

**Protocol for a longitudinal mixed-methods study of psychosocial determinants of health behaviour,
health and well-being outcomes during the COVID-19 pandemic: The UK COVID-19 Public Experiences
(COPE) Study**

Authors

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Abstract

Introduction: The COVID-19 pandemic is having a profound and wide-reaching effect on society globally. Understanding what influences health behaviour and how the pandemic impacts on subjective health and well-being in the general population is vital in planning government and health agency responses to current and future pandemics.

Methods and analysis: Mixed-methods longitudinal study comprising a large-scale prospective online survey with three phases of data collection at baseline (March/April 2020), 3-months (June/July 2020), and 12-months (March/April 2021); data linkage with Electronic Health Records, pre-pandemic self-reported health and lifestyle data, and; longitudinal qualitative interviews with up to 30 individuals in May 2020, November 2020, and March 2021. The Capability, Opportunity, Motivation model of Behaviour (COM-B) will be used as the theoretical framework for the study. Participants will be >10,000 adults (18+ years) living in the UK at the time of recruitment to the baseline online survey, invited via social media snowballing and advertising (Facebook, Twitter, Instagram) and the HealthWise Wales (HWW) research registry. Interview participants will be purposively sampled from survey respondents using a maximum variation approach. We will use multivariable mixed regression models, accounting for the clustered nature of repeated observations within individuals, to examine changes in health behaviour over time and

identify psycho-social predictors of health and well-being outcomes. Qualitative data will be analysed thematically. Methodological, data, and investigator triangulation approaches will be used to integrate our findings.

Ethics and dissemination: The COPE study received ethical approval from the Cardiff Metropolitan University Applied Psychology ethics panel on 13.3.20 (reference Sta-2707). Findings will be disseminated through rapid knowledge exchange with policy makers and public health agencies, publications in peer-reviewed journals, and co-produced public-facing summaries.

Keywords: COVID-19, SARS CoV2, longitudinal, mixed-methods, health behaviour, protocol, cohort profile, COM-B.

Strengths and limitations of this study

- This study adopts a prospective longitudinal mixed-methods approach and was launched in the very early stages of the COVID-19 outbreak in the UK (March 2020), enabling us to build a detailed and unique understanding of health behaviours and subjective health and well-being of a UK cohort over the course of the first 12 months of the pandemic.
- We are using an established theoretical framework, the COM-B model, to guide the design of the study, analysis, and interpretation of findings.
- Data analysis and interpretation will be complex and will require consideration of the policy, disease prevalence and severity, and wider social context during each phase of data collection.
- We are not employing a random sampling technique, therefore, our study population will be self-selecting; we will need to consider the socio-demographic profile of our cohort relative to the

general UK population when interpreting our findings and considering our ability to generalize from them.

Introduction

The COVID-19 pandemic is having a profound and wide-reaching effect on society globally¹. Public perceptions of pandemic threats and government policies can influence adherence to containment, delay, and mitigation policies such as physical distancing, hygienic practices, use of physical barriers (e.g. face coverings), and uptake of testing, contact tracing, and vaccination programs²⁻¹⁴. There are marked social inequalities in the risk of harm to health and well-being during the COVID-19 pandemic, in particular in relation to ethnicity, occupational status, social deprivation, gender, housing, and pre-existing physical and mental-health conditions¹⁵⁻¹⁸. Understanding the impact of the pandemic and related policies on physical health and psychological well-being is a high priority for government and public health agencies¹¹⁹. High-quality research that adopts a holistic approach to behaviour, health, and well-being is needed to inform the immediate response to and long-term recovery from the COVID-19 pandemic^{1 18}.

The Behaviour Change Wheel (BCW) provides an integrated method for characterising and designing behaviour change interventions²⁰. The Capability, Opportunity, and Motivation model of Behaviour (COM-B) forms the hub of the BCW framework, providing a system for identifying potentially modifiable determinants of behaviour and allowing these to be mapped against the intervention functions and policy categories of the BCW²⁰. The COM-B model has been used to explain a range of infection-related health behaviours, including hand hygiene, environmental disinfection, use of personal protective equipment (PPE), uptake of screening and testing, use of antivirals and antibiotics for respiratory tract infections, uptake of influenza vaccines, and lifestyle behaviour in the context of respiratory tract infection outbreaks

Using the COM-B model as a theoretical framework²⁰, we rapidly developed a mixed-methods prospective longitudinal study during the early stages of the COVID-19 outbreak in the UK to enable us to investigate changes in health behaviour, health and well-being over the first 12 months of the pandemic. The COPE study launched on the 13th of March 2020 and data collection is scheduled to be completed in April 2021. In this protocol, we describe the COPE study methods, analysis approach, ethical considerations and dissemination plan.

Aims

The COPE study aims to build a detailed understanding of how people experience and respond to the COVID-19 pandemic and government policy during the first 12-months since the start of the UK outbreak, focusing on understanding the:

- Determinants of infection transmission-prevention and lifestyle behaviours.
- Impact of the pandemic on subjective and objective health and well-being.
- Specific challenges affecting sub-groups of the population that are at increased risk of adverse health and well-being outcomes during the pandemic.

Study design

This mixed-methods study design includes three work packages: a longitudinal prospective online survey, data linkage, and qualitative interviews. The objectives of each work package are described below:

Work Package 1: Longitudinal online survey

1. Assess health behaviour in a large cohort at three time points over the first year of the COVID-19 pandemic in the UK, focusing on:

- a. Infection transmission-prevention behaviours (e.g. social distancing, hygiene, physical barriers to infection, engagement in testing, tracing and vaccination programs).
 - b. Lifestyle behaviours (e.g. physical activity, diet, alcohol, smoking, and management of pre-existing health conditions).
2. Identify psychosocial barriers to infection-transmission prevention behaviour at each phase of the survey.
3. Establish how attitudes, behaviour, and self-reported health and well-being change across the three phases of data collection and contextualise this based on COVID-19 case numbers, hospitalisation and mortality, government policy, and media and social media discourse at each phase of data collection.
4. Identify differences in health behaviour, determinants of health behaviour, and health and well-being outcomes at each phase of the survey by socio-demographic group.
5. Assess the association between self-reported health behaviour and self-reported health and well-being outcomes.
6. Identify and investigate additional emerging issues affecting individual outcomes and planning the public health response at each phase of the survey, depending on the UK context at that point in time.

Work Package 2: Linkage with routine electronic health record (EHR) data and pre-pandemic lifestyle and self-reported health and well-being data for participants recruited via the HWW cohort⁴⁴:

1. Describe pre-pandemic health and lifestyle data for our cohort including data on diet, exercise, alcohol, smoking, work, well-being, mental health, general health, coping mechanisms and resilience, family composition, neighbourhood and health literacy.

2. Identify pre-pandemic health and lifestyle predictors for self-reported health behaviour during the first 12-months since the start of the UK COVID-19 outbreak.
3. Assess the association between health behaviour and objective health outcomes (confirmed and suspected COVID-19 infection, mortality, primary care General Practitioner (GP) consultations, secondary care hospital admissions and outpatient care via EHR data).

Work package 3: Longitudinal qualitative interviews:

1. Explore how people perceive the impact of the COVID-19 pandemic on their lives over time.
2. Explore beliefs about the virus, vaccine attitudes, behaviour, physical and psychological well-being over time.
3. Identify perceived barriers and facilitators to following government advice during the different stages in the pandemic development (containment, delay, mitigation), including trust and credibility of information.
4. Investigate how physical distancing measures have impacted on people’s lives, with a specific focus on coping strategies, digital interaction, use of healthcare services, psychological well-being, physical activity, financial and caring responsibilities.

Table 1 provides a summary of the topics we plan to cover in each work package over the course of the study.

Table 1: COPE study data collection plan

Topic	Online survey	Data linkage	Qualitative interviews
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	Phase 1: Mar/ Apr 20	Phase 2: Jul/ Aug 20	Phase 3: Feb/ Mar 21	HWW: Pre-pandemic data	EHR: Extracts in Jan & Apr 21	Phase 1: May 20	Phase 2: Nov 20	Phase 3: Mar 21
Health behaviour								
COVID-19 transmission prevention behaviour	X	X	X			X	X	X
Lifestyle behaviour (smoking, diet, physical activity, social contact, self-care)	X	X	X	X		X	X	X
Psychosocial determinants of health behaviour								
Socio-demographic data	X	X		X	X			
Capability: COVID-19 knowledge and information needs	X	X	X			X	X	X
Opportunity: availability/accessibility of healthcare services and treatment		X	X			X	X	X
Motivation: COVID-19 perceived impact, susceptibility and severity, self-efficacy, fear, anxiety, hyper-vigilance	X	X	X			X	X	X
Motivation: attitudes towards COVID-19 vaccination, community testing, and contact tracing apps		X	X				X	X
Motivation: attitudes towards future COVID-19 waves/new pandemics			X				X	X
Opportunity: social isolation/support, neighbourhood cohesion, social norms relating to COVID-19, portrayal of risk in media/government/public health messaging, life events (e.g. bereavement, job losses)		X	X	X		X	X	X
Health and well-being outcomes								
Subjective physical and mental health	X	X	X	X		X	X	X
Patient experience (use of NHS services, patient safety, bereavement)		X	X	X	X	X	X	X

Primary healthcare use	X	X	X	X
Objective health outcomes (including COVID-19 suspected/confirmed infection, mortality, hospital admissions, COVID-19 vaccination uptake)		X		X

HWW: HealthWise Wales cohort pre-pandemic data, EHR: Electronic Health Record data

COPE Study Context

On the 9th of January 2020, the Chinese authorities informed the World Health Organization (WHO) that an outbreak of viral pneumonia cases in Wuhan had been caused by a novel coronavirus ⁴⁵. The first confirmed case of COVID-19 disease, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was identified in the UK on the 31st of January 2020. On the 5th of March 2020, the first death as a result of COVID-19 was confirmed in the UK, with a total of 115 people having tested positive ⁴⁶. The World Health Organization (WHO) declared the COVID-19 outbreak a pandemic on the 11th of March 2020 ⁴⁷. It was clear by this stage that COVID-19 posed a significant threat to health and well-being globally and in the UK population ⁴⁸.

There are many uncertainties relating to the progression and impact of the COVID-19 pandemic and government responses to it. Fixed time points for survey data collection facilitate effective resource, delivery, planning and the potential for repeated core measures over time. Building in flexibility to the design will enable us to capture additional data in each phase in response to emerging issues, using the WHO pandemic phase descriptions to contextualise our data⁴⁹. Our plans for data linkage and analysis will adapt as additional data becomes available as part of Electronic Health Record (EHR) data that can be accessed via the Secure Anonymised Information Linkage (SAIL) Databank ⁵⁰⁻⁵², such as COVID-19 testing, contact tracing, and vaccination data. We will contextualise our findings based on the policy context during each phase of data collection. Details of the UK and Welsh Government response to the COVID-19

pandemic are available at <https://research.senedd.wales/research-articles/coronavirus-timeline-welsh-and-uk-governments-response/> (accessed 19.1.21). We will map prominent themes and key events in mainstream media relating to COVID-19 during each data collection phase to be able to relate these to public perceptions and attitudes towards the pandemic.

Longitudinal online survey

Participants and sampling

A target number of 10,000 adults (18+ years) living in the UK at the time of recruitment will be recruited to the COPE study through the Phase 1 online survey between March 13th and April 14th 2020. This large sample will enable us to capture data on a wide range of experiences and carry out sub-group analysis by socio-demographic group. Recruitment to the Phase 1 survey will occur via two routes:

1. A multi-faceted sampling method based on convenience sampling, snowballing, and purposive sampling via Social Media (Facebook, Twitter, and Instagram). We have created dedicated Facebook (@COVID19publicexperiencesUK), Instagram (@covid19publics1) and Twitter (@COVID19publics1) feeds, and a study website (<https://copestudy.yolasite.com>). Through these, we will regularly post information about the study and invitations to take part in the baseline survey, which will include a hyperlink to the online survey. Social media feeds will be regularly monitored and moderated. Facebook and Instagram's paid promotion feature will be used to boost posts, tailored as recruitment progresses to focus on reaching under-represented demographic groups.
2. From the 20th of March, the study will be advertised via HealthWise Wales (HWW), a national population survey and research register of residents who live or receive healthcare in Wales. Invitations to take part will be e-mailed to HWW participants on two occasions, providing a summary of the COPE study and a hyperlink to the survey.

Phase 1 data will be collected using the Onlinesurveys.ac.uk platform. Phase 2 and Phase 3 data will be collected using Qualtrics.com for pragmatic reasons, as the Cardiff Metropolitan University institutional subscription for Qualtrics includes additional functionality for contacting and following up participants.

Online survey measures

Phase 1 and Phase 2 survey questions are provided in Supplemental Material 1 and 2.

Phase 1 measures:

- Demographic information: age, gender, socio-economic status, highest level of education, employment status, occupation, religion, ethnicity, caring responsibilities (children under 18-years of age, children under the age of 5-years, children with pre-existing health conditions, adults with pre-existing health conditions, older adults), sexual orientation, religion, recent travel outside of the UK, and whether the UK was participants' country of birth.
- Experiences of COVID-19: Suspected or confirmed cases of COVID-19 oneself and for close family/household members, experience of key symptoms of COVID-19 (continuous cough, fever, loss of taste or smell).
- Open text items: Participants will be asked to describe the impact of the pandemic on their day-to-day life, whether they have done anything to avoid getting the COVID-19 infection, whether they have done anything to prepare for measures that might come in (such as school closures and travel restrictions), and barriers and facilitators to following government guidance. These items will be included to capture information on a rapidly changing situation in a flexible way, and to inform the design of closed-response measures to be used in future phases of the survey.
- Perceived risk, anxiety and behavioural responses: The core questions in this section were adapted from surveys conducted during previous viral pandemics⁵³⁻⁵⁵. Questions focus on

perceived severity and vulnerability to the COVID-19 infection, perceived efficacy of preventative measures, self-efficacy, intention to take measures, vaccination intention, maladaptive responses (underestimation, fatalism, and avoidance), information (quantity, attention paid, reliability of government information and communication preferences), and knowledge about modes of transmission, infectiousness and fatality. To establish how the perceived personal risk from COVID-19 compared with other infectious diseases in circulation in the UK in recent years, we will include questions on susceptibility to and harmfulness of seasonal influenza, swine flu (H1N1), the common cold, measles and stomach bugs.

- COVID-19 transmission-prevention behaviour: 10 items relating to hygiene, social distancing, and use of physical barriers (e.g. face coverings and disposable gloves). These were based on emerging guidance at the time of the Phase 1 survey in early March 2020, and will ask people to indicate whether they are engaging in each behaviour less often, about the same, more often than usual, or not applicable.
- Self-reported health and well-being: Three items will be included to assess psychological well-being and one to assess general health based on the SF-36 measure⁵⁶. Participants will be asked whether they have pre-existing medical conditions, which conditions these are, and whether they have received a seasonal flu vaccination in the last 12-months.
- Lifestyle behaviour: Participants will be asked whether there had been a change in their lifestyle behaviour during the pandemic (increase, decrease, or no change) using 14 items relating to physical activity, diet, alcohol, smoking, and self-care and socialising.

Phase 2 measures:

The phase 2 survey will include a core module relating to health behaviour, health and well-being, which everyone will be asked to complete. There will be three additional optional modules relating to neighbourhoods, use of NHS services and bereavement that participants can choose to complete. These will be made optional to reduce participant burden while capturing valuable information on a range of relevant emerging issues.

Phase 2 core module

- Items on COVID-19 risk perception, lifestyle, and subjective health and well-being included in Phase 1 will be repeated (perceived susceptibility, harm, worry, thinking about COVID-19, psychological well-being and general health SF-36 items).
- New measures of infection-transmission prevention behaviour, psychosocial determinants of infection-transmission prevention behaviour, and attitudes towards vaccination, community testing and tracing will be developed for use in the Phase 2 survey based on the Phase 1 qualitative and open-text survey data. Analysis of the psychometric properties of these measures is underway in preparation for scoring for analysis and use in the Phase 3 data collection point in February/March 2021 (details available from authors on request).
- Experiences of COVID-19: Questions on suspected or confirmed cases of COVID-19 for self or close contacts will be repeated from Phase 1, but the section has been updated and expanded to obtain further detail based on the roll-out of community testing services and emerging knowledge of symptoms associated with COVID-19.
- Additional demographic and health data: current UK nation of residence, pregnancy and birth, changes to employment, and shielding.
- The PHQ-4⁵⁷ will be added to enable comparability with international longitudinal studies of the impact of the pandemic on mental health (see <https://www.covidminds.org>).

Phase 2 optional additional modules:

- Experiences of using NHS services: delays in seeking / accessing treatment, disruption to ongoing care, perception of whether experience of accessing / using services differed to pre-pandemic experiences, and patient safety concerns.
- Neighbourhoods: type of area (city, large town, small town, village or hamlet, isolated dwelling), access to private and public outdoor spaces, four items from the Neighbourhood Cohesion Scale ⁵⁸ (attracted to living in the neighbourhood, sense of community, advice, and friendships), and an additional item 'I feel my behaviour is being observed or judged by my neighbours'.
- Bereavement experiences during the pandemic: relationship to the person/people who died, whether COVID-19 was a suspected or confirmed cause of death, whether they had experienced limited contact with their loved one in their last few days of life, been unable to say goodbye properly, had restricted funeral arrangements, or experienced social isolation following bereavement, and an open question for further comments on their experience.

Phase 3 measures:

The Phase 3 survey (12-month follow-up) is due to take place in March/April 2021. All participants who completed the survey at baseline will be invited to take part. The Phase 2 core module will be repeated. Optional modules and additional items will be reviewed during January and February 2021 to ensure that information on relevant emerging issues is captured, such as attitudes towards vaccination, vaccination uptake, and attitudes towards the recovery phase of the pandemic.

Data linkage

Participants from the HWW cohort have completed a number of questionnaires relating to health, well-being, neighbourhoods, resilience, and lifestyle behaviours before the commencement of the COVID-19 pandemic⁴⁴. These data are securely record-linked⁴⁴ to administrative and EHR data via the Secure

Anonymised Information Linkage (SAIL) Databank and are stored and available for analysis via the Secure Analysis Portal and Protected HealthWise Wales Information Repository (SAPPHIRE) subject to HWW data governance procedures⁴⁴. COPE participants who are registered with HWW will be asked for consent to link their data during their 3-month and 12-month follow-up surveys. For those providing consent, personal identifiable information will be collected on full name, address and date of birth which will be merged with data on gender provided during the Phase 1 survey to facilitate accurate data linkage using a secure split-file procedure⁵¹. This will provide access to unique data on:

- Pre-pandemic self-report measures of health behaviour (diet, physical activity, alcohol, smoking), neighbourhood cohesion, mental health, well-being, resilience, and socio-economic status.
- Patient-driven healthcare service usage during the pandemic: GP consultations (frequency and reason); Accident and Emergency (A&E) attendances; Outpatient appointments and attendances; use of NHS 111.
- Objective health outcomes during the pandemic: mortality, all cause and COVID-19 specific hospital admissions, COVID-19 test results and if available, vaccine uptake.

A full list of data requested for the first data download (anticipated date of download: January 2021) is included in Supplemental Material 3.

Longitudinal qualitative interviews

The COPE study includes longitudinal interviews with up to 30 individuals at three time points; Phase 1 (May 2020), Phase 2 (November 2020) and Phase 3 (March 2021) to establish how people's experiences of the pandemic, attitudes, and perception of risk develop and change over the course of the pandemic. The qualitative study incorporates a range of visual and creative methods, enabling participants to drive the direction of the interview and share the experiences that are most important to them⁵⁹⁻⁶¹.

Participants and sampling: Longitudinal qualitative interviews

Up to 30 participants will be purposively sampled for the qualitative interviews from those who complete the baseline online survey via the UK-wide social media recruitment route and have agreed to be contacted for follow-up interviews. A maximum variation sampling approach will be used to capture a range of views and experiences based on gender, age, socioeconomic status, pre-existing conditions, and caring responsibilities, perceived susceptibility and severity of COVID-19. Sample adequacy⁶² has been determined by considering the composition as well as the size of the sample and pragmatic considerations relating to resources and the timeframe for the study, and previous studies of attitudes towards novel respiratory tract infections⁶³⁻⁶⁵.

Qualitative interview procedure:

Interview participants can choose to take part in the interviews over telephone, Skype, Zoom, MS Teams, or WhatsApp. Qualitative data will be audio-recorded, transcribed verbatim and anonymized prior to analysis.

Phase 1 interviews: Semi-structured baseline interviews

Phase 1 (baseline) interviews will be conducted in May 2020, using a flexible narrative approach guided by a semi-structured interview schedule (Supplemental Material 4). Topics will include: personal experience of COVID-19 infection in self or others; perceptions of symptoms/symptom congruence and behavioural and emotional responses; perceptions of government and health agency responses to the outbreak; perceived social responsibility; perceived barriers and facilitators to engaging with government/health agency guidance and infection control measures; perceived impact of COVID-19 on

behaviour including eating habits, quality of life; coping methods including physical activity, activities of daily living and social connectivity.

Phase 2: Visual artifact facilitated narrative interviews

Follow-up interviews will use an artefact-facilitated approach^{66 67} to enable participants to discuss the issues that are most important to them. Three pre-selected images depicting events during the COVID-19 pandemic will be included towards the end of the interview to stimulate further discussion about societal aspects of the pandemic. The images focus on everyday life (shopping, childcare, being at home), and were selected based on feedback from the study patient and public representatives. In order to avoid psychological distress, none of the images represent highly emotive topics related to the pandemic (e.g. critical care). Participants will be provided with copies of the images ahead of the interview to allow them to reflect on these and on their experiences.

Phase 3: Timeline facilitated narrative interviews

In March 2021, we will conduct timeline-facilitated interviews^{61 68} with participants to enable them to reflect on their experiences over the last year, and talk about their hopes, fears, and expectations for the future. Visual qualitative approaches help to shift the power-dynamics in interviews, enabling participants to take control over their own narratives providing high quality rich data⁶¹. An example timeline template is provided in Supplemental Material 5. The accompanying topic guide for the 12-month follow-up interviews will be finalised in February 2021 to take into account the changing landscape of the COVID-19 pandemic and the findings of earlier phases of the qualitative study and survey.

Patient and public involvement

Members of the public were consulted informally to comment on the online baseline survey design, which needed to be developed rapidly before we had secured any external funding for the project. We subsequently invited two members of the public to formally join our research team. They have commented on the design of the study, including the survey and interview questions in each phase, are co-applicants on funding applications, and are included as co-authors on key study outputs. They will also be supporting us with the preparation of public-facing updates and summaries of our findings as the project progresses.

Analysis approach

Descriptive statistical analysis will be carried out on data from each of the survey phases and data linkage download points to characterise our sample in terms of their demographic profile, health behaviour, and health and well-being outcomes. We will use multivariable mixed regression models, accounting for the clustered nature of repeated observations within individuals, to examine changes in health behaviour over time, and investigate whether previous attitudes and behaviours are associated with subsequent and self-reported health and well-being outcomes. To investigate how the association between health attitudes and behaviours and subsequent health and well-being outcomes vary across different sub-groups (e.g. ≥ 70 years of age, pre-existing health condition, health/frontline occupation, insecure employment), models will be extended to include subgroup-predictor interactions. We will explore the use of post-stratification weights and regression adjustments to allow for differences in socio-demographic and clinical factors between sample and population (e.g. age, gender, socio-economic status, ethnic group, long-term conditions, shielding and vaccination priority categories, pregnancy).

Qualitative data from each phase of data collection will be analysed using thematic analysis⁶⁹, with consistency and discrepancy between themes across the three time points being explored to enable us to

understand how people's experiences, views, and perceptions change over time. The coding framework will be built around the COM-B model⁷⁰ to enable us to develop a theoretical model of behavioural responses to the COVID-19 outbreak and logic model of potential interventions. To ensure rigour and reflexivity we will use regular qualitative research team meetings to discuss data production, development of the coding framework and data analysis, with each member of the qualitative research group adding their unique perspective to the analysis.

We will triangulate data^{71 72} from our survey, data linkage, and qualitative work to build a comprehensive understanding of changes in health behaviour, and objective and subjective mental and physical health outcomes. Three approaches to triangulation will be applied: methodological (survey and interviews), data (survey responses and EHR data), and investigator (i.e. more than one data analyst) triangulation⁷³.

Ethics

Ethical approval was obtained for the COPE Study from the Cardiff Metropolitan University Applied Psychology ethics panel on 13.3.20 (Project reference Sta-2707). Participants will provide consent and confirm eligibility electronically at the beginning of the online survey, and informed verbal consent will be sought and audio-recorded at the start of each qualitative interview. This ethical approval also covers recruitment and data linkage supported by the Health Wise Wales research database (Wales Research Ethics Committee: approvals 15WA0076/20WA0064). Approval for use of evolving COVID related datasets and other anonymised healthcare and administrative datasets, provisioned by the Secure Anonymised Information Linkage (SAIL) Databank to HWW, will be achieved by amendment of existing permissions granted by the SAIL independent Information Governance Review Panel (IGRP) to HWW reference Project 0415. HWW will make available data only on COPE UK participants who have provided

consent for record linkage. As described above, access to all HealthWise Wales data are via SAPPHIRE and subject to HWW governance and access procedures⁴⁴.

Dissemination

The COPE study will enable us to identify potentially modifiable psychosocial determinants of the health behaviour specified using the Capability, Opportunity, and Motivation model (COM-B)^{8 20}. In line with WHO guidance⁷, this research will enable us to provide timely in-depth information to key stakeholders including members of the public, governments, public health agencies and health and social care providers to inform the design and implementation of the COVID-19 pandemic response. We will engage with partners in UK and the devolved nation governments and our international infection research networks to contribute to collaborative efforts to understand and inform the short- and long-term response to the pandemic and increase preparedness for future pandemic threats. Guided by our Public and Patient Involvement members, we will disseminate public-facing summaries, infographics, and videos via the project social media feeds and website.

Acknowledgements

We are grateful to our patient and public involvement members for their invaluable contributions to designing and steering this research. This study was facilitated by HealthWise Wales, the Health and Care Research Wales initiative which is led by Cardiff University in collaboration with SAIL, Swansea University. We are grateful for their invaluable support and expertise. This study will make use of data held in the Secure Anonymised Data Linkage (SAIL) system, which is part of the e-health national records research infrastructure for Wales. We would like to acknowledge all the data providers who make anonymised data available for research. We would like to thank Cardiff Metropolitan University, Cardiff University, PRIME Centre Wales, and Swansea University who have all been immensely supportive of this work, allowing our

team the time, resources and infrastructure to get the study up and running quickly during the very early stages of the pandemic.

Funding

This work is supported by Health Data Research UK, which receives its funding from HDR UK Ltd (HDR-9006) funded by the UK Medical Research Council, Engineering and Physical Sciences Research Council, Economic and Social Research Council, Department of Health and Social Care (England), Chief Scientist Office of the Scottish Government Health and Social Care Directorates, Health and Social Care Research and Development Division (Welsh Government), Public Health Agency (Northern Ireland), British Heart Foundation (BHF) and the Wellcome Trust. Phase 1 & 2 of this research were supported by internal resources at Cardiff Metropolitan University, Cardiff University, HealthWise Wales, and PRIME Centre Wales. This included allowing core team members time to design, set up, and conduct the baseline and 3-month data collection. Financial support was provided by internal Cardiff Metropolitan University 'Get Started' and Cardiff University Division of Population funds to support transcription of the Phase 1 qualitative data. In August 2020, we were awarded a Sêr Cymru III Tackling COVID-19 grant (Project number WG 90) to cover the period between the 1st of August 2020 to 30th of April 2021 to support our Phase 3 follow-up data collection, analysis and dissemination. PRIME Centre Wales, HealthWise Wales (HCRW 519709) and the Centre for Trials Research are part of Health and Care Research Wales infrastructure. Health and Care Research Wales is a networked organisation supported by Welsh Government.

Author contributions

Britt Hallingberg produced the first draft of this protocol. Denitza Williams drafted the section on the qualitative methods, Rhiannon Phillips drafted the section on the survey methods, Rebecca Cannings-

John, Pauline Ashfield-Watt, Kathryn Hughes and Ashley Akbari drafted the sections relating to the data linkage component. David Gillespie and Rebecca Cannings-John drafted the quantitative analysis approach section. Rhiannon Phillips co-ordinated the process of gathering and acting on feedback and further specialist from co-authors. Susan H. Campbell and Sarah Peddle commented on the manuscript from a Public and patient Involvement perspective. Fiona Wood, Bethan Pell, Paul A. Sellars, and Anna Torrens-Burton contributes to the sections on qualitative methods and analysis approach. Emma Thomas-Jones (common infections research, study design and management), Delyth James (behaviour relating to medication), Diane Crone (physical activity), Catherine Heidi Seage (eating behaviour), Nick Perham (risk perception), Wouter Poortinga (environmental psychology), Karin Wahl-Jorgensen (media), James Blaxland (microbiology), Natalie Joseph-Williams (healthcare communication and patient safety), Emily Harrop (bereavement), Khadijeh Taiyari (statistician) have all been involved with the design of the study and have commented on their specific areas of expertise. All authors have read, provided comments on, and approved the final version of this manuscript.

Conflicts of Interest

None to declare.

Word count: 3,981

Data Availability Statement

Raw data from our COPE online survey and qualitative data will not be made publicly available due to security and ethical considerations. The data provided is of a detailed and sensitive nature, and our public contributors as well as potential research participants expressed concerns about privacy and security during the development and recruitment stages of this research. Where participants have provided

consent for their data to be linked to HealthWise Wales Survey data and administrative health care and EHR provisioned by the SAIL databank, these data will be available only via the HealthWise Wales secure portal SAPPHIRE which is held on the UK Secure eResearch Platform UKSeRP, Swansea University, Swansea, UK⁴⁴. A multistage application process is required for data sharing and access <https://www.healthwisewales.gov.wales/for-researchers/>

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