



Original Article

# Design and Region-Specific Adaptation of the Dietary Intervention Used in the SODIUM-HF Trial: A Multicentre Study

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## ABSTRACT

**Background:** Restricting dietary sodium consumption has been considered a major component of self-care management in heart failure (HF); however, the evidence supporting this recommendation has not been conclusive. The Study of Dietary Intervention Under 100 MMOL in Heart Failure (SODIUM-HF) trial aims to assess the effects of dietary sodium reduction on clinical outcomes in a HF population using a pragmatic design to provide empirical evidence to guide dietary sodium intake recommendations in patients with chronic HF.

**Methods:** SODIUM-HF is a multicentre, open-label, blinded adjudicated endpoint, randomized controlled trial in ambulatory patients with chronic HF. This trial involves participants recruited from sites in Canada, Australia, New Zealand, Mexico, Colombia, and Chile, who are

## RÉSUMÉ

**Contexte :** La restriction de l'apport en sodium alimentaire est considérée comme étant un élément important de l'auto-prise en charge de l'insuffisance cardiaque (IC); or, les données à l'appui de cette recommandation ne sont pas concluantes. L'étude SODIUM-HF (*Study of Dietary Intervention Under 100 MMOL in Heart Failure*) vise à évaluer en contexte réel les effets de la réduction de l'apport en sodium alimentaire sur les résultats cliniques au sein d'une population de patients atteints d'IC, afin d'obtenir des données empiriques qui serviront à orienter les recommandations en matière d'apport en sodium alimentaire chez les patients atteints d'IC chronique.

**Méthodologie :** L'étude SODIUM-HF est un essai multicentrique contrôlé avec répartition aléatoire et mené en mode ouvert auprès de

Heart failure (HF) is a complex clinical syndrome caused by structural and/or functional cardiac abnormalities. These abnormalities result in reduced cardiac output and decrease in mean arterial pressure, leading to sodium and water retention and fluid overload in the long-term.<sup>1,2</sup> Because of this disruption in sodium balance observed in HF, restricting dietary sodium consumption has been considered a major component of self-care management. However, the evidence

supporting this recommendation has not been conclusive, resulting in a lack of consistency and consensus related to the effects of dietary sodium reduction across multiple clinical practice guidelines for management of HF.<sup>3–5</sup>

The Study of Dietary Intervention Under 100 MMOL in Heart Failure (SODIUM-HF) trial was designed to assess the effects of reduction of dietary sodium on clinical outcomes in a HF population, using a pragmatic design to provide empirical evidence to guide dietary sodium intake recommendations for patients with chronic HF.<sup>6</sup> Participants are recruited from sites in Canada, Australia, New Zealand, Mexico, Colombia, and Chile.

As an international pragmatic dietary clinical trial, the SODIUM-HF dietary intervention protocol was developed to address several challenges: in particular, defining the most suitable intervention strategy to account for country-specific variations in diet. These include differences in sodium

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**Ethics Statement:** The research reported adheres to the relevant ethical guidelines.

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See page 13 for disclosure information.

followed up to 24 months. Rationale and methods of the SODIUM-HF trial were published elsewhere. As an international pragmatic dietary trial, SODIUM-HF was designed to address several challenges, such as defining the most suitable intervention to account for country-specific variations in food intake and availability. In SODIUM-HF, we implemented the Nutrition-Care Model to provide a comprehensive intervention delivered directly to patients, focusing on modifying the nutrient composition of the diet (sodium restriction), using a personalized counselling and close follow-up.

**Results:** Available upon completion of the trial.

**Conclusions:** This long-term dietary trial is one of the first in its type in the HF field. This article describes in detail the rationale and methods for the dietary intervention employed and the region-specific adaptation of the SODIUM-HF intervention, so that the learning and processes taken in this trial can be applied to future multicountry dietary clinical trials.

content in processed foods across countries, the availability of foods that may determine food preferences—and, ultimately, food intake—but also cooking methods and food preparations: for example, a tendency for more home-made meals in Mexico and South America but also a higher consumption of street food in this region compared with Canada, New Zealand, and Australia. The dietary strategy used in this trial was designed to address regional variations in diet while considering that the results must be as generalizable as possible. Thus, a behavioural counselling approach rather than a controlled feeding scheme was chosen as the best strategy to achieve these objectives. Although the latter approach offers optimal conditions to investigate the efficacy of an intervention—that is, how a strict adherence to a dietary intervention affects metabolic and physiologic parameters and clinical health outcomes—its generalizability is limited. In contrast, behavioural counselling studies evaluate the effectiveness of dietary interventions under more realistic conditions, increasing the feasibility and generalizability of the findings to real-world clinical practice.<sup>7</sup> The aim of this paper is to describe, in detail, the rationale for the dietary intervention employed and to describe the region-specific adaptation of the SODIUM-HF intervention so the learning and processes taken in this trial can be applied to future multicountry dietary clinical trials.

## Materials and Methods

### Study design and study population

SODIUM-HF is a multicentre, open-label, blinded, adjudicated endpoint, randomized controlled trial of ambulatory patients with chronic HF to evaluate the efficacy of a low-sodium diet defined as 1500 mg/day compared with usual care, defined as general dietary advice to limit dietary sodium,

patients ambulatoires atteints d'IC chronique, dont les paramètres sont évalués à l'insu. Les participants sont recrutés dans des centres situés au Canada, en Australie, en Nouvelle-Zélande, au Mexique, en Colombie et au Chili, et font l'objet d'un suivi pendant 24 mois. La raison d'être et la méthodologie de l'étude SODIUM-HF sont présentées ailleurs. Comme il s'agit d'une étude internationale sur l'alimentation menée en contexte réel, l'étude SODIUM-HF a été conçue de manière à résoudre plusieurs difficultés, dont la façon la plus appropriée de tenir compte des variations entre pays en matière d'apport alimentaire et de disponibilité des aliments. L'étude met en œuvre le processus de soins en nutrition, afin d'assurer directement auprès des patients une intervention exhaustive axée sur la modification de la composition en nutriments de l'alimentation (restriction de l'apport en sodium) et faisant appel à des conseils personnalisés et à un suivi étroit.

**Résultats :** Les résultats seront publiés à la fin de l'étude.

**Conclusions :** Cette étude de longue durée sur l'alimentation est l'une des premières en son genre dans le domaine de l'IC. Les auteurs décrivent en détail la raison d'être et la méthodologie des mesures d'intervention alimentaire employées ainsi que les adaptations propres à chaque région mises en œuvre dans le cadre de l'étude SODIUM-HF, afin que les apprentissages et les processus issus de l'étude puissent être utilisés dans d'autres études cliniques multinationales sur l'alimentation.

on a composite clinical outcome of all-cause mortality, cardiovascular (CV) hospitalizations, and CV visits to emergency departments.

This international dietary trial was designed to allow generalizability of the results by taking into account regional variations in dietary patterns and including a broad spectrum of participants as recruited from diverse regions including sites in Canada (n = 19), Mexico (n = 1), Chile (n = 2), Colombia (1), Australia (n = 4), and New Zealand (n = 3). The SODIUM-HF study was approved by the Health Research Ethics Board of the University of Alberta (Coordinating Centre) and by the local Health Research Ethics Board at each participating site. The region-specific adaptations of the dietary materials being used in this trial to suit different populations are detailed here.

Rationale and methods of this trial were published elsewhere.<sup>6</sup> Patients are screened from heart-function clinics and general cardiology wards by the research team members. Patients with average dietary intakes of less than 1500 mg of sodium per day are excluded. Registered dietitians (RDs), or trained nurses where RDs are unavailable, are responsible for dietary screening and implementing and monitoring the dietary intervention, as described here.

### Dietary screening and baseline assessment of sodium intake

Screening for sodium intake is key to ensure inclusion of participants with a sodium intake above the level of restriction to be tested in this trial. When there is insufficient information in patients' clinical records to determine whether their usual daily sodium intake is below 1500 mg per day, the research dietitian or designee screens dietary sodium intake, using the Sodium Calculator (<http://archive.projectbiglife.ca/sodium/>).<sup>8</sup> Specific written informed consent for this

screening evaluation must be obtained. If results of this assessment indicate that a patient's daily sodium intake is more than 1500 mg, and all other selection criteria are met, the study personnel may proceed to obtain informed consent from the patient to participate in the study.

The use of the Sodium Calculator is advisable only for the Canadian sites, as this tool was developed based on Canadian food-intake patterns and the sodium content of Canadian foods. For those sites where the use of the Sodium Calculator is not applicable, the dietitian or designate interviews the patient on the frequency of consumption of high-sodium foods for that country, including frequency of eating out, to determine if sodium intake was high or not. Ultimately, in all cases, as dietitians will be involved in this dietary sodium screening, they can use their clinical knowledge to assess further whether a patient's sodium intake is too low to meet the dietary sodium-inclusion criteria.

Once the dietary screening process is complete, patients who meet the inclusion criteria provide written informed consent to participate in this study. Patients then undergo baseline evaluations, including a detailed assessment of dietary intake by a 3-day food record to obtain a formal pre-intervention assessment of sodium intake. Food records were chosen as the principal dietary assessment methodology for sodium intake, as opposed to 24-hour urine collection, as loop diuretics attenuate the relationship between dietary intake and urinary sodium excretion for patient with HF. It was reported that these 2 methods were correlated in patients with non-HF CV disease and in patients with HF who were not taking loop diuretics but not in those who were taking this medication.<sup>9</sup> In light of these considerations, we chose the food-record method as the most appropriate for our study population, in which there is a high rate of loop diuretic use. In addition, although a 7-day food record might provide more accurate overall dietary intake estimates, we chose a 3-day food record, as it has been reported that the average dietary sodium intake estimated from 3 days is highly correlated to that obtained from 6 days (0.93).<sup>10</sup> Thus, we considered 3 days as appropriate and feasible for the purpose of this pragmatic randomized controlled trial (RCT). Methods employed to collect and process dietary data in this trial were previously reported.<sup>6</sup>

### Study treatments and follow-up

Recruited patients are randomly allocated to a low-sodium diet (65 mmol or 1500 mg daily) or usual care (general advice to limit dietary sodium as provided during routine clinic practice). Participants in either group are followed for a total of 24 months. During the first 12 months, patients attend in-person study visits every 3 months for clinical assessments. The second year of follow-up includes only telephone contacts at 18 and 24 months to verify clinical events (all-cause mortality, CV hospitalizations, or CV ED visits). Patients in both groups are required to complete a 3-day food record at baseline, 6, and 12 months to assess dietary sodium intake. Food records collected at these time points are also used to guide the dietary counselling in the low-sodium group. Also, patients in this group fill out a 3-day food record form at 3 and 9 months, with the purposes of monitoring and reinforcing compliance to the diet, as described in the Adherence Monitoring section of this article.

### Rationale and design of the study intervention: low-sodium diet

SODIUM-HF research intervention relies on the Nutrition-Care Model developed by the American Dietetic Association.<sup>11,12</sup> This model focuses on prevention and health promotion provided directly to patients/clients rather than indirect nutrition interventions such as social marketing campaigns. The Nutrition-Care Model has 3 components: trigger event, nutrition-care process, and nutrition-related outcomes. The nutrition-care process specifies the essential components of effective nutrition care: assess, establish goals and determine nutrition plan, implement intervention, document and communicate, and evaluate and reassess.

In this model, several intervention approaches are identified depending on the assessment findings. These include modifying macro- or micronutrient composition, consistency, or flavour; prescribing/specifying food and nutrient intake; translating nutrition prescriptions into meals plans, food choices, preparation techniques, and so forth; fostering behavioural change by educating, counselling, motivating, and advising; providing complete or supplemental nutrients through food or enteral or parenteral formula; and referring to other service providers.<sup>11</sup>

In SODIUM-HF, we implemented the Nutrition-Care Model to provide a comprehensive intervention delivered directly to patients, focusing on modifying the nutrient composition of the diet (sodium restriction), using personalized counselling and close follow-up with nutrition-counselling sessions every 3 months. Although the SODIUM-HF intervention is targeted to modify a single dietary nutrient, the sodium reduction intervention required an unintended change in dietary patterns. Because sodium is ubiquitous in the food supply, and the principal source of sodium in the participating countries is derived from prepared and packaged foods, the intake of multiple types of foods required modification to meet the trial dietary objective of 1500 mg sodium per day. This approach, however, is pragmatic and reflective of real-world experience for individuals who are seeking to modify their dietary intake. For this reason, SODIUM-HF relies on an intervention strategy that induces a reduction in sodium intake while promoting a healthy dietary pattern by providing dietary guidance to follow a specific nutrition plan—as described here—to ensure the consumption of foods from all food groups and key nutrients. To this end, the nutrition plan for a heart-healthy low-sodium diet was translated into a daily meal plan, as endorsed by the Nutrition-Care Model as an intervention approach, which was designed to allow flexibility to fit individual food preferences, as described here. In addition, our intervention includes an education component to favour acceptability and promote adherence to the dietary treatment. Dietary intervention is prescribed after randomization during baseline visit.

### Nutrition plan

**Energy requirements.** Patients are prescribed a normocaloric diet. Resting metabolic rate (RMR) of each patient is estimated by using the Mifflin-St. Jeor equation, using current body weight.<sup>13,14</sup> Total energy requirements (TER) are estimated by adjusting the calculated RMR by a stress factor of

1.2 (20% of the RMR). We do not include a physical-activity factor because of its complexity to be estimated accurately and because patients with HF do not usually perform vigorous physical activity that accounts for a higher proportion of the TER. In patients who are overweight or obese, it may be considered to subtract 500 kcal to the TER<sup>15</sup> (TER = RMR + 20% stress factor) to promote a healthy weight (if weight loss is considered appropriate for the patient as per the discretion of the dietitian and/or clinician). The use of specific diets for losing weight, such as very low in calories (less than 800 kcal/day), low in fat or low in carbohydrates, are not be considered as part of this study.

**Daily energy distribution.** Regardless of energy requirements, all patients are prescribed a diet with the following energy distribution: 15% to 20% protein, 50% to 55% carbohydrates, 25% to 30% total fat, and <7% saturated fat, which is consistent with the guidelines for a heart-healthy diet.<sup>16,17</sup>

### Daily meal plan

To achieve the energy requirements, energy distribution and desired level of sodium restriction (65 mmol or 1500 mg/day), patients are provided with a meal-plan form (Supplemental Appendix S1) containing common foods with portion sizes divided into groups adapted from 2007 Canada's Food Guide. Each group contains a list of recommended and nonrecommended foods based on their sodium content per serving. Patients are encouraged to select from the recommended foods the appropriate number of servings per food group calculated for them based on their energy requirements. The meal plan also contains guidance to the patient on behavioural strategies to reduce sodium in the diet: to avoid sodium-rich foods (processed, packaged, preprepared, cured, and fast foods) and condiments such as mustard, ketchup, soy sauce, teriyaki sauce, and salad dressings; to reduce the frequency of eating out in restaurants or other food-service establishments; and to eat fresh or home-made meals most of the time. In addition, patients are discouraged from using table salt or salty seasoning for cooking or at the table and are subsequently encouraged to flavour foods with lemon juice, vinegar, herbs, spices, garlic, onions and no-added-salt seasonings instead. The meal plan also includes tips to keep a low sodium diet when eating out (Supplemental Appendix S1).

**Sample daily menus.** Six samples of daily menus at different calorie levels (1400, 1600, 1800, 2000, 2200 kcal/day) were designed according to the energy distribution and level of sodium restriction used for this study (Supplemental Appendix S2). Patients are provided with the set of daily sample menus that better match their energy requirements. Participants are told to use the menus as a guide and are able to interchange any of the food items included in the menus by another one included in the recommended foods list of the same food group, as listed in the meal-plan form. This allows flexibility to include individual preferences in the daily diet while avoiding high-sodium foods and to take into account other dietary restrictions such as reducing intake of high-potassium foods when hyperkalemia coexists. Dietary materials (meal plan

and menus) were developed by a dietitian and tested in the pilot study preceding this trial.<sup>18</sup>

**Region-specific adaptation of the meal plan.** We assembled a Dietitian Working Group (Supplemental Appendix S3), which is made up of all the site dietitians involved in the trial. This working group was responsible for locally adapting dietary materials according to local dietary variations to reflect the nature of diets in each study region.

Dietitians at international English-speaking sites (Australia, New Zealand) reviewed the meal plan form originally developed for the Canadian sites and removed certain food items that were not representative of local diet and included others more commonly consumed, following the same food-group classification and portion-size definition used for the Canadian materials. For instance, canned sardines in spring water (159 mg sodium in a can) were included in the Meat and Alternatives food group, within the recommended foods list, whereas mussels (442 mg sodium in 8 steamed pieces) were included in the same food group but in the nonrecommended foods list. Both food items are commonly consumed in these regions, and therefore both were included, but mussels were listed in the nonrecommended foods because of their sodium content. Also, local terms to refer to certain foods were used: for example, silverbeet instead of Swiss chard and kumara instead of sweet potato.

The Canadian meal plan form was translated into Spanish and then adapted for the Mexican diet, also following the same food-group classification and portion-size definition used for the Canadian materials. Local common foods, such as tuna, corn tortilla, chapata bread, bolillo, and requesón, were included in their respective food groups. Further adaptations for the Colombian sites were made on the Mexican meal-plan form, accounting for food items such as curuba, arepas, maracuyá, and arracacha. In the case of arepas, a highly consumed food in Colombia, recommendations for preparing low-sodium arepas were included. The site in Chile was the only one that did not make any written adaptations to the study materials and used those adapted for Mexico, providing verbal recommendations to the patients during the nutritional counselling sessions to fit them into the Chilean diet.

Sample menus were also modified to account for the foods included in the region-specific adapted meal plan forms but maintaining the same number of portion sizes per food group according to calorie level considered in the original Canadian menus. Sodium content for each menu was re-estimated after adaptation to make sure it remained below 1500 mg/day.

### Patient education

As part of the education strategies, patients are taught that dietary sodium is derived mostly from packaged foods and meals eaten out in restaurants,<sup>19</sup> not from salt added at the table or during cooking. It is reiterated that packaged foods may have large amounts of sodium even though they do not taste salty, which is called "hidden salt." Thus, patients are instructed on how to read nutrition-fact tables on food labels to identify how much sodium is in packaged foods and to compare products. This is thought to assist patients in identifying the most suitable option when selecting foods at the point of purchase. Patients are advised that 5% of the daily



value (DV) (120 mg) or less of sodium per serving is considered low, whereas 15% DV (360 mg) or more of sodium per serving is considered high.<sup>20</sup> They are also instructed to choose foods with sodium claims on labels such as no salt added, free of sodium or salt, or low sodium.<sup>21</sup> Instruction on reading food labels is conducted by using real samples of food nutrition labels in counselling sessions. In Mexico, Colombia, and Chile, where the consumption of street foods may be highly common, and as this type of food does not have nutrition-fact labels available to verify sodium and other nutrient content, patients are advised to avoid them and to prepare healthy homemade versions instead, such as non-deep-fried quesadillas with unsalted filling in Mexico and non-deep-fried, low-salt arepas in Colombia. Overall, patients are encouraged to eat homemade meals as much as possible so they can have more control on the salt and salty ingredients they use for cooking.

### Adherence monitoring

Study patients randomized to the intervention are required to fill out 3-day food records and meet with their dietitians every 3 months (baseline, 3, 6, 9, and 12 months) to assess overall dietary intake, monitor adherence to the meal plan and sodium intake, and provide further guidance when needed. Food records are reviewed by the study dietitian, with the patient, to ensure legibility, clarify food-item descriptions, and identify any missing food items. Dietary counselling during these sessions is guided by the information gathered in the food records and by specific questions or concerns the patients may have regarding the dietary intervention. Dietary sodium intake, as determined by the previous visit's food-record analysis, might also be used to guide dietary counselling and provide feedback to the patient on his or her progress in reducing sodium intake.

The on-site research dietitian also contacts patients by phone every month to reinforce dietary compliance. Importantly, participants are told that the occasional lack of compliance is to be expected. In that way, patients may feel more confident with the dietary intervention, maintain therapeutic relationship with the dietitian, and be willing to continue to adhere.

### Additional strategies to improve adherence

During periodic online meetings, research dietitians discuss and share ideas, based on their experiences, to promote patients' adherence to the intervention. Dietitians are uniquely trained to perform this education and guide these discussions with participants, having a pivotal role in promoting adherence to the intervention.

Examples of some additional patient-centred strategies taken by the research dietitians:

1. Brainstorming meal ideas with personalized discussions on modifying recipes to reduce added salt so meals are acceptable, considering both the patient preferences and study requirements.
2. Suggesting cookbooks that include recipes low in sodium.
3. Tailored discussions on how to manage a low-sodium diet during special circumstances such as being on vacation or dining out. This included strategies while choosing and consuming foods, as well as alternative suggestions such as

having a snack before eating out to help with satiety and prevent overeating.

4. Reviewing the food records closely with patients to help them identify foods high in sodium that they would have otherwise overlooked, such as sauces and gravies, as some patients have stated. Some patients have also expressed that reviewing the food record with the dietitian helped them to see the importance of getting back on track when they had occasionally gone off track.
5. Discussing challenges with the low sodium diet and ways to stay on track during these times.
6. Accessing online grocery stores during face-to-face visits to compare similar products to help patients identify lower-sodium choices when purchasing products.
7. Using measuring cups, measuring spoons, and food models to review portion sizes that contribute to patients' overall sodium intake, especially for foods that have hidden sources of sodium.
8. Advising patients to write down all the recommended food alternatives within each food group that they would prefer to use, so they have access to it anytime they go grocery shopping to assist with their purchases.
9. Advising patients to call the clinic and talk to their dietitians any time they have questions or concerns regarding their diets or anytime they felt less motivated to follow their recommended meal plans.

### Control group: usual care

Usual care includes general, nonspecific advice to limit dietary sodium, as provided during routine clinical practice. Participants in this group are asked to fill out 3-day food records every 6 months (baseline, 6, and 12 months) to measure sodium and overall dietary intake. Food records are reviewed by dietitians with patients to check for clarity, completeness, and legibility.

### Training for dietary intervention

A manual of operations (English and Spanish) was designed to standardize dietary-intervention procedures among participating sites. Training occurs in person at the study site or remotely via WebEx. When needed, sites are retrained on dietary intervention and 3-day food records collected to ensure completeness and quality of the dietary data.

### Discussion

The effects of sodium restriction in patients with chronic HF remain unclear. As an international dietary trial, SODIUM-HF faced a key anticipated challenge, which was the potential heterogeneity of the intervention related to regional variability in food availability, preferences, and preparation. Thus, the dietary intervention in SODIUM-HF was designed to minimize this bias by regionally adapting all the intervention-related materials by local dietitians to fit local dietary patterns and food availability. In addition, the exchange food system that is used to prescribe the meal plan at all sites allows patients to incorporate personal food preferences into their daily diets while keeping low-sodium intake, as all food choices are requested to be made from the list of

recommended foods previously defined by a dietitian, according to their sodium content. Also, by using a comprehensive dietary approach that considers inclusion of foods from all food groups, we expect to minimize the well-recognized negative impact of sodium reduction on calorie and other nutrient intake.<sup>22,23</sup>

Dietary trials base their intervention on different approaches, including the use of nutritional supplements, a direct provision of meals (feeding studies), replacement of meals, dietary counselling, or a comprehensive intervention with dietary counselling by a health care professional and a structured meal plan to follow at home. In the HF field, RCTs aimed to test the effects of sodium restriction on clinical outcomes and/or quality of life have employed the provision of meals (NCT02467296<sup>24</sup>, NCT02148679<sup>25</sup>) and the dietary-counselling plus nutrient-supplementation (NCT01733017) approaches. Features of the general feeding and behavioural counselling studies are described in [Supplemental Table S1](#).<sup>7</sup>

The SODIUM-HF dietary intervention was tested in the pilot study of this trial.<sup>18</sup> Results showed an overall effectiveness of the intervention to induce a reduction in sodium consumption to less than 1500 mg/day, as denoted by a decline in median sodium intake from 2137 to 1398 mg/day in the group receiving this intervention, after 6 months of follow-up. In addition, an overall good acceptance of the intervention was observed, as the number of dropouts in the groups prescribed the low-sodium diet (1500 mg/day sodium) (n = 19) and the moderate-sodium diet (2300 mg per day sodium) (n = 19) were similar (only 1 patient in each group withdrew consent). Importantly, a subanalysis of this pilot study found that calcium intake was the only studied nutrient that showed a statistically significant reduction associated to this intervention aimed for sodium reduction,<sup>26</sup> suggesting that this comprehensive dietary approach considering the whole diet can induce a reduction in sodium intake without significantly compromising overall dietary intake.

The adapted dietary materials being used outside Canada were not pilot tested; however, no acceptance issues have been reported by the on-site study dietitians, although they have commented on the need of providing further dietary advice to the patients in the presence of specific conditions, such as hyperkalemia and diabetes, and also the importance of making clear to patients that the menus are merely guides, so they do not feel overwhelmed trying to fit their daily diet into these precise menus. Upon completion of the trial, we would be able to report formally on any further recommendations to improve the dietary intervention strategy and the region-specific adaptation process based on the experience reported by the on-site study dietitians.

Frequent visits with the dietitian (every 3 months) and monthly phone calls are key strategies to reinforce adherence to the dietary intervention in SODIUM-HF; however, as a pragmatic trial in free living subjects consuming self-selected diets, occasional episodes of noncompliance are anticipated. In this circumstance, patients will be encouraged to continue to follow the meal plan despite nonadherence, as this is reflective of real life. Whether there might be country-related differences in the level of adherence to the dietary intervention, as reflected by the magnitude of change in the dietary sodium intake from baseline to the end of the study, will be

informed upon completion of the trial. Thus, even when adherence to the dietary intervention will be measured and reported, lack of compliance will not imply the need to withdraw a participant from the study. Indeed, the main analysis of this trial will follow the intention-to-treat principle.

## Conclusions

SODIUM-HF (NCT02012179) is a pragmatic trial, expected to inform on the effects of sodium reduction in HF, which intervention relies on a comprehensive dietary intervention that involves patients' teaching, counselling, and structured nutrition plans translated into daily meal plans to follow at home while allowing flexibility to incorporate personal food preferences.

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## Disclosures

The authors have no conflicts of interest to disclose.

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### Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Open* at [www.cjcoopen.ca/](http://www.cjcoopen.ca/) and at <https://doi.org/10.1016/j.cjco.2019.11.006>.