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## Long title: Protocol for evaluating a Consultation for Suffering at work in French-speaking Switzerland



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#### ABSTRACT

Introduction: Psychosocial suffering entails human, social and economic costs. In Switzerland, 34.4% of workers report chronic work-related stress. Our medical Consultation for Suffering at Work aims to preserve—or restore—the patient's capacity to act and make decisions after a diagnosis of work-related psychological suffering; it also aims to help employees get back to or remain at work. Our hypothesis is that the dynamic of the consultation itself and adherence to its medical advice are active factors of these results.

*Objectives*: Understand changes in patients' work and health status 12 months after a Consultation for Suffering at Work. Determine the effects of the consultation on health and working status via identified active factors: the consultation dynamic and the ability to adhere to the consultation's advice. Evaluate the consultation's effects qualitatively.

Materials and Methods: This longitudinal, monocentric study with a quasi-experimental design will include patients consulting between 1 January and 31 December 2018. Changes in patients' work and health status will be analysed using data collected via questionnaires at 0, 3 and 12 months. Qualitative data will be collected via a semi-structured telephone interview 3 months after the consultation. The quantitative part will include 150–170 patients; the qualitative part will include 30.

Conclusion: This exploratory research project will provide a better understanding of issues of work-related psychological suffering and effective strategies to support patients. The absence of a control group and the impossibility of applying a randomised controlled design are constraints on this study.

#### 1. Introduction

#### 1.1. Background

#### 1.1.1. Psychological suffering and psychosocial risks

Gollac defines psychosocial risks as "the risks to mental, physical and social health entailed by working conditions and the organisational and relational factors which may interact with mental function" [1].

Suffering at work is the unpleasant and destabilising psychological experience "which arises when the subject runs into insurmountable and persistent obstacles, after having used up all his resources in an attempt to improve the organization of his work with regards to quality and safety" [2].

Psychological suffering at work can entail human [3–6], social and economic costs [7]. Nevertheless, work remains a major factor in the construction of an individual's identity [8].

#### 1.1.2. Psychological health at work in Switzerland

Comparing Swiss data with European Union (EU) data shows that the perceived professional pressures of working in Switzerland are greater [9,10] but that the country's working environment give workers greater latitude in decision making about their jobs and more support from company hierarchies. It is of note that in 2014 Switzerland's unemployment rate was 3.2% [11] versus 10.2% in the EU [12].

Despite these protective factors, the results of recent studies on the mental health of employees in Switzerland are worrying [7,13]. In 2010, 34.4% of employees reported chronic stress linked to their occupations; in 2000, the rate was 26.6% [14].

#### 1.2. The Consultation for Suffering at work

#### 1.2.1. History

In 2008, the Institute for Work and Health (IST) carried out a survey

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of 806 primary care physicians in French-speaking Switzerland. This revealed that 14.9% of their new diagnoses involving working-age adults had an occupational link and that they subsequently required specialist advice [15]. In 2009, the IST began to work with Lausanne University Hospital's (CHUV) Community Psychiatric Service to develop an occupational health consultation dedicated specifically to psychological suffering at work. A pilot phase helped the partners to make the necessary adjustments to these consultations [16].

#### 1.2.2. Theoretical underpinnings of the consultation

The Consultation for Suffering at Work involves an analysis of both the professional and private aspects of the patient's suffering. The consultation adopts an approach to occupational psychopathology developed out Dejours's occupational psychodynamics and Clot's "clinical activity intervention" within the framework of the traditional practice of clinical occupational medicine. The specificity of clinical occupational medicine is that it approaches the worker's psychological problems from the point of view of his relationship with his work activity. Clinical occupational medicine enables a subjective analysis of aspects of occupational situations which are harmful to the worker's psychological function and the mechanisms that he might use to maintain both his professional commitment and his psychological balance [17].

The Consultation for Suffering at Work is a complex intervention [18]. Its effects can be multiple, progressive, variable and time-deferred, depending on the individual [18,19]. There are multiple, nonlinear causal relationships with feedback loops between health and employment [18,20].

#### 1.2.3. Goals of the consultation

The main goal of the Consultation for Suffering at Work is to preserve—or restore—the patient's capacity to make decisions and take action (empowerment) and his feelings of professional effectiveness. The notion of empowerment—a rather difficult one to translate into French—describes the process through which an individual or a group acquires the means to reinforce his capacity for action and his ability to take the initiative in order to become an actor in his own life [21].

Another of the consultation's goals is to encourage the restoration or maintenance of the patient's psychological relationship with employment, and this can assist primary care physicians to manage such situations.

#### 1.2.4. How the consultation works

Any employee may spontaneously ask for a Consultation for Suffering at Work, or it can be requested via a patient's care network. Both routes lead to the same consultation unless there is an urgent need to deal with a psychiatric emergency or there is an occupational physician in the employee's company.

A report on the consultation is sent to both the patient and his attending physicians, with a summary of the analyses carried out and the chosen approaches for dealing with the problem, in the form of advice or recommendations formulated with the patient. In general, the patient only participates in a single consultation. However, if deemed necessary, this could be supplemented by an intervention in the workplace by an occupational physician from the IST. Around one third of cases require the combined analyses of an occupational physician and a psychiatrist, and these take place at the IST's premises every two weeks.

#### 1.2.5. Active factors of the consultation

The consultation process follows a two-stage process leading to the formulation of recommendations that will be formulated in a report and which the collaborator will be invited to implement.

These steps were identified following critical thinking by a group of expert clinicians and researchers in this field, including some of the authors (CBG, CB, BD and PW) together with Dominique Chouanière\* and Christine Cohidon\*\*. They used a systematic approach to study

each stage of the consultation in order to identify the most probable active factors. The potential factors were then proposed to the physicians carrying out the consultations for Suffering at Work. They validated the most probable active factors of the consultation as the dynamic of the consultation itself and the patient's adherence to the recommendations formulated during the consultation.

The dynamic of the consultation itself is the analysis of the situation carried out by the physician, with the patient, using the patient's narrative:

- During the first step, the clinician will allow the patient to re-contextualize the problem by integrating different perspectives to broaden his initial vision. Its aim is to grasp the process of settling suffering in order to identify its contributing aspects and their interlinkages.
- The second step is to help the person to overturn from the factors of shift to support factors related to his/her work. These support factors may relate to the individual's functioning, relationship to work or place of work. By allowing concrete tracks, this second stage will try to unblock the feeling of impasse or the anxious anticipation of return to work in the same configuration. Advice relative to the patient's job is aimed at supporting a reconfiguration of the relationship to work by trying to push back against the factors which contributed to the patient stopping work or experiencing an occupational crisis there. This shift enables risk factors to become a part of the solution—factors of reconstruction and support—and help to begin a new, positive connection with the working environment. It allows the person to project himself, to be legitimated in a proactive attitude towards himself and his professional situation in order to try to reconfigure it. This second step supports the return of an individual's ability to act and an "empowered" position [22].

The consultation's recommendations and advice are formulated in partnership with the patient using the potential paths to a solution retained during the consultation. Advice can be about the work situation, medical care or the patient's administrative and health insurance situations.

Our analysis is that the consultation Work and suffering acts through its active factors which are its two-stage dynamic and the elaboration of recommendations. The two-stage-dynamics are the passage through the two steps described above: the re-contextualization and the identification of positive levers. The recommendations are codeveloped with the patient (Fig. 1).

It is probable that adherence to recommendations and the dynamic of the consultation itself have a mutual influence on each other.

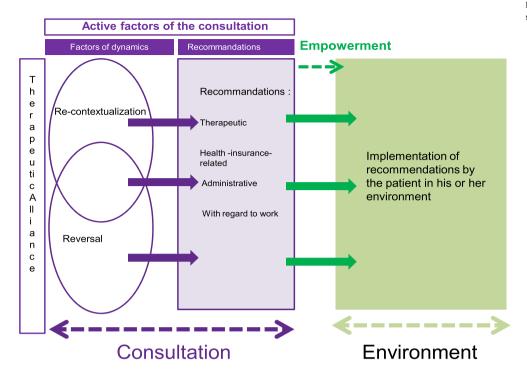
The Consultation for Suffering at Work in its current form was put in place in 2014. It is now time to evaluate its effects.

#### 1.3. Study objectives

The study's objectives are to understand the changes in the patient's employment situation and health at 12 months after the consultation and to evaluate the consultation's effects on the patient's health and his employment situation via two variables: the dynamic of the consultation itself and the patient's adherence to the medical advice given to him. Our hypothesis is that indicators of a patient's health and employment status after a consultation will be more favourable if he perceived a positive dynamic during his consultation and/or he was successfully able to adhere to the medical advice and recommendations that resulted from it.

A secondary objective is to qualitatively evaluate the effects of the Consultation for Suffering at Work by exploring patients' perceptions of it.

Fig. 1. Modeling the active factors of the consultation



#### 2. Materials and methods

This will be a longitudinal, monocentric study of patients who attend a Consultation for Suffering at Work at the IST between 1 January and 31 December 2018. This choice of design was dictated by how such consultations are organised: due to ethical considerations, it is impossible to randomly select patients who would receive the Consultation for Suffering at Work and those who would not. Patients who failed to attend their consultation could perhaps have formed a control group, but it would be a very small one. This is probably because of the initial selection of patients who are referred to this type of consultation. The study is monocentric because the IST is the only institute providing this type of consultation in French-speaking Switzerland.

#### 2.1. Study population

Given the current activity in our clinic, we estimate that the study will involve 150–170 consecutive patients who attend a Consultation for Suffering at Work between 1 January and 31 December 2018.

All Francophone patients attending a Consultation for Suffering at Work will be eligible for inclusion, whether or not they present with an associated somatic problem. Participants will be contacted 3 months (M3) and 12 months (M12) after the consultation. Patients will be considered lost to follow-up if their M12 data is unobtainable. With regards to similar studies in other countries, the percentage of patients who will be lost to follow-up at M12 is estimated to be between 20% and 40% [23]. Refusal to participate in the study or an inability to fill in the written questionnaires will also constitute reasons for non-inclusion. The exclusion criterion will be the patient's refusal to participate in the study's planned follow-up.

The informed consent form for this research study will be sent to patients along with their written invitation to attend their Consultation for Suffering at Work and the standard occupational questionnaire. The patient will sign the written informed consent form as an annexe to his medical record. If requested or if necessary, this can be done after further explanations by the physician. A copy of the form will be given to the patient.

#### 2.2. Evaluation criteria

The first evaluation criterion is the patient's employment situation at M12, measured using a questionnaire at that future date. For a more sensitive analysis, this criterion is also examined at M3. At M0, the employment situation is evaluated using the standard IST questionnaire that each patient completes at home before attending the Consultation for Suffering at Work (Annexe 1). Another bespoke IST questionnaire about the patients' current links to employment is sent out to them at M3 and M12 (Annexe 2).

The second criterion is the change in the patient's health status between M0 and M12. This change is objectified using two self-administered questionnaires at M0, M3 and M12. These questionnaires are the General Health Questionnaire (GHQ-28) and the World Health Organization Quality of Life questionnaire (brief version, WHOQOL-BREF). The GHQ-28 enables an estimation of psychological distress [24]. It has been previously validated in French and contains 28 items which use a four-point Lickert scale. Answers will be dichotomised: 0 for replies of "less than usual" or "not more than usual" and 1 for replies of "a little more than usual" or "much more than usual". The possible total score can vary between 0 (best overall health) and 28 (worst overall health). Above a score of 6, a patient is considered to present signs of psychological distress. This questionnaire requires 5-10 min to complete properly. The WHOOOL-BREF questionnaire [25] contains 26 questions selected from the WHOQOL-100 questionnaire, using items on a five-point Lickert scale. The WHOQOL-BREF has been validated in French. It enables an evaluation of the quality of life according to four parameters: mental health, physical health, social relationships and the environment. A calculation is made for each of the four parameters and a mean score is taken. The higher the score, the better the patient's state of health. The quality of life score for each of the four parameters is considered low if the patient falls in the bottom third of the population's scores. This questionnaire also requires 5–10 min to complete properly.

#### 2.3. Explanatory variables

The explanatory variables are made up of descriptive variables and variables relating to the active factors of the consultation.

Table 1
Research protocol diagram.

M0 – prior to IST Consultati

M0 – prior to IST Consultation	onsultation	M0 – Immediately post-consultation	ost-consultation		M3 – 3 months: Questionnaires and telephone interview	M12-12 months: Questionnaires	જ
Written informed consent form	Self-administered questionnaires Professional situation: Education, Career path (linear or non-linear).  Non-professional aspects: Sociodemographic information; Health insurance information; Prior psychiatric problems; Social support (SSQ6); Significant life or health events.  Coping (WCC); Psychological symptoms (GHQ 28) <sup>b</sup> ; Quality of life (WHOQOL) <sup>b</sup> ; Personality traits (IPDE).	Consultation for Suffering at Work	Physician's Questionnaire Questionnaire on the perceived dynamic during the consultation Weighting of the patient's personal and professional components of suffering at work Recommendations: Preparation of a checklist of recommendations	Self-administered questionnaires  Questionnaire on the perceived dynamic in the Consultation	Self-administered questionnaires Professional situation:	Self-administered questionnaires Professional situation*:  Non-professional aspects Health insurance information Significant life or health- related events in the past nine months Psychological state: Coping (WCC); Psychological symptoms (GHQ 28)2; Quality of life (WHOQOL)2; Quality of life (WHOQOL)2; Recommendations: "Were you able to follow the recommendations?"	End of participation in the study (total duration: 12 months)

 $^{\rm a}$  Evaluation criterion: in employment at M12.  $^{\rm b}$  Evaluation criterion: health status at M0 and M12.

#### 2.3.1. Descriptive variables

The descriptive variables are:

- Individual factors: age, sex, household structure, level of education (Annexe 3);
- Patient's situation with regard to health insurance (disabilitity insurance, sick leave insurance,...);
- Patient's professional situation: employment situation, career path (linear or non-linear), current job, type of company, etc.;
- The respective weights of the occupational and personal parts of the patient's current psychological problems, as evaluated at M0 by the consulting physician using a bespoke IST scale using one question with three possible answers (Annexe 4);
- Results from the Ways of Coping Checklist (WCC) [26], which comprises 27 items and characterises the different methods used to manage stress. It has been validated in French;
- Results from the Perceived Social Support Questionnaire (PSSQ) which enables patients to evaluate the availability of and their satisfaction with social support.

#### 2.3.2. Variables relating to the active factors of the consultation

According to our analysis, the variables relating to the active factors of the consultation are the dynamic of the consultation itself and the patient's adherence to the medical advice or recommendations formulated with the consulting physician:

- The consultation dynamic is evaluated by both the physician and the patient using *ad hoc* questionnaires which mirror each other by using four questions on a five-point Lickert scale (Annexe 5). Results will be dichotomised, with subjects scoring 3 or 4 considered as having perceived a positive dynamic and those scoring 0, 1 or 2 considered as not having perceived a positive dynamic in the consultation
- The nature of the medical recommendations and advice given at M0 (whether purely therapeutic, administrative, to do with health insurance issues or relative to the patient's work), together with how well that advice was adhered to, will be recorded at M3 and M12 using a bespoke IST questionnaire (Annexe 2).

#### 2.3.3. Confounding factors

The possible confounding factors identified are: certain personality traits, such as those revealed by the International Personality Disorder Evaluation (IPDE) questionnaire [27], which comprises 124 items that enable the characterisation of an individual's personality traits; the quality of social support as evaluated using the Social Support Questionnaire (SSQ6) [28]; and prior psychiatric problems or significant life events as evaluated using a bespoke IST questionnaire (Annexe 4).

#### 2.4. Data collection

The patient attends the Consultation for Suffering at Work at M0. The consulting physician collects any data on the patient's antecedent problems and his current socio-professional situation. The patient completes the five questionnaires mentioned previously: the GHQ-28, WHOQOL-BREF, IPDE, SSQ6 and WCC.

After the Consultation for Suffering at Work (M0'), both the patient and the consulting physician evaluate the dynamic perceived in the consultation using *ad hoc* questionnaires that were designed for the needs of this protocol (Annexes 5 and 6).

The physician notes the recommendations and advice given to the patient on a form that is attached to the patient's medical record. At M3 and M12, information on whether those recommendations were adhered to is noted on the same form during a follow-up telephone interview with the patient.

Also at M3 and M12, the patient's health status is estimated using the WHOQOL-BREF, GHQ and WCC questionnaires. These, together with questionnaires about the patient's personal situation and professional status (Annexe 2) are sent to the patient together with a stamped envelope addressed to the Consultation for Suffering at Work. Telephone interviews at M3 and M12 are carried out to make a qualitative evaluation of the consultation and adherence to its recommendations. The two main questions in the qualitative evaluation are: "What impact did the Consultation for Suffering at Work at the IST have on your situation?" and "Which recommendations helped you the most?" These telephone interviews should take 10–15 min. If the patient was unattainable in M3, for example, telephone contact will be attempted again in M4 and, failing that, email will be attempted in M5 as a last try at contact.

For the M12 evaluations, patients will be contacted in sub-groups of approximately 15 subjects at a time. This means that the average follow-up length for each patient will equal one year  $\pm$  15 days. The end of the data collection period should, therefore, be in December 2019. Data input should be completed by June 2020. Data analysis should be finished in November 2020. Table 1 is a summary of all these procedures.

#### 2.5. Data analysis plans

#### 2.5.1. Quantitative data

An initial descriptive analysis will describe the population's characteristics.

Statistical analysis will be structured around the two principal evaluation criteria and the protocol's formulated hypotheses.

The first evaluation criterion—employment status at 12 months—is a qualitative variable, collected once. Analysis will be by multiple logistic regression. The potential effects of the consultation on the patient's return to work will be evaluated using an "adherence to recommendations" variable at M3 and by an estimation of the perceptions of the consultation's dynamic. These regressions will systematically take into account the patient's age and sex. The other potential confounding factors will be included one by one if their statistical significance is characterised by a p < .20.

The second evaluation criterion is the patient's change in health status, as estimated using the scores from the repeated use of the WHOQOL-BREF and GHQ questionnaires. Each one of the scores will be analysed using a mixed linear model with a random effect and with the moment of data collection as the fixed effect. The normality of the random effects and the normality of the baseline residuals of both scores will be checked. If necessary, transformation of the scores (e.g. logarithmic) will be done. If none leads to acceptable normality, the scores will be discretized in low/high scores and logistic mixed models will be applied. The effect of the consultation itself on return to work will be estimated partially by the differential change in the patient's health status, partially by the differences between the subjects who followed the recommendations and advice given and those who did not, and partially by the perceived dynamics in the consultations. The differential changes will be obtained by examining the interaction of these variables and the health indicators collected at different measurement time points. The potential confounding factors will be included one by one, together with their interaction with the collection time point if their statistical significance is characterised by a p < .20.

The models' validity will be evaluated by examining their residuals at a subject level and at each measurement time point. Scores transformations (notably logarithmic) could be applied to normalise the residuals.

For all the statistical tests, a p < .05 will be considered significant. All these analyses will be carried out with the most recently available version of Stata software.

#### 2.5.2. Qualitative data

Thirty of the telephone interviews carried out to collect information on patients' adherence to medical recommendations will become extended interviews on the effects of the Consultation for Suffering at Work itself. Subjects for these 30 extended interviews will be selected so as to cover all the profile types in the study population. These interviews will be recorded, transcribed, anonymised, analysed and coded using independent double coding. The transcriptions will be subjected to a contents analysis (theme occurrence analysis) as part of a comprehensive approach (intuitive iterative reading, identification of invariables in different scenarios and interpretation). The use of specialist software is not foreseen for this part of the study.

#### 2.6. Theoretical and ethical aspects

This protocol will be submitted for approval by the relevant Swiss human research ethics committees.

#### 3. Discussion

#### 3.1. Strengths

To the best of our knowledge, this will be the first exploratory study to evaluate consultations for Suffering at Work. Likewise, it will be the first time these two active factors of the consultation—the consultation dynamic and adherence to the consultation's medical recommendations—have been proposed as explanations for the success of consultations for Suffering at Work.

Furthermore, the qualitative evaluation of the consultation will provide a deep understanding of the overall effects of the consultation, both from the point of view of the consulting physician and the suffering patient.

#### 3.2. Limitations

The selection bias in this study is significant because most requests for a consultation come from primary care physicians and the consultation clinic's secretariat filters the requests made directly by employees/patients themselves. The study design had to be adapted to take into account the absence of a control group. Another limiting factor is the absence of repeated measurements of the variables of interest prior to the consultation. We are thus unable to compare trends by carrying out segmented regressions.

Moreover, an evaluation of the consultation's effects must consider "all the possible effects of an intervention" without limiting itself to the effects specifically targeted by the study. The qualitative part of the study enables this will enable us to do this.

#### 3.3. Future perspectives

This study will allow us to develop a greater understanding of the most effective strategies to support patients, adjust and improve the Consultation for Suffering at Work, and coordinate with other medical consultations for treatment or for tertiary preventative interventions.

International comparisons of the patient profiles of the employees experiencing Suffering at Work and of the care strategies used will become possible.

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#### Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.

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