

# **Elemental Diet Protocol**

# Introduction

An elemental diet (ED) offers significant clinical benefit for patients with digestive dysfunction, including those with Crohn's disease, rheumatoid arthritis, celiac disease, irritable bowel syndrome (IBS), and small intestinal bacterial overgrowth (SIBO). An ED provides complete nutrition, including amino acids, mono and disaccharides (organically sourced), medium chain triglycerides, as well as vitamins and minerals. By providing all needed nutrients in a pre-digested hypoallergenic form, an ED allows for healing of the GI mucosa, and potentially a shift in the GI microbiota.

## <u>Assessment</u>

Depending on the patient's condition, various means of assessment may be applied. For example, clinical trials for participants with Crohn's disease typically monitor the frequency of remission, though one trial assessed small bowel permeability with sugar markers of permeability. All children enrolled in this trial had an elevated lactulose/rhamnose ratio before beginning dietary therapy, and by six weeks of an ED all had significant improvement, with 50% achieving normal values.<sup>1</sup> For individuals with increased intestinal permeability, sugar ratios may be one simple method of monitoring progress.

For individuals with suspected SIBO, a common non-invasive test is the lactulose breath test (LBT). Among participants with IBS and SIBO, after two weeks of an ED, 80% had normal LBTs, while 85% achieved normal results after an additional week of dietary therapy. Normalization of LBTs also correlated closely with clinical improvement in bowel symptoms.<sup>2</sup>

For those with rheumatoid arthritis, standard clinical measures can be used for assessment, such as early morning stiffness, pain on a visual analog scale, etc.<sup>3</sup>

## **General Recommendations**

With any dietary supplement or medical food, administration and dosing are important components in achieving desired outcomes, and EDs are no different. Understanding these protocols can help the health care practitioner achieve the treatment objectives. An important factor in the administration and selection of an ED protocol is the health care practitioner's assessment and purpose for using it. These considerations will be important in calculating the proper protocol for each patient.

The most clinically studied of the EDs is the full elemental diet (full ED), with most clinical trials employing 100% of calories from an ED for a two-week period, though some have extended it for 4–6 weeks. This type of ED was first used in patients with limited or impaired capacity to digest, absorb, and/or metabolize foods. As mentioned earlier, an exclusive ED is implemented in inflammatory bowel disease (IBD) and those conditions that go hand in hand with IBD, such as SIBO and even IBS. Continued research into the microbiome and the relationship between gut health and systemic health, including the brain-gut connection, has also led to the development and use of shorter EDs, which may help jump-start gut healing.

In addition to use as a short-term therapy, a half elemental diet (half ED) may extend the benefits achieved with a full ED. In clinical practice, once the ED has produced the required effects, a half ED can be implemented. In this type of diet, half of the human physiological caloric requirements are met with the ED formula and the other half through whole, hypoallergenic foods. Clinical studies have shown that patients have better overall long-term effects when they employ a half ED immediately following a full ED in the management of conditions such as CD.<sup>4,5</sup>

# **Protocols**



### Part A: Calculating nutritional requirements

- 1. First calculate the patient's basal metabolic rate (BMR):
  - a. Women: **BMR** = 655 + (4.35 x weight in pounds) + (4.7 x height in inches) (4.7 x age in years) **OR**
  - b. Women: **BMR** = 655.1 + (9.563 × weight in kg) + (1.850 × height in cm) (4.676 × age in years)
  - c. Men: BMR = 66 + (6.23 x weight in pounds) + (12.7 x height in inches) (6.8 x age in years) OR
  - d. Men: BMR = 66.5 + (13.75 × weight in kg) + (5.003 × height in cm) (6.755 × age in years)<sup>6-8</sup>
- 2. Final calculation with the Harris-Benedict Equation. This formula uses the calculated BMR and then applies an activity factor to determine the patient's actual total daily energy expenditure in calories. The more active a person is, the more calories they will use. Harris-Benedict Factors are the following:
  - a. Little-to-no exercise: BMR x 1.2 = total daily calories
  - b. Light exercise/sports 1-3 days/week: BMR x 1.375 = total daily calories
  - c. Moderate (moderate exercise/sports 3-5 days/week): BMR x 1.55 = total daily calories
  - d. Very active (hard exercise/sports 6-7 days/week): BMR x 1.725 = total daily calories
  - e. Extra active (very hard exercise/sports 6–7 days/week): BMR x 1.9 = total daily calories.<sup>6-8</sup>

### PART B: Different forms of the ED

#### 1. Full ED

The patient consumes 100% of caloric requirements using the ED. This becomes the patient's sole source of nutrition for the designated time period, which normally spans 14 days (as evidenced by clinical trials).<sup>9-19</sup>

#### Application: CD, SIBO, and IBS.<sup>11,18</sup>

**Dosage:** To accurately calculate the patient's total caloric needs, determine their BMR and then use the Harris-Benedict equation above to calculate total caloric requirements (approximately 1,800 calories per day). Advise the patient to take the calories in divided doses during the day: approximately 200–300 calorie servings every 2–3 hours over a 30-minute period until the caloric requirements are met.

**Duration:** Two weeks has been clinically validated. This time period can be extended at the sole discretion of the health care practitioner, if necessary.

### 2. Half ED

The patient consumes 50% of their daily caloric needs from the ED and the other 50% from a whole food diet. The scientific literature has found that half EDs (sometimes called partial EDs) help with maintaining remission of CD.<sup>20</sup> They can also be used when compliance becomes difficult for patients on full EDs for SIBO and IBS. In addition, half EDs can be used as starting and exiting conduits to full EDs, easing the patient's experience and possibly improving compliance.<sup>5</sup>

Application: Maintaining remission of CD after completion of the full ED, used as conduits to full EDs and in place of full EDs for patients having difficulty with compliance. This will be at the discretion of the health care practitioner.<sup>5</sup>

**Dosage:** The dose supplied by the half ED is 50% of the daily total calories divided into 200–300 calorie servings, consumed every 2 hours (use either first or second half of day). Whatever part of the day where the half ED is not used, the patient consumes a whole food diet.

To accurately calculate the patient's total needs, determine their BMR and then use the Harris-Benedict equation (see above) to calculate total caloric requirement (divide this by half to give the calories needed from the half ED, which should be approximately 900 calories per day).<sup>5</sup>

**Duration:** There are no published reports specifically demonstrating the optimal duration of a half ED, however, 4–6 weeks can be a good starting point. The duration would be calculated at the discretion of the health care practitioner, considering patient symptomatology and other markers deemed important.

#### 3. Short ED

This can be used to give the gastrointestinal tract a "rest" by avoiding all the complex processes involved in digestion, including allergen and by-product exposure created through digestive and absorption processes. This can be useful in helping support gut mucosal healing processes. Due to the short duration, compliance is usually very good and may be used as a "bridge" to introduce the full ED.

Dosage: In a short ED, dosing can follow either the full-ED or half-ED directives and calculations can be made accordingly.

**Duration:** There are no published data regarding the duration of a short ED, however 1–3 days is generally the accepted time frame.



#### 4. Intermittent ED

Although intermittent EDs have no clinical research, some health care practitioners believe that some benefit could be gained from giving the gastrointestinal tract a period of "rest" during parts of the day. In particular, the possible restoration of the migrating motor complex and, in turn, overall gastrointestinal health may benefit from an intermittent ED acting as a type of fast without compromising nutritional status.

Dosage: Intermittent EDs will entail consuming 300 calories over a 15-minute period.

**Duration:** There are no published studies on this type of use of the ED, but much like intermittent fasting, it can go on for several months. It is important to always be under the guidance of a health care practitioner during this time.

Note: No food or beverages should be consumed during the ED (water is unrestricted), however in specific cases there can be continued observable therapeutic effects with the addition of chicken or steak (no fat), herbal or black tea, or black coffee.

#### Part C: After the ED

Upon completion of the ED, a transition diet is recommended along with prokinetics with meals to prevent bloating and help with motility.

- Prokinetics with meals:
  - Ginger: 500 mg with each meal
  - Prescription medication at night
- Transition diet:
  - 1. Days 1-2: No fibre, meats, eggs, lactose
  - 2. Days 2-3: Add cooked pureed low FODMAP/fibre vegetables (e.g., carrots, zucchini)
  - 3. Day 4: Back to whole foods diet

#### Part D: Patient monitoring

Elemental diets are completed under the supervision of a health care practitioner, where several markers are monitored:

- 1. Compliance Ensure that patients report the correct number of calories being consumed per day, according to directives.<sup>21</sup>
- 2. Weight Monitoring weight is important as there will be some weight reduction in the first week of treatment on the full ED. Monitoring this marker also ensures that caloric consumption needs are being met during the diet.<sup>21</sup>
- 3. Symptoms Monitor symptoms throughout the program, such as cramping and diarrhea due to osmolality, constipation, and nausea. The patient should report all of these symptoms as the diet may need to be adjusted as a result.<sup>21</sup>
- 4. Lactulose breath test (LBT) This test helps diagnose SIBO, a condition that often goes hand in hand with IBS and IBD. Lactulose is a large sugar that is not digested by the body and thus has the ability to travel through the entire small intestine. During the test, patients are given a bolus of lactulose and then they collect breath over a period of time. Bacteria will take the lactulose and produce gases that include hydrogen and methane, depending on the type and quantity of bacteria. If certain percentages of gases are found in the breath, a diagnosis of SIBO is given.<sup>22</sup> As noted previously, the vast majority of individuals with IBS and abnormal lactulose breath tests had normal values after three weeks of following an ED diet. Repeat testing may be considered if symptoms return, particularly if the ED diet has been discontinued.



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