# ASSESMENT OF THE TREATMENT MANAGMENT PROTOCOLS OF THE BIOLOGIQUE CENTER FOR ADVANCED MEDICINE IN THE DOMINICAN REPUBLIC -YU METHOD[1]

**SANTO DOMINGO, DOMINICAN REPUBLIC**

**DECEMBER 2013**

[1] Report prepared by Eddy Pérez-Then, MD, MPH, MSPH, PhD, Director of the Research Center for Global Health and Biotechnology, with the collaboration of Marija Miric, BA, PhDc and Hendrick Guerra, MD, MPH

**TABLE OF CONTENTS**

## I) BACKGROUND AND RATIONALE

Health is not just the absence of illness; it is the state of integral well being and systemic balance, which depends on certain genetic, psychological and environmental factors, and in great measure depends on how we absorb and make efficient use of nutrients and eliminate wasteful toxins, in order to seek an adequate internal balance.

In recent years, due to an increase in lifespan of people in different world latitudes, there has been an increase in curiosity to acquire more in-depth knowledge on how to slow down the cell's breakdown in order to prolong aging and have a greater quality of life, especially in those population groups that benefit from medical innovations, therefore prolonging their lives and capacity to work. [1-4]

Every day, interest in conserving health becomes more evident, especially in the adoption of healthy lifestyles, not just for its effects on physical wellbeing, yet also pertaining to eating habits, both of which have clearly indicated the need to obtain scientific information on the impact of nutrition, exercise and nutritional supplementation, particularly the elements that attempt to reduce cellular breakdown or oxidative stress. [3-4]

In the Dominican Republic, there exists the Biologique Center for Advanced Medicine, which offers personalized protocols of cellular restructuring, based on the principles of integrated, preventive, orthomolecular and anti-aging medicine with the highest standards of quality and biosecurity, certified by renowned national and international institutions and supported by cutting edge technology. This technique allows for the reduction of chronic inflammation and creates a positive impact on the quality of life and performance of its patients.

In ***Biologique*****,** *the* conditions and expectations of each patient are important and unique, thus providing advanced, world class treatments for those who want to increase their physical performance, re-establish their body balance, strengthen their immune system and autodefense capacity, but do not dispose of the ideal tools to do so, or have not obtained the expected results with conventional treatment. In these instances, they require the support of specialized medical protocols that are based on regenerative, orthomolecular and functional medicine in order to treat not only the consequences of their ailments, but also their causes and origins.

The multidisciplinary team, assembled by leading physicians in their areas of expertise as well as staff from other health areas is coupled with cutting edge technology that allows to implement the "5 Step Program" as well as personalized medical protocols, promoting a comprehensive approach and obtaining exceptional results in patients who benefit from the program.

Biologique's "5 Step Program" consists of the following:

**STEP 1. Enlightened Nutrition.** According to experience up to date, 8 out of 10 people don't have the necessary tools or information needed to obtain an optimum body balance, which is why ***Biologique*** with its specialists in Nutrigenomics, Integrative Medicine and Orthomolecular Medicine, have designed a guide to empower their users with certain, complete and simple information that will allow them to dominate the art of efficient metabolic and individual synergy.

**STEP 2. Nutraceuticals.** Oral Orthomolecular Nutraceutical therapy based on advanced vitamins, nutrients, minerals and enzymes that favor the cardiovascular, immune, gastrointestinal systems alongside integral health, revitalizing cell function.

**STEP 3. IV Ortomolecular.** Intravenous orthomolecular therapy to restore cellular and biochemical deficiencies that allow us to maximize metabolism through personal treatments with vitamins, minerals, aminoacids and enzymes of the highest quality and bioavailability.

**STEP 4. B-CORE, (Biochemical body balance & metabolic efficiency).** Advanced and safe protocol of extracorporeal oxygenation, which lasts 60 minute duration per session, enriching 100 per cent of the patient's blood flow with activated medical oxygen and separating toxic blood waste products that the body cannot eliminate by conventional means, such as heavy metals, petroleum byproducts, inorganic substances, cellular waste and fat macroparticles, therefore reducing the inflammatory effects that are related with aging and chronic diseases.

**STEP 5. Vitality Coaching.** Specialized medical support received by patients during their experience at Biologique. This includes guaranteed continuous support to its users, where the Enlightened Nutrition's guidelines are reinforced thus allowing the patients to be empowered with information and practices which guarantee optimal and sustainable results.

After finishing two uninterrupted years of implementation of the personalized treatment management protocols, it is the interest of the Biologique Center for Advanced Medicine to evaluate these protocols with the aim of providing evidence on its impact in clinical, laboratory and imaging parameters, as well as the quality of life of the user who benefits of these services. This motivates the present quantitative and qualitative assessment in a group of selected users in order to provide evidence in the implementation of the personalized protocols of Biologique and its results on the impact in this population.

## II) OBJECTIVES

### General

Evaluate the treatment management protocols of the Biologique Center for Advanced Medicine, quantitatively and qualitatively, in selected patients in the Dominican Republic.

### Specific

1. Describe clinical result indicators in a retro-prospective cohort of selected patients of the Biologique Center for Advanced Medicine in the Dominican Republic
2. Compare clinical indicators of total cholesterol, triglycerides, HDL, LDL, Weight and Body Mass Index (BMI), before and after the recommended intervention in the protocols of the Biologique Center for Advanced Medicine, in those selected patients who were followed prospectively during 3 months.
3. Assess the quality of life, by qualitative interviews, of a selected sample of selected patients who were followed prospectively before, during and 3 months after the intervention.

## III) HYPOTHETICAL APPROACH

The treatment management protocols of the Biologique Center for Advanced Medicine in the Dominican Republic have a different impact according to the baseline condition of the patient.

## IV) INCLUSION CRITERIA

1. Patients that have been selected from the Biologique Center for Advanced Medicine's database in order to revise their clinical history, laboratory and imaging data, and their symptoms before and after their inclusion to the treatment management protocols of the center.
2. Patients who have started the treatment management protocols of the Biologique Center for Advanced Medicine and permitted to be interviewed for three months prospectively.
3. Patients who accepted to participate in an informed consent process, which concluded with the signing of an informed consent form, in order to collect their sociodemographic, clinical, laboratory and therapeutic data, which permitted the construction of result indicators in order to assess an improvement or not of their baseline condition.

## V) EXCLUSION CRITERIA

1. Patients who attended the Biologique Center for Advanced Medicine but were not selected to revise their clinical chart because required information required to assess an improvement or not of their base condition was insufficient in order to build the result indicators.

2. Patients that started their inclusion in the Biologique Center for Advanced Medicine program but could not be assessed prospectively during three months.

3. Patients that did not accept to participate in an informed consent process, or had accepted to participate but refused to sign the informed consent form.

## VI) MATERIALS & METHODS

### a. Study design

The study consists of a quanti-qualitative assessment of the treatment management protocols of the Biologique Center for Advanced Medicine in the Dominican Republic. This assessment model is guided by case study guidelines in order to assess the intervention processes of the treatment management protocols of this Advanced Medicine Center and its effects on the improval of patients' clinical symptoms three months into their participation.

### b. Study population

The study will include the records of 10 patients that had been incorporated in the treatment management protocols of the Biologique Center for Advanced Medicine in the Dominican Republic (retrospective cohort) and 20 patients that were evaluated prospectively during three months (prospective cohort).

### c. Procedures

We revised 10 patient records that had been included in the treatment management protocols of the Biologique Center for Advanced Medicine in the Dominican Republic, which we obtained their sociodemographic, clinical and laboratory data in a collection form made for this study. We also evaluated 20 patients prospectively during three months who, before their inclusion in the assessment, were asked for their participation and were included in an informed consent that ended with the signing of an informed

consent form. This group of patients was also included in a standardized collection form in order to obtain their sociodemographic, clinical and laboratory information. Four of these patients were chosen according to their clinical and pathological base characteristics and were asked for their participation in qualitative interviews before, during and three months after their interventions indicated as part of the treatment management protocols of the Biologique Center for Advanced Medicine in the Dominican Republic.

Specifically, the interviews were conducted during different application times of the treatment management protocols of the Biologique Center for Advanced Medicine in the Dominican Republic, which consists of three major axes, including 5 steps, which are described below:

*Self care*

1. Adequate Nutrition
2. Nutraceuticals

*Clinical*

3. Intravenous Therapy
4. B Core

*Coaching*

5. Vital Coaching

In order to enter the 5-Step Program of the Biologique Center for Advanced Medicine these steps have to be followed:

1. Patient makes an appointment for initial Biologique assessment (via email, telephone or in person).
2. Patient attends the initial Biologique appointment, where the medical team performs a comprehensive medical evaluation, including a complete medical history and performing an InBody assessment. Analytical tests and other medical tests that are required are indicated as needed for the patient and the medical record is completed according to design the treatment protocol.
3. The patient provides the laboratory and medical study results to Biologique.

4. The Biologique Medical Team designs a personalized protocol for the patient, according to his or her diagnosis and expectations.
5. The patient undergoes an optional ALCAT (food intolerance) test, on which Biologique may offer personalized nutritional services based on their personal information.
6. The patient accepts the designed protocol proposal which will be based, in most cases, on the personalized selection of services offered in the *Advanced Biologics 5 Step Program.*

Following the previously described admittance system, we performed three interviews on each of the four patients, which were seleted from the initial 20 who were chosen to be followed prospectively during three months, for a total of 12 interviews.

The interviews were performed in different time frames: before the start of the managment protocols, before the clinical (intravenous) intervention and one month after the protocols are implemented, that is, approximately two months after the start of the treatment. If the patient did not return to the consult after two months, he or she was given a 30-day window to have the interview.

At the end of the 5-step program, we evaluated the patients' clinical symptoms, considering an improvement or not of the symptoms according to the initial presentation reported by the patient before they began the treatment management protocols of the Biologique Center for Advanced Medicine in the Dominican Republic. Patient evaluation was performed case by case, taking into consideration the patient's inherent characteristics to their base condition in order to create the clinical indicators that measured the outcome results.

**d. Statistical Analysis of the Quantitative Component.**

We created a database for the inclusion of quantitative data, which were posteriorly analyzed, and proccesed for their interpretation. The analysis of the quantitative data was performed with the SPSS 20.0 statistical package. Simple proportions and measurements of central tendencies were calculated (mean, median, mode). Fisher's Exact Test was used when the expected cells were less than five, and the Wilcoxon signed-rank test was used when comparing the clinical and laboratory parameters before and after de implementation of the standardized five-step protocol of the Biologique Center for Advanced Medicine. All p values $< 0.05$ were considered statistically significant.

**e. Qualitative Component Analysis**

We prepared discussion guides for the qualitative interviews in order to guide the interaction between the interviewer and participants. The guides were constructed after the quantitative data was collected from the retrospective cohort and after observing the diffents program steps, we adapted its contents as a facilitation instrument instead as a persuasive one, during the interview conduction process.

We recorded and transcribed the qualitative interviews, while maintaining patient confidentiality. If the patient preferred to protect their privacy, their name was changed during the interview for a pseudonym of their choice. We asked all interviewed patients to participate in an informed consent process, which ended with a written consent (see qualitative interview informed consent forms annex). All qualitative data was analyzed by three different reviewers in order to standardize their interpretation.

**f. Study indicator Operationalization**

On table 1 we can observe the operationalization of the study indicators, including the study objectives description, the hypothetical approach, evaluation model selection, study population, selected methodology and the end results of the evaluation.

**Table 1. Operationalization of the work methodology by objective, hypothetical approach, evaluation model, study population, methodology and results.**

| Objective | Hypothetical Approach | Evaluation Model | Study Population | Methodology | Outcomes |
|---|---|---|---|---|---|
| Evaluate the treatment management protocols of the Biologique Center for Advanced Medicine in the Dominican Republic, quantitatively and qualitatively, in patients who were selected retrospective and prospectively. | The treatment management protocols of the Advanced Medicine Center in the Dominican Republic have a different impact according to the condition of the patient. | Case study. | Users who were selected retro and prospectively in the treatment management protocols of the Advanced Medicine Center in the Dominican Republic. | Review of medical charts, laboratory and imaging results in order to construct clinical indicators.<br>Qualitative interviews, direct observation. | Improvement or absence of improval of the patient's clinical baseline condition at the end of the intervention. |

## VII) ETHICAL CONSIDERATIONS

The present evaluation was designed with adherence to international ethical standards, including relevant aspect of the Helsinki Declaration and the guidelines of the Council for International Organizations of Medical Sciences (CIOMS).

The data collection process did not expose participants to significant psychological, physical or social risks. All members of the data collection team were properly trained for these purposes, being instructed to perform the assigned tasks as least inquisitively as possible and building an atmosphere of trust with the patients who were interviewed. Additionally, all patients were appropriately informed of their right to partially or complety withdraw from the study, or to refuse to complete the interview without being asked to explain his or her decision and without implications for the services that the patient receives in Biologique.

While this study did not include direct benefits to the participants, it is expected that their results will help to contribute to the evidence of the clinical impact the Biologique Health Improvement Program offers to people who receive it.

Seeking to protect the human rights of the participants, we requested informed consent in writing, both for collecting quantitative data as for qualitative interviews. The informed consent form was presented and explained to each participant individually by the team that was responsible for these tasks, who were properly trained for these purposes prior to the date specified for the data collection. Before granting permission, the participants were given sufficient time to read the form carefully and, if they so wished, were also allowed to consult with their family or friends.

The informed consent form included a brief description of the purposes and procedures for the evaluation as well as the risks and potential benefits foreseen in its design. Among other aspects, this form included the contact information of investigators who could be contacted for any question, clarification or complaint concerning their participation in the evaluation.

All data collected in this evaluation was managed with strict adherence to confidentiality. Participant identification was protected at all times, by providing each with a Participant Code (ID). All registries corresponding to a participant, except the informed consent form (which was handled and stored separately in sealed envelopes), were assigned a code, which was the only way to relate the participant with their information regarding sociodemographic, clinical, laboratory, treatment and perception of the program under evaluation.

**VIII) SCOPE OF INVESTIGATION**

With the present assessment, which is limited under the guidelines of the Case Study model (Neutens JJ and Rubinson L)[5], we intended to obtain information from selected users who participated in the treatment management protocols of the Biologique Center for Advanced Medicine in the Dominican Republic, trying to understand its management perceptions and its effects on clinical, laboratory and lifestyle parameters.

The methodology used to collect quantitative data was by reviewing records. The revision of records allowed us to obtain laboratory, imaging and symptom data before and after the inclusion of the patient in the treatment management protocols under evaluation.

It should be noted that the methodology by which this assessment is governed by is essentially of the qualitative type in which participant observation, interviews, study documents and the participant's own words were used to analyze the data.

Therefore, this type of model is based on the assessment of the evaluator's insight on the perceptions of users of the Biologique Program of the Dominican Republic, taking into account that the evaluation team came to their conclusions about the effectiveness of the program from informed patient experiences and interaction with clinical evaluators team working in the Biologique Center for Advanced Medicine.

## IX) RESULTS

### a. Sociodemographic and clinical patient characteristics.

Table 2 presents the sociodemographic characteristics of all patients included in the assesment whose information was collected retro (n=10) and prospectively (n=20), observing that 69% (n=20) of the subjects were male, and that the age groups with the highest number of patients was 30-39 (n=8) and 50-59 years (n=8) of age, respectively, representing 27.6% of the total sample. Table 2 also shows that the most frequently reported symptoms were fatigue (n=26, 23.9%), followed by pain (n=20, 20.2%) and symptoms related to the cardiovascular and respiratory system (n=19, 17.4%), as well as gastric symptoms (n=16, 14.7%), amongst others.

**Table 2. Sociodemographic characteristics and symptoms at the start of treamtent. Santo Domingo, Dominican Republic. March-December, 2013.**

| Variable | Frecuency | % |
|---|---|---|
| **Sex (n=29)** | | |
| Male | 20 | 69.0 |
| Female | 9 | 31.0 |
| **Age in years (n=29)** | | |
| 20-29 | 1 | 3.4 |
| 30-39 | 8 | 27.6 |
| 40-49 | 6 | 20.7 |
| 50-59 | 8 | 27.6 |
| ≥ 60 | 6 | 20.7 |
| **Symptoms (n=29)** | | |
| Fatigue | 26 | 23.9 |
| Pain | 22 | 20.2 |
| Cardiovascular/Respiratory | 19 | 17.4 |
| Gastric | 16 | 14.7 |
| Neurological | 9 | 8.3 |
| Others | 17 | 15.6 |

Table 3 presents the sociodemographic characteristics of the patients included in the assessment whose information was collected retrospectively; we observed that 90% (n = 9) were male, and the age groups with the largest number of patients fell in the 30-39 (n = 3, 30%) and 60 years or older (n = 3, 30%) age range. The symptoms that were reported most frequently were fatigue (n = 10, 29.4%), followed by symptoms associated with the cardiovascular and respiratory system (n = 7, 20.6%), followed by pain (n = 5, 14.7%) and gastric symptoms (n = 4, 11.8%), amongst others.

**Table 3. Sociodemographic characteristics and symptoms at the start of treatment of patients included in the assessment, whose information was obtained retrospectively. Santo Domingo, Dominican Republic. March-December, 2013.**

| Variable | Frecuency | % |
|---|---|---|
| **Sex (n=10)** | | |
| Male | 9 | 90.0 |
| Female | 1 | 10.0 |
| **Age in years (n=10)** | | |
| 30-39 | 3 | 30.0 |
| 40-49 | 2 | 20.0 |
| 50-59 | 2 | 20.0 |
| **≥ 60** | 3 | 30.0 |
| **Symptoms (n=10)** | | |
| Fatigue | 10 | 29.4 |
| Cardiovascular/Respiratory | 7 | 20.6 |
| Pain | 5 | 14.7 |
| Gastric | 4 | 11.8 |
| Neurological | 3 | 8.8 |
| Others | 5 | 14.7 |

Table 4 presents the sociodemographic characteristics of patients whose information was collected prospectively, showing that 58% (n = 11) of them were male, the age groups with the largest number of patients were 30-39 (n = 5, 26.3%) and 50-59 years or more (n = 6, 31.6%) and the most frequently reported symptoms were pain (n = 17, 22.7%), followed by fatigue (n = 17, 22.7%) and symptoms related to the cardiovascular & respiratory system (n = 12, 16.0%) as well as gastric (n = 12, 16.0%), amongst others.

**Table 4. Sociodemographic characteristics and symptoms at the start of treatment of patients included in the assessment, whose information was obtained prospectively. Santo Domingo, Dominican Republic. March-December, 2013.**

| Variable | Frecuency | % |
|---|---|---|
| **Sex (n=19)** | | |
| Male | 11 | 57.9 |
| Female | 8 | 42.1 |
| **Age (n=19)** | | |
| 20-29 | 1 | 5.3 |
| 30-39 | 5 | 26.3 |
| 40-49 | 4 | 21.1 |
| 50-59 | 6 | 31.6 |
| ≥ 60 | 3 | 15.8 |
| **Symptoms (n=19)** | | |
| Cardiovascular/Respiratory | 12 | 16.0 |
| Pain | 17 | 22.7 |
| Fatigue | 16 | 21.3 |
| Gastroenterologic | 12 | 16.0 |
| Neurologic | 6 | 8.0 |
| Others | 12 | 16.0 |

**b. Results before and after structured treatment at the Biologique Center for Advanced Medicine.**

Table 5 presents the difference in mean values of different clinical and laboratory parameters obtained before and after the five step treament of the Biologique Center for Advanced Medicine, observing that there was, after treatment, a statistically significant reduction in weight (p = 0.0001), Body Mass Index – BMI (p = 0.0001) and visceral fat (p=0.0001) of patients that were included retro and prospectively in the assement of this health center. Also, in Table 5 we can observe a statistically significant decrease, after the Biologique five step treatment, of total cholesterol (p = 0.028) and triglycerides (p = 0.0001). There was no statistical difference between the mean values of HDL (p = 0.171) and LDL (0.239) of patients included in the evaluation, before and after the Biologique five step treatment completion.

**Table 5. Mean differences of weight, body mass index (BMI), visceral fat, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides, before and after the Biologique Center for Advanced Medicine five step treatment program in 29 (prospective and retrospective) patients included in the assessment analysis of this center of Santo Domingo, Dominican Republic. March-December 2013.**

| Variable | Before Treatment (Mean ± SD) | After Treatment (Mean + SD) | Mean differences | 95% CI of the difference | p |
|---|---|---|---|---|---|
| Weight[a] | 211.45 +48.45 | 195.31 +42.55 | 16.14 | 11.40 - 20.88 | 0.000[g] |
| BMI[a] | 31.61 ± 5.48 | 29.11 ± 4.60 | 2.51 | 1.82 - 3.20 | 0.000[g] |
| Visceral Fat[b] | 189.62 ± 57.47 | 146.29 ± 49.20 | 43.33 | 32.80 - 53.85 | 0.000[g] |
| Total Cholesterol[c] | 210.60 ± 44.68 | 182.92 ± 37.47 | 27.68 | 3.35 - 52.00 | 0.028[g] |
| HDL[d] | 44.04 ± 10.12 | 45.91 ± 10.33 | -1.87 | -4.64 – 0.88 | 0.171[g] |
| LDL[e] | 129.13 + 33.71 | 119.51 + 33.56 | 9.63 | -6.89 - 26.15 | 0.239[g] |
| Triglycerides[f] | 185.16 ± 102.35 | 110.17 ± 45.43 | 74.98 | 37.11 - 112.85 | 0.000[h] |

a. There was no data on Post-Treatment Weight and BMI in one patient.
b. There was no data on Pre-Treatment Visceral Fat in one patient. There was no data on Post-Treatment Visceral in two patients.
c. There was no data on Pre-Treatment Total Cholesterol in two patients. There was no data on Post-Treatment Total Cholesterol in seven patients.
d. There was no data on Pre-Treatment HDL Cholesterol in three patients. There was no data on Post-Treatment HDL Cholesterol in seven pacientes.
e. There was no data on Pre-Treatment LDL Cholesterol in three patients. There was no data on Post-Treatment HDL Cholesterol in seven patients.
f. There was no data on Pre-Treatment Triglycerides in three patients. There was no data on Post-Treatment Triglycerides in seven patients.
g. Student's *t* test.
h. Wilcoxon signed-rank test.

When stratifying patients with the obtained retrospective or prospective information, we observed that, in patients who were included retrospectively in the assessment, there was a mean difference in weight (p = 0.03), BMI (p = 0.01), visceral fat (p=0.03) and triglycerides (p = 0.009) values obtained before and after the Biologique Five Step Treament, observing a statistically significant difference between mean values at the end of the treatment (Table 6). In this retrosepctive cohort, we did not observe a significant difference between the mean values obtained before and after the Biologique five-step treatment in Total Cholesterol (p = 0.182), HDL Cholesterol (p = 0.901) and LDL Cholesterol (p = 0.963) (Table 6).

**Table 6. Mean differences of weight, body mass index (BMI), visceral fat, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides, before and after the Biologique Center for Advanced Medicine five step treatment program in the 10 retrospective patients included in the assessment analysis of this center of Santo Domingo, Dominican Republic. March-December 2013.**

| Variable | Before Treatment (Mean ± SD) | After Treatment (Mean ± SD) | Mean difference | 95% CI of difference | p |
|---|---|---|---|---|---|
| Weight[a] | 205.740±40.43 | 194.367± 38.61 | 15.08 | 6.97 – 23.18 | 0.03[g] |
| BMI[a] | 30.94 ±3.86 | 28.78± 3.61 | 2.51 | 1.31 – 3.71 | 0.001[g] |
| Visceral Fat[b] | 174.91 ± 53.12 | 138.14± 46.65 | 37.70 | 17.35 – 58.06 | 0.003[g] |
| Total Cholesterol[c] | 204.29 ± 53.64 | 172.48 ± 24.46 | 44.30 | -29.26 – 117.86 | 0.182[g] |
| HDL[d] | 43.79 ±7.86 | 42.80±9.12 | -0.27 | -5.50 – 4.96 | 0.901[g] |
| LDL[e] | 121.55± 43.56 | 130.65± 36.47 | -0.48 | -26.30 – 25.33 | 0.963[g] |
| Triglycerides[f] | 205.90± 120.19 | 129.20 ± 61.49 | 116.47 | 43.57 – 189.37 | 0.009[g] |

a. There was no data on Post-Treatment Weight and BMI in one patient.
b. There was no data on Pre-Treatment Visceral Fat in one patient. There was no data on Post-Treatment Visceral Fat in one patient.
c. There was no data on Pre-Treatment Cholesterol in four patients. There was no data on Post-Treatment Cholesterol in two patients.
d. There was no data on Pre-Treatment HDL in two patients. There was no data on Post-Treatment HDL in four patients.
e. There was no data on Pre-Treatment LDL in two patients. There was no data on Pre-Treatment LDL in two patients.
f. There was no data on Pre-Treatment Triglycerides in three patients. There was no data on Pre-Treatment Triglycerides in seven patients.
g. Student's *t* test.

In patients whose information was obtained prospectively, (Table 7), we observed that there was a reduction between mean values obtained before and after the Biologique five step treatment in weight (p = 0.0001), BMI (p = 0.0001), visceral fat (p = 0.0001), total cholesterol (p = 0.028) and triglycerides (p = 0.0001), observing statistically significant differences in these clinical and laboratory parameters, at the end of the treatment. We did not observe significant differences between mean values before and after the Biologique five step treament in HDL Cholesterol (p = 0.901) and LDL Cholesterol (p = 0.963) in this prospective cohort (Table 7).

**Table 6. Mean differences of weight, body mass index (BMI), visceral fat, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides, before and after the Biologique Center for Advanced Medicine five step treatment program in the 19 prospective patients included in the assessment analysis of this center of Santo Domingo, Dominican Republic. March-December 2013.**

| Variable | Before Treatment (Mean ± SD) | After Treatment (Mean ± SD) | Mean Difference | 95% CI of the difference | p |
|---|---|---|---|---|---|
| Weight[a] | 211.45 ±48.45 | 195.31 ±42.55 | 16.14 | 11.40 - 20.88 | 0.000[g] |
| BMI[a] | 31.61 ± 5.48 | 29.11 ± 4.60 | 2.51 | 1.82 - 3.20 | 0.000[g] |
| Visceral Fat[b] | 189.62 ± 57.47 | 146.29 ± 49.20 | 43.33 | 32.80 - 53.85 | 0.000[g] |
| Total Cholesterol[c] | 210.60 ± 44.68 | 182.92 ± 37.47 | 27.68 | 3.35 - 52.00 | 0.028[g] |
| HDL[d] | 44.04 ± 10.12 | 45.91 ± 10.33 | -1.87 | -4.64 – 0.88 | 0.171[g] |
| LDL[e] | 129.13 ± 33.71 | 119.51 ± 33.56 | 9.63 | -6.89 - 26.15 | 0.239[g] |
| Triglycerides[f] | 185.16 ± 102.35 | 110.17 ± 45.43 | 74.98 | 37.11 - 112.85 | 0.000[h] |

a. There was no data on Post-Treatment Weight and BMI in one patient.
b. There was no data on Pre-Treatment Visceral Fat in one patient. There was no data on Post-Treatment Visceral Fat in two patients.
c. There was no data on Pre-Treatment Cholesterol in two patients. There was no data on Post-Treatment Cholesterol in seven patients.
d. There was no data on Pre-Treatment HDL in three patients. There was no data on Post-Treatment HDL in seven patients.
e. There was no data on Pre-Treatment LDL in three patients. There was no data on Pre-Treatment LDL in seven patients.
f. There was no data on Pre-Treatment Triglycerides in three patients. There was no data on Pre-Treatment Triglycerides in seven patients.
g. Student's *t* test.
h. Wilcoxon signed-rank test.

Table 8 presents the patient evolution according to how their information was obtained (prospectively or retrospectively), their clinical, laboratory and quality of life outcomes, noting that in all patients there was an improvement in all three parameters, most of all in quality of life which manifested itself in different aspects such as reduced fatigue, increased energy and better concentration, among others. Remarkably, 90% (n = 26) of participants noted improvement in pain, as well as cardiovascular and gastric symptoms within three months of completing the five steps of the standardized Advanced Medicine Center Biologique protocol regardless of the underlying disease for which they came to this center.

**Table 8. Baseline pathology, patient type, clinical outcomes, laboratory parameter outcomes and quality of life outcomes of the 30 selected patients to assess the treatment management protocols of the Biologique Center for Advanced Medicine.**

| Patient ID | Baseline Pathology | Patient Type* | Clinical Outcomes | Laboratory Parameter Outcomes | Quality of Life Outcomes |
|---|---|---|---|---|---|
| 1A | Metabolic syndrome, morbid obesity, severe hepatic steatosis, sleep apnea, gastroesophageal reflux, longstanding microscopic Hematuria. | Prospective | Patient reduced 46 pounds in weight, 56 $cm^2$ in visceral fat and 19 cm in waist circumference, disappearance of dyspnea, grayish skin color and dizziness, and abdominal pain and loss of Gastroesophageal reflux. | Sonography reflects improved hepatic steatosis from severe to moderate. Disappearance of hematuria in urinalysis. Before starting treatment patient underwent spirometry which was tolerated presenting syncope, at the end of treatment patient completed spirometry which resulted as normal. | Patient reported improved breathing, absence of abdominal pain and the presence of more energy, improved physical performance and vitality as well as better quality and quantity of sleep. |
| 2A | Morbid Obesity, Metabolic Syndrome, newly diagnosed Hypertension, gastritis, chronic esophagitis, GERD, liver steatosis. Patient reported sleep apnea, fatigue, back pain, limited flexibility and lower limb edema. | Prospective | Disappearance of GERD symptoms. Disappearance of back pain and lower limb edema. Subsequent Arterial tension was normalized to treatment without using antihypertensive medication. | Reduction of low-density cholesterol. | Reports increased energy, flexibility and better concentration. Disappearance of dyspnea. |
| 3A | Morbid obesity since childhood, Metabolic Syndrome, Hepatic Steatosis, Severe Chronic Gastritis, GERD, migraines and sinusitis. The patient | Prospective | Patient lost 36 pounds and 52.7 $cm^2$ of visceral fat. Disappearance of migraine and sinusitis. Patient couldn't sleep in supine position because | | Reports more energy, better concentration. Increased physical performance, and improved mood. Quality of life |

| Patient ID | Baseline Pathology | Patient Type* | Clinical Outcomes | Laboratory Parameter Outcomes | Quality of Life Outcomes |
|---|---|---|---|---|---|
| | had recurrent flu episodes, fatigue, myalgia, and dyspnea on moderate exertion. | | of reflux and required use of Esomeprazole 40 mg daily, after treatment does not require this medication and doesn't report GERD symptoms. | | improved significantly- no longer presents myalgia, dyspnea or require sleep in lateral position because of GERD. No need to use NSAIDs for muscle aches and Gastric Protectors for gastritis. |
| 4A | DM2, overweight, Familial hypertriglyceridemia, hyperuricemia, COPD, deep venous insufficiency, Chronic Gastritis and Back Pain. Patient referred dyspnea, lower back muscle pain and postprandial fullness sensation. | Prospective | Lost 20 pounds, reversed metabolic syndrome, hypertriglyceridemia and diabetes without medication. Significantly improved lung condition, no longer requires use of inhaled steroids. Gabapentin dose was reduced, no longer routinely uses NSAIDs. | Glycemia decreased from 112 to 96 mg / dL; HgA1c decreased from 7.1 to 4.9%; Triglycerides from 219 to 114 mg / dL Basal Insulin from 25.7 to 36.5, Post-prandial Insulin from 328 to 20.98 u/ L (without medication). | Reports disappearance of dyspnea, muscle and back aches that allowed to enjoy a normal life. No longer required to use backache medication, inhaler or statins. |
| 5A | Fibromyalgia, gastritis, GERD, Asthma, Dermatitis | Prospective | Improved muscle and joint pain, headaches decreased and disappearance of Gastrointestinal symptoms. Decrease in the frequency of influenza episodes and urinary tract infections and disappearance of spots on the skin. | | Reports improvement in quantity and quality of sleep and reduced muscle and joint pain. |
| 6A | Tropical sprue, Hypothyroidism, Hypercholesterolaemia, Scleroderma, gastritis, chronic colitis. Altered bowel patterns consisting of | Prospective | Disappearance of explosive diarrhea which had 50 years of evolution, absence of dyspepsia and flatulence, with regular bowel movements. Disappearance of | | Reports increased energy, disappearance of dizziness, pruritus and improval in concentration, short term and |

| Patient ID | Baseline Pathology | Patient Type* | Clinical Outcomes | Laboratory Parameter Outcomes | Quality of Life Outcomes |
|---|---|---|---|---|---|
| | explosive diarrhea alternating with constipation treated in multiple centers with no improvement. Dizziness, general weakness, difficulty concentrating and generalized pruritus. | | erythematous spots on the back and thigh. Scleroderma back and waist lesions disappeared entirely, along with the accompanying pruritus. Dizziness and imbalance have disappeared. | | medium term memory. |
| 7A | Obesity, Postsurgical bariatric surgery, hepatic steatosis, osteoarthritis, constipation, depression and dyslipidemia. Presents arthralgia in hands and knees, cramps, constipation and general weakness. | Prospective | Lost 13 pounds and 24.9 $cm^2$ of visceral fat. Constipation disappeared. | Total cholesterol from 219.5 to 193 mg / dL, LDL Cholesterol from 136.1 to 119 mg / dL. | Reports having greater physical performance and energy, having a better quality of life and no joint pain in the knees and hands, bowel pattern was regularized. |
| 8A | History of Lung Cancer, right pleural effusion, left carotid atheromatous plaques, hypertension, deep venous insufficiency, metabolic syndrome | Prospective | Patient discontinued treatment due to personal commitments, and multiple trips abroad. | | |
| 9A | Moderate Hepatic steatosis, Hypercholesterolemia, skin lesions, Hypertension, Hyperglycemia, Overweight. Reports fatigue, polyphagia, dyspnea on moderate exertion, back pain, arthralgia in both knees, GERD, dyspepsia and sleep apnea. | Prospective | Dropped 16.3 pounds, 48.2 $cm^2$ visceral fat area and 15 cm waist circumference. Reports disappearance of gastrointestinal symptoms, arthralgia and back pain. Disappearance of dyspnea. | Glycemia decreased from 324 to 141 mg / dL, triglycerides from 435 to 107 mg / dL, total cholesterol from 263 to 189 mg / dL, LDL-cholesterol from 143 to 128 mg / dL. Urinalysis Glucose from 4 (+) to Normal. Abdominal sonography was normal at the end of treatment. | Reports more energy, better concentration and short term memory. No gastrointestinal symptoms and joint pain. |

| Patient ID | Baseline Pathology | Patient Type* | Clinical Outcomes | Laboratory Parameter Outcomes | Quality of Life Outcomes |
|---|---|---|---|---|---|
| 10A | Overweight, Hypertension, Benign prostatic hyperplasia, colitis, moderate hepatic steatosis. Erectile dysfunction and recurrent urinary tract infections. Fatigue and abdominal pain. | Prospective | Weight loss and 50.4 $cm^2$ visceral fat reduction. Reports improvement in their sexual performance and disappearance of urinary symptoms, and better control of blood pressure. | Triglycerides decreased from 192 to 162 mg / dl, total bilirubin of 1.6 to 1.2 mg / dL. | Reports more vitality and improval in sex life, absence of abdominal pain and improvement in quantity and quality of sleep. |
| 11A | Morbid obesity, type 2 diabetes, hypertension, dyslipidemia, Severe Hepatic Steatosis, Depression, Dyspepsia, bloating, polyphagia, dizziness, generalized weakness, myalgia. | Prospective | Patient lost 32.9 pounds and 138.6 $cm^2$ of visceral fat. Decreased the dose of metformin used daily by 50%. | Basal glycemia decreased from 136 to 96 mg / dL; HgA1c 7.1 to 4.9%, triglycerides from 201 to 114 mg / dL, basal insulin from 34.9 to 25.7 uU / L, post-prandial insulin from 76.39 to 20.98 uU / L. Abdominal Sonography initially reported severe Hepatic steatosis, ultrasound treatment at the end of abdomen reported mild hepatic steatosis. | Reports increased self-esteem, energy and quality of life. Higher performance, disappearance of myalgia and gastrointestinal symptoms. |
| 12A | Moderate obesity, lumbar herniated L1-L2, L2-L3, L3-L4, sleep apnea, renal lithiasis. Reports lack of energy, shortness of breath and palpitations. | Prospective | Lost 22 pounds in weight, decreased 37.5 $cm^2$ in visceral fat. Reports disappearance of dyspnea and heart palpitations. | | Increased energy, improved physical performance. Improved quality and quantity of sleep. Disappearance of dyspnea and back pain. |

| Patient ID | Baseline Pathology | Patient Type* | Clinical Outcomes | Laboratory Parameter Outcomes | Quality of Life Outcomes |
|---|---|---|---|---|---|
| 13A | Morbid obesity (history of bariatric surgery), Hypercholesterolemia, Hypertension, benign prostatic hyperplasia, bronchial asthma and GERD. Reports fatigue, dyspnea on slight exertion and fronto-temporal headaches and back pain. | Prospective | Patient lost 30.4 pounds and 73.7 $cm^2$ of visceral fat. Reports disappearance of dyspnea and headaches. | Total cholesterol from 235 to 56 mg / dL, LDL-C from 153 to 91 mg / dL. Abdominal sonography at baseline presented moderate hepatic steatosis, at the end of treatment abdominal sonography without pathological findings. | Reports improved physical and sexual performance, more energy and vitality. Does not require daily inhaler treatment. |
| 14A | Type 1 Obesity, Hypertension, mixed dyslipidemia, hyperglycemia, cholelithiasis without cholecystitis and sinusitis. | Prospective | Lost 7 pounds of weight and 53 $cm^2$ of visceral fat. | Decreased blood glucose levels from 117 to 92 mg / dL, triglycerides 245 to 152.46 mg / dL. | Reports greater vitality and disappearance of heartburn and headaches. |
| 15A | Breast lump, Overweight, Hypercholesterolemia, moderate to severe, metabolic syndrome, hypertension, hyperglycemia, hepatic steatosis. Reports insomnia, high levels of stress, back pain and frequent urinary tract infections. | Prospective | Lost 7.5 pounds and 21.4 $cm^2$ of visceral fat. Reports loss of back pain and controlled stress levels. Disappearance of insomnia. | Glycemia from 101 to 98 mg / dL, total cholesterol from 288 to 145 mg / dL, LDL-C from 194 to 73 mg / dL, triglycerides 161 1 50 mg / dL. Initial abdominal sonography reported moderate to severe hepatic steatosis, after treatment abdominal sonography reported hepatic steatosis grade 1 (Mild). | Increased energy, improved back pain and absence of urinary tract infections. |

| Patient ID | Baseline Pathology | Patient Type* | Clinical Outcomes | Laboratory Parameter Outcomes | Quality of Life Outcomes |
|---|---|---|---|---|---|
| 16A | Gastritis, esophagitis, hepatic steatosis, Hypercholesterolemia, recurrent urinary tract infections pathways, diverticulosis, uterine fibroids, reports general weakness, back pain, arthralgia in right knee, bloating, flatulence, postprandial fullness feeling, nervousness, headaches and repeated flu-like episodes. | Prospective | Lost 7.9 pounds, decreased 28.3 $cm^2$ visceral fat area. Disappearance of back pain and arthralgia, frank improvement of gastrointestinal symptoms. Has not reported anxiety attacks, no palpitations | Total cholesterol from 235 to 163 mg / dL, triglycerides from 152 to 95 mg / dL LDL-C from 162 to 112 mg / dL | Reports more energy, disappearance of tiredness and fatigue. Reports feeling rejuvenated, with smoother skin and absence of abdominal distension and flatulence. |
| 17A | Hypertension, chronic abdominal pain, eosinophilic colitis, marked progressive abdominal distension, frequent nausea, general weakness, severe constipation, dizziness, palpitations and dyspnea. Reports abdominal pain, fatigue and difficulty sleeping. | Prospective | Lost 22 pounds. Decreased 19 cm waist circumference, visceral fat decreased 57.7 $cm^2$. Reports decreased bloating and abdominal pain. | Abdominal CT scan at baseline reported hepatic steatosis. At the end of treatment abdominal sonography without pathological findings. | Reports more energy and better quality of life, self-esteem and quality of sleep. Feels like a renewed person which no longer has to buy their dresses in the maternity ward. Improval in sex life. |
| 18A | Overweight, Hypercholesterolemia, GERD, hiatal hernia, chronic gastritis, proctocolitis, hepatic steatosis, hypertransaminasemia, reports weakness, back pain, arthralgia in both knees, myalgia, headache, insomnia, dyspepsia, chronic abdominal pain, frequent diarrhea, flatulence , bloating and leg cramps | Prospective | Lost 11 pounds and 64.3 $cms^2$ of visceral fat. Reports disappearance of myalgia, arthralgia, and gastrointestinal symptoms. Disappearance of leg cramps. | Triglycerides decreased from 165 to 97 mg / dL, ALT from 166 to 59 U / L; Alkaline Phosphatase from 121 to 75 U / L. At the start of treatment abdominal sonography reported mild hepatic steatosis, abdominal sonography at the end of treatment reports no liver fat infiltration. | Reports improved physical performance, more vitality. Improved quantity and quality of sleep. Had 4 year with different GI specialists using multiple medications to decrease liver tests and treat gastritis which did not improve. For the first time feels great and does not require medication. |

| Patient ID | Baseline Pathology | Patient Type* | Clinical Outcomes | Laboratory Parameter Outcomes | Quality of Life Outcomes |
|---|---|---|---|---|---|
| 19A | Generalized Osteoarthritis, Fibromyalgia, Hypertension, hypercholesterolemia, hypothyroidism, bronchial asthma, bilateral cervical and lumbar radiculopathy. Reports headaches, back pain, myalgia, and generalized arthralgia. Insomnia, dizziness, dyspnea on moderate exertion, GERD, dyspepsia, changes in bowel patterns, flu episodes and of recurrent urinary tract infections. | Prospective | Patient lost 11.2 pounds. Reports disappearance of headaches, dyspepsia and GERD. Radical improvement of myalgia, back pain and arthralgia. Improved lung capacity. Decreased frequency of influenza processes and urinary tract infections. | | Reports that can walk without cane assistance, radical improvement of arthralgias and myalgias, for the first time in 20 years can sleep the whole night. |
| 20A | Type II obesity, asthma, severe hepatic steatosis, Hyperuricemia, reports general weakness, lack of energy, dyspepsia, gastroesophageal reflux disease, dyspnea on moderate exertion, edema of lower limbs. Urinary tract infections and recurrent flu-like processes. | Prospective | Lost 26.2 pounds and decreased 39.5 $cm^2$ visceral fat. Reports disappearance of gastrointestinal symptoms, dyspnea and edema of lower limbs. No recurrent influenza processes or urinary tract infections. | Uric acid decreased from 7.0 to 5.2 mg / dL, ALT 54 to 41 U / L, direct bilirubin from 0.24 to 0.20 mg / dL. Abdominal sonography at baseline reports Severe Hepatic steatosis and the end of treatment reflects hepatic steatosis grade 1 (mild). | Reports greater physical performance, more energy, improved self-esteem and gastro-intestinal symptoms, muscle pain and dyspnea have disappeared. |
| 21B | Prostate Cancer, Dyslipidemia, Hypertension, reports fatigue, constipation and trouble sleeping. | Retrospective | Normalized blood pressure without use of antihypertensives. Disappearance of sleep disturbances and fatigue. | Total cholesterol of 216.4 to 188.8 mg / dL, LDL-C from 118. 7 to 116.6 mg / dL VLDL-C from 55.0 to 37.2 mg / dL, triglycerides from 274.9 to 185.9 mg / dL | Reports to have greater physical and sexual performance and does not require using medications to control blood pressure or to have sex. |

| Patient ID | Baseline Pathology | Patient Type* | Clinical Outcomes | Laboratory Parameter Outcomes | Quality of Life Outcomes |
|---|---|---|---|---|---|
| 22B | Dyslipidemia, moderate hepatic steatosis, obesity type 1, palpitations, reports fatigue, poor performance (being a high-level athlete), decreased energy and drowsiness. | Retrospective | Lost 14.2 pounds and reports drowsiness disappeared. | Total cholesterol of 301.7 to 124.7 mg / dL, VLDL-C from 91.3 to 44 mg / dL, triglycerides from 456.4 to 220.2 mg / dL, SGOT from 38.2 to 26.1 U / L, SGPT from 63.4 to 32.6 U / L | Reports feel rejuvenated, disappearance of fatigue, improved physical performance, more focus and energy. |
| 23B | Fibromyalgia with a history of post-traumatic seizures in childhood, ventricular extrasystoles, vasovagal syncope, RGE, overweight, who reports generalized myalgias, arthralgias, decreased vision, frequent headaches, memory loss and difficulty sleeping, causing to withdraw from work activities. | Retrospective | Decreased 9.5 pounds and 30.6 $cm^2$ visceral fat. Decreased from taking multiple drugs to only Pregabalin 75 mg / day | | Reports significant improvement in muscle aches and headaches, improved sleep, more focus and improved mood. Could return to work activities, after several years of inactivity and consulting many local and international specialists. |
| 24B | Obesity type 1, L4-L5 disc herniation, hypertension, coronary heart disease catheterization and coronary stenting, Barrett's esophagus, benign prostatic hypertrophy, hypercholesterolemia, which referred back pain, dyspepsia, tremor, fatigue, exhaustion and physical deterioration. | Retrospective | Reduced 15 pounds, 18.9 $cm^2$ of visceral fat and 4 cm of waist circumference. Reduced use of oral antihypertensives and statins. Reports disappearance of low back pain and gastrointestinal symptoms. | | Reports more energy and concentration, as well as improvement in intimacy. |

| Patient ID | Baseline Pathology | Patient Type* | Clinical Outcomes | Laboratory Parameter Outcomes | Quality of Life Outcomes |
|---|---|---|---|---|---|
| 25B | Sarcoidosis, Takayasu arteritis, coronary artery disease, who reports anginal chest pain, generalized sensitivity, lack of energy, shortness of breath on minimal exertion, edema of upper and lower limbs. | Retrospective | Lost 17 pounds and 31.2 $cm^2$ visceral fat area. Patient reduced medication, currently not on steroids, inhibitors of folic acid synthesis, antiallergy, proton pump inhibitors and statins. | Prior to the start of treatment patient underwent a modified Bruce type II stress test, which was positive both qualitatively and quantitatively as patient reported at 48 seconds squeezing pain in sternum, with electrocardiographic ST depression of 1.5 mm in AVF and D2 and 1mm at D3, V3 and V6. Upon completion of treatment, unmodified Bruce stress test, did not present clinical symptoms, although it was positive for ischemic heart disease. | Patient reported significant improvement in health, disappearance of dyspnea and edema in both lower and upper limbs, previously only took two steps and looked tired and had chest pain, now can go for a walk with friends and family and enjoy sex life. |
| 26B | Hypertension. Tremors, GERD, overweight, dyslipidemia. | Retrospective | Lost 25.5 pounds and 54.8 $cm^2$ visceral fat area. | Total cholesterol reduction from 217.6 to 165.2 mg / dL, LDL-C from 147.2 to 138.8 mg / dL, VLDL-C from 41.7 to 23.2 mg / dL, triglycerides from 208.7 to 116.1 mg / dL. | Reports more energy, better concentration, significant improvement of neurological signs such as tremors, controlled blood pressure levels and a significant decrease in blood lipids without statin use. |

| Patient ID | Baseline Pathology | Patient Type* | Clinical Outcomes | Laboratory Parameter Outcomes | Quality of Life Outcomes |
|---|---|---|---|---|---|
| 27B | Type 2 obesity, asthma, hepatic steatosis, hemorrhoids, chronic gastritis, hiatal hernia, GERD, sleep apnea, reports lack of energy, heartburn, bloating, constipation, dyspnea on slight exertion, drowsiness and general weakness. | Retrospective | Patient decreased 35.8 pounds. Reports disappearance of cardiopulmonary and gastrointestinal symptoms. | Total cholesterol from 232 to 178 mg / dL, LDL-C 147 to 108 mg / dL, triglycerides from 200 to 84 mg / dL | Reports disappearance of fatigue and sleepiness and improved gastro-intestinal symptoms. |
| 28B | DM2, ischemic heart disease, coronary artery disease with previous catheterization and placement of stents, Diverticulosis, Crohns, gastritis, hemorrhoids, obesity. Reports tiredness, lack of energy, changes in the bowel patterns, chronic abdominal pain and bloating. | Retrospective | Lost 20 pounds. Reports regularization of bowel patterns, no pain and abdominal distension. Significant reduction in the amount of drugs used, previously used 11 and now only uses insulin and plavix 75 mg per day. | PSA from 6.78 to 6.33 ng / ml; Free PSA from 1.49 to 1.13 ng / ml; Triglycerides from 198 to 60 mg / dL. Prior to the start of treatment abdominal sonography reported mild hepatic steatosis, after treatment abdominal sonography does not reflect the pathological findings. | Reports significant increase in energy levels, improved cognitive abilities and reduced use of many medications. |
| 29B | Type II obesity, renal abscess, hypercholesterolemia, GERD, elevated transaminases longstanding constipation who reports lack of energy, abdominal pain and feeling of gastric fullness. | Retrospective | Patient lost 9 pounds and 60.3 $cm^2$ of visceral fat area. | GGTP from 232.1 to 86.7 U / L, SGOT from 223.2 to 47.4 U / L, SGPT from 419.6 to 110.5 U / L; Glycemia from 127.8 to 99 mg / dL. | Reports significant increase in energy levels as well as radical improvement in gastrointestinal symptoms. |

| Patient ID | Baseline Pathology | Patient Type* | Clinical Outcomes | Laboratory Parameter Outcomes | Quality of Life Outcomes |
|---|---|---|---|---|---|
| 30B | Benign prostatic hyperplasia with significant elevation of total PSA, chronic arterial hypertension, dyslipidemia, atherosclerotic plaques in carotid, presbyopia and cataracts. Reports micturition disorders, dyspnea on moderate exertion and general weakness. | Retrospective | Reports improvement in their urological symptoms including loss of micturition disorders. | TotalPSA from 9.97 to 3.82 ng / mL, free PSA from 0.5 to 0.39 ng / mL. | Reports higher energy level and sense of wellbeing and disappearance of urinary symptoms. |

**c. Qualitative Component.**

The qualitative component included four patients in the prospective cohort. In general, the four patients perceived a marked improvement in their styles and quality of life. This component is described in full in the qualitative report that is included in the Appendix section that accompanies this report.

**X) DISCUSSION**

Assessing the treatment management protocols of the Biologique Center for Advanced Medicine led to an iterative analysis of information retrieval, record review and participant observation during approximately 9 months.

Performing this evaluation enabled to follow the evolution of ten patients retrospectively, and nineteen patients whose data was collected prospectively. Several points of the analysis of both patient cohorts deserve comment.

Firstly, in the prospective cohort, only one patient was unable to complete treatment due to work commitments outside of the country which prevented the continuation of the five-step protocol given by the Biologique Center for Advanced Medicine, which could be interpreted as a very high adhesion rate to said management protocol in patients who benefit from the program.

Secondly, we observed that both in patients whose data were prospectively collected, and those that were retrospectively obtained, a significant improvement in clinical and laboratory parameters and in quality of life.

Regarding clinical parameters, we observed a substantial improvement at the end of the Biologique five-step protocol on weight reduction, visceral fat and BMI as compared to the basal values reported in both cohorts of patients, which suggests that the protocol has a significant effect in reducing these parameters (about 3 months after implementation of the protocol to observe improvements).

Regarding laboratory parameters related to total cholesterol and triglycerides, we also observed a significant reduction after patients were included in the Biologique five-step protocol, reflecting the effectiveness in reducing these parameters in a short time. We note that even though the values of these laboratory parameters were significantly reduced after the implementation of the Biologique protocol, they did not reduce to normal values that are included in the guidelines for the management of metabolic syndrome.

It should however be noted that when the patient enters the Biologique five-step management protocol, they are advised not to use medications, such as statins to lower cholesterol, which in some way might influence not only in the reduction to normal values of total cholesterol and triglycerides, but also in the reduction of LDL and a significant increase in HDL which also was not observed in the study population.

It should also be noted that the assessment only included, a three-month follow-up in prospective patients, which could be an aggravating factor to observe a greater impact in the protocol of the previously discussed laboratory parameters, factor that must be taken into perspective when analyzing the results reported in this assessment.

With regard to the improvement in quality of life, perhaps this is the point of greatest impact of the Biologique Center for Advanced Medicine five-step protocol. Characteristically, all patients reported having more stamina and better concentration in their daily lives compared to what they reported before starting the protocol. Qualitative evaluation corroborated even more what patients reported to the treating physician of the evaluated center.

In this sense, the improvements observed in patients whom were included in the qualitative assessment, not only could be perceived in their life stories before and after their inclusion in the management protocol of the Biologique Center for Advanced Medicine, but we also found evident weight loss and an improved attitude toward life when they were interviewed about their experience. This improvement could be seen as the most significant and of greatest impact of the management protocol and should be considered for further analysis, not just as a narrative, but measured in a tangible way through psychometric techniques, before and after the inclusion of the patient to the protocol.

Regarding the third aspect, there are potential limitations to consider in the evaluation. The small number of patients and their selection process, the fact that they were chosen according to their compliance (prospective cohort) and the quality of the collected data (retrospective cohort) limits on the one hand, the extrapolation of data to every possible case that has benefited from the management protocol of the Biologique Center for Advanced Medicine, and, moreover, how the selection process could be interpreted as a possible selection bias that may have influenced the final results of the evaluation. Furthermore, the short evaluation time of the results could be a determining factor as to the sustainability of results and compliance with the protocol being assessed.

These limitations give way to recommend the implementation of an assessment with a larger number of patients, increased monitoring and a random sample selection, this being a crucial aspect to ensure ultimate balance to any demographic or clinical difference when starting the protocol management and a better assessment of the quality of the data collected.

Another important limitation is that the assessment cannot determine which of the five steps of the standardized study protocol could have the greatest impact on the obtained results, or if it is the combination of all the steps which makes the patient improve their quality of life and clinical and laboratory parameters previously described in this report.

Despite these limitations, which are inherent to the design of an assessment that corresponds to the guidelines of a case study, the obtained results orient us to note that the implementation of the Biologique Center for Advanced Medicine five-step standardized protocol looks be an option to consider in patients with certain health conditions that warrant an improvement in clinical and laboratory parameters which showed statistical significance in the participants of this evaluation.

In particular, the improvement in the observed and reported quality of life by the participants could be considered as the most portentous point of this evaluation and should be taken into account by the team that makes up the Biologique Center for Advanced Medicine, to promote the Center as an entity of impact on orthomolecular medicine and in the reduction of oxidative stress that is associated with a number of acute and chronic conditions as well as the recommended treatment in the same, which disrupt daily functioning, both on a personal and work level, of patients affected by these conditions.

## XI) CONCLUDING REMARKS

1. We observed a substantial improvement by the end of the Biologique five-step protocol reduction of the following: weight, visceral fat and BMI compared with baseline values reported in both groups of patients, suggesting that the protocol significantly influences and improves the reduction of these clinical parameters shortly after implementing the protocol under evaluation (about 3 months observe improvement).

2. Laboratory parameters related to total cholesterol and triglycerides were significantly reduced after the patient was included in the Biologique five-step protocol, reflecting the effectiveness in reducing these parameters in a short time. The values of these laboratory parameters, however, did not decrease to normal values that are included in the guidelines for management of metabolic syndrome, which may be associated the recommendation to the the patient to discontinue the use of, as well as not commence, statin therapy when participating in the five-step protocol of the Biologique Center for Advanced Medicine.

3. In 90% (n = 26) of participants we noted an improvement in pain, as well as cardiovascular and gastric symptoms three months after completing the five steps of the standardized Biologique Advanced Medicine Center protocol, regardless of the underlying disease, which led them to this center.

4. The improvement in quality of life based on this assessment could be considered as the point of greatest impact of the five-step protocol of the Biologique Center for Advanced Medicine. Characteristically, all patients reported having more stamina and better concentration in daily life compared with those reported before starting the protocol. Qualitative analysis substantially corroborated what was reported by patients to the attending physician of the Centre who confirmed the improvement in their quality of life, which was recorded in all patient record included in the assessment, and described in full in a subsample of participants in the qualitative component of this report.

## XII) RECOMMENDATIONS

1. Conducting an evaluation with a larger number of patients, increased monitoring and a random sample selection, to be able to make comparisons with greater statistical weight which would allow to infer the results to the entire population that would benefit from the standardized five step protocol of the Biologique Center for Advanced Medicine, and would result in an improved assessment of the data collected.

2. From the results obtained in the present assessment of the standardized five-step protocol of the Biologique Center for Advanced Medicine, it may be recommended for patients with certain health conditions that warrant an improvement in clinical and laboratory parameters that showed statistical significance in the participants in this evaluation.

3. The improvement in the observed and reported quality of life by the participants could be considered as the most portentous point of evaluation and should be taken into account by the team that makes up the Biologique Center for Advanced Medicine, to promote the Center as an entity of impact on orthomolecular medicine and reducing oxidative stress that is associated with a number of acute and chronic conditions as well as the recommended treatment in the same, and that disrupt daily functioning, both on a personal and work level, of patients affected by such conditions.

4. Based on the findings of the qualitative component, the significant impact of the Biologique program to the improval and, in some cases, disappearance of chronic physical symptoms, the need to revise previously defined concepts around these symptoms could be implied to be of some benefit for the patients, which at times deserve appropriate professional support from the mental health field. In this case, even by taking into account the support needs and psychological intervention in cases that warrant it, and by referring patients in these situations to the right specialist, this could warrant the construction of routine monitoring and systematic assessment protocols of the mental health of its users, in order to avoid the interferance of emotional and psychological factors with the sustainability of the treatment outcomes in the medium and long term.

**XII) REFERENCES**


1. Campos D, Austerlitz C, Allison RR, Povoa H, Silbata C. Nutrition and Orthomolecular Supplementation in Lung Cancer Patients. Integrative Cancer Therapies 2009;8(4):398-408.

2. Wick G. ¨Anti-aging medicine¨: does it exist? A critical discussion of ¨anti-aging¨ health products´. Experimental Gerontology 2002;37:1137-1140.

3. Schmitt J, Ferro A. Nutraceuticals: Is there good science behind the hype? British Journal of Clinical Pharmacology 2013;75(3):585-587.

4. Gattinoni L, Carlesso E, Langer T. Clinical review: Extracorporeal membrane oxygenation. Critical Care 2011;15:243-249.

5. Neutens JJ, Rubinson L. Evaluation Research. Research Techniques for the Health Sciences. Boston: Benjamin Cummings; 2002. p. 195.

**XIV) APPENDICES**

a. Qualitative Report.
b. Informed Consent Forms.

**Center for Research in Global Health and Biotechnology**

**O&M University Medical School (O&Med)**

# ASSESMENT OF THE TREATMENT MANAGEMENT PROTOCOLS OF THE BIOLOGIQUE CENTER FOR ADVANCED MEDICINE IN THE DOMINICAN REPUBLIC-YU METHOD*

**Qualitative Component**

**Final Report**

Santo Domingo, Dominican Republic
December 2013

* Prepared by Marija Miric, BA, PhDc in collaboration with Eddy Pérez-Then, MD, MPH, MSPH, PhD.

**CONTENTS**

**Assessment of the treatment management protocols of the Biologique Center for Advanced Medicine in the Dominican Republic**
**Qualitative Component**
**Final Report**

## I. INTRODUCTION

The Bioloque Center for Advanced Medicine, located in the city of Santo Domingo, Dominican Republic, offers, since 2011, custom protocols of cellular restructuring, based on the principles of integrative, preventive, orthomolecular and anti-aging medicine, and focused on reducing chronic inflammation and impact in a positive manner the quality of life and performance of its patients.

Complementing the testimonies and other anecdotal evidence accumulated over the two years of implementation of these protocols in the country, which demonstrates high levels of user satisfaction and perceived high impact of these interventions on quality of life, the Biologique team, focusing on evidence-based medicine, proposed to conduct an external evaluation of these protocols, employing for this purpose the Centre for Research in Global Health and Biotechnology, affiliated with the O&Med School of Medicine.

This report summarizes the methodological issues and key findings obtained from the qualitative component of the conducted evaluation, focusing primarily on the users' experience of Biologique's services, the perceived impact of the interventions they received, and their expectations related to the sustainability and the evolution of their health condition. In this sense, this paper complements and extends the quantitative and qualitative aspects described in the general report of the evaluation.

## II. OBJECTIVES

Integrated to the overall objective of this initiative to assess the treatment management protocols of the Biologique Center for Advanced Medicine in different aspects, the qualitative component of this evaluation, based on the longitudinal follow-up of four selected patients is therefore proposed to:

1. Describe the users' experience of Biologique at different stages of treatment, including their sources of information about the program, the factors that influenced their involvement in it, and their perception of the quality of received services.

2. Assess the perceived impact of the Biologique five-step program on different dimensions of quality of life of the interviewed users, specifically analyzing the evolution of their daily performance and personal independence, food and health habits, sexual and emotional life satisfaction, interpersonal relationships and the emotional and cognitive aspects, at the start of treatment, midterm and at the end of the treatment.

3. Browse the users' Bioloqique service expectations regarding the evolution of their health status and quality of life, including the sustainability perspective of the results achieved on a short, medium and long term.

## III. METHODOLOGICAL ASPECTS

### 3.1. Design

The Qualitative component of this study was based on sequential qualitative interviews given to a subsample of four users of Biologique's services. These, users were recruited and interviewed before they began their treatment (T0), midway (T1) and after they concluded their treatment.

Data collection instruments and constructed categories for their analysis were based on preliminary findings of the quantitative component of the evaluation, which contributed to the integration of both methodological approaches in order to obtain a more complete picture of the impact of Biologique's interventions on the health of its users, from a bio-psycho-social perspective.

### 3.2. Data collection techniques and instruments

The data required for the qualitative component of the study was gathered through qualitative interviews conducted with each participant at three different times: Pre-intervention (T0), mid-intervention (T1), and after concluding their treatment. To complement this, we performed unstructured interviews with different team members of Biologique, in order to obtain additional information on the different interventions in the treatment program administered to service users.

The implementation of the interviews was directed by guidelines developed from the specific objectives of this component, adjusted to the characteristics of each phase of the development of received treatment. The most relevant thematic categories and related topics included in the guidelines are shown in Table 1.

**Table 1.** Synthesis of categories and topics of the qualitative component

| Category | T1<br>Pre-intervention | T2<br>Mid-intervention | T3<br>Post-intervention |
|---|---|---|---|
| **Context** | • How did patient hear about Biologique / related sources of information<br>• Main signs and symptoms: history and evolution<br>• Factors taken in consideration for choosing engaging in treatment<br>• Treatment expectations/ Personal success indicators | • Advances in treatment to date<br>• Evolution of signs and symptoms since the beginning of treatment.<br>• Contrast between previous references and current experience with Biologique.<br>• Personal sucess indicators: orignal vs. current expectations<br>• Which other treatment(s) patient is using / plans to use in | • Treatment received<br>• Evolution of signs and symptoms since the beginning of treatment.<br>• Contrast between previous references and current experience with Biologique.<br>• Fulfillment of Personal sucess indicators<br>• Satisfaction with received treatment and its results.<br>• Other treatment received in combination |

| Category | T1<br>Pre-intervention | T2<br>Mid-intervention | T3<br>Post-intervention |
|---|---|---|---|
| | • Which other treatment(s) is patient using / planning to use in combination with Biologique | combination with Biologique | with Biologique.<br>• Post-treatment expectations.<br>• Would you recommend Biologique to a friend? Why or why not? What would you say about your experience? |
| **Biologique Experience** | • Evaluations / interventions received to date<br>• Perception of quality of service (infrastructure, equipment, staff treatment and preparation, cost, effectiveness, etc.)<br>• Highlights and shadows of experience to date | • Evaluations / interventions received to date<br>• Perception of quality of service (infrastructure, equipment, staff treatment and preparation, cost, effectiveness, etc.)<br>• Highlights and shadows of experience to date | • Evaluations / interventions received to date<br>• Perception of quality of service (infrastructure, equipment, staff treatment and preparation, cost, effectiveness, etc.)<br>• Highlights and shadows of experience to date<br>• Evolution of original perception of highlights and shadows. |
| **Quality of life** (emphasis on expectations / experiences of change in physical health, psychological welfare and social functioning) | • Daily performance and personal independence<br>• Food and health habits<br>• Sexual and emotional life<br>• Interpersonal relationships and leisure activities<br>• Social support networks<br>• Emotional and cognitive dimension | • Daily performance and personal independence<br>• Food and health habits<br>• Sexual and emotional life<br>• Interpersonal relationships and leisure activities<br>• Social support networks<br>• Emotional and cognitive dimension | • Daily performance and personal independence<br>• Food and health habits<br>• Sexual and emotional life<br>• Interpersonal relationships and leisure activities<br>• Social support networks<br>• Emotional and cognitive dimension |

The interview guides were designed as flexible formats used for data collection and were related to the set objectives, without impeding in any way the free development of the interviews. At the same time, these guidelines were based off open themes, which allowed participants to spontaneously provide the most important experiences in their particular context, gradually evolving towards more targeted questions which helped focus any judged aspects as particularly relevant in each evaluated case and clarify any facet that was insufficiently addressed in the previous phases of the discussion.

### 3.3. Sample

The sub-sample of users included in the qualitative component of the evaluation was suggested by the Biologique team and validated by the investigators, taking into account de heterogenicity of their profiles according to their socio-demographic characterisitics, gender, age, presented health condition, as well as the signs and symptoms that led to their treatment at this Center for Advanced Medicine. On table 2 we summarize these profiles:

Table 2. Profile of participants in the qualitative sub-sample.

| Code | Sex | Age | Interviews | | | Social and Family Context | Chief complaints and symptoms |
|---|---|---|---|---|---|---|---|
| | | | T0 | T1 | T2 | | |
| **BC01** | **F** | **38** | 15.3. | 10.5. | 14.8. | • Lives with husband and three children (aged 17, 15, 8), 35 km from Santo Domingo.<br>• Housewife, with a stable relationship with mutual support.<br>• Presented multiple health problems that lacked a clear diagnosis, although they implied important limitations to her self-image and lifestyle quality. | Arterial Hypertension, chronic and severe abdominal pain, progressive abdominal distension, generalized weakness, severe constipation, dizziness, palpitations, fatigue, difficulty sleeping and depression. |
| **BC02** | **M** | **37** | 20.3. | 8.5. | 26.7. | • Lives with wife and 2 children (aged 6 and 11)<br>• Businessman, with active and demanding proffesional lifestyle.<br>• Reported low work performance due to insomnia, lack of energy and chronic fatigue, as well as concern about chronic dependence on medication to control gastric symptoms. | Weakness, myalgias, knee arthralgias, headaches, lumbalgia, insomnia, cramps, dyspepsia, chronic abdominal pain, flatulence, episodes of frequent diarrhea, gastric reflux. |

| Code | Sex | Age | Interviews | | | Social and Family Context | Chief complaints and symptoms |
|---|---|---|---|---|---|---|---|
| | | | T0 | T1 | T2 | | |
| **BC03** | **F** | **54** | 20.3. | 10.5. | 26.7. | • Lives with husband and teenaged daughter (aged 14).<br>• Accountant, with stable government job.<br>• Follower of Catholic Religion.<br>• Presented multiple health problems since early youth, including chronic pain conditions. Referred that this taught her to accept pain and insomnia as part of life and copes with both conditions. | Lumbalgia, mialgias and generalized arthralgias, insomnia, dizziness, dyspnea on moderate exertion, gastroesophageal reflux, changes in stool patterns, dyspepsia and frequent urinary infections. |
| **BC04** | **F** | **51** | 21.3. | 8.5. | 6.8. | • Lives with husband and 2 children (aged 20 and 18)<br>• Works in private sector, in area that implies frequent travel outside of the city.<br>• Reported unhealthy eating habits all her life, with a fat and carbohydrate based diet.<br>• Went to Biologique on an invitation by a team member, after was diagnosed in another health center, so her costs were covered by Biologique. | Obesity, generalized weakness, intestinal inflamattion, lack of energy, dyspepsias, gastroesophageal reflux, myalgias, lower limb edema, frequent urinary infections. |

### 3.4. Methods

The qualitative interviews of service users were held in Biologique's administrative offices, dating from previously coordinated appointments with the team. All interviews were conducted individually and in a setting that guaranteed the confidenciality of shared information. Prior to the start of each interview, all participants underwent an informed consent process, which ended in the signing of the corresponding form (see Annex).

The four participants included in this sub-sample were interviewed on three differents periods:

- T0 (March 2013): Before starting their treatment at Biologique, coinciding with their initial labwork and diagnostic procedures.
- T1 (May 2013): Approximately half of the treatment process had undertaken.
- T2 (July-August 2013): When the Biologique treatment had just finished.

The interview duration ranged from 30 minutes to 1 hour, with the initial interviews (T0) being the most extensive due to personal context, family and social information which were collected at this time. After each block of interviews (T0, T1 and T2), the research team met to share impressions of the collected data and to extract first inferences for data analysis and the possible integration of quantitative and qualitative data.

All interviews with the service users were audio recorded as backup for the data processing and analysis, in addition to notes and other records produced by the investigators in context with the data collection. All data was processed and analyzed using a content analysis approach, constructing categories of analysis from the objectives and framework elaborated for the purpose of this evaluation (see Table 1). Contributing to the rigor and validity of the qualitative findings, the data analysis process of this component was carried out by three different investigators which agreed and integrated the results of this process in the final report.

### 3.5. Ethical considerations

The qualitative component of this evaluation did not expose its participants to significant psychological, physical or social risks. In order to prevent and/or alleviate possible reactions of discomfort due to topics of personal nature during interviews, the participants were previously informed of their right to refuse to respond to any formulated question, or to retire from the interview if they so wish, without any need to explain their decision, thus guaranteeing the confidentiality of the shared information.

We requested in writing the informed consent of each participant in the qualitative sub-sample of the evaluation. The written consent form (ANNEX I: Written consent forms), developed for this purpose, was presented and explained by the main qualitative investigator in a private and confidential setting prior to the completion of each interview, ensuring full comprehension of their assumed rights and commitments with each conducted evaluation. Among other aspects, this form guaranteed the confidentiality of exchanged information in context with the interview, explicitly establishing the disengagement of the conducted evaluation to the services received in Biologique, and the voluntary nature of the participation in itself. Before consent was obtained, the participants disposed of sufficient time to carefully read the form, and consulting it with family members and companions.

### 3.6. Limitations

While the process of collecting data for the qualitative component of the evaluation was conducted seeking the greatest possible rigor, it is important to note some methodological limitations of this process when interpreting the gathered information. The following aspects stood out in this regard:

- All interviews were conducted in Biologique's installations and coordinated by its staff, which may have hindered the disengagement from participation in the evaluation of health services received in this Center for Advanced Medicine by the interviewed users.
- Some of the particpants in the qualitative sub-sample were patients invited to receive Biologique's services free of charge, something that reduced their ability to assess the benefits of treatment received according to their costs.
- In a manner consistent with the qualitative approach of this component of the evaluation, the members of the sub-sample were selected in a targeted basis out of suggestions from the Biologique team, so their profiles may differ from other service users this center for Advanced Medicine.

## IV. PRESENTATION AND DISCUSSION OF RESULTS

### 4.1. Bioloque experience

*4.1.1. Sources of information on Biologique*

Several of the participants expressed to have heard of Biologique's existence and services via television programs, which noted testimonies of some public personalities on the positive impact of these services in their health situation. Some also reported to have found Biologique's promotional materials in waiting rooms of other healh centers:

> *"I saw two or three pamphlets in the waiting table and started to read… … I noticed that it is something new, something uncommon… I did not imagine that an institue like that exists in the Dominican Republic." [BC04, T0]*

However, the most significant impact on the decision to seek an appointment in Biologique, according to the statements of the interviewees, tended to be the positive experiences and testimony of acquaintances and significant others, whose opinions tend to inspire more trust than printed materials and television promotions:

> *" And she [a known person] told me 'This is a wonderful experience. I have two weeks in and I'm happy, I no longer have high cholesterol…'. This piqued my interest. I said 'I have to go and see this doctor because… according to what Huchi Lora said, but more because of the experience that I saw right there, nearby, that it wasn't some commercial but somebody close to me. This got my attention and I said 'I'll go'" [BC01, T0]*

In this context, the high satisfaction of Biologique's services observed among its users, significantly strenghtens the formal initatives in the media and other forms of promotions thereof, through the spontaneous diffusion of positive experiences among family members, friends and significant others.

*4.1.2. Resons for initiating treatment*

The common denominator of many of the persons attending Biologique is composed of multiple previous failed attempts at finding an answer to their health status in the context of traditional medicine. Usually this process has involved repeated visits to specialists from various branches of medicine and consequent disappointment by having chronic symptoms that interfere significantly with their quality of life, including in some cases chronic pain, limiting changes in body image and the consequent reduction in the everyday performance of personal, family, social and work.

In some cases, since the chronic physical problems could not be diagnosed by traditional medicine, they tended to be ruled out by doctors as an "objective" reality and defined as states of hypochondria, thus triggering a significant psychological distress in the affected person:

> *"In all my wanderings from doctor to doctor, I found doctors that did not respect me, they understood that I was crazy or a hypochondriac. There is nothing more difficult, in my point of view, than going to a doctor, saying that I'm dying, feeling diseased and being told that I'm making it up." [BC03, T1]*

At the same time, the discomfort caused by physical symptoms, often have a very negative impact on the emotional state and mental health of the people interviewed, including self-concept, self-esteem and relationships:

> *" For the past two months my life has been… in every way, emotionally and with my partner, I no longer want him to see me. I don't let him touch me…" BC01, T0*

Also, the long hours of wakefulness and exhaustion caused by insomnia were reported by several participants as particularly detrimental to their psychological wellbeing:

> *"It's just terrible, terrible not being able to sleep. You think up of weird things at night, because you're awake and everybody else is at peace sleeping. Everything… you want to fix all the problems that the whole world has, on top of your familys and personal problems. All of this happens at night because there is nothing else to do" [BC03, T1]*

Nevertheless, beyond the multiple biomedical problems that the interviewed persons presented before going to Biologique (Table 3), and the psychological suffering linked to those, many of the interviewed pointed out that the most important motive in their decision to undergo this treatment program was the impact of their health status in their lifestyle and family, social and work quality of life. In this regard, they stated many times feeling responsible for the suffering of their close family members, linked by their, in most cases, chronic health situation:

> *"I've been through a lot, I've suffered a lot and those that are next to me, I know they are also going through a lot. They don't tell me so, but I know. If we're going out to dinner, I don't want to go. If we're going to a lunch, I don't want to go. I mean, it's not that I wouldn't want to go, I would like to go, share and enjoy it, but it's not easy". [BC01, T0]*

> *"Sometimes the family wants to go somewhere and I'm tired and I have to rest because I am overwhelmed… so, even one's mood changes when you're feeeling sick. That means that family-wise it has affected me, obviously, and also at work, I don't give as much as I used to. There are things that I could do that I just simply don't because I'm tired". [BC02, T0]*

> *"It musn't be nice for him [husband] to see that I can't sleep. But most of all when I wake up, not that I want to, I try to do it as lightly as possible, but I moan, because the pain is strong enough for me to sit up and he'll wake up… …It's just difficult when you have a sick patient in the family, it's very difficult that the rest doesn't suffer. I try not to do it, to complain… …When they ask how I feel, I tell them 'enduring quietly, like all good women'". [BC03, T0]*

Based on the points mentioned above, at the time of making the decision to go to Biologique as an alternative treatment, the person had reached a significant level of despair to the possibility of finding a satisfactory response to their physical, psychological and social unrest:

> *"A disaster. You could say that I feel like I've been defeated. Like I'm throwing the towel, and I don't like feeling like this. Because this is part of my recovery, that I don't throw in the towel… Then I'm in that process right now and am afraid to stumble." [BC01, T0]*

> *"I went to church and I fell on my knees and said 'forgive me Lord, I don't want to sin against you, but I really no longer have hope that I can be healed. Then if I am not going to get better, I'm not going to keep wasting money, taking medicines for nothing, because I am hurting myself, poisoning myself with all this for no reason" [BC03, T1].*

Thus, knowing of the existence of Biologique and getting in contact with the positive experiences of ther people with the 5 step program offered by the Center for Advanced Medicine, tends to be perceived as the reason to renew the previously lost hope:

> *"That was my concept: I no longer have anything to lose… I've played them all. I've seen seven <Gastroenterologists>, among the best and worst of this country. Seven, eight, nine… And none have told me what I have. At least I'm with someone that tells me what I have, and that it has a solution, that I only need patience. And that I will heal and get better… So, why not? [BC01, T1]*

In this context, at the time of making the decision to begin the treatment with Biologique, the people with their chronic suffering in the physical, emotional, family and social planes, and their many failed attempts to find an acceptable solution, tended to present high levels of motivation to fully achieve the different components of the 5 step program, in which they involved themselves with enthusiasm.

### *4.1.3. Evaluation of the different components of the program*

The "5 Step Program" that the Biologique Center for Advanced Medicine applies, integrates different complementary components of which it is expected that, synergistically, have an impact on the significant improval of the health status of the person.

**Steps 1 and 5 ("Enlightened Nutrition" and "Vitality coaching")** are focused on providing the person the necessary tools and information in order to achieve an optimal body balance, facilitated in an opportune manner by specialists in Nutrigenomics, Integrative Medicine and Orthomolecular Medicine, as well as the required support and backing needed for the important change that the Biologique program tends to imply to their lifestyle. An important part of these steps constitutes the indication of specific diets, suggesting during the first weeks of the program a green diet which helps detoxify the body, to later create a specific nutrition plan for each person, based on their results of the ALCAT (Antigen Leukocyte Antibody) test that claims to measure reactions to dietary substances.

Due to the strict requirements of the indicated diets for the success of the 5 Step Program, many of the interviewees pointed out this component as their biggest concern regarding their ability to adhere to, prior to initiation of their treatment:

> *" I believe that the only thing that worries me a bit is the food, because I eat in a very disorganized way. I am a very bad eater; I don't like to eat much… That is the only thing that I believe worries me the most" [BC01, T0]*

In support of this percepttion, once they began the program, the participants pointed out in their followup interviews that the adherence to the indicated diet and, in particular, the adherence of the green diet, as one of the major challenges of the Program, yet they confirmed their motivation to keep complying with this food plan based on the observed benefits in their general health and quality of life:

> *"[The green diet] Is a little bothersome, because there comes a time that I say 'I'm not going to eat today', but I eat, because I get around it. What I do is what I'm supposed to have in the morning, I'll have it later at night or in the afternoon, I work around it, because they told me I could do that in the mean time…I could play with the menu, but within the protocol" [BC01, T1]*

The adherence to this diet, especially in its first phases, could present particularly important challenges for people who have an active work life and must adhere to a work Schedule outside of their homes:

> *"Broccoli and cauliflower are very particular, they smell horrible 5 minutes after they're cooked… … If I prepare them just when I'll eat them, I'll glady eat them and spend the day eating arugula and cauliflower. The problem lies when you eat at 12:00 or 1:00pm, you uncover those cooked vegetales in the office…that smell…" [BC03, T1]*

Even so, adherence to the personalized nutritional plan, and the adjustment of said plan based on the ALCAT results, were pointed out by many of the interviewed as an essential factor for the success of the Biologique Program and were willing to adhere to it:

> *"For me it was after I took the ALCAT, when felt the big change… Maybe ALCAT helped when I already had a month of my last treatment. But where I felt a big change was with the ALCAT, when I started to eat what didn't hurt me." [BC02, T2]*

In this sense, despite the implied challenges of adhering to an indicated nutritional plan in their everyday life, the participants expressed to perceive this nutritional counseling step as a crucial component not only for the success of this particular program, but as an important component in order to change their lifestyle in the long term:

> *"It's a tool one can use when one gets out of there, that it's not just the months when you are with them, but a tool that you can use everyday at home. I mean, it's not that I'm going to get obsessed with one thing, but when I'm eating something then I know what I'm eating, being conscious of it." [BC01, T2]*

**Steps 2 and 3 (Nutraceuticals and Orthomolecular IV)** imply the administration of orthomolecular therapy orally and intravenously, respectively, vitamins, nutrients, minerals and enzymes which favor the cardiovascular, immune, gastrointestinal systems as well as holistic health and revitalizing cell function.

Generally speaking, the interviewees pointed out perceiving a positive impact of this component of the program on their vitality and energy levels:

> *"When I take the vitamin supplements, I go bionic on the streets, it's like a boost of energy and I spend the whole week like that" [BC01, T1]*

It should be noted that, although a part of the vitamins are administered intravenously, this administration, due to the type of needle used, does not tend to be perceived as invasive by the participants, even by those who expressed feeling discomfort during the B-Core process:

> *"There's no problem with the IV, because it's a small needle, it's not like the B-core" [BC02, T1]*

**Step 4 (B-CORE: Biochemical Body Balance & Metabolic efficiency)** integrates an advanced and secure protocol of extracorporeal oxygenation, with a duration of 60 minutes per session, enriching 100 percent the patient's blood flow with activated medical oxygen and removing toxic wastes from the blood that the body cannot remove conventionally, such as heavy metals, petroleum derivates, inorganic substances, cellular waste and fat macroparticles.

This component of the program was perceived as highly positive by the interviewees, being identified as one of the main factors that influenced the experienced improval in their overall health. However, the procedure itself tended to be recognized as the most invasive component of the program, particularly with regard to the catheter placement, when not applied with local anesthesia:

> *"For the B-core it is a big needle, girl, like a catheter, the one they use to donate blood. And not just on one hand, but on both because it has to go through… And without anesthesia… there are people who like pain, but not me (laughs)." [BC02, T1]*

### *4.1.4. Cost-Benefit Relationship*

Even when, for those who paid for the treatment in Biologique, the treatment's costs was defined as significant, in terms of cost-benefit they rated this investment as very positive:

> *"If the treatment helps me stop taking [drug to control acidity], and if I keep up with the diet after this, and remain like this, for me it is excellent for the price, because for what I pay for these medications, in a couple of years I'll recoup the investment. If we look at it from the cost-benefit point of view, really… But obviously, health has no price, it's the most precious thing we humans have… And there also is an intangible benefit, that one is more productivity… doing more things, getting to places one couldn't before, when one was in a state of tiredness." [BC02, T1]*

However, even agreeing with that the treatment benefits provided by Biologique surpass their costs, some of the interviewed expressed not being able to dispose of sufficient resources to cover these costs in the future:

> *"Being able and wanting is different. Being able, I can't, wanting, I want, monetarily… … I mean, it's worth it, it really is worth it, whoever can afford this Biologique treatment uh, health has no cost but, the case of being able to, I can't. Because I am salaried and can't pay the cost, and thank God and the doctor to have given me the opportunity on this occasion". [BC04, T2]*

### *4.1.5. Highlights and downsides of the experience*

While it may be argued that the overall level of satisfaction with the health services received in Biologique reported by the interviewees was very high, the most valued aspect of this experience was, invariably, the preparedness and treatment by the staff who form part of the Center for Advanced Medicine, as a crucial factor for the sense of support and emotional wellbeing experienced throughout treatment:

> *"People working were, they don't work to work, and they have a vocation, they like what they are doing. I like that a lot, it's been missing a lot. One gets to those kind of places where they attend just to attend, but here everything is different…" [BC01, T1]*

In particular, the participants recognized the vocation and individualized dedication of Biologique's medical personnel involved in their care and monitoring:

> *"[When treatment ends] I'll have to come visit, even. Can you imagine that there's a doctor here that calls you to see how you are doing?! He doesn't have to be your friend… Because when I was sick and I had doctors who called my house, but they were my personal friends. However, I was there, lying down in that clinic and I got calls of 'How are you? How are you feeling? How are you doing…? From Biologique." [BC03, T1]*

On the other hand, despite recognizing the adaptable and pleasant atmosphere of Biologique's physical space ("It's very pretty. It has peace and tranquility which I like very much" [BC01, T1]), the aspect pointed out by the interviewed people as a possible area for improvement, was the location of the center inside the installations of a clinic which was operating while the data collection portion of this evaluation was taking place:

> *"You may pass a sick person here and there… who knows what you're exposed to, you don't know what that person has, what kind of disease, if it's contagious or not… and may pass next to you maybe seeking preventive health. It's a point I think needs to improve." [BC02, T1]*

Besides the issue of the location of the facilities, the overall assessment of health services received in Biologique was rated as highly positive by all interviewed participants in the qualitative component of this evaluation, highlighting in particular the preparedness and treatment received by the staff involved in this process.

## 4.2. Biologique Impact: Physical symptoms and quality of life

### *4.2.1. Physical symptom evolution*

Table 3, seen below, summarizes the situation of physical symptoms and major complaints presented by each of the people interviewed in the qualitative component, before starting treatment (T0), during treatment (T1) and after completion (T2), including their established personal goals before starting the Biologique Program and their future expectations concerning their health status.

**Table 3.** Evolution of signs and symptoms throughout treatment in Biologique

| Code | Main Complaints at T0 | Personal Goals | T1 | T2 | Satisfaction and Future Perspectives |
|---|---|---|---|---|---|
| **BC01** | • Chronic and severe abdominal pain<br>• Abdominal distention<br>• Weakness and fatigue<br>• Interference of symptoms with family, couple and | • Eliminate chronic pain and reduce abdominal distention: "The first thing I want is for them to take away the pain. That I won't feel pain. I know that the process of | • Has had "highs and lows" and "satisfied with improvements"<br>• "Pain is going away, I'm no longer feeling suffocated, uncomfortable, nervous"<br>• *[BC01, T1]*<br>• "My waist used to measure 103cms, a | • *"I've done very well. I've had highs and lows. There were moments that I felt well, there was no inflammation, and all of the sudden I fell back. It's been a dificult process… … I've had a lot of stress and maybe I* | • "Let's say a 10… No, well, let's give it from 1 to 10; let's give it an 8… I know that there are some things that the doctor and I will work on later… I want to feel sure that when I start to eat the foods that I said I would [meats] it won't backfire…". |

| Code | Main Complaints at T0 | Personal Goals | T1 | T2 | Satisfaction and Future Perspectives |
|---|---|---|---|---|---|
| | family life | slimming my gut is going to be a little difficult, but I am also positive, I think I will also accomplish that" *[BC01, T0]*<br>• Retake previous family and social way of life before aggravation of symptoms | disaster…now I'm measuring 90"<br>• "I've started to have a social life which I had lost… I've already started to get back my normal life activities" *[BC01, T1]* | *wasn't eating well" [BC01, T2]*<br>• *"My abdomen used to measure 105 and the last time it was at 84 or something like that… My weight was 162 pounds and now I weigh 138" [BC01, T2]*<br>• *"The pain is located…like in that corner there. I mean, it's there but compared to before, no, it was unbearable, I had to take two pain killers every day" [BC01, T2]*<br>• *"I'm trying to go out again, to socialize…But, it takes time to recover." [BC01, T2]* | *[BC01, T2]*<br>• *"It's a tool that I'll use when I get out of here, it's not just during the months I'm with them… I mean, it's not that I'm going to get obsessed with one thing but when I'm eating something I know what I'm eating, that I'll be conscious that… that I can eat but I know that the problem comes and goes". [BC01, T2]* |
| **BC02** | • Chronic gastritis / relies on drugs to keep under control<br>• Fatty Liver<br>• Limited quality of life: "*I haven't been able to sleep normally in a bed in thirty odd years with a constant hacking cough and gastric reflux… I had* | • Stop using medications to control gastritis<br>• Reduce levels of hepatic enzymes<br>• Increase energy levels and work performance: "*I used to work 12 and 14 hours and didn't get tired, I was a machine… Now I work* | • Has been doing "very well". Reports more energy and mental agility: "*I really have an unexpected energy level, and I feel more awake at the sensory level… It's like somebody flipped a switch on me" [BC02, T1]*<br>• Has decreased drug dosage for acidity. Is taking the drug every other day and at half the original dose. | • *"My acidity has reduced considerably. If I eat something out of ALCAT, I have some acidity. But I no longer take medications for that" [BC02, T2]*<br>• *"For the first time in 5 years my liver isn't fatty… I don't even have high liver enzymes" [BC02, T2]*<br>• *"I don't know, I felt like something woke up in my* | • Defines results as "Excellent".<br>• Rates it 9 points on a scale of 10: *"I give it a 9, because there are a few things that could improve …the place, location, also to tell the person to put some anesthesia for the B-core"*<br>• *"I want to return… like in a year, so I could have a medical checkup and if I need something… do it as part of preventive* |

| Code | Main Complaints at T0 | Personal Goals | T1 | T2 | Satisfaction and Future Perspectives |
|---|---|---|---|---|---|
| | *to do something about it" [BC02, T1]* | *but I'm dead tired, my energy levels have changed so much" [BC02, T1]* | • <br>• *"I haven't taken my liver tests after this, pero I no longer have that pang that I had there, on my right side" [BC02, T1]* <br>• Unexpected weight loss benefit: "*You have to tell that to the patient before you start: 'Look, prepare yourself to, on top of the treatment, also change your closet' All of my clothes are falling off. I have lost 25 pounds'"[BC02, T1]* | *health. In my health, and in my attention span" [BC02, T2]* <br>• *"I used to get in at 7.00 at night, wanting to throw myself into bed…not anymore…I urge you to have the treatment ". [BC02, T2]* | *health maintenance, like a strenghtening of what I've done so far" [BC02, T2]* |
| **BC03** | • Chronic severe and generalized pain <br>• Insomnia <br>• Movement quality of life limitations | • Reduce pain intensity to more bearable levels <br>• Improve sleep quantity and quality: *"If I could sleep, I understand that I could say I could rest" [BC03, T0]* <br>• Increase mobility and <br>• Incrementar la movilidad y la self-sufficiency in everyday life: *"That if I bend over to fix the bed sheets, I can be confident* | • Has been doing "very well", despite complications caused by bronchitis since T0. Being admitted to hospital for a week, and interrupting treatment at Biologique. <br>• *"I have improved my sleep quality, which was very important to me… Not sleeping is the most terrible thing to have, not even having pains" [BC03, T1]* <br>• *"Well, afther this flu, one felt bad. But I was better, my body didn't hurt at all, I felt with much* | • Has kept on improving since T1. However, had an adverse reaction to a contraindicated vaccine, which slowed progress with Biologique treatment. <br>• *"All of my lab work is pretty good. I've lowered not only my body fat levels, my pain has reduced considerably, and for example my muscles no longer hurt. I still have some bone pain, my condition is severe enough, but it's not the* | • *"[On a scale from 0 to 100] I would give them all of 100, if it weren't for the little lack of sleep and the little pain. Just compared with what I used to… I'll give them a 95. My life has changed so much that I would give them the 100, and keep the little pains and problems that I have". [BC03, T2]* <br>• *"My days were bad, very bad and horrible. When I was lucky to have a bad day, pain and all, it was unbearable pain. When very bad I had a little trouble pretending* |

| Code | Main Complaints at T0 | Personal Goals | T1 | T2 | Satisfaction and Future Perspectives |
|---|---|---|---|---|---|
| | | *that I'll stand up again". [BC03, T0]* | *more enthusiasm, was sleeping better, felt more clearer because I could sleep, I could rest. That awful tiredness that I had has permanently disappeared. I've*<br>• *. Ha desaparecido ese cansancio tan grave que yo antes tenía permanentemente. I have greatly improved." [BC03, T1]* | *same. I'm having a pretty normal life.* [BC03, T2]<br>• *"I was sleeping well. Now, I don't understand what happened, that I went back… I sleep a little more, I really slept two or three hours. Now I sleep four, four hours and a half, but no more.".[BC03, T2]* | *everything was ok. But I had horrible days that I had to be hospitalized. That was all the time. Now I have a bad day or a crisis… My days, I can almost all rate them as good and I have very good ones. BC03, T2]*<br>• *"Now I'm worried about two things: Fatty liver and lack of sleep. Especially the latter" [BC03, T2]* |
| **BC04** | • Sleep troubles<br>• Generalized Weakness and fatigue<br>• Intestinal Inflammation<br>• Obesity | • Improve sleep quality<br>• Increase energy levels<br>• Improve biochemical markers<br>• Lose weight<br>• *"If I see that I have a pleasant night's sleep without a pill, if I see my uric acid levels go down to normal, if I see that my fatty liver is healed, I mean, without problems and if also my bilirrubin levels are fixed, then I say yes, Biologique is* | • *"I sleep much better even though I keep waking up, I wake up because I drink too many glasses of water" [BC04, T1]*<br>• *"I was constantly sleepy…I mean, I would be talking to you and all of the sudden I got sleepy, just like that, inexplicably… Not anymore… I only sleep when I have to, at night" [BC04, T1]*<br>• *"It truly improved everything. Because I had, at the beginning, uric acid, and I'm almost at normal levels, my bilirrubin was also high and now it's normal" [BC04, T1]*<br>• *"I don't feel so swollen, people tell* | • *"Ever since I began, up to now, I've been improving, so far I feel good" [BC04, T2]*<br>• *"My energy has gone up, my health, my mental quickness also increased." [BC04, T2]*<br>• *"I've lost many pounds… more or less 20 pounds in 3 months during my treatment" [BC04, T2]*<br>• *"My fat levels have gone down, I'm very stable. I had high bilirrubin, now I'm normal, I'm still struggling with my uric acid." [BC04, T2]*<br>• *"I'm much less swollen, I mean* | • *"In these 3 months, I've improved a lot. If you give me a scale of 0 to 10, I would say I've reached 9… because I'm still fighting with uric acid" [BC04, T2]*<br>• *"It was a moral compromise that I made, a compromise that I fulfilled, that I'm following, not as strong as the first 3 months but I am following it… … I think it was a little hard but it was worth it." [BC04, T2]*<br>• *"I wish to lose around seven pounds, more or less… … I think I should stick to my diet, a proper diet, uh, try to stay consciencious around things that could hurt me that I* |

| Code | Main Complaints at T0 | Personal Goals | T1 | T2 | Satisfaction and Future Perspectives |
|---|---|---|---|---|---|
| | | *OK! Let's recommend this!... And of course, my weight. I want to lose a little weight" [BC04, T0]* | *me now that they have seen me like that 'but you were more swollen, you could see it in your chest, even in your face" [BC04, T1]* | *I'm almost inflammation free." [BC04, T2]* | *shouldn't eat. [BC04, T2]* |

A careful analysis of the data presented in Table 3, based on quotes extracted from conducted interviews, shows that the four interviewees in the qualitative component of this evaluation have met their established goals which were set as a priority before starting with the Biologique treatment, in some cases exceeding their respective expectations.

Health is constructed as a dynamic process, whose maintenance in satisfactory margins implies a long- term, continuous commitment. Data gathered in this component leaves no doubt of the significant positive impact of the Biologique 5 Step Program on the health status of all interviewed people, including the reduction, and in some cases, elimination of longstanding chronic symptoms. This impact is reflected in the levels of satisfaction expressed by users of the service when they concluded their treatment at Biologique, including the high evaluation of achieved goals and the motivation to introduce the components of this program as permanent changes in the long term to their lifestyle.

*4.2.2. Impact on quality of life and mental health*

According to what was pointed out on section 4.1.2 of this present report, one of the more important motives reported by participants to get involved in the Biologique 5 Step Program and start a general and radical change in their lifestyle, was linked to the impact of the chronic disease to their psychological welfare, everyday performance, family and social life:

> *"I notice that today we're invited to a dinner and I told him "I'm not going" and he told me "You're letting me go by myself?" I said "Yes, I'm not going". And it's not to hurt him, it's just that I'm not feeling well. So why if I'm not feeling well, do I have to be there, where I'll find a thousand people who are going to ask me: "What do you have", "Are you pregnant?" "Are you sick? I mean, people like to ask about your health… … I'll feel worse, so I decide to better stay in. I tell him "you go and share, on my behalf". And that there, hurts" [BC01, T0]*

> *"I had days at work that I had to look everywhere, covertly, until I saw that everybody was focused in their work, so I could struggle to stand up and go to the bathroom… … But once I got to the bathroom I had to go back, because I couldn't urinate, because I couldn't squat by myself. It was a terrible life, and it was my life." [BC03, T1]*

Thus, as evidenced in Table 3 presented in the previous section, the impact of Biologique's intervention reported by the interviewed people in the qualitative component, transcends the physical symptoms themselves, and directly affects the lifestyle and quality of life of the users of the service, particularly in the case of people who have spent decades of their life living with intense pain and other incapacitating symptoms. It is important to note, however, that although this impact tends to be perceived as highly positive by the interviewees, this continues to imply the need for a gradual adjustment to the new post-disease lifestyle, along with a social reinsertion process in the previously abandonded spaces:

> *"I had the problem for 3 years, and you know that when you've been isolated for 3 years, by yourself at home, well it's difficult to start to relate to the world. I'm trying to go out again, to relate… But it takes time to recover." [BC01, T2]*

This situation seems to be particularly relevant in the case of patients who have assumed their physical symptoms and consequent suffering as part of their self-concept. In this context, the person not only is exposed to the need to assimilate a new lifestyle based on eating habits and lifestyle recently acquired at Biologique, they also have to renounce their symptoms as an integral part of their identity before their elimination. This revision process of self-concept and revised identity based on the absence of chronic and incapacitating physical symptoms implies, paradoxically, a process of psychological mourning, pointing out the need of professional support to handle the demands of this process for the integrated health of the affected person.

While currently the Biologique team takes into account the needs of psychological support and intervention on those cases which require them, proceeding to refer the patients in this situation to the right specialist, monitoring and routine evaluation of mental and emotional health of the users of the service is not formally and systematically undertaken unlike with their biomedical markers. In this context it is possible that some of the symptoms go unnoticed and these emotional and psychological factors interfere with the sustainability of the treatment results in the medium and long term.

### 4.3. Sustainability perspectives

Given the significant impact of Biologique's 5 Step Program on physical symptoms and overall quality of life of the interviewed people in the qualitative component of this evaluation, there are medium and long term sustainability challenges, once the formal followup of Biologique's intervention ceases with each patient. In this sense, the educational interventions developed from within the program, including orientation and education on nutritional subjects that go hand in hand with the process, seem to play an important role in empowering the individual on the assimilation of healthy eating and life habits in the long term:

> *"You are what you eat. Depending on what you eat, that's how your health is going to be, or not to be. I didn't understand that until I underwent the treatment. Because they teach you, they tell you 'Look, this is because of this and that…Notice that you're blood work shows this so this happens', and it really worked for me, I get it now…" [BC02, T2]*

Ultimately, this sustainability without a doubt depends on the affected individual and his or her assimilation of new eating habits as part of an integrated lifestyle, having this challenge noted as such by many of the interviewed:

> *"I can't eat avocado, can you imagine, and I love avocado… But if it hurts my blood, my organism, why am I eating it? There are 20 good things that don't hurt me. I can eat turkey meat, chicken meat, pork…" [BC02, T1]*

In this context, although relapses in previous eating and lifestyle habits before Biologique's intervention, and the consequent revival of original symptoms, both represent a possible scenario and, likely in many cases, after they received their intervention in Biologique, those people will take measures to recover back a satisfactory status of health, from their vivid and assimilated experiences. In the words of one interviewee:

> *"Now I really have expectations. Now I do have hope. Because they were created here, realistically." [BC03, T2]*

## QUALITATIVE COMPONENT CONCLUSIONS

At the time of making the decision and assuming Biologique's treatment, the affected persons, starting from their chronic suffering on the physical, emotional, family and social backgrounds, and having multiple failed attemps to find an acceptable solution to these, tend to present high levels of motivation to fully comply with the different components of the 5 Step Program that this Center for Advanced Medicine offers. This motivation contributes to the adherence of the program, in synergy with the offered nutritional counseling as a crucial factor not only for the success of this particular program, but as an important component for the long-term lifestyle change.

Except for the location of Biologique's installations, which at the moment of data collection for this present evaluation was located inside a private clinic, the overall assessment of health services experience received in this Center for Advanced Medicine was rated highly positively by all interviewed participants in the qualitative component of this evaluation Of particular note was the preparedness and personal treatment involved in this process as a crucial factor for the aura of support and emotional wellbeing experienced by the users all throughout their treatment.

Although health is constructed as a dynamic process whose maintenance in satisfactory margins implies a continuous and long term compromise, data gathered in this qualitative component of this evaluation leaves no doubt of the important positive impact of Biologique's 5 Step program on the health status of all respondents, including the reduction and, in some cases, elimination of chronic and long term symptoms which, in the case of all four participants, had previously failed to receive a timely solution. This impact is reflected on the levels of satisfaction expressed by the users when they completed their treatment at Biologique, including a high value placed on their achieved goals and the motivation to introduce the components of this program as permanent and long-term changes in their lifestyles.

It is important to note however, that particularly in the case of patients who assumed their physical symptoms and consequent suffering as part of their identity, this process not only implies the necessity to assimilate to a new lifestyle, but also an identity review due to the absence of these symptoms, noting the necessity of professional assistance in this process. In this sense, even when the Biologique team takes into account the needs of psychological intervention and support, routine psychological, emotional and mental health evaluation and followup aren't performed in a formal and systematic way unlike they do with biomedical markers. In this context it is possible that some symptoms go unnoticed and that emotional and psychological factors interfere with the sustainability of treatment results in the medium and long term.

The sustainability of the positive impact of Biologique's 5 Step Program depends greatly on the post-intervention taken on by each patient. Thus, relapse in eating and lifestyle patterns found before Biologique's intervention, and the consequent resurgence of original symptoms, represent a possible and (in some cases) probable scenario. It should however be noted that since the intervention received at Biologique, participants are familiarized with steps needed to recover to a satisfactory health status, parting from previously lived and assimilated experiences, which could guarantee patient compromise in maintaining their health and lifestyle in the medium and, potentially, long term.

**ANNEX I**. Informed Consents Forms

**Global Health and Biotechnology Research Center**

**ASSESMENT OF THE MANAGMENT PROTOCOLS OF THE BIOLOGIQUE CENTER FOR ADVANCED MEDICINE IN THE DOMINICAN REPUBLIC**

**INFORMED CONSENT FORM**

**Qualitative Interviews *(T1)***

**Date: / /**

Greetings:

We are conducting a study to determine the users' perception of the treatment management protocols of the Biologique Center for Advanced Medicine. Therefore we ask you to participate in an interview, as a conversation with an interviewer, which will take you approximately 30 minutes. The topics of this conversation will talk about experiences that either you or others you know have had with the services offered in this Center for Advanced Medicine, including your related needs and suggestions. The conversation will be audio recorded to facilitate further processing and analysis.

Your participation in this study does not represent any risk towards you. Even so, if any of the subjects cause you any discomfort, you are not obligated to have your say in the matter, and are entitled to withdraw from the study whenever you wish.

We assure you that all the information that you give us will be handled confidentially, and only as a group, never individually. The audio recording of this conversation will only be identified by a number, which will not include names nor identifying remarks. If you wish to use a nickname (like Robin Hood or Cinderella), you may do so and we would address you, while we conduct the interview, with this pseudonym.

Your participation must be voluntary at all times. Although you will not receive any direct benefit from participation, the results of this study will help the center's health team to make decisions and provide health services that will better adjust to the needs of its users.

The fulfillment of this interview does not form part of the services offered by this Health Center, nor any other institution. Therefore, you do not lose any of your rights related to these services by denying to participate in this study. If you decide to help us, we kindly ask you to answer with the utmost sincerity to each of the questions and feel free to express yourself.

If you have any comment or question regarding your participation in this interview you may do so now, or if you prefer, you may later contact Dr. Eddy Pérez-Then at the phone number 809-876-7760. You will receive a copy of this consent form for personal use. If you wish, you may share this with your family, other professionals, or friends before signing it.

If you agree to participate in this interview under these conditions, please, write down your name and sign on the lines below, to give your informed consent. This means that you have decided to be a volunteer in this study, and understand its objectives and your rights.

| | |
|---|---|
| *Interviewer's name* | *Participant's name* |
| *Interviewer's signature* | *Participant's signature* |

**Global Health and Biotechnology Research Center**

**ASSESMENT OF THE MANAGMENT PROTOCOLS OF THE BIOLOGIQUE CENTER FOR ADVANCED MEDICINE IN THE DOMINICAN REPUBLIC**

**INFORMED CONSENT FORM**

***Qualitative Interviews (T2)***

**Date: / /**

Greetings:

As we commented in your previous interview, we are conducting a study to determine the users' perception of the treatment management protocols of the Biologique Center for Advanced Medicine. On this occasion, we ask you to participate in a follow up interview as a conversation with an interviewer, which will take you approximately 30 minutes. The topics of this conversation will talk about experiences that either you or other people you know have had with the services offered in this Center for Advanced Medicine, including your related needs and suggestions. The conversation will be audio recorded to facilitate further processing and analysis.

Your participation in this study does not represent any risk towards you. Even so, if any of the subjects cause you any discomfort, you are not obligated to answer, and are entitled to withdraw from the study whenever you wish.

We assure you that all the information that you provide will be handled confidentially, and only as a group, never individually. The audio recording of this conversation will only be identified by a number, which will not include names nor identifying remarks. If you wish to use a nickname (like Robin Hood or Cinderella), you can do so and we would address you, while we conduct the interview, with this pseudonym.

Your participation must be voluntary at all times. Although you will not receive any direct benefit from participation, the results of this study will help the center's health team to make decision and better adjust health services to the needs of its users.

The fulfillment of this interview does not form part of the services offered by this Health Center, nor any other institution. Therefore, you do not lose any of your rights related to these services by denying to participate in this study. If you decide to help us, we kindly ask you to answer with the utmost sincerity to each of the questions and to feel free to express yourself.

If you have any comments or questions regarding your participation in this interview you may inquire now, or if you prefer, you may later contact Dr. Eddy Pérez-Then at phone number 809-876-7760. You will receive a copy of this consent form for personal use. If you wish, you may share this with your family, other professionals, or friends before signing it.

If you agree to participate in this interview under these conditions, please, write down your name and sign on the lines below, to give your informed consent. This means that you have decided to be a volunteer in this study, and understand its objectives and your rights.

| | |
|---|---|
| *Interviewer's name* | *Participant's name* |
| *Interviewer's signature* | *Participant's signature* |

**Global Health and Biotechnology Research Center**

**ASSESMENT OF THE MANAGMENT PROTOCOLS OF THE BIOLOGIQUE CENTER FOR ADVANCED MEDICINE IN THE DOMINICAN REPUBLIC**

**INFORMED CONSENT FORM**

***Qualitative Interviews (T3)***

**Date: / /**

Greetings:

As we commented in your previous interview, we are conducting a study to determine the users' perception of the treatment management protocols of the Biologique Center for Advanced Medicine. On this occasion, we ask you to participate in the closing interview as a conversation with an interviewer, which will take you approximately 30 minutes. The topics of this conversation will talk about experiences that either you or others you know have had with the services offered in this Center for Advanced Medicine, including your related needs and suggestions. The conversation will be audio recorded to facilitate further processing and analysis.

Your participation in this study does not represent any risk towards you. Even so, if any of the subjects cause you any discomfort, you are not obligated to answer, and are entitled to withdraw from the study whenever you wish.

We assure you that all the information that you give us will be handled confidentially, and only as a group, never individually. The audio recording of this conversation will only be identified by a number, which will not include names nor identifying remarks. If you wish to use a nickname (like Robin Hood or Cinderella), you may do so and we would address you, while we conduct the interview, with this pseudonym.

Your participation must be voluntary at all times. Although you will not receive any direct benefit from participation, the results of this study will help the center's health team adjust better to the needs of its users.

The fulfillment of this interview does not form part of the services offered by this Health Center, nor any other institution. Therefore, you do not lose any of your rights related to these services by denying to participate in this study. If you decide to help us, we kindly ask you to answer with the utmost sincerity to each of the questions and feel free to express yourself.

If you have any comment or question regarding your participation in this interview you may ask now, or if you prefer, you may later contact Dr. Eddy Pérez-Then at phone number 809-876-7760. You will receive a copy of this consent form for personal use. If you wish, you may share this with your family, other professionals or friends before signing it.

If you agree to participate in this interview under these conditions, please, write down your name and sign on the lines below, to give your informed consent. This means that you have decided to be a volunteer in this study, and understand its objectives and your rights.

| | |
|---|---|
| _____ | _____ |
| *Interviewer's name* | *Participant's name* |
| _____ | _____ |
| *Interviewer's signature* | *Participant's signature* |

CLINICAL RESEARCH AND EVALUATION OF TREATMENT MANAGEMENT PROTOCOL RESULTS OF THE BIOLOGIQUE CENTER FOR ADVANCED MEDICINE, PREPARED BY THE GLOBAL HEALTH AND BIOTECHNOLOGY RESEARCH CENTER

We conducted a quantitative and qualitative evaluation, before and after patients underwent the treatment management protocols of the Biologique Center for Advanced Medicine, in order to evaluate the results, clinical symptoms, laboratory parameters and quality of life of treated patients three months after they started their protocols and one month after they had completed their protocols.

We studied 30 cases (2 prospective and 10 retrospective) of patients with cardiovascular, gastrointestinal, endocrinological and immunological diseases, which had precarious health status that significantly affected their quality of life and had not obtained satisfactory results with previous medical treatment. Patients discontinued statin drug therapy before their treatment began. Of the 30 patients, only 1 interrupted their treatment due to personal travel, which denotes a high adherence rate to the treatment management protocols of the Biologique Center for Advanced Medicine.

At the end of the Biologique five step protocol, we observed a substancial improment regarding weight loss, visceral fat and body mass index compared to basal values on both patient cohorts, which suggests that the protocol significantly influenced the reduction of these clinical parameters in the short time the implementation of the management protocol was under evaluation (approximately 3 months elapsed until improvement was observed)

Laboratory parameters such as total cholesterol and tryglicerides were significantly reduced after the patient was included in the Biologique five-step protocol, which reflects its effectiveness in reducing these parameters in a short time.

90% (n = 26) of participants noted improvements in pain, as well as cardiovascular and gastric symptoms three months after completing the standardized Biologique Center for Advanced Medicine five step protocol, independently of the underlying disease for which the patient attented this center. The main diseases that were managed and had a positive impact were metabolic syndrome, diabetes, cardiovascular disease, arthritis, gastritis, colitis and fibromyalgia.

Characteristically, all patients reported having more stamina and better concentration in their daily life compared with those reported before starting the protocol.

The qualitative analysis substancially corroborated what was reported by patients to the attending physician in this center on the improvement in their quality of life, which was logged in all patient records included in the assessment and described in full in a subsample of participantes in the qualitative component of this report.

The overall assessment of the experience of health services received in the Center for Advanced Medicine was rated as highly positive by all interviewed participantsin the qualitative component of this evaluation.

Although health is constructed as a dynamic process whose maintenance in satisfactory margins implies a continuous and long term compromise, data gathered in this qualitative component of this evaluation leave no doubt the important positive impact of Biologique's 5-Step program on the health status of all respondents, including the reduction and, in some cases, elimination of chronic and long term symptoms which had previously failed to have received a timely solution.