

BMJ Open Impact of CAre-related Regret Upon Sleep (ICARUS) cohort study: protocol of a 3-year multicentre, international, prospective cohort study of novice healthcare professionals

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ABSTRACT

Introduction Healthcare professionals are particularly at risk of developing numerous physical and psychological health problems. The experiences of emotional burden associated with providing healthcare, notably care-related regret, have been associated with these health problems, but only using cross-sectional data so far. Evidence of a causal impact of regret has not been assessed. The Impact of CAre-related Regret Upon Sleep (ICARUS) study is the first prospective and international cohort study established to examine how newly practising healthcare professionals adapt to their challenging job by assessing the impact of care-related regret on sleep and job quitting.

Method and analysis The ICARUS cohort study will include newly practising healthcare professionals working in acute care hospitals and clinics recruited between May 2017 and November 2019. Data collection, which will begin as soon as the participant starts working with patients, will consist of a 1-year weekly assessment using a secure web survey. Follow-up data will be collected at 6, 12, 18 and 24 months after the end of the first year. We will collect detailed information on the experience of care-related regret (ie, highest regret intensity, accumulation of regrets and coping strategies related to regrets), sleep problems and job quitting. Moreover, quality of life, health status and burnout will be assessed during the follow-up. Several confounders factors, including sociodemographic characteristics, personality, night shifts and work environment characteristics, will be assessed.

Ethics and dissemination The study was approved by the Ethics Committee of Geneva Canton, Switzerland (CCER2016-02041), the Ethics Committee of London South Bank University (HSCSEP/17/06) and the University Research Ethics Committee of Bedfordshire (UREC106). Other study centres deemed local ethical approval unnecessary since the main ethics committee (Geneva) had already accepted the project. Results will be published in relevant scientific journals and be disseminated in international conferences. Fully anonymised data and questionnaires will be freely accessible to everyone (scientists and general public).

Strengths and limitations of this study

- The Impact of CAre-related Regret Upon Sleep (ICARUS) study is the first prospective and international cohort study of healthcare professionals examining the impact of care-related emotional burden, especially regret related to clinical decisions or actions, on sleep and job quitting.
- ICARUS population are newly practising healthcare professionals selected from a random sample of medical and nursing schools from the French-speaking, English-speaking, German-speaking or Danish-speaking countries recruited between May 2017 and November 2019.
- The ICARUS study uses an intensive longitudinal data collection allowing to capture the real-time impact of care-related regret on sleep problems.
- The ICARUS study will collect rich data giving a detailed image of the development of critical coping skills necessary to healthcare professionals to provide good quality healthcare to patients while themselves remaining in good health.
- The ICARUS study is designed to minimise the inherent risks of bias associated with observational studies, but, as the participation is voluntary, a potential selection bias, due to attrition, cannot be excluded.

INTRODUCTION

Healthcare professionals are particularly at risk of numerous physical and psychological health problems, including back pain (eg, prevalence among home nurses: 19%),¹ sleep problems,²⁻⁵ depression (prevalence among medical doctors: 28.8%)⁶ and suicide (twofold increase in incidence among nurses and physicians).⁷ An increased rate of burnout from 45% to 54% between 2011 and 2014 was observed in Americans physicians,⁸ a trend similar in European countries,^{9,10} with newly practising physicians being particularly at risk.¹¹⁻¹⁴ These outcomes often results



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in sleep problems,^{2 3} prolonged sick leave,^{15–17} job quitting^{18–20} and have serious consequences on organisation and quality of patient care,^{21–26} and dramatic costs for the healthcare system.^{27–29}

While the causes of these health problems involve multiple factors such as the clinical working environment, night shifts and job strain,^{30 31} one cause lies in the emotional burden associated with providing healthcare.^{5 32} Along with the emotional states that may affect healthcare providers' own health, such as moral distress,³³ moral sensitivity,¹⁹ perception of inappropriate care provided to patients,³⁴ loss of control over the care process³⁵ or involvement in medical errors,³⁶ regret, a normal and frequent emotion,³⁷ has recently increased attention.³⁸ Regret is the emotion people feel when they think that the outcome would have been better if they had acted differently.³⁹ For instance, if healthcare professionals believe that a patient's situation would have been better if they had behaved differently, they will experience regret.⁴⁰ Of note, regret is associated both with negative outcomes, such as sleep problems,^{41 42} but also with positive outcomes, such as enhanced learning.^{43 44} The regret regulation theory asserts that regret generate ameliorative cognitions.^{39 45} Indeed, regret allows making sense of the past, and facilitating approach and avoidance behaviours when appropriate, and preserving social harmony.⁴⁶ In the clinical working environment, regrets occur frequently. Physicians and nurses perform countless clinical decisions and actions during their workday, in a context characterised by time pressure, information overload, increase in patient care complexity and uncertainty.^{47 48} Thus, many clinical events or situations may lead to feeling regret, whether there was a medical error or not.^{49 50}

Dealing with healthcare-related difficult events (eg, discovering that a patient is experiencing a lot of pain and should have received his medication half an hour earlier) or situations (eg, palliative care, paediatric and intensive cares) relies on coping strategies. One known classification of these strategies proposes two categories: problem-focused and emotion-focused.⁵¹ Problem-focused strategies aim at preventing similar situations in the future (eg, 'I will make a change in my schedule to visit my patient on time' or 'I will provide more pain medication in advance'). Emotion-focused strategies include suppression of regret-related thoughts (eg, 'It happened but let's not think about it'). In addition, social strategies (ie, seeking either an attentive ear or obtaining concrete support from others, such as a 5 min break) are either problem-focused or emotion-focused. How these strategies are used by physicians and nurses, and how effective they are in the context of providing healthcare, is still poorly understood.

Based on qualitative studies,⁴⁹ we developed a framework to model the process of feeling regret, how these feelings and the associated coping can be characterised as exposure and the potential consequences of these exposures. Highest regret intensity, accumulation of regrets over time and coping strategies have a wide range of consequences on three levels (figure 1, outcomes).³⁸ First, regret influences physical and mental health at the individual level. The intensity of regret is associated with feelings of loss⁵² and with a wide range of physical and psychological symptoms.^{53 54} Regret also disturbs sleep.^{41 42 55} Given that sleep loss may lead to attention deficits⁵⁶ and thus to an increased risk of errors and regretted decisions,⁵⁷ a vicious circle between errors, regrets and insomnia could emerge.⁵⁸ Second,

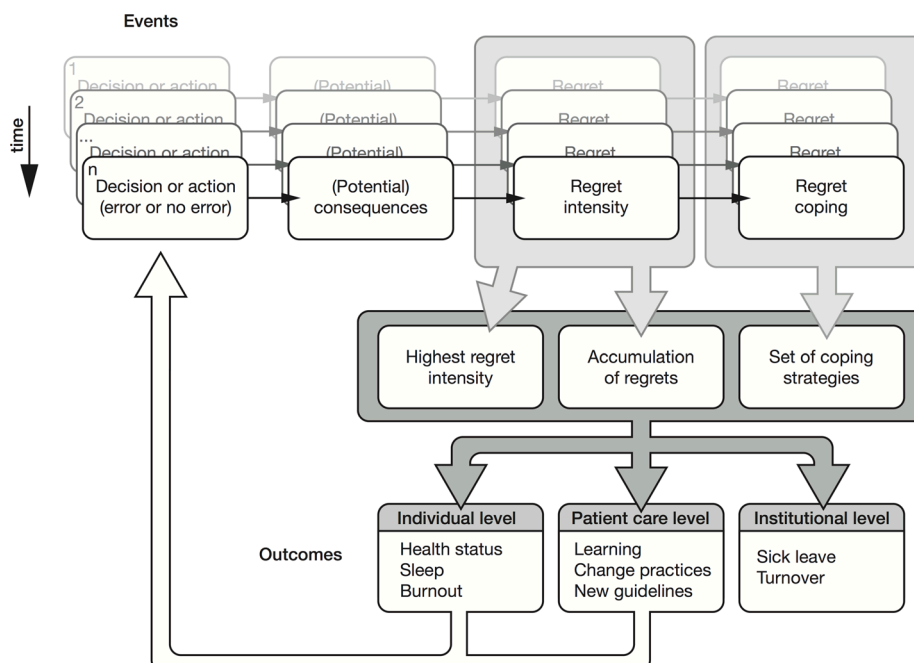


Figure 1 Theoretical relationships between regret, regret regulation and outcome variables.³⁸

regret may influence safety decisions⁵⁹ and clinical decision-making,^{60–63} either at the individual level, through learning or clinical test ordering,^{64 65} at the ward level, through changing practice in the ward (eg, rigorously applying identity bracelet checking), or at a more global level, through the diffusion of new guidelines. Finally, intense regrets decrease job satisfaction⁴⁹ and may lead to more sick leave,⁶⁶ and eventually to the decision to change jobs (figure 1).

Previous studies could not assess the causal impact of regret because of the cross-sectional nature of the designs.⁶³ This limitation led to the initiation of the ICARUS cohort study in 2017 to examine how healthcare professionals adapt to their challenging job by assessing the impact of care-related emotional burden, especially regret related to clinical decisions or actions, on sleep and job quitting. Assessing causality in an observational study is very difficult. But at the minimum, it requires that the exposure occur before the outcome and that potential confounding variables were assessed and controlled. The Impact of CARE-related Regret Upon Sleep (ICARUS) cohort study attempts to meet these requirements by investigating regret and regret regulation as they occur in an ecological momentary assessment study, with a 1-week interval between each measure.

The project focuses on two primary outcomes: (1) sleep problems and (2) job quitting. Sleep problems are a very important issue for healthcare professionals because work characteristics (eg, shift work) already have a detrimental impact on sleep,^{5 28} especially among residents doctors.⁶⁷ Furthermore, sleep problems increase the risk of medical error.^{26 68} Career abandonment is also of particular interest since the costs of training doctors and nurses are considerable,⁶⁹ that is, a loss of >5% of the total annual operating budget.⁷⁰

METHOD AND DATA ANALYSIS

Study design

The ICARUS cohort study is a prospective, longitudinal, multicentre and international study of newly practising healthcare professionals working in acute care hospitals and clinics. The ICARUS cohort study consists of 1-year weekly assessment using a secure web survey hosted by the University of Geneva, Switzerland. The rationale for this 1-week interval is that it should correspond to the time granularity necessary to assess the causal impact of regret on sleep, that is, regret should impact sleep for the next week and maybe a few weeks afterwards. Participants will be sent the survey on Monday afternoon and, if they do not answer, will receive up to two reminders per week, on Wednesday and Friday.

Follow-up

A questionnaire will be sent every 6 months in years 2–3 to obtain longer-term information on job quitting, as well as on quality of life, health status and burnout.

Population

Newly practising healthcare professionals working in acute care hospitals and clinics. We selected novice healthcare professionals because young age is a significant factor of turnover intentions.⁷¹ Moreover, young clinicians are at higher risk of regretted decisions and actions as they are still learning skills to do their job. Finally, a qualitative study⁴⁹ suggested that many clinicians described intense experiences that dated back to their first years of clinical practice.

Between May 2017 and November 2019, students in nursing and medical schools will be invited to participate in the ICARUS study during their last year of training. Participants will be selected from a random sample of schools from the French-speaking, English-speaking, German-speaking and Danish-speaking countries. Specifically, before contacting participants, an email will be sent to the dean to ask for the permission to contact their students to invite them to take part in a study concerning the difficulties encountered by healthcare professionals when they start treating patients. As incentive, a small donation to a charity (Theodora foundation) of 0.5 CHF for each completed survey will be made. To be included in the study, participants must be healthcare professionals, speak French, English, German or Danish and be willing to complete one short web survey per week for a maximum of 1 year and the four follow-up questionnaires. We exclude respondents who already provided healthcare in a professional capacity (ie, excluding internships). Data collection begins as soon as the participant starts working with patients.

Sample size

The estimates are based on expected number of career change among nurses (18% over 3 years).¹⁵ We have five regret variables (number of regret over the past week, intensity of the most significant regret over the past week, three coping strategies). Current guidelines on sample size for predictive models require a minimum of 5 events (ie, turnover in this study) per predictor (ie, the five regret variables in this study), yielding a minimum of 25 necessary events.⁷² We expect a loss to follow-up of 10%. Thus, we need a minimum of 153 nurses (25 events divided by 0.18 (incidence of turnover) times 1.1 (to compensate 10% loss to follow-up)). An additional 47 nurses will be recruited to allow for a potential lower incidence of turnover and the potential inclusion of covariates in the model. For medical doctors, turnover rates are much lower and are also less documented. For this reason, sample size calculations are based on the sleep outcome, and more specifically on sleeping pill use. In a cross-sectional study, the regular use of sleeping pill was 14.3% among medical doctors younger than 30 years.⁴² Thus, the same sample size of 200 is necessary.

Measures

Table 1 summarises the measures of the ICARUS cohort study taken in year 1, with which instrument and at which

Table 1 Measures in year 1 of the Impact of CAre-related Regret Upon Sleep cohort study

Measure	Items (n)	Frequency of measurement	Instrument
Most intense care-related regret overall in the last week	10	Variable (1–52×): skip if no regret this week.	RIS-10 ⁸³
Number of regrets in the last week	1+10	52×: first question is a filter, skip if no regret this week. Nine questions to describe event and regret intensity.	
Regret coping in the last week	15	52×.	RCS-HCP ^{84 85}
Change of practice in the last week	1	52×.	
Satisfaction with work in the last week	5	52×.	GSWW ⁸⁶
Number of work hours, night shifts and sick days in the last week	3	52×.	
Sleep, including dreams and pill use, in the last week	9	52×.	ISI ⁷⁷ + two items from PSQI ⁷⁸
Intention to change profession	1	12× (monthly).	
Back pain	2	12× (monthly).	

GSWW, Global Satisfaction with Work (Echelle de satisfaction globale au travail); ISI, insomnia severity index; PSQI, Pittsburgh Sleep Quality Index; RIS-10, Regret Intensity Scale; RCS-15, Regret Coping Scale.

frequency. Each weekly survey (65 questions) takes a maximum of 10 min.

To allow for careful adjustment and thus reduce confounding bias, several confounders both at baseline and overtime are measured. In particular, we measure personality Ten-Item Personality Inventory (TIPI)⁷³ and sociodemographic characteristics at baseline, but we also measure number of night shifts and work environment safety climate Safety Attitudes Questionnaire (SAQ).⁷⁴

In addition, each 6 months over the remaining 2 years of the study, the survey will measure quality of life using EuroQol (EQ-5D),⁷⁵ health status Short-Form health survey (SF-36),⁷⁶ sleep problems (ISI⁷⁷ and two questions from the Pittsburgh Sleep Quality Index (PSQI)⁷⁸ on dreams and pill use), burnout Professional Quality Of Life Scale (ProQOL)⁷⁹ and professional status (ie, whether caregivers still work with patients). These surveys should take <30 min.

Analysis

Job quitting

We will use survival analysis to examine the impact of the five regret variables (frequency, highest intensity and three coping strategies) on job quitting. This analysis will be done separately by profession. Since regret is an exposure, which varies over time, several ways of characterising this exposure will be tried. In addition, we will also examine the possibility to characterise individuals as having efficient versus inefficient coping skills using cluster analysis. We will then determine if people with inefficient coping are more at risk of job quitting or sleep problems.

Sleep problems

In this analysis, regret intensity will influence regret coping, and both should have a causal impact on sleep. At the same time, sleep problems are known to worsen regret regulation. Thus, analysis will require careful statistical modelling of circular causality. We will examine the circular causality between regrets and sleep problems in a series of cross-lagged Bayesian models. In these models, we will estimate the cross-lagged association of regret in a given week with sleep problems of the following week, simultaneously with the cross-lagged association of sleep problems in a given week with regret of the next week and with the autoregressions of both sleep problems and regret.⁸⁰ All analyses will be performed with R using lme4, lmerTest, CODA, r2winbugs packages and WinBUGS.^{80 81}

Ethics and dissemination

Other study centres deemed local ethical approval unnecessary since the main ethics committee (Geneva) had already accepted the project. All participants will give an informed consent to participate in the study.

Results will be published in relevant scientific journal and be disseminated in international conferences. In line with the Swiss National Science Foundation guidelines, data in a fully anonymised version and questionnaires will be freely accessible to everyone (scientists and general public).

DISCUSSION

The ICARUS cohort study is a prospective, multicentre, international and longitudinal study of newly practising healthcare professionals. So far, the ICARUS study is the only prospective cohort study examining the impact of

care-related regrets on health-related outcomes. The uses of an intensive longitudinal data collection will help to capture the real-time impact of regret on sleep problems. The rich data will also give a detailed image of the development of critical coping skills necessary to provide healthcare while remaining in good health.

The ICARUS cohort study is designed to minimise the inherent risks of bias associated with observational studies. To minimise forgetting and memory biases, data will be collected at short time lag intervals (each week) using an internet-based survey. Another advantage of this method of data collection is that subjects feel more comfortable reporting higher level of distress and feelings such as guilt, shame, humiliation or anger when they are using automated systems.⁸² As the study relies on voluntary participation, the potential bias of selection cannot be excluded. However, because we are interested in changes within a given individuals, this selection bias will be unlikely to explain the pattern of results. Furthermore, the use of self-reported questionnaires for regret and sleep problems may artificially inflate the association between them due to self-reporting bias. Yet, the sleep scales possess sound psychometric properties and good concurrent validity with polysomnography measures⁷⁷ and the regret questionnaires have satisfactory construct validity.^{83 84} Finally, attrition is an issue in longitudinal studies, leading to a potential selection bias in the remaining sample. Yet, the planned analyses will allow to include all the healthcare professionals in the models, even those who only answer once, thereby limiting this bias.

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Contributors DSC conceived the study and is the principal investigator. BC, SC, JP-T, DM, MVA and PC contributed to the conception of the study. All authors approved the version to be published and are responsible for its accuracy.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval The study was approved by the Ethics Committee of Geneva Canton, Switzerland (reference number: CCER2016-02041), the Ethics Committee of London South Bank University (reference number: HSCSEP/17/06) and the University Research Ethics Committee of Bedfordshire (reference number: UREC106).

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

Data sharing statement In line with the Swiss National Science Foundation guidelines, fully anonymised data and questionnaires will be freely accessible to everyone (scientists and general public).

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