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## Protocol Registration

### EATING BEHAVIOR AND QUALITY OF LIFE OF NIGHT WORKERS IN FOOD AND NUTRITION UNITS

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#### Sponsor:

Pontifical Catholic University of Rio Grande do Sul, PUCRS

#### Information provided by (Responsible Party):

Ana Maria Pandolfo Feoli, Pontifical Catholic University of Rio Grande do Sul, PUCRS

**Date of study approval by the Ethics and Research Committee/PUCRS:** May 11, 2021.

#### Study Description

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##### Brief Summary:

Cognitive Behavioral Therapy (CBT) is used for a group of techniques in which there is a combination of a cognitive approach and a set of behavioral procedures. The basic principle of CBT can be described as follows: emotional and behavioral responses, as well as motivation, are not directly influenced by situations, but by the way in which these situations are usually processed. The worker is any person who has a work activity, regardless of being inserted in the formal or informal market. And, nightshift work, due to its wide application and demand, for technical, social and economic reasons is a topic of great relevance today. However, it can lead to health risks, both in biological and psychological functioning, among other emotional problems, causing greater propensity to stress, anxiety crisis and emotional tiredness. In the food and nutrition units, where the organization of work is strongly guided by Taylorist-Fordist principles, structured based on routines, technical standards and organization charts for the meals production, giving attention and dedication to the behaviors and habits of employees, become some strategies for maintaining and improving motivation for work and quality of life in this environment. Objective: to evaluate the effects of an intervention to change eating

behavior on the perception of quality of life and eating habits of night workers in food and nutrition units. Method: This is a research project, involving a systematic review (study I) and a clinical trial (study II). The systematic review aim to investigate whether there is a difference in eating behavior between workers, the one that works during the day and the other at night. The second study will consist of two groups; one control and one intervention. The research will consist on a web-based strategies, with two evaluative moments, before and after intervention. To assess the eating behavior outcome, the Dutch Eating Behavior Questionnaire (DEBQ) will be used; for eating practices, the Self-Applicable Scale for Food Assessment will be included, according to the Recommendations of the Food Guide for the Brazilian Population. For analysis of quality of life, the WHOQOL-Bref, short version of the WHOQOL- 100 instrument, will be used.

Condition or disease	Intervention/treatment
Eating Behavior	Behavioral: Intervention group

**Detailed Description:**

The clinical trial will be a blind randomized study, in order to contemplate the objectives. This study, which will be fully conducted online, the individuals surveyed (1: 1) will receive, or group intervention, with behavioral cognitive strategies to change eating behavior, or group intervention without the problematization proposed for the change, just working on the transmission of knowledge about healthy lifestyle. The study presents two evaluative moments (before and after the intervention), by filling out questionnaires, which will be used to assess the change in eating behavior. Participants, by their own adherence to the study, will use digital platforms for electronic questionnaires - qualtrics, and for the materials, an interactive electronic mural, padlet (padlet.com). The sample will consist of night workers employees (night and early morning shifts), only women, that work in food and nutrition units. The recruitment of participants will take place from the invitation sent to multiple food and nutrition units, in the southern region of Brazil (states of Paraná, Santa Catarina and Rio Grande do Sul). Workers with less than 3 months working in the unit and on the night shift will be excluded from the sample; as well as interns, under 18 and pregnant women. Poorly completed or incomplete questionnaires will be also excluded from the sample. To obtain a power of 80% and error  $\alpha = 5\%$ , with an estimated sample loss of 20% in a total of 2 groups, the minimum number for each group is 29 investigated, totaling 58 individuals. For the sample calculation, the program SISA (Simple Interactive Statistical Analysis) was used. A sociodemographic questionnaire; a health diagnosis questionnaire; a self-applicable scale for Food Assessment; the Dutch Eating Behavior Questionnaire (DEBQ) and the WHOQOL- Bref will be used in this research. Employees who accept the invitation to participate in the study

will receive a link to answer an online questionnaire, prepared by the Qualtrics platform. This questionnaire will allow to evaluate the inclusion criteria for the research. For those who not gets to participate in the study, will be invited to visit, through the indication of the website and social networks of the research group (@pevspucrs), the educational materials, such as e-books and planners. Those employees to be included will receive a welcome message to the study, and at the same time, read and sign the Informed Consent Form (ICF), which will also be available online. Reaching the required sample size, the groups will be randomized.

Randomization will be per cluster (will be performed according to the workplaces of the employees to be included in the study). This type of randomization strengthens the blinding of research. The locations (food units) will be randomized using the Random Allocation Software, version 2.0 in two groups: Control Group (CG) and Intervention Group (IG). The first task for both groups, before the intervention, will be to complete those questionnaires: sociodemographic questionnaire; anamnesis with anthropometric information; the Self-Applicable Scale for the Assessment of Food, according to the Recommendations of the Food Guide for the Brazilian Population; the Dutch Questionnaire to assess Eating Behavior and the WHOQOL-Bref, to assess quality of life.

As soon as everyone is completely filled in, the intervention process will begin. The online intervention it will be in asynchronous modality way. Members will self-manage activities. Materials for the sessions, such as videos, presentations (canva, mentimeter), infographics and icons, for sending tasks, will be available on an electronic wall (padlet).

The intervention program materials will be available every week, during all the six (06) sessions for each group. At the end of the intervention, one week after the last session, the participants completed those questionnaires again. And after three months, from the secondstage of filling in the instruments, the employees will answer the questionnaires again, in order to verify whether the effect of the intervention has been maintained. Data will be entered in the MS Excel application. The database will be imported into the statistical softwareStatistical Package for the Social Sciences (SPSS) IBM version 22.

Variables, for the purposes of statistical analysis, will be the following:

- a. Body Mass Index: eutrophy, overweight, obesity and severe obesity;
- b. Socioeconomic class: A, B1, B2, C1, C2 and D-E.
- c. Self-Applicable Scale for the Assessment of Food, according to the Recommendations of the Food Guide for the Brazilian Population: dimensions, such as the choice of food, ways of eating, domestic organization and planning.
- d. Quality of Life: quality of life domains to be assessed are: physical, psychological, social relations and the environment.

- e. Eating Behavior: domains through the DEBQ questionnaire to be evaluated are: restricted food, emotional food and external food.

Primary outcome: eating behavior, which will be assessed through the *Dutch Questionnaire for the Assessment of Eating Behavior (DEBQ)* and the assessment of eating practices, by the Self-Applicable Scale for Food Assessment, according to the Recommendations of the Food Guide for the Brazilian Population.

Secondary outcome: quality of life.

For the ethical aspects of the research, this study has already been submitted and approved by the PUCRS research ethics committee, under the registration number 44556321.5.0000.5336, in May 11, 2021.

As the whole study will be done online, the risks known for participating in the research are attributed to some uncomfortable moments, like answering the various questionnaires, or due to the time dedicated for the questions, and also due to participate in some activity, such as the delivery of a task. If the participant does not feel comfortable during the intervention, will be possible to stop participating at any time during the research. In addition of uncomfortable moments, it is possible that the internet connections fail or show a certain slowness, or that the participant will have doubts on how to save their answers. In the IC, there will be guidance on how to proceed in these cases. The possible benefits of participating in the research can be the diagnosis of the nutritional status, that will be delivered individually, and the probable benefits already indicated in the scientific literature by the change in eating behavior.

## Study Design

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Study Type:	Interventional
Estimated Enrollment:	58 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
	two groups: intervention and control
Masking:	Single (Participant)
	participants will not know whether they will be in the control or intervention group.
Primary Purpose:	Treatment

Official Title: EATING BEHAVIOR AND QUALITY OF LIFE OF NIGHT WORKERS IN FOOD AND NUTRITION UNITS

Estimated Study Start Date: October 15, 2021

Estimated Primary Completion Date: December 15, 2021

Estimated Study Completion Date: June 1, 2022

## Arms and Interventions

Arm	Intervention/treatment
<b>No Intervention: Control group</b>	In this modality of intervention, the focus will be on the development of skills through educational actions in health, using the pedagogy of transmission. The focus will be based on content related to food, nutrition and quality of life. Materials like videos, podcasts, booklets and short films will be available weekly, following a schedule of sessions.
<b>Experimental: Intervention</b>  In the intervention group, the focus will be the development of skills through educational health actions that provide the development of autonomy and empowerment for behavior change, based on cognitive behavioral interventions, which involve eating behavior and impact on quality of life. Cognitive behavioral therapy (CBT) is based on ten principles that influence and / or determine treatment attitude and approach. Intervention group sessions will be based on principles.	<b>Behavioral: Intervention group</b>  Materials to be weekly available for intervention group, following a schedule of sessions (six in total): videos, podcasts, booklets, films, books and other presentations. The intervention will be based online, in a asynchronous modality. Members will self-manage activities.

## Outcome Measures

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Primary Outcome Measure:

## 1. Eating practices

It will be evaluated through the assessment of eating practices, by the Self-Applicable Scale for the Assessment of Food, according to the Recommendations of the Food Guide for the Brazilian Population. Diet rating scale according to the Food Guide for the Brazilian Population: minimum value: from 0 to 31 points; maximum value: above 41 points.

High score means better result.

[Time Frame: through study completion, an average of 19 weeks]

## 2. Eating behavior

It will be evaluated through the Dutch Questionnaire for the Assessment of Eating Behavior (DUTCH): emotional eating, external eating and restricted eating. Dutch Eating Behavior Questionnaire: maximum possible score is 33 points; the higher the score, the lower the ability to control eating; and the lower the score, the higher the capacity.

[Time Frame: through study completion, an average of 19 weeks]

### Secondary Outcome Measures:

#### 1. Quality of life and quality of life at work

It will be evaluated through the World Health Organization Quality Of Life - Bref. World Health Organization Quality of Life - bref. Results in % from 0 to 100. The higher the percentage (closer to 100%) the better the quality of life.

[Time Frame: through study completion, an average of 19 weeks]

### Eligibility Criteria

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Ages Eligible for Study: 18 Years and older

Sexes Eligible for Study: Female

Gender Based:

Gender Eligibility Description: female only

Accepts Healthy Volunteers:

### Criteria

Inclusion Criteria: women, night workers in food services; in the southern region of Brazil (Paraná, Santa Catarina and RioGrande do Sul).

Exclusion Criteria: male, workers with less than 3 months of experience in food services; as well as interns, under

18 and pregnant will be excluded. Poorly completed or incomplete questionnaires will be excluded from the sample.

## More Information

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Responsible Party: Ana Maria Pandolfo Feoli, Professor, Pontifical Catholic University of Rio Grande do Sul, PUCRS

ClinicalTrials.gov Identifier:

Other Study ID Numbers: 44556321.5.0000.5336

Last Verified: May 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

Plan Description:

Human Subjects Protection Review Board Status: Approved

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

## Statistical Analysis

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Initially, the data will be entered into the MS Excel application. Afterwards, the database will be imported into the Statistical Package for Social Sciences (SPSS) IBM version 22 statistical program.

### **Variables**

The variables used for statistical analysis purposes will be as follows:

- a) Body Mass Index: eutrophy, overweight, obesity and severe obesity;
- b) Socioeconomic class: A, B1, B2, C1, C2 and D-E.
- c) Self-applicable Scale for Food Assessment, according to the Recommendations of the Food Guide for the Brazilian Population: dimensions such as food choice, eating habits, household organization and planning.
- d) Quality of Life: quality of life domains to be evaluated are: physical, psychological, social relationships and the environment.
- e) Eating Behavior: the domains of the AC by the use of the Dutch questionnaire to be evaluated are: restricted eating, emotional eating and external eating.

## INFORMED CONSENT FORM (ICF) FOR ONLINE STUDIES

### "EATING BEHAVIOR AND QUALITY OF LIFE OF NIGHT WORKERS IN FOOD AND NUTRITION UNITS"

Please read the following text about the study. If you feel like participating in the research, express your consent by selecting the option "I have read and agree to participate in the research" presented at the end of this term. As it is a ICF on a web page, and without the possibility of physical signature, after the consent after the information, the message will appear "By clicking on the button below, you agree to participate in the survey under the terms of this ICF. If you do not agree to participate, just close this page in your browser".

Please, if you have any questions before, during or after your participation, send an email to the main researcher of the study: Profa Ana Feoli, cell: (51) 999113014, email: [anafeoli@pucrs.br](mailto:anafeoli@pucrs.br). If you have any questions about your rights as a research participant, please contact the Research Ethics Committee of the Pontifical Catholic University of Rio Grande do Sul (CEP-PUCRS), located at Ipiranga avenue, 6681/building 50, room 703, ZIP Code: 90619-900, Partenon, Porto Alegre/RS, e-mail: [cep@pucrs.br](mailto:cep@pucrs.br), Monday to Friday from 8:00 am to 12:00 pm and from 1:30 pm to 5:00 pm. The Ethics Committee is an independent agency made up of professionals from different areas of knowledge and members of the community. Its responsibility is to ensure the protection of the rights, safety and well-being of participants through review and approval of the study, among other actions.

#### CONSENT TO PARTICIPATE IN THE RESEARCH

You are being invited to participate in a survey developed by Luísa Rihl Castro called "Eating Behavior and Quality of Life of Night Workers in Food and Nutrition Units" of the Graduate Program in Psychology at PUCRS. The objective is to evaluate the effects of a (nutritional) intervention to change eating behavior in the perception of quality of life and eating habits of night workers in food and nutrition units. Please read the information below and, if you do not understand or have any further questions, you can contact us by e-mail [luisa.castro@pucrs.br](mailto:luisa.castro@pucrs.br), before deciding whether or not to participate. This survey is voluntary, and you have the right not to respond to any item and also to discontinue your participation at any time for any reason. The study predicts their participation over seven (07) weeks, occupying around 2 days a week (more or less, one hour each day). The research will be conducted completely online, through the use of questionnaires and access to a platform, with interactive content on health and nutrition. Through a link to be shared, you will have access to the materials. The known risks of participating in this research model (online) are attributed to small discomforts in answering the questionnaires, due to the time to be devoted to the questions, and also to the delivery(online) of the activities. The survey will be divided into weekly sessions, with the completion and delivery of tasks. In addition to the discomfort, you may feel as a result of the responses to these questionnaires, it is possible that, unfortunately, your connection may fail or show some slowdown, or that you may have doubts about how to save your answers. Your survey will be saved automatically, don't

worry, OR you need to click “save” to properly collect your answers. In these cases, do not hesitate to contact the researcher, Profa Ana Feoli, cell phone: (51) 999113014, or email: anafeoli@puhrs.br; or with Luísa Rihl Castro, by e-mail luisa.castro@puhrs.br. The benefits arising from their participation in the research include the diagnosis of nutritional status (which will be delivered individually) and the likely benefits already indicated in the scientific literature by the change in eating behavior. The study is free and voluntarily and there will also be no form of reward (payment). No identifying information about you will be included in publications that may result from this search. The collection of information for this project will be completed between July and August 2021 and all information obtained will be securely stored for a period of five (05) years after this date, or until completion of the written work. By continuing this survey, you agree that any questions you had have been adequately answered and that you agree to participate in this study. I understand the procedures described above, and:

I agree and agree to participate in the survey

I do not agree and do not agree to participate in the survey

