

"Impact of remote therapeutic cooking workshops in the management of adult patients living with obesity on dietary balance : randomized interventional study in stepped wedge clusters"

Therapeutic Kitchen of Obese Patient Project (CuisTO)

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SYNOPSIS

PROMOTER	<p style="text-align: center;">Centre Hospitalier Frédéric Henry Manhès 8 rue Roger Clavier 91300 Fleury-Mérogis</p>
TITLE	<p style="text-align: center;">« Impact of remote therapeutic cooking workshops in the management of adult patients living with obesity on dietary balance : Stepped Wedge cluster-randomized interventional study »</p>
ACRONYM	<p style="text-align: center;">" CuisTO Project " (Cuisine Therapeutic of patient Obèse)</p>
Version	<p style="text-align: center;">Version of Protocol n°2 of 09/08/21</p>
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NUMBER OF CENTRES	6 (CHU Pitié Salpêtrière ; Georges Pompidou European Hospital ; CH Forcilles ; CH Bligny; CH Cognacq-Jay; CH Manhès)
TYPE OF STUDY	Open-label , multicenter randomized controlled intervention study in Stepped Wedge clusters »
CHARACTER-TIQUE RESEARCH	This is a multicenter, open-label, controlled intervention study with step-wedge sequential randomization. This is a <u>research in paramedical care</u> that has received PHRIP funding (Hospital Nursing and Paramedical Research Program) from the DGOS French Ministry of Health (Care Delivery Branch)
NUMBER OF PARTICIPANTS	<p>420 patients (i.e. 4.6 patients / center / month)</p> <ul style="list-style-type: none"> • 140 in the control group : Usual management + Questionnaires (arm A) • 280 in the interventional group: Usual care + Questionnaires + 6 cooking workshops: <ul style="list-style-type: none"> - either in "classic " form (arm B) - either in the form of "culinary challenge " (arm C)
DURATION OF THE STUDY	21 months of experimentation from the 1st inclusion

Context

The France does not escape the "epidemic" of obesity, as demonstrated by the latest results of the Constances cohort (BEH Matta J et al. 2016)(1): more than 33% of French adults are overweight, and more than 15%, or almost 7 million people, are obese. Because of cardio-metabolic, psychological and joint morbidity and associated mortality, obesity is responsible for major health and economic consequences. Its management requires the implementation of long-term lifestyle changes, placing therapeutic patient education (TPE) at the heart of care (Ziegler O, 2014)(2). The High Authority for Health (HAS) recommends a global approach along four distinct axes (HAS, 2011)(3) :

- Tips to promote physical activity
- A psychological approach
- medical follow-up
- dietary education

For the latter, the implementation of therapeutic cooking workshops during the management of obesity in hospitals is now well accepted and recognized as of potential interest on the nutritional level but also cognitive and social (Desport, 2015; Dagoneau C, 2008)(4)(5). The literature shows that adults participating in cooking workshops are satisfied and acquire cooking skills that are potentially useful for improving their health (Wolfson JA, Bleich SN, 2015; Caraher M, 1999)(6)(7). However, Reicks (2014, 2018)(8)(9) and Rees (2012)(10) point out the low methodological quality of most of the studies conducted and, in fact, the effectiveness of therapeutic cooking workshops has not been formally demonstrated by rigorous randomized studies.

Modification of the CuisTO protocol linked to the covid-19

The global COVID-19 pandemic has led to the unprecedented implementation of health measures in France (confinements, barrier gestures, social distancing, etc.) which initially led to the suspension of all collective therapeutic workshops on the hospital sites provided for in the protocol CuisTO. Initially planned as a research protocol on the impact of face-to-face cooking workshops when submitted and accepted by the Hospital Research Program in Nursing and Paramedical Care (PHRIP) of the DGOS (Ministry of Health) at the end of December 2019, the reflections related to the health crisis we are experiencing led us to reconsider our mode of operation concerning the cooking workshops.

Thus, the members of the scientific committee of the CuisTO protocol unanimously advise that CuisTO adapt to this health crisis by proposing not to measure the impact of face-to-face cooking workshops, but the impact of remote cooking workshops.

This suggestion would be in line with current recommendations, thus allowing the continuation of the care of patients, without risk to their health, and to begin our research as soon as possible.

Our funding partners (DGOS and ARS Ile de France) have given their agreement, as long as the entire protocol remains unchanged in its general form : 6 centers, same objectives (measurement of the impact on dietary balance and psycho-social behaviors), same judgment criteria (repercussions on the main recommendations of the PNNS-4) and same overall budget. Only an orientation of the budget lines can be envisaged.

DIFFERENCES COMPARED TO USUAL MANAGEMENT

Even if the usefulness of cooking workshops is well perceived by the medical profession (M Roussel, Picot, 2008)(11), they are not sufficiently implemented in the hospital management of patients living with obesity.

We also lack solid data regarding the effectiveness and value of therapeutic cooking workshops in the management of patients with one (or more) chronic disease(s). The only recommendations relating to the establishment of cooking workshops concern the regulation of hygiene standards (CCLIN-Ouest, 2002; DGAL 2011)(12)(13). Paradoxically, there are no recommendations for the facilitation of these workshops and the orientation of patients.

Our research must therefore not only establish the importance of cooking workshops , but also give the desire to the various hospitals, care structures or health networks to implement them, while proposing useful recommendations for their practice, particularly on animation. Pedagogical (" classic" or " challenge"), on the possibilities of distance learning (video) and patient orientation.

HYPOTHESIS

We hypothesize that the implementation of cooking workshops by video in the care of adult patients living with obesity allows the improvement of their dietary balance, particularly with regard to compliance with the recommendations of the PNNS (National Nutrition and Health Program), the consumption of fruits and vegetables, the frequency of cooking and the decrease in the consumption of already prepared dishes

PRIMARY OBJECTIVE

The main objective of this research is to evaluate the effectiveness of distance cooking workshops in the management of obesity, through two modalities of setting up therapeutic cooking workshops, for the improvement of dietary balance in the context of the management of adult patients living with obesity. The balanced diet will be estimated by compliance with the recommendations of the last National Health Nutrition Program (PNNS-4 2019-2023)(14), "judged" by the PNNS-GS2 score(15), the consumption of fruits and vegetables, the frequency of cooking and the decrease in the consumption of dishes already prepared ultra-processed

SECONDARY OBJECTIVES

- Evaluate the impact of cooking workshops on dietary balance at 6 months after the start of the intervention (i.e. 3 months after its cessation)
- To assess the impact of cooking workshops on weight and BMI at 3 and 6 months after the start of the intervention
- Identify individual predictors of the effectiveness of cooking workshops with the implementation of the prioritization of patients' personal goals
- To assess the impact of cooking workshops on the patient's sense of self-efficacy (16, given their involvement in obesity management (17), for improving nutrition and maintaining or losing weight (18), and on feelings of loneliness.
- Evaluate among dietitian facilitators the impact inherent in the "challenge" pedagogical approach and remote animation, through satisfaction, perceived advantages and obstacles, changes in practices outside obesity (ad hoc questionnaires with free comments, semi-structured interviews)

Primary Endpoint

The primary endpoint will be the absolute change at 3 months (M3) of the PNNS-GS2 score (15), allowing to understand in a global way the patient's adherence to the consumption benchmarks of the National Nutrition Health Program (PNNS) (14).

Secondary endpoints

- The dietary survey and the calculation of the PNNS-GS2 again measured but at M6 (6 months after the start of the intervention, i.e. 3 months after its discontinuation)
- The calculation of BMI (in m²/kg) measured at M0, M3 and M6
- The Feeling of Self-Efficacy measured by the SEPOB (Feeling of Self-Efficacy questionnaire specific to Obesity) makes it possible to measure the feeling of specific personal effectiveness related to the management of usable weight in obese, overweight or normo-weight subjects (16)
- The changes inherent in the "challenge" pedagogical approach as well as the remote animation will be evaluated through a semi-structured qualitative interview of the dieticians animating the cooking workshops. This measure is justified by the innovative nature of the "challenge" workshop and the distance learning
- Demographic data will be collected at M0 in order to identify possible predictive factors of the effectiveness of cooking workshops, including gender, age, CSP (socio-professional categories), background, food allergies, family situation, geographical location, experience in a cooking class / via a menu application, EPICES score (Evaluation score of precariousness and health inequalities in Examination and Health Centers

INCLUSION CRITERIA

- Patients with all of the following criteria may be included :
- adult with the ability to cook at home,
- BMI greater than or equal to 30 kg/m²,
- Being affiliated or beneficiaries of a social security scheme ,
- can be followed on an outpatient basis,
- with physical and mental autonomy to cook,
- with a kitchen in his place of accommodation (home, home ...),
- able to understand French,
- agreeing to answer the various questionnaires,
- having signed the information and consent form
- Patient with the necessary tools for a videoconference workshop (Smartphone, tablet or computer)
- Patient with sufficient connectivity to a videoconference in his kitchen (wifi, 4G ...)

NON-INCLUSION CRITERIA

Patients will not be included in the study if they meet any of the following criteria :

- bariatric surgery patient
- patient planning to have bariatric surgery within 6 months
- a patient who is not affiliated with or a beneficiary of a social security scheme ,
- Patient participating in other experimental research which may interfere with his physical or mental state to cook during the study.
- Patients with treatments that may impact the study criteria will be excluded (treatment with cortisone, neuroleptic ...) according to the judgment of the doctors of the services concerned
- patient with an unstabilized pathology (hyper or hypothyroidism ...) that may impact on the study criteria according to the judgment of the doctors of the departments concerned
- patient who has attended other cooking programs or workshops (whether therapeutic or not, such as "chefs' workshop") in the past 6 months
- patient who has planned to attend other programs or cooking workshops (whether therapeutic or not, such as "chefs' workshop") outside of those offered during the study

EXPECTED BENEFITS

For the patient:

- feel useful and active in its care ,
- gain autonomy to cook,
- improve self-esteem ,
- become aware of the importance of cooking,
- erase the constraints of daily life that lead to not cooking thanks to the "culinary challenge" workshop which is close to reality (in terms of time, dealing with everyday foods, etc.),
- losing weight,
- get closer to the recommendations of the National Health Nutrition Program (PNNS 2019-2023) in terms of balanced diet,
- fight against social isolation through group and playful workshops

For public health and healthcare professionals:

- Complete the care offer for the obese patient

- Provide healthcare professionals with a new pedagogical approach to lead a therapeutic patient education workshop
- Reduce hospitalizations and public health costs by improving the health of individuals through better nutrition
- Encourage other hospitals to include cooking workshops in their treatment of obese patients
- Allow better orientation of patients towards this or that type of cooking workshop animation according to their characteristics
- Check the impact of remote workshops

ASSESSMENT OF RESEARCH BENEFITS AND RISKS

The care includes the filling out of various questionnaires but no particular medical examinations.

Research Features

This is a multicenter, open, controlled, comparative intervention study with sequential cluster randomization (clusters) of the "stepped wedge" type (19)(20). The chosen experimental scheme is based on an innovative and pragmatic approach which will make it possible to evaluate the effectiveness of the two forms of dietary workshops compared to the usual approach. The intervention study proposed is a multicentre randomized comparative study in a cluster of the "stepped wedge" type. All the centers included will be evaluated during a "pre-interventional" period lasting from 3 months to 9 months corresponding to the management of patients living with obesity without a cooking workshop, then a post-intervention period. intervention of 6 to 12 months corresponding to the management of patients living with obesity with cooking workshops (whether in "classic" or "challenge" form). In total, 6 centers in Ile-de-France are invited to participate (Figure 1).

This is research in paramedical care that has received PHRIP (Hospital Program for Nursing and Paramedical Research) funding from the DGOS (General Directorate for Healthcare) of the French Ministry of Health

Statistical analyzes

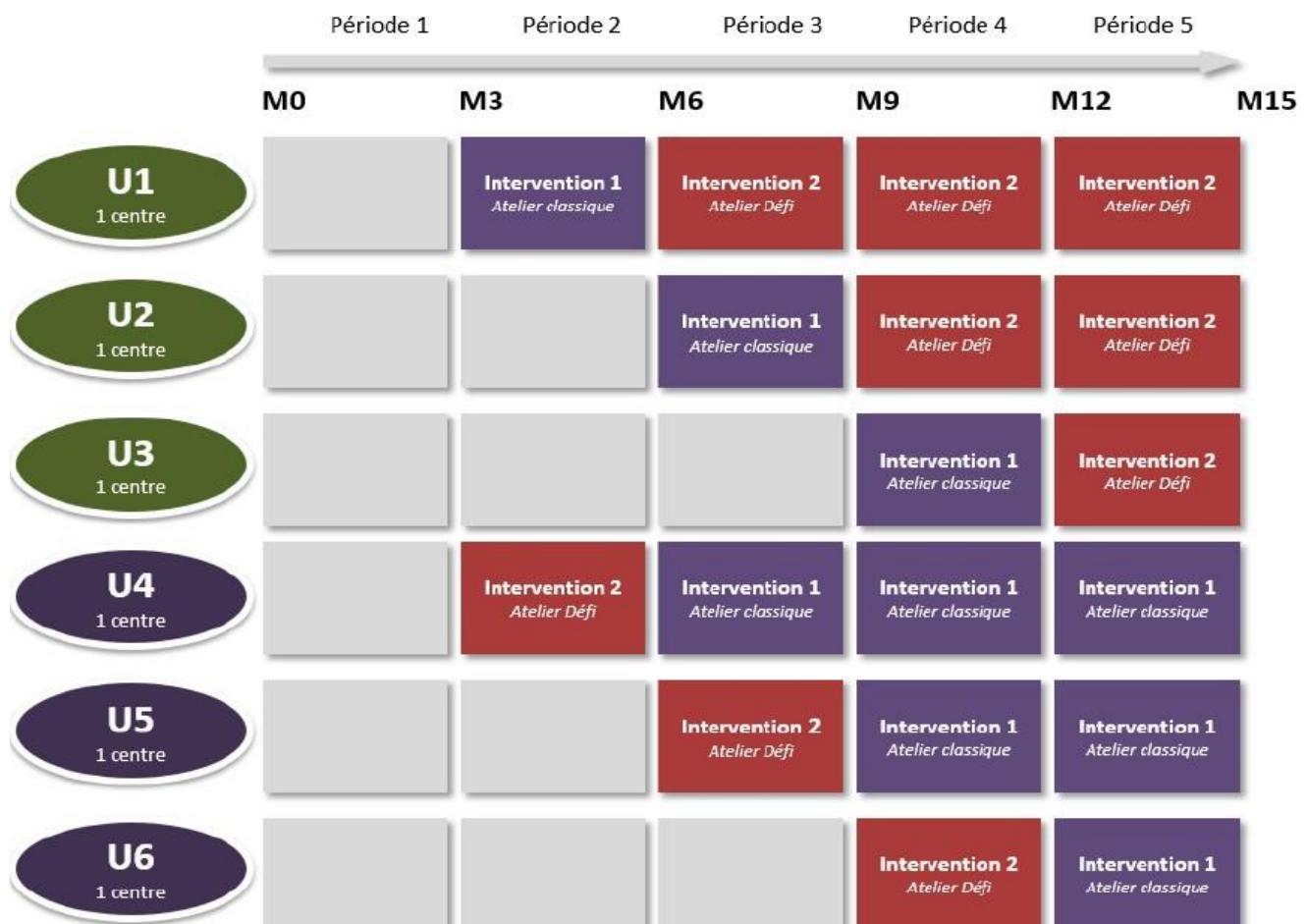
The analysis of the primary endpoint will be performed on an intention-to-treat basis and will compare the pre-intervention and intervention periods for all centers. The analysis of stepped wedge cluster trials presents a number of difficulties related in particular to the intra-cluster correlation, the one that exists

between data repeated over time, and the ability to control underlying temporal trends (21). Consequently, the analysis of the main judgment criterion and of the secondary quantitative criteria of the same nature (anthropomorphic data in particular) will be based on linear regression models with mixed effects, in order to introduce a random factor into the model taking into account the center level, a time term to evaluate the underlying evolution during the study period and an interaction term between time and treatment in order to identify a possible learning curve. The study will be sized to enable the main analysis to test the effectiveness of each intervention (challenge/classic workshop) with respect to the control periods at the bilateral alpha risk of 5%; in the event of significance of the two tests, a formal comparison will be carried out between the two interventions at the 5% risk following a hierarchical procedure in a pre-specified fixed sequence. Additional multivariate models will be carried out in order to take into account possible confounding factors and their evolution over time.

The analysis of secondary criteria of a binary nature will be based on mixed-effects logistic regression models, following modeling principles identical to the description for the primary criterion.

All analyzes will be carried out using Stata v15.1 software (StataCorp, College Station, TX, USA), within the Public Health Department of Henri Mondor Hospital and under the responsibility of Pr Etienne Audureau.

Figure 1. Experimental design of the CuisTO study



Chaque unité de randomisation U1 à U6 est constituée d'un centre participant. Les phases interventionnelles sont mises en place dans un ordre aléatoire au sein de chaque unité de randomisation : les cellules grises représentent les phases pré-interventionnelles (contrôles), les cellules de couleur représentent les phases post-interventionnelles pour l'intervention 1 (« atelier classique », en violet) et 2 (« atelier défi », en rouge).

Funding sources

The source of funding for the CuisTO protocol comes from two institutions:

- The French Ministry of Health, Directorate General for the Care Offer (DGOS) thanks to the obtaining of the Hospital Nursing and Paramedical Research Program, letter of intent accepted in June 2019, file and financing accepted during the appearance before the jury in December 2019
- The Ile de France Regional Health Agency (ARS IdF) in the additional financial contribution for coordination assistance

Provisional timetable

- duration of the research from the 1st inclusion (February 2023) : 21 months
- duration of participation for 1 patient : 6 months
- main forecast dates :
 - 1st Control Group inclusion in the 6 centers: February 2023
 - 1st Intervention Group inclusion in 2 centers (out of 6): May 2023
 - Last Control Group inclusion in 2 centers (out of 6): November 2023
 - Last inclusion Groupe Intervention in the 6 centers: May 2024
 - End of experimental study: November 2024
 - End of statistical analysis: January 2025
 - Publication and communication: from February 2025

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