

BMJ Open Protocol of the COVID-19 Health and Adherence Research in Scotland (CHARIS) study: understanding changes in adherence to transmission-reducing behaviours, mental and general health, in repeated cross-sectional representative survey of the Scottish population

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ABSTRACT

Introduction COVID-19 has unprecedented consequences on population health, with governments worldwide issuing stringent public health directives. In the absence of a vaccine, a key way to control the pandemic is through behavioural change: people adhering to transmission-reducing behaviours (TRBs), such as physical distancing, hand washing and wearing face covering. Non-adherence may be explained by theories of how people think about the illness (the common-sense model of self-regulation) and/or how they think about the TRBs (social cognition theory and protection motivation theory). In addition, outbreaks of infectious diseases and the measures employed to curb them are likely to have detrimental effects on people's mental and general health. Therefore, in representative repeated surveys, we will apply behavioural theories to model adherence to TRBs and the effects on mental and general health in the Scottish population from June to November 2020, following the initial outbreak of COVID-19.

Methods and analysis Repeated 20 min structured telephone surveys will be conducted with nationally representative random samples of 500 adults in Scotland. The first 6 weeks the survey will be conducted weekly, thereafter fortnightly, for a total of 14 waves (total n=7000). Ipsos MORI will recruit participants through random digit dialling. The core survey will measure the primary outcomes of adherence to TRBs, mental and general health, and explanatory variables from the theories. Further questions will be added, enabling more detailed measurement of constructs in the core survey, additional themes and questions that align with the evolving pandemic.

Ethics and dissemination Ethical approval for this study was granted by the Life Sciences and Medicine College Ethics Review Board (CERB) at the University of Aberdeen

Strengths and limitations of this study

- The CHARIS study will provide insights into the link between (changes in) adherence to transmission-reducing behaviours and explanatory factors, and their effects on mental and general health, including event-related changes (eg, when government directives change).
- CHARIS will provide fast, real-time, information in a representative sample, making the findings generalisable to the Scottish population, to support and inform decision making for policy-makers, public health and service commissioners.
- CHARIS is underpinned by evidence-based psychological theories, therefore, our study can draw on a large existing evidence base that informs the measures used, and details how individual constructs are meaningfully related.
- The primary limitation of this study is the use of a limited set of self-report measures that would open to a number of sources of error, including memory errors and social desirability bias.

(CERB/2020/5/1942). Results will be made available to policy makers, funders, interested lay people and other researchers through weekly reports and three bimonthly bulletins placed on the CHARIS website and advertised through social media.

BACKGROUND

In December 2019, a new coronavirus (SARS-CoV-2) emerged, leading to a pandemic of an acute respiratory syndrome (COVID-19) in humans.¹ The impact of the

pandemic on European countries has been highly variable, and the UK has one of the highest case and death rates from COVID-19 in Europe.²

As in previous outbreaks of infectious disease (eg, SARS, H1N1 influenza),³⁻⁵ stringent public health measures were implemented to curtail the spread of SARS-CoV-2.⁶ However, in the current pandemic, social isolation measures were applied to whole populations rather than limited to those who are known to have been in contact with the virus. This is an unprecedented response by individual governments and the international community.

Until a vaccine against coronavirus or an effective treatment for COVID-19 becomes available, adherence to transmission-reducing behaviours (TRBs) is crucial to protect lives and halt, or at least slow, transmission. Therefore, understanding the factors that determine adherence to TRBs is essential. While TRBs lessen both personal risk of acquiring COVID-19 and population level rates of COVID-19, they may have detrimental impacts on people's health, especially their mental health.⁷⁻⁹ Further, the impact of the COVID-19 pandemic on mental health may vary between groups in the general population due to pre-existing differences, including stresses of living in areas of high deprivation with low income, less secure housing and related effects.¹⁰ Moreover, the impact of COVID-19 may also be more pronounced for people with long-term conditions requiring supported self-management,¹¹ or people who are self-isolating (shielding) for instance due to older age.¹² Thus, our understanding of adherence to TRBs requires concomitant study of mental and general health to enable the investigation of the relationship between them and the impact of the pandemic on health more broadly.

TRANSMISSION-REDUCING BEHAVIOURS

Health policy, including guidelines on TRBs, is the remit of each devolved nation within the UK. The Scottish Government required the population to adopt strict physical distancing (including staying at home and only going out for a very few specific reasons, such food, medicine, work or exercise and always staying at least 2 m from other people), thorough hand hygiene measures and latterly recommended the wearing of face coverings when shopping for food or using public transport (for the Scottish roadmap out of the lockdown see¹³).

As COVID-19 is thought to spread via contact between individuals through respiratory droplets,¹⁴ TRBs, such as physical distancing should be effective to reduce transmission. Indeed, an early modelling study found that physical distancing measures can be effective in reducing the progression of the coronavirus that causes COVID-19, delaying the epidemic peak, and delaying a potential secondary peak.¹⁵ In addition to direct social exposure to respiratory droplets, COVID-19 is also thought to spread by contact with infected surfaces and subsequently touching the eyes, nose or mouth.¹⁴ Since face-touching is frequent and habitual,¹⁶ prevention of transmission

focuses on improving hand hygiene.¹⁷ Good hand hygiene means washing your hands frequently, using soap and water, and for at least 20 s.^{18 19} Hand washing is advised every time one enters a building, including entering one's home, when you blow your nose, sneeze or cough, and eat or handle food.²⁰ Hand washing has been shown to reduce the incidence of infectious diseases, especially when hand washing is done correctly and at the correct times.²¹⁻²³

A study investigating public awareness of hand washing found that higher numbers of Google searches for 'hand washing' were associated with lower spreading speed of COVID-19 in 21 countries including England,²⁴ suggested public interest in and adherence to effective hand washing practices might go hand in hand. In contrast, the evidence for the effectiveness of wearing facemasks or face coverings remains a topic of debate.^{25 26} WHO reiterated that there is limited evidence that wearing medical masks by the public is an effective preventive measure,^{27 28} but have recently changed their advice to recommend non-medical masks of face coverings in settings where physical distancing difficult.²⁹ Wearing of a face covering (including nonmedical face coverings) in places where social distancing is difficult, such as food shops and public transport, has been advised worldwide, including recently at the start of Phase One after the lockdown in Scotland.³⁰

It is not only necessary for the public to adopt these TRBs, it is also essential that they maintain adherence to TRBs consistently over the long term, certainly until a vaccine or other effective treatments for COVID-19 become available. Prem *et al*,¹⁵ in their study of the effectiveness of physical distancing, concluded that little is known about maintenance of the behaviour changes required of the population over time. Further, there are some easily identifiable challenges to the maintenance of TRBs. Hand washing is a highly habitual behaviour that is particularly resistant to sustained change,³¹ and the COVID-19 response required an increased frequency and probably thoroughness of hand washing for people in the general population. While some have argued that the precautionary principle be applied to the recommendation to wear face coverings,^{25 32} others have cautioned against recommending their use without careful consideration of their potential side effects,²⁶ such as the potential to engender a false sense of security in relation to other TRBs, such as physical distancing and hand washing. This could result in reduced adherence to these TRBs that have demonstrated efficacy in relation to COVID-19 control.³² In addition, to wear face coverings safely might necessitate adoption of additional TRBs, such as not touching the masks, otherwise their use may be counterproductive.²⁶ There is an important and urgent need, therefore, to understand adherence to TRBs over time. This need is especially pressing as lockdown restrictions are eased and adherence to TRBs, especially physical distancing, arguably becomes more challenging.

THEORETICAL APPROACHES TO HUMAN MOTIVATION AND BEHAVIOUR EXPLAINING TRB ADHERENCE

Three types of psychological theory are particularly pertinent to the situation of a pandemic and explaining how people behave when faced with an illness threat and with the requirement or advice to change their behaviour. First, models of how people think about the illness are important, second how people think about the recommended behaviours and third how people think about the risks.

The common-sense model of self-regulation (CS-SRM) is a model of how an individual represents a potential illness threat, in this case COVID-19,³³ and has for example previously been applied to predict psychological responses to Influenza A, H1N1.³⁴ The CS-SRM identifies cognitive and emotional representations of illness and proposes that these representations affect the behavioural response to it. Cognitive representations that CS-SRM identifies are beliefs about illness identity (eg, label, symptoms), personal consequences of the illness, timeline including duration and fluctuations, whether and how the illness can be cured or controlled by the individual or by medical treatment and what causes the illness.³⁵ Emotional representations indicate the emotions that are engendered by the illness threat (such as anxiety or worries). The person's response, or way of coping with the threat, may be directed at the cognitive or emotional representations or at both: for example, they might engage in TRBs to reduce anxiety and/or to control exposure to the illness, but it is also possible that they might manage the emotional representation by avoiding thinking about the illness to avoid anxiety and so neglect to engage in TRBs.

Very few studies have looked at how illness representations change over time, as information about a disease spreads through a population, and experiences and government directives potentially change how the illness is represented.^{34 36} In the CS-SRM, behaviours are determined by illness representations, but TRBs may also be influenced by representations of the behaviours, for instance, the beliefs people have regarding their capability to adhere to the TRBs.

Social cognitive theory (SCT³⁷) posits that people's motivation and action are extensively regulated by forethought about the behaviour.³⁸ Key constructs of SCT are self-efficacy and outcome expectancies. Self-efficacy refers to the belief that one is capable of performing a recommended behaviour to attain a desired outcome (ie, not getting COVID-19). Outcome expectancies refer to beliefs about the consequences of a given behaviour (eg, if I wash my hands regularly with soap and water, I will reduce my risk of getting COVID-19). A category of belief that is often explored in relation to infectious disease outbreaks, but that is not specified explicitly in SCT, is risk perception, or perceived vulnerability to the infectious disease.³⁹

Protection motivation theory (PMT^{40 41}) was developed to understand the impact of fear appeals and includes the

perception of vulnerability. PMT posits that people make a threat appraisal based on evaluating how severe the threat is, and how vulnerable they perceive themselves to be to the threat. In addition, an individual makes a coping appraisal based on two efficacy beliefs, self-efficacy (as in SCT, eg, how confident is the person that they can wash their hands every time they enter a building) and response efficacy (how effective is washing hands every time they enter a building at mitigating vulnerability to getting COVID-19). Considering both the threat and coping appraisal could result in greater understanding of the engagement in protective behaviours, in this case adherence to TRBs.³⁹

Given the importance of motivational and behavioural factors to get COVID-19 under control, it is vitally important to determine how these theorised factors are linked to adherence to TRBs and how this affects mental and general health. Previous research has shown that greater perceived susceptibility, perceived severity of the illness as well as, perceived efficacy of behaviour and self-efficacy of TRBs during previous infectious disease pandemics were associated with more avoidance (ie, physical distancing) or preventive behaviour (ie, hand washing).⁴² Furthermore, during the current COVID-19 pandemic in Vietnam, perceived risk was associated with increased likelihood of wearing a face covering.⁴³ Multiple theoretical positions applied to TRBs, and measured over repeated epochs, should provide novel insights into behavioural changes emerging from the population in Scotland.

THE CHARIS STUDY AND OBJECTIVES

The majority of other surveys about COVID-19, including the large international surveys, collect data from self-selecting participants who complete the survey online; they are not random samples of a population. The representativeness of that sample is assessed relative to selected nationally representative socio-demographic characteristics and the sample adjusted so that it matches those characteristics. In contrast, the participants in the CHARIS study will be selected randomly and interviewed until predefined quotas for particular sociodemographic characteristics are met. The interviews will be conducted over the telephone, so participants do not require the financial resources or any computer literacy to take part or have any predisposition to complete an online survey about the pandemic. This will ensure that we have a nationally representative sample. Further, to our knowledge, ours is the only survey that employs three distinct theoretical approaches to understanding adherence of eight key TRBs.

The aim of the CHARIS study is to investigate adherence to TRBs required and advised by The Scottish Government and how adherence changes over time, as postlockdown restrictions are lifted across four graduated Phases.¹³ CHARIS will examine what theorised motivational and behavioural factors explain (changes in) TRB

adherence, and mental and general health over time. The following objectives will be addressed:

1. To describe people's adherence to TRBs, and their mental and general health status.
2. To describe people's beliefs about COVID-19 and beliefs about TRBs.
3. To explain variations in people's adherence to TRBs by examining associations between these behaviours and sociodemographic factors, and theorised motivational and behavioural factors, specifically considering,
4. To explain variations in people's mental and general health status by examining associations between health and sociodemographic and theorised motivational and behavioural factors.
5. To examine the influence of government guidance and media reporting of COVID-19 on people's beliefs and behaviours over time.

METHODS

Design

A cross-sectional observational study of 500 randomly selected adults will be conducted each week for the first 6 weeks, and fortnightly after that, for a total of 14 waves ($n=7000$). We will compare motivations, behaviours and health in different population groups (eg, age group, gender, area deprivation) and use these data to understand population-level changes in adherence to TRBs and health from 3 June 2020 and to 07 November 2020. While a serial cross-sectional design will not allow for the assessment of actual causal relations over time it does allow rapid and adaptive monitoring of crucial variables over time, the assessment of the relations between them and, importantly, since there is no attrition, maintains the representativeness of the sample over the whole study period.

Setting and participants

The study will be conducted across Scotland which has a total population of 5.4 million, 83% of whom are adults. Adult men and women aged 16 or older, able to speak English, and currently living in Scotland are eligible to participate. No other inclusion criteria will be applied. The CHARIS study will be administered by a commercial polling company (Ipsos MORI Scotland). They sample participants using random digit dialling to both landlines and targeted mobiles. Quotas are applied to ensure that a representative sample of Scotland adults is achieved. Quotas are based on gender (48% male), age, working status (42% working fulltime) and geographical locations (distribution over the Scottish Parliament regions). A leeway on the quotas (30% approximately) is allowed to help ensure the overall sample is achieved in a reasonable time, any resulting data skews will be corrected with statistical weighting in analyses.

Sample size for assessing the proportion of people who adhere to government guidelines was determined by the following formula for the sample size n : $n=N*X / (X+N$

$- 1)$, where, $X=Z\alpha/22 * p*(1 p) / MOE^2$, and $Z\alpha/2$ is the critical value of the Normal distribution at $\alpha/2$ (we used a confidence level of 95%, α is 0.05 and the critical value is 1.96), MOE is the margin of error (we used 5%), p is the sample proportion (as we did not know adherence beforehand this was set at 50%), and N is the population size (5 438 100 for the adult Scottish population). This returns a sample size of $n=385$. In addition, we wanted to be able to look at subgroups and evidence over time, based on these calculations and advice from the polling station on the number required to reach a representative sample for the Scottish population in each data wave was determined at $n=500$.

Ipsos MORI will conduct telephone interviews using Computer Aided Telephone Interviewing (CATI). Interviewers from Ipsos MORI have received training and have significant experience in conducting interviews into sensitive topics including mental and general health.

Patient and public involvement statement

During the design of the study and the development of the questionnaire, we engaged with two patient and public involvement groups. The Scottish Health Council Public Engagement Group and the National Health Service (NHS) Research Scotland Primary Care Patient and Public Involvement group. They have explored the suggested topic the questionnaire was going to include, and have reviewed and critiqued the survey questions and suggested items. This led to the addition of more questions about physical or mental health conditions, and their effect on day-to-day activities. Additionally, the two patient and public involvement groups in addition to the core research group and members of the consortium were welcome to suggest topic to be assessed in the non-core part of the questionnaire. The core research group will make the final decision on all proposed inclusions. People from the patient or public involvement groups were not directly involved in the recruitment to and conduct of the study, but could be recruited through the random digit dialling procedure. All study participants had access to the weekly published reports on the CHARIS website.

Questionnaire development and procedure

Using methods from studies of previous pandemics (eg, SARS, Middle East Respiratory Syndrome or MERS, H1N1) and theories of human motivation and behaviour, the survey will assess adherence to TRBs, and mental and general health. Where possible, validated and reliable scales will be used. However, some of the standard measurement scales have been adapted to fit with the CATI methodology.

A core set of questions will be administered weekly (further details on questionnaire development online supplemental appendix 1). In addition, each week a changing set of questions will assess non-core themes and questions based on triggers/events over time as required (up to 15% of the total questionnaire is available for modification each week). The additional themes and questions

will be sent to Ipsos MORI 4 days in advance for review, scripting and testing. Weekly, Ipsos MORI takes 3 days for data processing and will provide the primary researchers with a raw data set for analysis (Statistical plan in online supplemental appendix 2).

Core survey variables

The questions of the wave one questionnaire, including the core survey are detailed in online supplemental appendix 3.

Transmission-reducing behaviours

Adherence for TRBs will be assessed for three domains of behaviours, namely physical distancing, hand washing and wearing a face coverings, based on Scottish Government directives and NHS Scotland advice.^{20 44} TRBs will be assessed using eight items.^{45 46} Questions will be preceded by an introductory text, which aims to reduce socially desirable responding by providing individuals with implied permission to report either a lack of, or lapses in, adherence.

Mental and general health

We will measure general health by a standard single self-report item.⁴⁷ Depression and anxiety will be assessed with an adaption of the brief anxiety and depression scale (Patient Health Questionnaire-4⁴⁸). Finally, participants will be asked whether they received a letter from their general practitioner telling them that they were at high risk and should stay at home. If they answered 'Yes', they will be asked whether they have been in isolation because they have been shielding.

Theorised motivational and behavioural explanatory factors

The guiding theoretical frameworks for understanding COVID-19 will be Leventhal's CS-SRM⁴⁹, SCT³⁷ and PMT⁴⁰. We have adapted the brief illness perception questionnaire⁵⁰ for COVID-19. The brief illness perception questionnaire uses a single statement to assess each of the constructs from the CS-SRM, namely: identity, consequences, duration (time-line), recurrence (time-line), personal control, treatment control and emotional representation (worried and anxious); participants indicate their level of agreement with each statement. Questions are differently phrased for participants who currently have (or suspect they have) COVID-19, who have had (or suspect they have had) COVID-19 in the past. The causal component of the COVID-19 representation is assessed with seven items; participants indicate the extent to which they believe each item is/was/would likely be the cause of their getting COVID-19 using a 4-point scale (1=to a great extent, 4=not at all).

We will assess outcome expectancies, self-efficacy (towards the avoidance of COVID-19 and performing the TRBs⁵¹), perceived COVID-19 severity, perceived vulnerability, comparative vulnerability, response efficacy, behavioural norms and intentions to perform the TRBs (adapted from references 52 53).

Sociodemographic variables

Sociodemographic information included in the core survey are; place of residence and area deprivation (based on post-code), age, indicated gender, ethnicity, number of adults and children living in people's household, household tenure and employment status.⁴⁷

Additional variables

In addition to the measures of the core, the survey will also include measures of additional factors that are likely to predict one or both of the outcome variables; adherence to TRBs and mental and general health (online supplemental appendix 1). These variables can also be related to changes in government guidelines and event-related questions.

ETHICS AND DISSEMINATION

Participants will be informed about the purpose of the CHARIS study, how their data will be treated and stored, of their right to terminate their participation in the study at any time without giving a reason, and for each question where we are asking personal/sensitive information participants will explicitly be reminded that they do not have to answer if they prefer not to. All participants will then be asked to provide verbal informed consent prior to starting the survey, and for sharing their personal information for follow-up research related to the study (online supplemental appendix 2). Verbal debriefing will inform participants that if the survey has raised any concerns about their health that, they should contact their general practitioner. Ethical approval was granted by the Life Sciences and Medicine College Ethics Review Board (CERB) at the University of Aberdeen (CERB/2020/5/1942).

This study aims to have academic and conceptual development impact by making a demonstrable contribution to understanding theorised human motivations and behaviours, adherence to TRBs, and mental and general health in a global pandemic. Key outputs will therefore include articles for publication in peer-review journals.

More importantly, the study also aims to have societal and instrumental impact by influencing the measures used to reduce COVID-19 transmissions and monitor measures that address impacts on mental and general health that are being developed by UK governments and other decision-makers. Key outputs are, therefore, weekly bulletins that describe the data and present univariate analyses that will provide fast, real-time insights. These weekly bulletins will be complemented with bimonthly in-depth reports that will present the multivariate predictive data, and illustrate how the results might be used to support adherence and mental and general health. The bulletins and reports will be distributed to the Scottish Government and their agencies, and will be made immediately available on the study website (<https://www.abdn.ac.uk/CHARIS>), and study's own twitter feed (@CHARIS CVD19).

DISCUSSION

The CHARIS study will provide insights into TRBs, and how adherence to these TRBs changes over time as the COVID-19

outbreak progresses, and government restrictions are change. Additionally, this study will identify the beliefs derived from CS-SRM, SCT and PMT, and sociodemographic factors that predict adherence to TRBs. This understanding will support the tailoring and targeting of interventions to improve adherence to TRBs, and support general and mental health. For example, the content of public health messages could be tailored to strengthen beliefs associated with higher levels of adherence, and targeted at communities who are struggling to adhere. Similarly, CHARIS will identify communities with declining mental health enabling support services to be better targeted.

Strengths

The CHARIS study has several strengths. First, CHARIS is underpinned by evidence-based psychological theories and thus supports a cumulative approach to conceptual development and evidence. CHARIS can draw on a large existing evidence base that informs the measures used, and details how individual constructs are meaningfully related. Use of three universal theories of behaviour avoids the much criticised 'cafeteria' style research that is not conducive to the development of a cumulative approach to evidence building.^{54 55} A cumulative approach is vital to support our understanding of the behaviour of populations during a pandemic, which is crucial in circumstances where changing behaviour is the only available route to halting the pandemic.

Second, CHARIS will provide fast, real time, information to support and inform decision making for policy-makers, public health and service commissioners. Third, the weekly data collection, enables fine-grained analyses of people's reactions to government directives and instructions as they are happening. The repeated measurement over 14 waves makes it possible to directly assess the impact of directives and advice from the government for TRBs, in contrast to previous retrospective studies or studies applying hypothetical situations.⁵⁶ Fourth, our study will start as the Government-imposed restrictions went in to phase 1 postlockdown. The restrictions began to be eased, and more people are allowed to go back to their workplaces, and to start to meet with others outside of their own households. The timing of the CHARIS study places it in the unique position to assess (changing) adherence to TRBs, in response to potentially changing beliefs about the behaviours and the illness, as the Scottish government implements new Phases to gradually lift the restrictions. Moreover, we can assess the effects of prolonged adherence to TRBs, and beliefs about behaviours and illness on mental and general health. Fifth, CHARIS study data is collected via telephone, which requires the survey to be succinct and the questions easily understood. Therefore, the majority of adults will be able to take part in CHARIS, in line with the call that there is a need for more representative research, particularly in vulnerable populations.^{57 58} People can be included who do not have online access, who are typically older, who are more deprived, typically those who are also most at risk from COVID-19. Sixth, recruitment will aim for a representative sample, making the findings generalisable to the Scottish population.

Limitations

Our study also has some limitations. First, the use of a telephone survey necessitates the use of self-report measures only. This is not a limitation in relation to the measurement of beliefs or mental and general perceived health as these are only available for measurement via self-report. However, measuring behaviour by self-report is open to a number of sources of error, including memory errors and social desirability bias. Social desirability to report adherence is likely, however, we have mitigated the impact of social desirability where possible by employing the introductory text from the medication adherence reporting scale.^{45 46} The text on this scale was designed specifically to reduce social desirability by providing individuals with implied permission to report either a lack of, or lapses in, adherence. Furthermore, it is impossible to assess adherence to all the TRBs included in CHARIS by any method other than by self-report. Overall, we believe the advantages of telephone interviewing in terms of population reach and generalisability far outweigh the disadvantages.

Second, the telephone call is limited to 20 min duration. This means we have had to use brief measures of mental and general health, however, both measures are validated and reliable. Similarly, some constructs were measured very briefly in the core questionnaire. While this enables tracking of a larger number of themes over time, we recognised this as a limitation. To address the use of brief measures we have planned less frequent inclusion of some constructs, for example, access to open spaces is measured with one question in the core questionnaire, focused only on the home, but will be measured much more extensively during one specified week to provide a context for the single question in the core questionnaire, and provide an opportunity to have in-depth analysis of this theme with the data collected in one of the weeks. Moreover, some themes were not part of the core at all, and only will only be assessed less frequently. In addition, we plan a companion qualitative study that will purposefully sample from the survey participants each week to understand the contextualised, multifaceted nature of people's beliefs, TRBs and mental and general health.

The CHARIS Study is well placed to make a significant contribution to the knowledge base around (changes in) adherence to TRBs, mental health and potential explanatory variables, in the current COVID-19 pandemic. Further, findings should provide valuable insights to assist preparation for any future events.

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