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The health and coping strategies of nursing home residents and their relatives during the COVID-19 pandemic: a mixed-methods study protocol

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Title Page

a) **Title:** The health and coping strategies of nursing home residents and their relatives during the COVID-19 pandemic: a mixed-methods study protocol

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e) Keywords: coping, nursing home residents, nursing home relatives, stressors, mixed-methods, confinement measures, COVID-19 pandemic.

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Title: The health and coping strategies of nursing home residents and their relatives during the COVID-19 pandemic: a mixed-methods study protocol

Introduction: The COVID-19 pandemic hit older adults particularly hard, especially those living in nursing. The present study's primary aim is to quantify the states of physical and mental health of nursing home residents and their relatives following the implementation of the exceptional confinement measures. The secondary aim is to explore the lived experiences of the stressors perceived by older adults and their relatives, as well as the support strategies implemented by health professionals and their results.

Methods and analysis:
We chose a mixed-methods (quantitative/qualitative) study to best deliver a profound understanding of this phenomenon.

Quantitative phase: Participants are asked to complete several questionnaires. The study population includes all the nursing home residents in four French-speaking cantons of Switzerland (and their relatives) who are living through the COVID-19 pandemic. Descriptive statistics will be calculated for the scores of the GHQ-12, IES-6, PSS, Brief Cope, PTGI-SP, WHOQOL-BREF and WHOQOL-OLD scales. Correlational analyses will be considered.

Qualitative phase: Data are collected from several sources (individual semi-structured interviews, focus groups, field notes). Interviews are planned with about 12 representatives of each group of participants (residents and relatives). Two focus groups made up of healthcare professionals will be constituted to explore their perceptions of residents' and relatives' lived experiences of stressors, the coping strategies those two groups implemented to deal with them. The interviews and focus groups will be subjected to a thematic contents analysis.

Integrating the quantitative and qualitative data will take place jointly with data interpretation.

Ethics and dissemination: This project was approved by the Human Research Ethics Committee of the Canton of Vaud on 14 December 2020 (Project-ID: 2020-02397). The prior written informed consent of the study subjects is collected by a member of the research team before data collection.

Trial registration: ISRCTN12345167

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STUDY STRENGTHS AND LIMITATIONS

- This study explores the lived experiences of nursing home residents and their relatives during the COVID-19 pandemic.
- It will enable an analysis of the coping strategies adopted by nursing home residents and their relatives and the strategies implemented by their healthcare and support professionals.
- Using a mixed-methods design facilitates a deep investigation of lived experiences.
- Using a transversal methodology does not enable an investigation of changes over time.
- The study begins roughly one year after the start of the COVID-19 pandemic, and numerous residents living in our participating nursing homes have since died.

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INTRODUCTION

In China, in December 2019, the COVID-19 pandemic was just beginning—the latest in a series of epidemics that humanity has had to face over the last 100 years. Indeed, just this century, we have had SARS in 2002–2003, H1N1 in 2009 and MERS in 2012 (1). Lived experiences of these epidemics have affected communities' physical and psychological health (2). The general population, including those not infected by the disease itself, still bears psychological scars (3-6). Older adults within that general population were also affected (5). Zurich University of Applied Sciences and the University of Zurich launched a study entitled "COVID-19 Social Monitor" among home-dwelling older adults, and its initial findings revealed that 41% of those questioned estimated that their overall quality of life (QoL) had deteriorated relative to before the pandemic, 50% presented with symptoms of psychological stress and exhaustion, and 9% suffered from loneliness (7). We sought to examine these issues among the residents of nursing homes caring for the very oldest people—those who often present with several comorbidities. Although this population has been the most vulnerable to the last 20 years' epidemics, the scientific research focus on it has been small (8). COVID-19 badly affected nursing homes in many countries when they became the centres of epidemic outbreaks (9). To date, half the deaths due to COVID-19 in French-speaking Switzerland have been in nursing homes (10). Drastic measures were taken to stem this grim tide, including physical isolation, one-way walking systems to reduce meetings, and bans on visiting (11).

Brooke and Jackson (12) have denounced the ageism that has clearly entered into public discourse since the beginning of the COVID-19 pandemic, mentioning some shocking reports about how nursing home residents were almost abandoned (13). Expressions of flagrant ageism have appeared and been rapidly amplified since the beginning of the pandemic, for example, under the hashtag #BoomerRemover, a nickname given to COVID-19. The coronavirus caused a resurgence of intergenerational conflict (14). Although some concerns were expressed about how older adults were being represented or positioned in this discourse, it was also often accompanied by unappreciative and disparaging language (15). Online discussions and comments about care rationing were also recurrent subjects of media attention, going so far as to suggest that the death of an old person was less important than that of a young one (16).

The people stigmatised and discriminated against (both COVID-19 survivors and members of the general population) have reported their feelings of abandonment and isolation (17-19). Survivors have declared feeling abandoned by their communities and kept at a distance from their caregivers by the personal protective equipment that has become so ubiquitous (17-19). Quarantine or isolation was previously an uncommon, disagreeable experience involving separation from one's family and friends and a total break from daily routines. Isolation is known to cause psychosocial problems and could affect any human being. Those already known to be vulnerable to them and particularly at risk of psychological harm include children and adolescents, nursing home residents, minority groups, people from socioeconomically disadvantaged groups, women and individuals suffering from pre-existing mental disorders (20). Even though people who are isolated or in quarantine understand the necessity of those measures, they nevertheless feel a sense of abandonment that can persist beyond those periods (21). Social isolation in association with quarantine can affect the state of mental health of previously healthy people. They can present with symptoms linked to acute stress disorders, irritability, sleeping disorders, emotional distress, mood disorders, depressive symptoms, fear and panic, anxiety, frustration and the boredom of solitude (22-26). Furthermore, longer periods of confinement have been associated with more severe symptoms of post-traumatic stress disorder, avoidance behaviours and greater feelings of anger (25). The longest periods of quarantine are particularly associated with increased symptoms of post-traumatic stress disorder, which may indicate that quarantine itself is lived as a traumatic experience (23).

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Because of their inherent organisational characteristics and the strict confinement measures imposed on them during the pandemic, long-term residential care facilities generated stressors among their residents that the general population did not feel: isolation and solitude had particularly negative impacts on residents' physical and mental health, including their risks of anxiety, depression, cognitive dysfunction, heart diseases and mortality (27, 28). It should be noted that stress does not only lead to negative impacts. The strategies and processes put in place to cope with these enable individuals to change, adapt and appreciate their results. People can thus find the resources they need, experiment with different positive changes and grow out of their trauma (17, 21, 29-31).

To the best of our knowledge, nursing home residents and their relatives have yet to be the subjects of much scientific research despite their clear vulnerabilities in the face of the pandemic. The American Association for Geriatric Psychiatry has announced that it will support the scientific and healthcare communities worldwide in order to help plan effective care for nursing home residents, avoid the risks of this population becoming marginalised in political discussions surrounding COVID-19 and produce the greatest amount of valid, evidence-based data with which to orient more effective care during this critical period (8). This clear positioning by one of the world's most active professional associations in the field of care home residents' mental health shows how urgent the need is for more knowledge in this domain.

Our research is framed within the concepts and processes of the Neuman systems model (2011), which takes a holistic perspective oriented towards well-being. The model conceptualises the individual as an open system subject to stressors that may or may not lead to damage to their health. Stressors are considered neutral a priori, and their positive effects (eustress) or negative effects (distress) are largely dependent on a person's perceptions and their capacity to face up to that stress. Following the prolonged lockdown implemented towards the beginning of the COVID-19 pandemic, older adult residents in nursing homes and their relatives were exposed to a variety of stressors susceptible of destabilising them.

It is also essential to study the perceptions that healthcare and support professionals have of the lived experiences of nursing home residents and their relatives. Indeed, they have a special relationship with them. Thanks to these relationships, they are crucial to initiating any in-depth evaluation of the effects of the internal and external stressors to which residents are exposed and their capacity for coping with them (32, 33).

The present study will attempt to evaluate the physical and mental health statuses of nursing home residents and their relatives following the exceptional lockdown measures implemented due to the COVID-19 epidemic. The research objectives are the following:

- Describe the level of symptoms (post-traumatic stress, anxiety, depression, social maladjustment and somatic disorders), post-traumatic growth and QoL of nursing home residents and their relatives after the COVID-19 pandemic.
- Describe the strategies implemented (by residents and relatives) for coping with the COVID-19 pandemic.
- Explore residents and relatives lived experiences of their perceived stressors during the COVID-19 pandemic and their links to any potential physical or mental health symptoms, post-traumatic growth and QoL.
- Explore which stressors healthcare and support professionals observed affecting residents and their relatives.
- Explore which strategies healthcare and support professionals implemented to support residents and their relatives and help them cope with the stressors they faced during the COVID-19 pandemic, including their results.

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METHODS AND ANALYSIS

Study design overview

This study is based on a mixed-methods (quantitative/qualitative) design chosen because there are very few available data on nursing home residents. The variety and complexity of residents' health statuses, the different living environments in their nursing homes and the changing relationships with their relatives made us hypothesise that findings that might seem obvious or natural in Switzerland's general population might not be readily transferable to our subjects without significant adjustments. Using a mixed-methods study design would help us develop a deeper understanding of our phenomenon of interest (34, 35).

Quantitative phase

Data collection

We use a paper questionnaire format to explore and respond to our research questions. We ensured that validated French-language versions of the questionnaires selected had the necessary psychometric qualities and that they were appropriate with regards to our study's concepts, thus safeguarding the validity of our recorded data.

Data collected from our participating nursing home residents come from several sources (36). In order to describe our sample, we decided to measure residents' sociodemographic variables (age, sex, marital status, year of entry into the nursing home) as well as those of their relatives (age, sex, marital status, relationship with the nursing home resident, current nature and frequency of contact with the resident).

We also collect data on the lockdown measures implemented in the participating older adults' nursing homes (residents isolated in their rooms, availability of communication tools such as tablet computers, preparation of screened visiting rooms, etc.).

Participants

Our potential study population includes all nursing home residents aged 65 years old or more and their relatives (spouses, children, siblings, friends, cousins) living through the COVID-19 experience in one of Switzerland's four majority French-speaking cantons.

For residents, inclusion criteria are: being over 65 years old, being able to discern and being able to speak and understand French; and exclusion criteria are: the presence of major irreversible neurocognitive disorders. For relatives, inclusion criteria are: being able to discern and being able to speak and understand French; and there is no exclusion criteria. For healthcare professionals are: working on the unit for more than 3 months and to have a care relationship with the residents and the family member; and exclusion criteria are: being a temporary worker or a student.

Sample and recruitment

The recruitment procedure for our study's quantitative arm involves nursing home residents and their relatives. We aim for a sample of 150 residents and 150 relatives. This is done via the intermediary of care unit heads who identify residents susceptible of participating in our study because they fulfil our inclusion criteria. Investigators then visit the nursing homes and speak individually to potential subjects to inform them about the study. Residents are given time to reflect and to declare their consent to participate. A researcher then returns to sit with them while they complete their questionnaires. Relatives complete the questionnaires on their own.

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Measurements

We use the following questionnaires to help us answer our research questions:

- The **General Health Questionnaire (GHQ-12, 12 items)** for detecting mental disorders in the general population (Cronbach's alpha: 0.91) (61).
- The **WHOQOL-BREF scale (26 items)** for relatives to establish their subjective QoL (Cronbach's alpha: ≥ 0.65).
- The **WHOQOL-OLD scale (24 items)** for residents to evaluate their QoL (Cronbach's alpha: 0.72–0.83) (37).
- The **Impact of Event Scale 6 (IES-6, 6 items)** for measuring the symptoms associated with post-traumatic stress in individuals who have undergone a traumatic event (Cronbach's alpha: 0.95) (38).
- The **Post-traumatic Growth Inventory (PTGI-SP, 10 items)** for evaluating post-traumatic growth, i.e. positive, lived psychological change following a traumatic event (Cronbach's alpha:= 0.90) (39).
- The **Perceived Stress Scale (PSS, 14 items)** for evaluating perceptions of stress (Cronbach's alpha: 0.74) (40).
- The **Brief Cope (28 items)** for evaluating coping strategies (Cronbach's alpha: 0.50–0.90) (41).

Analysis procedures for quantitative data

Data will be examined using Stata® statistical software, version 16. Data will first be cleaned, and if more than 10% of responses are missing from a particular scale, then that subject's observations will be discarded. Total scores and subscale scores for each questionnaire will be calculated following their authors' particular recommendations. For categorical or discrete variables, frequencies, percentages and modes will be calculated. For continuous variables, means, medians, standard deviations and interquartile ranges will be calculated. Skewness and kurtosis coefficients will be calculated to evaluate distributions and their normality. We will calculate descriptive statistics for the total scale scores and subscale scores of the GHQ-12, IES-6, PSS, Brief Cope, PTGI-SP, WHOQOL-BREF and WHOQOL-OLD scales. Finally, we will perform correlational analyses between the subscale scores for the GHQ-12, IES-6, PTGI-SP, WHOQOL-BREF and WHOQOL-OLD scales and the subscales scores of the Brief Cope scale.

Sociodemographic variables will be analysed using descriptive statistics depending on the variable measured.

Qualitative phase

Data collection

Qualitative data are collected from a number of sources (36):

- Individual, semi-structured, 20–30-minute interviews are carried out with **residents**, with the aid of an interview guide, to explore their perceptions of their lived experiences of stressors, the coping strategies that they implemented to deal with them and the results they obtained.
- Individual, semi-structured, 30–40-minute interviews are carried out with **relatives**, with the aid of an interview guide, to explore their perceptions of their lived experiences of stressors, the coping strategies that they implemented to deal with them and the results they obtained.
- Two 60–90-minute focus groups will be run with **nursing home professionals**, with the aid of an interview guide, to explore their perceptions of residents' and relatives' lived experiences of stressors, the coping strategies those two groups implemented to deal with them and the results they obtained.

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- The research team keeps field notes about visits to nursing homes and during interviews. In particular, this information includes investigators' notes on participants' behaviours.

Participants

The nursing home residents and their relatives selected for this qualitative data collection phase are subject to the same selection criteria used in the quantitative data collection phase. The inclusion criteria for nursing home professionals are to have worked in the unit for at least three months and to have regular contact with both residents and their relatives. Exclusion criteria include being a temporary employee, a part-time employee, or a student.

Sample and recruitment

Participants are selected using purposive sampling to ensure representativity across several variables (severity of symptoms, post-traumatic growth, QoL, varied coping strategies). Interviews are planned with about 12 representatives of each group of participants (residents and relatives) or until data saturation.

Two discussion groups made up of healthcare professionals will be constituted to explore their perceptions of residents' and relatives' lived experiences of stressors, the coping strategies those two groups implemented to deal with them and what those strategies' results were. All the healthcare professionals in our partner nursing homes will be invited to participate.

Analysis procedures for qualitative data

Data analysis began as soon as data collection began and continues iteratively. Interviews are to be recorded. All interviews will be audio-recorded in full and transcribed verbatim into a Word 365 ProPlus® file. Investigators' field notes will also be added to that Word 365 ProPlus® file. Data will subsequently undergo a thematic contents analysis that will enable the investigators to identify pertinent information, relationships and meanings in the data with regard to our research questions. These analyses will be carried out using MAXQDA textual data analysis software. Verbatim citations will be used to illustrate tendencies, provide the phenomena of interest with context and aid in our in-depth understanding of COVID-19's impacts on older adult nursing home residents.

We will draw up tables describing the absolute and relative frequencies of item responses. The reliability and validity of constructs will be ensured by the detailed documentation maintained in investigators' field notes at each stage of the research. The study's internal validity will be ensured by triangulating data from multiple sources. The validity of external data will be ensured by selecting several subjects over the course of the study, using purposive sampling to provide a diverse subject set until data saturation.

Integrating quantitative and qualitative data

The integration of the study's quantitative and qualitative elements will occur jointly at the data interpretation stage. This will be based upon the treatment of the quantitative data from our sociodemographic and clinical questionnaires and from the treatment of our qualitative data from our interviews with residents, their relatives and their healthcare and support professionals and the research team's field notes:

- We will describe the stressors reported by residents and their relatives who present with high and low scores on the GHQ-12, IES-6, WHOQOL-BREF or WHOQOL-OLD, PSS and PTGI-SP scales.
- Data integration will provide us with information about the links between the stressors experienced by residents and their relatives and the consequences on their health.

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- We will describe the coping strategies used by residents and their relatives who present with high and low scores on the GHQ-12, IES-6, PSS, WHOQOL-BREF or WHOQOL_OLD and PTGI-SP. This integration will provide us with information about the relative effectiveness of some of their coping strategies with regards to others.
- We will compare residents' and their relatives' reported frequency of use of the different coping strategies measured in the Brief Cope scale. Integrating this information will deepen our understanding of the coping strategies implemented by residents and their relatives during the pandemic.
- We will describe the stressors that healthcare and support professionals perceived residents and their relatives were facing. Integrating this information will help us to evaluate residents' and their relatives' needs and whether those needs were considered or not.
- We will compare the coping strategies reported by residents and their relatives with those support interventions actually put into practice by healthcare and support professionals. Integrating this information will help us understand how appropriate the support provided by healthcare and support professionals actually was, how different support measures complemented each other and where support was lacking.

In summary, putting our questionnaires findings into perspective regarding the health statuses of residents and their relatives and the results from our interviews will help us to identify their needs in terms of the preventive health interventions that could be developed to optimally maintain their health in the ongoing COVID-19 pandemic or a future one. The results from the focus group discussions involving healthcare and support professionals will help us to specify priority interventions that currently do not exist.

Study status

The present study began on 1 January 2021 and is planned to finish on 31 December 2022. Data collection began on 1 April 2021 because of the evolving epidemic situation in Switzerland, and collection is set to finish on 28 February 2023.

Discussion

The present exploratory study will contribute to a greater understanding of nursing home residents' and their relatives' lived experiences of COVID-19, the strategies they employed to cope with the pandemic and the consequences of those strategies. This will provide valuable knowledge about the epidemic's effects on this vulnerable and severely affected population. The study will provide essential data on the perceptions residents and their relatives had about their psychological health soon after the stage of strict lockdown, but also about the stressors to which they were exposed, the coping strategies they attempted to put in place and the results of those strategies. Our data should reveal the different types of stressors stemming from an epidemic situation in Switzerland's nursing homes as well as the adaptations and changes made to the processes of support provided to residents and their relatives. Exploring the results of residents' and relatives' strategies will allow us to assess them and formulate appropriate preventive-care interventions that will ensure the quality and safety of care for nursing home residents in case of future severe public health crises. It will also give indicators on how to protect their health and that of their relatives. New approaches could contribute to mitigating the impact of future pandemics and the consequences on the health of older adults living in nursing homes and their relatives. Furthermore, our findings could help to prioritise the development of preventive health interventions to counteract the effects of prolonged lockdowns for both of those groups. Our study considers the points of view of the diverse actors involved, which is essential when developing, testing and implementing new care practices. Its findings will provide the deeper understandings of patients' contexts and settings that are essential for anchoring changes in clinical practice, collaboration with relatives, training for healthcare professionals and managing nursing homes in general.

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Ethics and dissemination

This project was approved by the Human Research Ethics Committee of the Canton of Vaud on 14 December 2020 (Project-ID: 2020-02397). The prior written informed consent of the study subjects is collected by a member of the research team before data collection. Major change to the study protocol will be announced to the Human Research Ethics Committee of the Canton of Vaud.

All the data collected is coded and kept securely at La Source School of Nursing. When dealing with quantitative data, each participant will be attributed an anonymous administrative code. Data will be installed on an SRP directory on La Source School of Nursing's server, which is housed in a data centre in Switzerland.

All interviews are audio-recorded in full. When this qualitative data is transcribed verbatim onto a Word 365 ProPlus® file, each participant is attributed an anonymous administrative code instead of their name. Residents' codes begin with the letters 'RES' and the letter 'Q' for qualitative data, followed by a two-digit number, starting with RESQ01 for the first resident interviewed and so on in chronological order. The same system is followed with relatives (e.g. RELQ04) and healthcare professionals (e.g. PROQ12).

All the participants are free to withdraw from the study at any moment without incurring any penalties or consequences with regards to the future care or services they might rightfully expect. Should a participant decide to withdraw, for whatever reason or at whatever moment, any data that have already been anonymised will not be destroyed but rather will still be analysed as specified in the research information sheet. Results will be presented in an aggregated form so that no participants will be identifiable in lectures or publications.

Only the principal investigator will have access to the key linking participants' codes to their names and identities, and this will only be used if absolutely necessary. All other researchers working on the study will only have access to coded data. The file containing the key to participants anonymity will be protected by a password known only to the principal investigator.

Data and material will be available on request from the authors.

Patient and public involvement

Patients and/or the public were not involved in the design or conduct of this research. Refer to the Methods and analysis section for further details.

Dissemination of results

Our results will be disseminated in various ways. A document containing the key facts will be prepared specifically for the participating care homes and other care homes on request. Public conferences will also be organised in those institutions. Scientific manuscripts will be addressed to international and French-language professional and scientific journals for publication. We will also disseminate our results at appropriate local and international conferences. Finally, a research report containing the study's highlights and most important findings will be produced for the libraries of our institutional partners and all the actors that participated financially in our work. Authorship will be defined using recommendations of the International Committee of Medical Journal Editors.

Author contributions

COB is the principal investigator. COB, MA, LB and CC contributed to the study design. MA, LB and CC are collecting the data. All authors are responsible for the data analyses. All authors read and approved the final manuscript.

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Competing interests (for all authors)
The authors have no conflict of interest to declare.

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page.2
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	Page 2
Funding	4	Sources and types of financial, material, and other support	Page 3, par. 2
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 1 Page 11, par 1
	5b	Name and contact information for the trial sponsor	Page 1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Pages 4-5
	6b	Explanation for choice of comparators	NA

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Objectives	7	Specific objectives or hypotheses	Page 5, par.5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 6, par.1
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 8, par 1
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 6, par 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	NA
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 7, par 1-2 Page 8, par 3-4
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	NA

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Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 6, par 7
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6, par 7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 6, par 2 Page 7, par 3
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

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Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 10, par. 4
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 7, par 2 Page 8, par 4/6-8
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 7, par 2
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 10, par 2

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Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 10, par 2
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 10, par 2
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 10, par 5
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 11, par 4
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 10, par 3
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 10, par 7
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Page 11, par 7
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	NA
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

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*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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BMJ Open

The health and coping strategies of nursing home residents and their relatives during the COVID-19 pandemic: a mixed-methods study protocol

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SCHOLARONE™
Manuscripts

Title Page

a) **Title:** The health and coping strategies of nursing home residents and their relatives during the COVID-19 pandemic: a mixed-methods study protocol

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Title: The health and coping strategies of nursing home residents and their relatives during the COVID-19 pandemic: a mixed-methods study protocol

Introduction: The COVID-19 pandemic hit older adults particularly hard, especially those living in nursing homes. The present study's primary aim is to quantify the states of physical and mental health of nursing home residents and their relatives following the implementation of the exceptional confinement measures. The secondary aim is to explore the lived experiences of the stressors perceived by older adults and their relatives, as well as the support strategies implemented by health professionals and their results.

Methods and analysis:
We chose a mixed-methods (quantitative/qualitative) study to best deliver a profound understanding of this phenomenon.

Quantitative phase: Participants are asked to complete several questionnaires. The study population includes all the nursing home residents in four French-speaking cantons of Switzerland (and their relatives) who are living through the COVID-19 pandemic. Descriptive statistics will be calculated for the scores of the GHQ-12, IES-6, PSS, Brief Cope, PTGI-SP, WHOQOL-BREF and WHOQOL-OLD scales. Correlational analyses will be considered.

Qualitative phase: Data are collected from several sources (individual semi-structured interviews, focus groups, field notes). Interviews are planned with about 12 representatives of each group of participants (residents and relatives). Two focus groups made up of healthcare professionals will be constituted to explore their perceptions of residents' and relatives' lived experiences of stressors, the coping strategies those two groups implemented to deal with them. The interviews and focus groups will be subjected to a thematic contents analysis.

Integrating the quantitative and qualitative data will take place jointly with data interpretation.

Ethics and dissemination: This project was approved by the Human Research Ethics Committee of the Canton of Vaud on 14 December 2020 (Project-ID: 2020-02397). The prior written informed consent of the study subjects is collected by a member of the research team before data collection. Study results will be disseminated via professional and peer-reviewed publications.

Trial registration: ISRCTN12345167

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STUDY STRENGTHS AND LIMITATIONS

- This study explores the lived experiences of nursing home residents and their relatives during the COVID-19 pandemic.
- Our research is framed within the concepts and processes of the Neuman systems model (2011)
- The psychometric qualities of the questionnaires and their suitability for the concepts under study ensure the validity of the data collected. Using a mixed-methods design facilitates a deep investigation of lived experiences.
- This study is limited because using a transversal methodology does not enable an investigation of changes over time.

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INTRODUCTION

Lived experiences during epidemics affect communities' physical and psychological health (1). Indeed, just this century, we have had SARS in 2002–2003, H1N1 in 2009 and MERS in 2012 (2). The general population, including those not infected by the disease itself, still bears psychological scars (3-6). Older adults within that general population were also affected (5). Zurich University of Applied Sciences and the University of Zurich launched a study entitled "COVID-19 Social Monitor" among home-dwelling older adults, and its initial findings revealed that 41% of those questioned estimated that their overall quality of life (QoL) had deteriorated relative to before the pandemic, 50% presented with symptoms of psychological stress and exhaustion, and 9% suffered from loneliness (7). We sought to examine these issues among the residents of nursing homes caring for the very oldest people—those who often present with several comorbidities. Although this population has been the most vulnerable to the last 20 years' epidemics, the scientific research focus on it has been small (8). COVID-19 badly affected nursing homes in many countries when they became the centres of epidemic outbreaks (9). To date, half the deaths due to COVID-19 in French-speaking Switzerland have been in nursing homes (10). Drastic measures were taken to stem this grim tide, including physical isolation, one-way walking systems to reduce meetings, and bans on visiting (11).

Brooke and Jackson (12) have denounced the ageism that has clearly entered into public discourse since the beginning of the COVID-19 pandemic, mentioning some shocking reports about how nursing home residents were almost abandoned (13). Expressions of flagrant ageism have appeared and been rapidly amplified since the beginning of the pandemic, for example, under the hashtag #BoomerRemover, a nickname given to COVID-19. The coronavirus caused a resurgence of intergenerational conflict (14). Although some concerns were expressed about how older adults were being represented or positioned in this discourse, it was also often accompanied by unappreciative and disparaging language (15). Online discussions and comments about care rationing were also recurrent subjects of media attention, going so far as to suggest that the death of an old person was less important than that of a young one (16).

The people stigmatised and discriminated against (both COVID-19 survivors and members of the general population) have reported their feelings of abandonment and isolation (17-19).. Isolation is known to cause psychosocial problems and could affect any human being. Those already known to be vulnerable to them and particularly at risk of psychological harm include children and adolescents, nursing home residents, minority groups, people from socioeconomically disadvantaged groups, women and individuals suffering from pre-existing mental disorders (20). Even though people who are isolated or in quarantine understand the necessity of those measures, they nevertheless feel a sense of abandonment that can persist beyond those periods (21).. They can present with symptoms linked to acute stress disorders, irritability, sleeping disorders, emotional distress, mood disorders, depressive symptoms, fear and panic, anxiety, frustration and the boredom of solitude (22-26). Furthermore, longer periods of confinement have been associated with more severe symptoms of post-traumatic stress disorder, avoidance behaviours and greater feelings of anger (25). The longest periods of quarantine are particularly associated with increased symptoms of post-traumatic stress disorder, which may indicate that quarantine itself is lived as a traumatic experience (23).

Because of their inherent organisational characteristics and the strict confinement measures imposed on them during the pandemic, long-term residential care facilities generated stressors among their residents that the general population did not feel: isolation and solitude had particularly negative impacts on residents' physical and mental health, including their risks of anxiety, depression, cognitive dysfunction, heart diseases and mortality (27, 28). It should be noted that stress does not only lead to negative impacts. The strategies and processes put in place to cope with these enable individuals to change, adapt and appreciate their results. People can thus find the resources they need, experiment with different positive changes and grow out of their trauma (17, 21, 29-31).

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The American Association for Geriatric Psychiatry has announced that it will support the scientific and healthcare communities worldwide in order to help plan effective care for nursing home residents, avoid the risks of this population becoming marginalised in political discussions surrounding COVID-19 and produce the greatest amount of valid, evidence-based data with which to orient more effective care during this critical period (8).

Our research is framed within the concepts and processes of the Neuman systems model (2011), which takes a holistic perspective oriented towards well-being. The model conceptualises the individual as an open system subject to stressors that may or may not lead to damage to their health. Stressors are considered neutral a priori, and their positive effects (eustress) or negative effects (distress) are largely dependent on a person's perceptions and their capacity to face up to that stress. Following the prolonged lockdown implemented towards the beginning of the COVID-19 pandemic, older adult residents in nursing homes and their relatives were exposed to a variety of stressors susceptible of destabilising them.

It is also essential to study the perceptions that healthcare and support professionals have of the lived experiences of nursing home residents and their relatives .They are crucial to initiating any in-depth evaluation of the effects of the internal and external stressors to which residents are exposed and their capacity for coping with them (32, 33).

The main objective of this study is to evaluate the physical and mental health statuses of nursing home residents and their relatives following the exceptional lockdown measures implemented due to the COVID-19 epidemic. The secondary research objectives are the following:

- Describe the level of symptoms (post-traumatic stress, anxiety, depression, social maladjustment and somatic disorders), post-traumatic growth and QoL of nursing home residents and their relatives during the COVID-19 pandemic.
- Describe the strategies implemented (by residents and relatives) for coping with the COVID-19 pandemic.
- Explore residents and relatives lived experiences of their perceived stressors during the COVID-19 pandemic and their links to any potential physical or mental health symptoms, post-traumatic growth and QoL.
- Explore which stressors healthcare and support professionals observed affecting residents and their relatives.
- Explore which strategies healthcare and support professionals implemented to support residents and their relatives and help them cope with the stressors they faced during the COVID-19 pandemic, including their results.

METHODS AND ANALYSIS

Study design overview

This study is based on a mixed-methods (quantitative/qualitative) design chosen because there are very few available data on nursing home residents. The variety and complexity of residents' health statuses, the different living environments in their nursing homes and the changing relationships with their relatives made us hypothesise that findings that might seem obvious or natural in Switzerland's general population might not be readily transferable to our subjects without significant adjustments. Using a mixed-methods study design would help us develop a deeper understanding of our phenomenon of interest (34, 35).

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Quantitative phase

Data collection

We use a paper questionnaire format to explore and respond to our research questions. We ensured that validated French-language versions of the questionnaires selected had the necessary psychometric qualities and that they were appropriate with regards to our study's concepts, thus safeguarding the validity of our recorded data.

Data collected from our participating nursing home residents come from several sources (36). In order to describe our sample, we decided to measure residents' sociodemographic variables (age, sex, marital status, year of entry into the nursing home) as well as those of their relatives (age, sex, marital status, relationship with the nursing home resident, current nature and frequency of contact with the resident).

We also collect data on the lockdown measures implemented in the participating older adults' nursing homes (residents isolated in their rooms, availability of communication tools such as tablet computers, preparation of screened visiting rooms, etc.).

Participants

Our potential study population includes all nursing home residents aged 65 years old or more and their relatives (spouses, children, siblings, friends, cousins) living through the COVID-19 experience in one of Switzerland's four majority French-speaking cantons.

We want to have as many people as possible so that the sample can be representative, which is why we chose a convenience sample. To do this, we set very broad inclusion criteria in order to recruit as many people as possible, bearing in mind that, unfortunately, we have to deal with the fact that some people have died in the meantime and that it is always complicated to enter a retirement home.

For residents, inclusion criteria are: being over 65 years old, being able to discern and being able to speak and understand French; and exclusion criteria are: the presence of major irreversible neurocognitive disorders. For relatives, inclusion criteria are: being able to discern and being able to speak and understand French; and there is no exclusion criteria. For healthcare professionals are: working on the unit for more than 3 months and to have a care relationship with the residents and the family member; and exclusion criteria are: being a temporary worker or a student.

Sample and recruitment

The recruitment procedure for our study's quantitative arm involves nursing home residents and their relatives. We aim for a sample of 150 residents and 150 relatives. This is done via the intermediary of care unit heads who identify residents susceptible of participating in our study because they fulfil our inclusion criteria. Investigators then visit the nursing homes and speak individually to potential subjects to inform them about the study. Residents are given time to reflect and to declare their consent to participate. A researcher then returns to sit with them while they complete their questionnaires. Relatives complete the questionnaires on their own.

Measurements

We use the following questionnaires to help us answer our research questions:

- The **General Health Questionnaire (GHQ-12, 12 items)** for detecting mental disorders in the general population (Cronbach's alpha: 0.91).
- The **WHOQOL-BREF scale (26 items)** for relatives to establish their subjective QoL (Cronbach's alpha: ≥ 0.65).

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- The **WHOQOL-OLD scale (24 items)** for residents to evaluate their QoL (Cronbach's alpha: 0.72–0.83) (37).
- The **Impact of Event Scale 6 (IES-6, 6 items)** for measuring the symptoms associated with post-traumatic stress in individuals who have undergone a traumatic event (Cronbach's alpha: 0.95) (38).
- The **Post-traumatic Growth Inventory (PTGI-SP, 10 items)** for evaluating post-traumatic growth, i.e. positive, lived psychological change following a traumatic event (Cronbach's alpha:= 0.90) (39).
- The **Perceived Stress Scale (PSS, 14 items)** for evaluating perceptions of stress (Cronbach's alpha: 0.74) (40).
- The **Brief Cope (28 items)** for evaluating coping strategies (Cronbach's alpha: 0.50–0.90) (41).

Analysis procedures for quantitative data

Data will be examined using Stata® statistical software, version 16. Data will first be cleaned, and if more than 10% of responses are missing from a particular scale, then that subject's observations will be discarded. Total scores and subscale scores for each questionnaire will be calculated following their authors' particular recommendations. For categorical or discrete variables, frequencies, percentages and modes will be calculated. For continuous variables, means, medians, standard deviations and interquartile ranges will be calculated. Skewness and kurtosis coefficients will be calculated to evaluate distributions and their normality. We will calculate descriptive statistics for the total scale scores and subscale scores of the GHQ-12, IES-6, PSS, Brief Cope, PTGI-SP, WHOQOL-BREF and WHOQOL-OLD scales. Finally, we will perform correlational analyses between the subscale scores for the GHQ-12, IES-6, PTGI-SP, WHOQOL-BREF and WHOQOL-OLD scales and the subscales scores of the Brief Cope scale.

Sociodemographic variables will be analysed using descriptive statistics depending on the variable measured.

Qualitative phase

Data collection

Qualitative data are collected from a number of sources (36):

- Individual, semi-structured, 20–30-minute interviews are carried out with **residents**, with the aid of an interview guide, to explore their perceptions of their lived experiences of stressors, the coping strategies that they implemented to deal with them and the results they obtained.
- Individual, semi-structured, 30–40-minute interviews are carried out with **relatives**, with the aid of an interview guide, to explore their perceptions of their lived experiences of stressors, the coping strategies that they implemented to deal with them and the results they obtained.
- Two 60–90-minute focus groups will be run with **nursing home professionals**, with the aid of an interview guide, to explore their perceptions of residents' and relatives' lived experiences of stressors, the coping strategies those two groups implemented to deal with them and the results they obtained.
- The research team keeps field notes about visits to nursing homes and during interviews. In particular, this information includes investigators' notes on participants' behaviours.

Participants

The nursing home residents and their relatives selected for this qualitative data collection phase are subject to the same selection criteria used in the quantitative data collection phase. The inclusion criteria for nursing home professionals are to have worked in the unit for at least three months and to

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have regular contact with both residents and their relatives. Exclusion criteria include being a temporary employee, a part-time employee, or a student.

Sample and recruitment

Participants are selected using purposive sampling to ensure representativity across several variables (severity of symptoms, post-traumatic growth, QoL, varied coping strategies). Interviews are planned with about 12 representatives of each group of participants (residents and relatives) or until data saturation.

Two focus group discussion groups made up of healthcare professionals will be constituted to explore their perceptions of residents' and relatives' lived experiences of stressors, the coping strategies those two groups implemented to deal with them and what those strategies' results were. All the healthcare professionals in our partner nursing homes will be invited to participate.

Analysis procedures for qualitative data

Data analysis began as soon as data collection began and continues iteratively. The interviews are conducted in the nursing home in a place that respects the confidentiality of the exchange: in the resident's room if he or she is alone or in an appropriate office for relatives. The interviews will be conducted by the research assistant, who is a PhD nurse specializing in qualitative research. The interviews will be audio-recorded and transferred to a secure server at the school. They will be transcribed by a specialist company and the verbatims will be inserted into a Word 365 Pro plus ® file. The data will be subjected to a thematic content analysis inspired by the Neuman model. This means that we will interpret the data by coding them according to this model. These analyses will be carried out using MAXQDA textual data analysis software. Verbatim citations will be used to illustrate tendencies, provide the phenomena of interest with context and aid in our in-depth understanding of COVID-19's impacts on older adult nursing home residents.

We will draw up tables describing the absolute and relative frequencies of item responses. The reliability and validity of constructs will be ensured by the detailed documentation maintained in investigators' field notes at each stage of the research. The study's internal validity will be ensured by triangulating data from multiple sources. The validity of external data will be ensured by selecting several subjects over the course of the study, using purposive sampling to provide a diverse subject set until data saturation.

Integrating quantitative and qualitative data

The integration of the study's quantitative and qualitative elements will occur jointly at the data interpretation stage. This will be based upon the treatment of the quantitative data from our sociodemographic and clinical questionnaires and from the treatment of our qualitative data from our interviews with residents, their relatives and their healthcare and support professionals and the research team's field notes:

- We will describe the stressors reported by residents and their relatives who present with high and low scores on the GHQ-12, IES-6, WHOQOL-BREF or WHOQOL-OLD, PSS and PTGI-SP scales.
- Data integration will provide us with information about the links between the stressors experienced by residents and their relatives and the consequences on their health.
- We will describe the coping strategies used by residents and their relatives who present with high and low scores on the GHQ-12, IES-6, PSS, WHOQOL-BREF or WHOQOL_OLD and PTGI-SP. This integration will provide us with information about the relative effectiveness of some of their coping strategies with regards to others.
- We will compare residents' and their relatives' reported frequency of use of the different coping strategies measured in the Brief Cope scale. Integrating this information will deepen our

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understanding of the coping strategies implemented by residents and their relatives during the pandemic.
- We will describe the stressors that healthcare and support professionals perceived residents and their relatives were facing. Integrating this information will help us to evaluate residents' and their relatives' needs and whether those needs were considered or not.
- We will compare the coping strategies reported by residents and their relatives with those support interventions actually put into practice by healthcare and support professionals. Integrating this information will help us understand how appropriate the support provided by healthcare and support professionals actually was, how different support measures complemented each other and where support was lacking.

In summary, putting our questionnaires findings into perspective regarding the health statuses of residents and their relatives and the results from our interviews will help us to identify their needs in terms of the preventive health interventions that could be developed to optimally maintain their health in the ongoing COVID-19 pandemic or a future one. The results from the focus group discussions involving healthcare and support professionals will help us to specify priority interventions that currently do not exist.

Study status

The present study began on 1 January 2021 and is planned to finish on 31 December 2022. Data collection began on 1 April 2021 because of the evolving epidemic situation in Switzerland, and collection is set to finish on 28 February 2023.

Discussion

The present exploratory study will contribute to a greater understanding of nursing home residents' and their relatives' lived experiences of COVID-19, the strategies they employed to cope with the pandemic and the consequences of those strategies. This will provide valuable knowledge about the epidemic's effects on this vulnerable and severely affected population. The study will provide essential data on the perceptions residents and their relatives had about their psychological health soon after the stage of strict lockdown, but also about the stressors to which they were exposed, the coping strategies they attempted to put in place and the results of those strategies. Our data should reveal the different types of stressors stemming from an epidemic situation in Switzerland's nursing homes as well as the adaptations and changes made to the processes of support provided to residents and their relatives. Exploring the results of residents' and relatives' strategies will allow us to assess them and formulate appropriate preventive-care interventions that will ensure the quality and safety of care for nursing home residents in case of future severe public health crises. It will also give indicators on how to protect their health and that of their relatives. New approaches could contribute to mitigating the impact of future pandemics and the consequences on the health of older adults living in nursing homes and their relatives. Furthermore, our findings could help to prioritise the development of preventive health interventions to counteract the effects of prolonged lockdowns for both of those groups. Our study considers the points of view of the diverse actors involved, which is essential when developing, testing and implementing new care practices. Its findings will provide the deeper understandings of patients' contexts and settings that are essential for anchoring changes in clinical practice, collaboration with relatives, training for healthcare professionals and managing nursing homes in general.

Ethics and dissemination

This project was approved by the Human Research Ethics Committee of the Canton of Vaud on 14 December 2020 (Project-ID: 2020-02397). The prior written informed consent of the study subjects is

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collected by a member of the research team before data collection. Major change to the study protocol will be announced to the Human Research Ethics Committee of the Canton of Vaud.

All the data collected is coded and kept securely at La Source School of Nursing. When dealing with quantitative data, each participant will be attributed an anonymous administrative code. Data will be installed on an SRP directory on La Source School of Nursing's server, which is housed in a data centre in Switzerland.

All interviews are audio-recorded in full. When this qualitative data is transcribed verbatim onto a Word 365 ProPlus® file, each participant is attributed an anonymous administrative code instead of their name. Residents' codes begin with the letters 'RES' and the letter 'Q' for qualitative data, followed by a two-digit number, starting with RESQ01 for the first resident interviewed and so on in chronological order. The same system is followed with relatives (e.g. RELQ04) and healthcare professionals (e.g. PROQ12).

All the participants are free to withdraw from the study at any moment without incurring any penalties or consequences with regards to the future care or services they might rightfully expect. Should a participant decide to withdraw, for whatever reason or at whatever moment, any data that have already been anonymised will not be destroyed but rather will still be analysed as specified in the research information sheet. Results will be presented in an aggregated form so that no participants will be identifiable in lectures or publications.

Only the principal investigator will have access to the key linking participants' codes to their names and identities, and this will only be used if absolutely necessary. All other researchers working on the study will only have access to coded data. The file containing the key to participants anonymity will be protected by a password known only to the principal investigator.

Data and material will be available on request from the authors.

Patient and public involvement

Patients and/or the public were not involved in the design or conduct of this research. Refer to the Methods and analysis section for further details.

Dissemination of results

Our results will be disseminated in various ways. A document containing the key facts will be prepared specifically for the participating care homes and other care homes on request. Public conferences will also be organised in those institutions. Scientific manuscripts will be addressed to international and French-language professional and scientific journals for publication. We will also disseminate our results at appropriate local and international conferences. Finally, a research report containing the study's highlights and most important findings will be produced for the libraries of our institutional partners and all the actors that participated financially in our work. Authorship will be defined using recommendations of the International Committee of Medical Journal Editors.

Author contributions

COB is the principal investigator. COB, MA, LB and CC contributed to the study design. MA, LB and CC are collecting the data. All authors are responsible for the data analyses. All authors read and approved the final manuscript.

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Competing interests (for all authors)

The authors have no conflict of interest to declare.

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page.2
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	Page 2
Funding	4	Sources and types of financial, material, and other support	Page 3, par. 2
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 1 Page 11, par 1
	5b	Name and contact information for the trial sponsor	Page 1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Pages 4-5
	6b	Explanation for choice of comparators	NA

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Objectives	7	Specific objectives or hypotheses	Page 5, par.5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 6, par.1
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 8, par 1
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 6, par 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	NA
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 7, par 1-2 Page 8, par 3-4
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	NA

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Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 6, par 7
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6, par 7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 6, par 2 Page 7, par 3
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

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Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 10, par. 4
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 7, par 2 Page 8, par 4/6-8
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 7, par 2
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 10, par 2

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Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 10, par 2
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 10, par 2
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 10, par 5
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 11, par 4
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 10, par 3
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 10, par 7
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Page 11, par 7
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	NA
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

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*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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