,701*	*(6·1 %)*
Ethnicity[b]						
White	113,886	(96·7 %)	109,596	(96·5 %)	*2,510,491*	*(94·0 %)*
Asian	1956	(1·7 %)	2178	(1·9 %)	*77,672*	*(2·9 %)*
Black	752	(0·6 %)	510	(0·4 %)	*21,427*	*(0·8 %)*
Mixed	667	(0·6 %)	696	(0·6 %)	*33,790*	*(1·3 %)*
Other	465	(0·4 %)	637	(0·6 %)	*27,477*	*(1·0 %)*
Missing[c]	5567	(4·5 %)	7380	(6·1 %)	*188,129*	*(6·6 %)*
Resident in Care Home	1316	(1·1 %)	1774	(1·5 %)	*12,030*	*(0·4 %)*
Frailty Index[b]						
Fit	44,001	(41·5 %)	59,545	(57·8 %)	*2,108,139*	*(86·3 %)*
Mild	40,929	(38·6 %)	29,501	(28·6 %)	*266,943*	*(10·9 %)*
Moderate	16,528	(15·6 %)	10,932	(10·6 %)	*57,254*	*(2·3 %)*
Severe	4441	(4·2 %)	3022	(2·9 %)	*11,764*	*(0·5 %)*
Missing[c]	17,394	(14·1 %)	17,997	(14·9 %)	*414,886*	*(14·5 %)*

[a] WIMD = Welsh Index of Mutliple Deprivation. Category 1 is the most deprived; 5 is the least deprived.
[b] Category percentages sum to 100 %.
[c] Missing data percentage based on cohort size.

Table 2
Outcomes by study cohort: SARS-CoV-2 tests, infections, deaths, and healthcare contacts.

	Shielded cohort										Matched cohort	*Others*
	All [n = 123,293]		Severe respiratory conditions [n = 41,616]		Immunosuppression therapy [n = 30,514]		[Cancer n = 22,591]		Other shielded [n = 28,572]		n = 120,997	*n = 2,858,986*
SARS-CoV-2 tests and infections												
	Observed	Comparison	Observed	Comparison	Observed	Comparison	Observed	Comparison	Observed	Comparison	Observed *Reference*	*Observed*
Persons tested: n (%)	47,601 (38·6 %)	OR = 1·300 (1·278, 1·323) (p < 0·001)	15,862 (38·1 %)	OR = 1·300 (1·268, 1·332) (p < 0·001)	10,470 (34·3 %)	OR = 1·047 (1·015, 1·077) (p = 0·001)	9531 (42·2 %)	OR = 1·595 (1·548, 1·644) (p < 0·001)	11,738 (41·1 %)	OR = 1·382 (1·344, 1·420) (p < 0·001)	39,781 (32·9 %)	*879,330 (30·8 %)*
Persons tested positive: n (%)	7469 (6·1 %)	OR = 0·970 (0·937, 1·004) (p = 0·082)	2538 (6·1 %)	OR = 0·932 (0·887, 0·979) (p = 0·005)	1726 (5·7 %)	OR = 0·910 (0·863, 0·963) (p = 0·001)	1305 (5·8 %)	OR = 0·950 (0·892, 1·011) (p = 0·106)	1900 (6·6 %)	OR = 1·085 (1·029, 1·145) (p = 0·003)	7509 (6·2 %)	*164,394 (5·8 %)*
Nosocomial COVID-19												
Hospital onset: n (%)	830 (0·7 %)	OR = 1·257 (1·129, 1·398) (p < 0·001)	332 (0·8 %)	OR = 1·242 (1·080, 1·428) (p = 0·002)	131 (0·4 %)	OR = 1·021 (0·840, 1·241) (p = 0·836)	154 (0·7 %)	OR = 1·253 (1·045, 1·502) (p = 0·015)	213 (0·7 %)	OR = 1·527 (1·302, 1·793) (p < 0·001)	639 (0·5 %)	*4105 (0·1 %)*
Hospital onset suspected: n (%)	1305 (1·1 %)	OR = 1·678 (1·529, 1·842) (p < 0·001)	478 (1·1 %)	OR = 1·550 (1·373, 1·749) (p < 0·001)	182 (0·6 %)	OR = 1·171 (0·986, 1·390) (p = 0·071)	335 (1·5 %)	OR = 2·307 (2·016, 2·639) (p < 0·001)	310 (1·1 %)	OR = 1·848 (1·609, 2·122) (p < 0·001)	759 (0·6 %)	*5106 (0·2 %)*
Mortality												
All cause: n (%)	8665 (7·0 %)	OR = 2·280 (2·190, 2·374) (p < 0·001)	3119 (7·5 %)	OR = 1·932 (1·834, 2·035) (p < 0·001)	784 (2·6 %)	OR = 1·181 (1·086, 1·284) (p < 0·001)	3009 (13·3 %)	OR = 4·561 (4·323, 4·813) (p < 0·001)	1753 (6·1 %)	OR = 2·295 (2·157, 2·441) (p < 0·001)	4192 (3·5 %)	*23,504 (0·8 %)*
COVID-19 related	1316 (1·1 %)	OR = 1·430 (1·308, 1·563) (p < 0·001)	616 (1·5 %)	OR = 1·531 (1·373, 1·707) (p < 0·001)	172 (0·6 %)	OR = 1·167 (0·980, 1·388) (p = 0·082)	264 (1·2 %)	OR = 1·484 (1·285, 1·714) (p < 0·001)	264 (0·9 %)	OR = 1·413 (1·224, 1·631) (p < 0·001)	936 (0·8 %)	*5033 (0·2 %)*
Unplanned healthcare contacts												
Emergency Department attendance	30,910 (25·1 %)	OR = 1·317 (1·291, 1·343) (p < 0·001)	11,750 (28·2 %)	OR = 1·441 (1·403, 1·481) (p < 0·001)	5964 (19·5 %)	OR = 1·050 (1·016, 1·086) (p = 0·004)	5766 (25·5 %)	OR = 1·362 (1·316, 1·410) (p < 0·001)	7430 (26·0 %)	OR = 1·413 (1·370, 1·458) (p < 0·001)	24,561 (20·3 %)	*384,631 (13·5 %)*
Critical Care admission	1058 (0·9 %)	OR = 1·861 (1·671, 2·072) (p < 0·001)	340 (0·8 %)	OR = 1·666 (1·443, 1·922) (p < 0·001)	198 (0·6 %)	OR = 1·518 (1·281, 1·800) (p < 0·001)	224 (1·0 %)	OR = 2·003 (1·703, 2·356) (p < 0·001)	296 (1·0 %)	OR = 2·471 (2·133, 2·863) (p < 0·001)	530 (0·4 %)	*4057 (0·1 %)*
Emergency admission	23,736 (19·3 %)	OR = 1·701 (1·682, 1·741) (p < 0·001)	8790 (21·1 %)	OR = 1·659 (1·608, 1·711) (p < 0·001)	3949 (12·9 %)	OR = 1·266 (1·217, 1·318) (p < 0·001)	5358 (23·7 %)	OR = 2·163 (2·084, 2·244) (p < 0·001)	5639 (19·7 %)	OR = 1·887 (1·821, 1·956) (p < 0·001)	15,043 (12·4 %)	*140,020 (4·9 %)*

Variables are presented as n (percentage); comparison is an Adjusted Odds Ratio (OR), with Matched Cohort as reference.
Comparisons adjust for sex (complete); age (complete) and WIMD (~95 % complete), treated as a continuous variable.
WIMD category is missing in 6624 cases in the Matched Cohort and 5958 cases in the Shielded (sub-cohorts: 1878; 1567; 979; 1534, respectively).

matched cohort: (0·7 % versus 0·5 %; OR 1·257; 95 % CI 1·129 to 1·398; and 1·1 % versus 0·6 %; OR 1·678, 95 % CI 1·529 to 1·842, respectively); both higher than the general population. Shielded sub-cohorts had significantly higher rates than those in the matched cohort except for the immunosuppression therapy sub-cohort.

All-cause and COVID-19 related mortality were higher in the shielded than the matched cohort (7·0 % versus 3·5 %; OR 2·280; 95 % CI 2·190 to 2·374; and 1·1 % versus 0·8 %; OR 1·430; 95 % CI 1·308 to 1·563, respectively). These rates were considerably higher than in the general population. Mortality rates across shielded sub-cohorts were generally higher than in the matched cohort.

Unplanned healthcare contacts were high in both the shielded and matched cohorts, relative to the general population, and significantly higher in the shielded cohort than in the comparator cohort: ED attendances rates: 25·1 % versus 20·3 %; OR 1·317; 95 % CI 1·291 to 1·343; Critical care admission rates: 0·9 % versus 0·4 %; OR 1·861; 95 % CI 1·671 to 2·072); and emergency hospital admission rates: 19·3 % versus 12·4 %; OR 1·701; 95 % CI 1·662 to 1·741). Rates were higher in all shielded sub-cohorts than in the matched cohort.

By the end of the first year of the pandemic, a higher proportion of the eligible shielded cohort received at least one SARS-CoV-2 vaccination compared with the matched cohort: (90·1 % versus 71·1 %; OR 5·460; 95 % CI 5·299 to 5·627); both rates were much higher than in the general population (37·5 %) (Supplemental Table 1). People in all shielded sub-cohorts were more likely to have been vaccinated than those in the matched cohort, with the highest rates in the immunosuppression therapy sub-cohort. In general, people in the shielded cohort also received their vaccinations at least a week earlier than those in the matched cohort (Fig. 1).

3.2. Self-reported data

We received 1015 responses, with 752 (n = 411 in the shielded cohort; n = 341 in the matched cohort) linkable to individual-level routine data outcomes.

Respondents in each linkable cohort had similar sex and age distributions, although those in the shielded cohort were generally more frail and more likely to live in deprived areas (Supplemental Table 2).

People in the shielded cohort reported lower quality of life physically (35·51 versus 39·1; D = −3·752; 95 % CI -4·823 to −2·682) but mental health scores were not significantly different (39·44 versus 41·01; D = −1 ·217; 95 % CI -2 ·580 to 0·145) (Table 3). Shielded people reported higher scores for depression (mean PHQ-9 scores: 6·53 versus 5·06; D = 1·204; 95 % CI 0·187 to 2·221). Anxiety scores were higher in the shielded cohort, with borderline statistical significance (mean GAD-7 scores: 4·69 versus 3·60; D = 0·788; 95 % CI -0·029 to 1·604).

Just over a quarter of people in each cohort reported experiencing a safety concern during the previous year, with almost no difference between rates in the shielded and matched cohorts.

Respondents in the shielded cohort were more likely to report reported that they had strictly self-isolated than counterparts in the matched cohort across most behaviours and activities covered in the questionnaire (Table 4).

A high proportion of respondents from both cohorts initially strictly avoided contact – with an even higher proportion in the shielded cohort (91·4 % versus 85 ·9 %; OR = 1·784; 95 % CI 1·107 to 2·877). Over 60 % of shielded respondents reported that they always stayed at home during March 2020, compared with just under half of people in the matched cohort. Over a third (35·2 %) of respondents in the shielded cohort reported always feeling scared to go outside during the initial period, more than twice the proportion (16·5 %) in the matched cohort. The proportion that reported never going out for shopping, leisure or travel was significantly higher in the shielded cohort (59·5 % versus 28·2 %); reliance on telephone/online services to contact GP or essential services was also higher in the shielded cohort, in which 7·5 % never made contact in this way, compared with 16·0 % in the matched cohort. There were no statistically significant differences in the proportions that: attended gatherings (a large majority in both cohorts reported avoiding these); used remote technology to keep in touch (approximately half of respondents in both cohorts always doing so); and regularly washed hands for 20 s (at least two thirds of respondents reported doing so).

Initially, more than half of the questionnaire respondents always used separate towels – the proportion was significantly higher in the Shielded cohort (55·5 % versus 44·5 %; OR = 1·528; 95 % CI 1·152 to 2·029). At the start of the pandemic, most respondents sometimes or always used the household kitchen alone or cleaned kitchenware thoroughly: significantly more doing so in the shielded cohort than in the matched cohort: (64·5 % versus 56·5 %; OR = 1·414; 95 % CI 1·074 to 1·862).

In contrast, there were no statistically significant difference in the

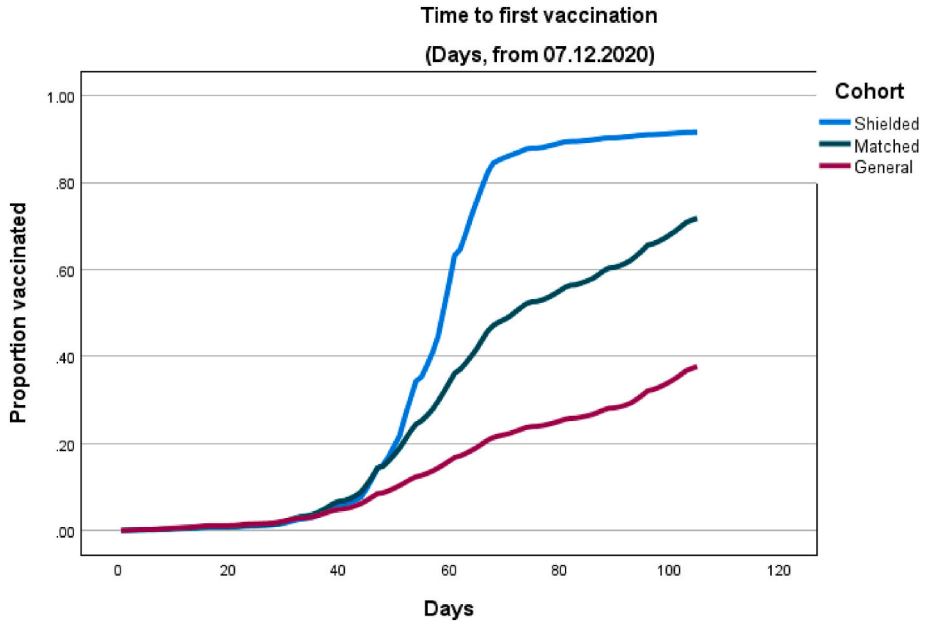

Fig. 1. Distributions of days to first vaccination during the initial phase of the mass vaccination programme.

Table 3
Self-reported outcomes for linkable respondents by sampled cohort: shielded, matched.

	Shielded cohort [n = 411]		Matched cohort [n = 341]		Comparison	
					Difference	95 % CI; p-value
SF12 (12-Item Short Form Survey) Physical component						
Completed: n (%)	364/411	(88·6 %)	304/341	(89·1 %)		
Mean score (sd)	35·5	(7·3)	39·1	(7·3)	D = −3·752	(-4·823, −2·682)
Median score (lq, uq)	35·3	(30·4, 41·3)	39·7	(33·4, 44·6)		(p < 0·001)
SF12 (12-Item Short Form Survey) Mental component						
Completed: n (%)	364/411	(88·6 %)	304/341	(89·1 %)		
Mean (sd)	39·4	(9·3)	41·0	(8·8)	D = −1·217	(-2·580, 0·145)
Median (lq, uq)	40·4	(31·1, 47·8)	43·0	(34·6, 48·5)		(p = 0·080)
PHQ-9 (Patient Health Questionnaire)						
Completed: n (%)	360/411	(87·6 %)	288/341	(84·5 %)		(0·187, 2·221)
Mean score (sd)	6·53	(7·28)	5·06	(6·10)	D = 1·204	(p = 0·020)
Median score (lq, uq)	4·00	(0·00, 11·00)	2·00	(0·00, 8·00)		
Depression identified: n (%)	167/360	(46·4 %)	116/288	(40·3 %)	OR = 1·217	(0·878, 1·688)
						(p = 0·238)
GAD-7 (Generalised Anxiety Disorder Assessment)						
Completed: n (%)	378/411	(92·0 %)	317/341	(93·0 %)	D = 0·788	(-0·029, 1·604)
Mean score (sd)	4·69	(6·00)	3·60	(5·25)		(p = 0·059)
Median score (lq, uq)	2·00	(0·00, 7·00)	1·00	(0·00, 5·00)		
Anxiety identified: n (%)	120/378	(31·7 %)	74/317	(23·3 %)	OR = 1·425	(0·999, 2·033)
						(p = 0·051)
Safety						
Concern expressed: n (%)	97/377	(25·7 %)	81/310	(26·1 %)	OR = 0·942	(0·665, 1·335)
						(p = 0·738)

Comparisons are Adjusted Odds Ratio (OR) for proportions, with Matched Cohort as reference, and an Adjusted Difference (D) for measurements. Comparisons adjust for sex; age; and WIMD, treated as a continuous variable.

proportions of the cohorts that: minimised time with others (with a fairly uniform spread of responses in both cohorts); kept shared spaces well-ventilated (with only small proportions in both cohorts never doing so); and used a separate bathroom or cleaned the bathroom after every use (with very similar proportions in both cohorts never doing so).

4. Discussion

4.1. Principal findings

SARS-CoV-2 infection rates were similar in the shielded cohort to the matched cohort and general population, although testing rates were higher. The nosocomial infection rate was considerably higher in the shielded cohort than in the matched cohort and general population. Deaths and COVID-19 related deaths were higher in the shielded cohort than the other two cohorts. Unplanned healthcare utilisation was higher in the shielded cohort, as was the proportion of people vaccinated against SARS-CoV-2 during the initial phase of the mass vaccination programme. Self-reported physical health related quality of life was significantly lower in the shielded cohort than the matched cohort, while mental health was marginally lower.

4.2. Strengths and weaknesses

This evaluation achieved very high linkage rates across Wales. We therefore report routinely available outcomes across a large population, with the power to detect small differences between cohorts. The evaluation used innovative methods to combine routine data and self-reported outcomes. Special arrangements put in place during the COVID-19 pandemic allowing data sharing between NHS partners made the study possible within time constraints.[23]

As shielding was introduced across the entire UK population, we were not able to use a randomised evaluation, but created a matched cohort based on factors including previous healthcare utilisation. This approach enabled comparisons between people who were included in the shielding intervention and others at a similar level of clinical vulnerability. However, there were some differences between cohorts. We did not undertake any unplanned subgroup analyses e.g. by sex or age.

Questionnaires relied on individuals recalling events and behaviours from more than 12 months previously, therefore recall bias is a limiting factor. Response rates were not high and were further reduced by requiring each respondent's permission to link their questionnaire responses to other routine data sources.

4.3. Implications for clinicians and policymakers

As the policy was introduced at the same time across all four nations of the UK, it has been challenging to measure effects – with no clear "control" group who did not receive the intervention. It is difficult to identify a comparator group with similar characteristics or risk of harm prior to the pandemic. As entire clinical codes were included in the shielding initiative across the UK e.g. many cancers, it was not possible to match these patients exactly. Some researchers have created comparator groups through methods such as propensity scores,[24,25] or identifying others at moderate risk or low risk.[26]

Zarif and colleagues included 77,360 shielded patients and the same number of propensity matched controls taken from a nationally representative database of primary care patients in England for the period 16th March 2020 to 27th September 2020, with a maximum observation period of 195 days depending on the date GPs contacted their patent with shielding advice.[24] They concluded that there was a short-term reduction in all-cause mortality, with a Hazard Ratio of 0.5 (95 % CI, 0.41–1.59) at 12 weeks; followed by increased risk of death over the following nine weeks (HR 1.54, 96 % CI 1.41–1.70) and then higher again after shielding ended (HR 2.61 95 % CI 2.38–2.87).

Filipe and colleagues evaluated the effect of the COVID-19 shielding programme on mortality in Liverpool,[25] comparing data from linked routine health records for shielded and propensity score matched non-shielded people from April 2020 to June 2021. They found that, over the entire study period, people on the shielding list were significantly more likely to die than a matched cohort (HR 1.55, 95 % CI 1.43–1.67). During pandemic waves (periods of high infection risk in the general population), mortality risk increased for both the shielding and non-shielding population; however, the increase in risk was greater in the non-shielding population. Statistical modelling conducted by the

Table 4
Self-reported behaviours and activities related to self-isolation by sampled cohort: shielded, matched.

	Initially (March 2020)						During last two weeks					
	Shielded		Matched		Comparison		Shielded		Matched		Comparison	
	n	(%)	n	(%)	OR	95 % CI p-value	n	(%)	n	(%)	OR	95 % CI p-value
Behaviours related to self-isolation (Questionnaire Section 1·4)												
Strictly avoided contact												
Never	20/396	(5·1 %)	26/327	(8·0 %)	1·784	(1·107, 2·877)	25/398	(6·3 %)	30/325	(9·2 %)	1·475	(1·068, 2·038)
Sometimes	14/396	(3·5 %)	20/327	(6·1 %)		(p = 0·017)	77/398	(19·3 %)	81/325	(24·9 %)		(p = 0·018)
Always	362/396	(91·4 %)	281/327	(85·9 %)			296/398	(74·4 %)	214/325	(65·8 %)		
Stayed at home												
Never	21/397	(5·3 %)	19/327	(5·8 %)	1·613	(1·209, 2·153)	43/404	(10·6 %)	48/327	(14·7 %)	1·701	(1·303, 2·222)
Sometimes	131/397	(33·0 %)	148/327	(45·3 %)		(p = 0·001)	301/404	(74·5 %)	247/327	(75·5 %)		(p < 0·001)
Always	245/397	(61·7 %)	160/327	(48·9 %)			60/404	(14·9 %)	32/247	(9·8 %)		
Scared to go outside												
Never	73/390	(18·7 %)	109/327	(33·3 %)	2·073	(1·581, 2·719)	128/395	(32·4 %)	174/327	(53·2 %)	2·270	(1·716, 3·003)
Sometimes	180/390	(46·2 %)	164/327	(50·2 %)		(p < 0·001)	231/395	(58·5 %)	138/327	(42·2 %)		(p < 0·001)
Always	137/390	(35·1 %)	54/327	(16·5 %)			36/395	(9·1 %)	15/327	(4·6 %)		
Attended gatherings												
Never	328/400	(82·0 %)	261/332	(78·6 %)	0·877	(0·604, 1·272)	133/403	(33·0 %)	70/331	(21·1 %)	0·594	(0·455, 0·775)
Sometimes/Always	72/400	(18·0 %)	71/332	(21·4 %)		(p = 0·488)	270/403	(67·0 %)	261/331	(78·9 %)		(p < 0·001)
Went for shopping, leisure, or travel												
Never	238/400	(59·5 %)	93/330	(28·2 %)	0·306	(0·230, 0·408)	43/401	(10·7 %)	17/330	(5·2 %)	0·481	(0·367, 0·631)
Sometimes	150/400	(37·5 %)	221/330	(67·0 %)		(p < 0·001)	309/401	(77·1 %)	247/330	(74·8 %)		(p < 0·001)
Always	12/400	(3·0 %)	16/330	(4·8 %)			49/401	(12·2 %)	66/330	(20·0 %)		
Kept in touch via remote technology												
Never/Sometimes	188/399	(47·1 %)	171/327	(52·3 %)	1·195	(0·901, 1·586)	245/403	(60·8 %)	207/328	(63·1 %)	1·179	(0·899, 1·547)
Always	211/399	(52·9 %)	156/327	(47·7 %)		(p = 0·217)	158/403	(39·2 %)	121/328	(36·9 %)		(p = 0·234)
Used telephone or online services to contact GP/essentials services												
Never	30/400	(7·5 %)	53/331	(16·0 %)	1·372	(1·051, 1·789)	46/402	(11·4 %)	60/331	(18·1 %)	1·283	(0·986, 1·670)
Sometimes	223/400	(55·8 %)	171/331	(51·7 %)		(p = 0·020)	243/402	(60·4 %)	190/331	(57·4 %)		(p = 0·063)
Always	147/400	(36·8 %)	107/331	(32·3 %)			113/402	(28·1 %)	81/331	(24·5 %)		
Regularly washed hands for 20 s												
Never/Sometimes	101/399	(25·3 %)	106/331	(32·0 %)	1·212	(0·871, 1·687)	173/405	(42·7 %)	167/332	(50·3 %)	1·319	(0·992, 1·752)
Always	298/399	(74·7 %)	225/331	(68·0 %)		(p = 0·253)	232/405	(57·3 %)	165/332	(49·7 %)		(p = 0·057)
Activity within household (Questionnaire Section 1·5)												
Minimised time with others												
Never	140/395	(35·4 %)	133/322	(41·3 %)	1·221	(0·929, 1·605)	192/397	(48·4 %)	181/319	(56·7 %)	1·493	(1·123, 1·985)
Sometimes	126/395	(31·9 %)	95/322	(29·5 %)		(p = 0·151)	148/397	(37·3 %)	111/319	(34·8 %)		(p = 0·006)
Always	129/395	(32·7 %)	94/322	(29·2 %)			57/397	(14·4 %)	27/319	(8·5 %)		
Kept shared spaces well ventilated												
Never	25/395	(6·3 %)	16/324	(4·9 %)	1·074	(0·815, 1·416)	30/397	(7·6 %)	24/322	(7·5 %)	1·078	(0·824, 1·411)
Sometimes	186/395	(47·1 %)	168/324	(51·9 %)		(p = 0·611)	236/397	(59·4 %)	198/322	(61·5 %)		(p = 0·585)
Always	184/395	(46·6 %)	140/324	(43·2 %)			131/397	(33·0 %)	100/322	(31·1 %)		
Used separate towels												

(*continued on next page*)

Table 4 (*continued*)

	Initially (March 2020)						During last two weeks					
	Shielded		Matched		Comparison		Shielded		Matched		Comparison	
	n	(%)	n	(%)	OR	95 % CI p-value	n	(%)	n	(%)	OR	95 % CI p-value
Never	82/391	(21·0	84/319	(26·3	1·528	(1·152, 2·029)	91/392	(23·2	91/317	(28·7	1·462	(1·108, 1·930)
Sometimes	92/391	%)	93/319	%)		(p = 0·003)	117/	%)	103/	%)		(p = 0·007)
Always	217/	(23·5	142/	(29·2			392	(29·8	317	(32·5		
	391	%)	319	%)			184/	%)	123/	%)		
		(55·5		(44·5			392	(46·9	317	(38·8		
		%)		%)				%)		%)		
Used separate bathroom/cleaned shared bathroom after every use												
Never	166/	(42·5	144/	(45·9	1·226	(0·928, 1·620)	173/	(44·0	158/	(50·3	1·276	(0·965, 1·689)
Sometimes	391	%)	314	%)		(p = 0·152)	393	%)	314	%)		(p = 0·088)
Always	120/	(30·7	100/	(31·8			140/	(35·6	100/	(31·8		
	391	%)	314	%)			393	%)	314	%)		
	105/	(26·9	70/314	(22·3			80/393	(20·4	56/314	(17·8		
	391	%)		%)				%)		%)		
Used kitchen alone/cleaned kitchenware thoroughly												
Never	140/	(35·5	137/	(43·5	1·414	(1·074, 1·862)	169/	(42·6	154/	(49·5	1·376	(1·040, 1·819)
Sometimes	394	%)	315	%)		(p-0·014)	397	%)	311	%)		(p = 0·025)
Always	130/	(33·0	101/	(32·1			139/	(35·0	102/	(32·8		
	394	%)	315	%)			397	%)	311	%)		
	124/	(31·5	77/315	(24·4			89/397	(22·4	55/311	(17·7		
	394	%)		%)				%)		%)		

Comparisons are Adjusted Odds Ratio (OR), with Matched Cohort as reference.
Comparisons adjust for sex; age; and WIMD, treated as a continuous variable.

authors suggested that shielding would have reduced mortality risk during these pandemic waves by 34 % (HR 0.66, 95 % CI:0.58 to 0.76). They also found that, during these waves, the protective effect of shielding was higher in more affluent areas (HR 0.27, 95 % CI: 0.16 to 0.44) compared to the most deprived areas (HR 0.75, 95 % CI: 0.7 = 64 to 0.87); the authors speculate that this may have been because they were likely to have been living in larger homes, which allowed for more effective separation. The authors reported that differences in mortality may have been due to differences between groups.

Jani and colleagues used linked health care records to study the impact of shielding in the population of Greater Glasgow and Clyde during the period March 2020 to May 2020.[26] Of the total regional population of 1,315,071, 2.03 % were on the shielding list due to being classed as clinically extremely vulnerable. The authors also identified 26.5 % of the population as "moderate risk" – those with some identified health conditions but who were not on the shielding list. The remainder of the population was classed as "low-risk". People on the shielding list were found to be eight times more likely to have confirmed COVID-19 infections recorded in their routine data source than the low-risk category; 299 people on the shielding list (1.12 % of those shielding) had confirmed infections during the study period, and 230 were admitted to hospital with COVID-19. The confirmed infection rate for people at moderate risk was 0.53 % (n = 1859) and for those at low risk 0.13 % (n = 1190). This association between inclusion in the shielding programme and rate of infection does not indicate that one caused the other. The authors note that rates of testing for COVID-19 are likely to have been much higher in the shielding group than in the general population, so this confounds these results to an unknown extent. Compared with the low-risk category, the shielded group were 18 times more likely to have been hospitalised but only 4 times more likely to have been admitted to ICU. The higher infection rates may have been partly related to higher testing rates and partly related to healthcare contact rates amongst the clinically vulnerable and extremely vulnerable at a time when healthcare transmission rates were not well controlled. Jani and colleagues reported that shielded people were five times more likely to die after confirmed infection than low risk people and 49 times more likely to die from COVID-19 overall. In this study of 1.3 million people in the west of Scotland from March to May 2020, 27,747 (2.03 %) were advised to shield, and 353,085 (26.85 %) were classified *a priori* as moderate risk. Covid-19 testing was more common in the shielded (7.01 %) and moderate risk (2.03 %) groups, than low risk (0.73 %). Compared to those at low-risk, the shielded group had higher confirmed infections (RR 8.45, 95 % 7.44–9.59), case-fatality (RR 5.62, 95 % CI 4.47–7.07) and population mortality (RR 57.56, 95 % 44.06–75.19). The moderate-risk had intermediate confirmed infections (RR 4.11, 95 % CI 3.82–4.42) and population mortality (RR 25.41, 95 % CI 20.36–31.71). These results are confounded by testing rates and differences between groups. The authors conclude that high risk individuals were at increased risk of death despite shielding and that criteria would have to be expanded for shielding to be effective, including for instance, the elderly.

Despite some mixed findings then, there is no robust evidence concerning the effectiveness of shielding across the UK, in England or Northern Ireland.

Methodological challenges have affected all attempts to measure effects of shielding. We do not attribute differences in overall mortality or in healthcare utilisation to the shielding intervention. However, if the shielding intervention had been successful, we would have expected reductions in infection rates and COVID-19 related mortality. Differences in physical and mental health may be related to the overall health status of people rather than effects of the shielding intervention. We have found clear, consistent and enduring differences between cohorts in self-isolating behaviours which may have impacted on quality of life or mental health.

With a high rate of healthcare contacts amongst the shielded cohort (>1 in five experienced a hospital admission), and known high risk of hospital acquired infection during this period,[9,27] it may have been impossible for CEV people to have been effectively shielded from COVID-19 during the early phases of the pandemic. We have not been able to quantify the risk of carer transmitted infection, but this was also probably high during this period. In the case of a further pandemic our findings indicate that focused efforts to avoid transmission by healthcare workers should have higher priority than advising CEV people to strictly self-isolate. People who adhered to advice to shield themselves from family, friends and community remained at risk of infection through their healthcare contacts. In a future pandemic we recommend that attention needs to be paid to healthcare transmission as a priority because shielding cannot work while infection rates from hospital and other healthcare contacts are high.[28]

One benefit we have found in this study was the higher proportion of

people vaccinated and earlier vaccination in the shielded cohort. The mechanism set up for shielding allowed effective targeting of the vaccination, once available, probably limiting further infection, morbidity and mortality in the shielded population.[29,30] A tailored algorithm to identify those at most risk of harm could potentially be used in a future pandemic.

We cannot exclude the possibility of other benefits of this intervention, as we do not know what would have happened to CEV people had there not been a shielding initiative. If differences between the groups reflected vulnerability to infection, then shielding may have limited higher levels of harm, although we do not have evidence to support this.

It is important to understand the effects of this UK wide public health policy which was introduced to try to protect the most clinically vulnerable from serious adverse health consequences of infection with SARS-CoV-2. Although at individual level strict self-isolation may be an effective way to avoid infection, at population level our findings do not indicate that the policy worked in terms of lowering infection rates or COVID-related deaths and may have carried consequences for mental and physical health.

This evidence can be used to inform policy response to any future pandemic.

Author statements

Ethical approval

The EVITE Immunity study has received approval from the Newcastle North Tyneside 2 Research Ethics Committee (IRAS 295050).

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Competing interests

HS and AE are expert witnesses to the UK COVID Inquiry. HS is an editor of the NIHR Journals Library. AW is a member of the NIHR HS&DR funding committee. HS, MK and AP have received grants from UKRI-MRC, NIHR and HCRW; RL and RP from UKRI-MRC, UKRI-ESCR and HDRUK; AE from HCRW; AW from UKR-MRC, NIHR and HCRW; JD from NIHR; JL from ADR Wales. SJ has received support from CSL Behring, Pharming, Octapharma, UCB Pharma, LFB, Biocryst, Kedrion, Biotest, SOBI, Grifols, Takeda, Sanofi, GSK, The Binding Site, Stratech and HCRW. The other authors declare no interests.

Data sharing

The data used in this study are available in the SAIL Databank at Swansea University, Swansea, UK. All proposals to use SAIL data are subject to review by an independent Information Governance Review Panel (IGRP).

Transparency

The lead author and manuscript guarantor (HS) affirms that the manuscript if an honest, accurate and transparent account of the study being reported, that no important aspects or the study have been omitted and that any discrepancies from the study as originally planned have been explained.

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Appendix A. Supplementary data

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