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# Effects of basic carbohydrate counting versus standard outpatient nutritional education (The BCC Study): study protocol for a randomised, parallel open-label, intervention study focusing on HbA1c and glucose variability in patients with type 2 diabetes

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## ABSTRACT

**Introduction** Recommendations on energy intake are key in body weight management to improve glycaemic control in people with type 2 diabetes (T2D). International clinical guidelines recommend a variety of eating patterns to promote energy restriction as the primary dietetic approach to body weight control in managing T2D. In addition, individualised guidance on self-monitoring carbohydrate intake to optimise meal timing and food choices (eg, basic carbohydrate counting (BCC)) is recommended to achieve glycaemic control. However, the evidence for this approach in T2D is limited. The objective of this study was to compare the effect of an educational programme in BCC as add-on to the usual dietary care on glycaemic control in people with T2D.

**Methods and analyses** The study is designed as a randomised, controlled trial with a parallel-group design. The study duration is 12 months with data collection at baseline, and after 6 and 12 months. We plan to include 226 adults with T2D. Participants will be randomised to one of two interventions: (1) BCC as add-on to usual dietary care or (2) usual dietary care. The primary outcome is changes in glycated haemoglobin A1c or mean amplitude of glycaemic excursions from baseline and after 6-month intervention between and within study groups. Further outcome measures include changes in time in range, body weight and composition, lipid profile, blood pressure, mathematical literacy skills, carbohydrate estimation accuracy, dietary intake, diet-related quality of life, perceived competencies in diet and diabetes and perceptions of an autonomy supportive dietician-led climate, physical activity and urinary biomarkers.

**Ethics and dissemination** The protocol has been approved by the Ethics Committee of the Capital Region, Copenhagen, Denmark. Study findings will be disseminated widely through peer-reviewed publications and conference presentations.

**Trial registration number** NCT03623139.

## Strengths and limitations of this study

- The study has a long-term follow-up and will provide knowledge on the effects of basic carbohydrate counting in people with type 2 diabetes (T2D).
- The study applies well-documented measures of glycaemic control as effect parameters.
- The results obtained have applicability beyond Denmark in the Caucasian population and has the potential to be included in the recommendations in future T2D guidelines.
- A limitation is the lack of a dietary 'untreated' control group; however, it would be unethical *not* to offer standard dietary care for participants in the control group for 1 year.
- The difference in the number of hours and type of dietary education and support between the two groups may also influence the participants' learning and knowledge.

## INTRODUCTION

Body weight management is central in managing people with type 2 diabetes (T2D) and even a modest weight loss is recommended to improve glycaemic control and reduce the need for glucose-lowering medication in people with T2D.[1–3] Accordingly, the national and international clinical guidelines for managing T2D recommend energy restriction as the primary dietetic approach for body weight control to improve metabolic control with no recommendations concerning the dietary distribution of energy from carbohydrates, fat and proteins.[1 3 4] However, carbohydrates are the main energy contributing nutrients in our diet with the highest impact on plasma glucose levels, and the total amount

of carbohydrates consumed in a meal is a significant predictor of the postprandial glucose response; furthermore, both the quantity and the quality (eg, dietary fibre, added sugar and glycaemic index) of carbohydrates influence plasma glucose levels.[5 6] In contrast, protein, fat and alcohol have more limited effects on postprandial plasma glucose levels but obviously have a significant impact on the total energy balance.[5 6] Thus, monitoring the dietary intake of carbohydrates is crucial to control postprandial glucose fluctuations, which may lead to clinical benefits such as a reduction in plasma glucose variability, the number of hyperglycaemic episodes and thereby improvements in glycated haemoglobin A1c (HbA1c).

Accordingly, the European and American clinical guidelines recommend that people with T2D receive individualised guidance on self-monitoring carbohydrate intake to optimise meal timing and food choices based on their current dietary intake and glucose-lowering medication.[3] This may include carbohydrate counting or similar methods for achieving glycaemic control in people with T2D.[5–8]

Two levels of carbohydrate counting have been defined internationally with different learning objectives and increasing complexity: a basic and an advanced level.[9–11] Basic carbohydrate counting (BCC) is a method aiming at increasing carbohydrate awareness. People with diabetes are educated in how to manage a consistent carbohydrate intake regarding time and amount, which foods are rich in carbohydrates, and how to read food labels and estimate carbohydrate portion sizes accurately. BCC aims to improve overall glycaemic control. Advanced carbohydrate counting (ACC) is targeted at the individual who ideally masters BCC and is on intensive insulin therapy and prepared to learn how to match mealtime insulin dosing according to carbohydrate intake using carbohydrate-insulin ratios and sensitivity factor. In other words, the ACC concept does not apply to all people with T2D because of the complex treatment regimens (eg, oral antidiabetic agents or other types of insulin than fast-acting meal insulin), potential patient barriers (eg, difficulties in implementing the method in a real-life context), lack of motivation to learn the method (eg, too time consuming to match insulin according to the carbohydrate content in each meal, or do preprandial and postprandial plasma glucose monitoring), and low levels of education, literacy and/or numeracy skills. Other barriers include lack of appropriate learning environments to promote behavioural change and availability of trained dietitians to facilitate the learning process. In the clinical guidelines and human studies, the term 'carbohydrate counting' is often used synonymously with ACC. Systematic reviews and meta-analyses of randomised controlled trials (RCTs) have shown that ACC can improve HbA1c in people with type 1 diabetes.[12–14] Only a few RCTs[15 16] have investigated the effect of ACC in people with T2D on intensive insulin therapy and found limited effects on HbA1c, while only one recent RCT has investigated the effect of BCC in people with T2D and found an effect on HbA1c only in a subgroup of the study population.[17] These study results need to be confirmed.

Accurate portion-size estimation is an important skill in BCC to obtain consistency in the daily carbohydrate intake and is also an important component of body weight management. Recent studies suggest that lower literacy and numeracy skills are associated with poorer portion-size estimation skills and understanding of food labels, increased body mass index (BMI) and poorer diabetes-related self-management abilities.[18–22] Studies have found that people with diabetes frequently assess their intake of carbohydrates inaccurately and this has been associated with a poorer HbA1c.[23–25] In particular, mixed meals, energy-dense foods and larger portion sizes resulted in inaccurate carbohydrate estimation. Thus, carbohydrate awareness and monitoring including gram counting, experience-based estimation of high-carbohydrate foods and practising numeracy skills seems to be important for obtaining better plasma glucose control. Increased carbohydrate awareness may also lead to a reduced carbohydrate consumption and thus a reduced energy intake, which has been shown to be an efficient dietary approach in people with T2D for body weight loss and improvement in HbA1c at least in the short term (<1 year).[3] The short-term effects of low-carbohydrate diets may be due to a decline in dietary adherence over time, indicating that the recommended intake of carbohydrates should be individualised and based on an assessment of the patient's current eating patterns and preferences as practised in the BCC concept. Diabetes management requires many daily self-management activities including managing dietary intake, and long-term dietary adherence remains

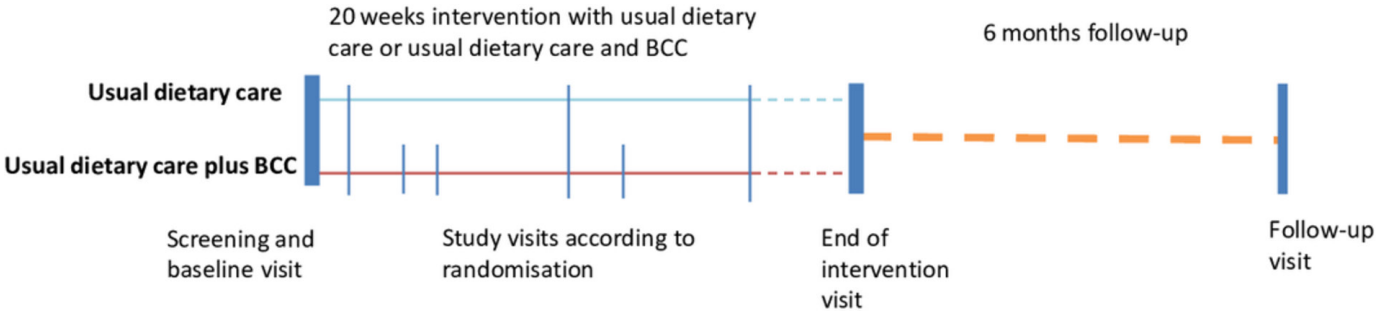


**Figure 1** Study design. BCC, basic carbohydrate counting.

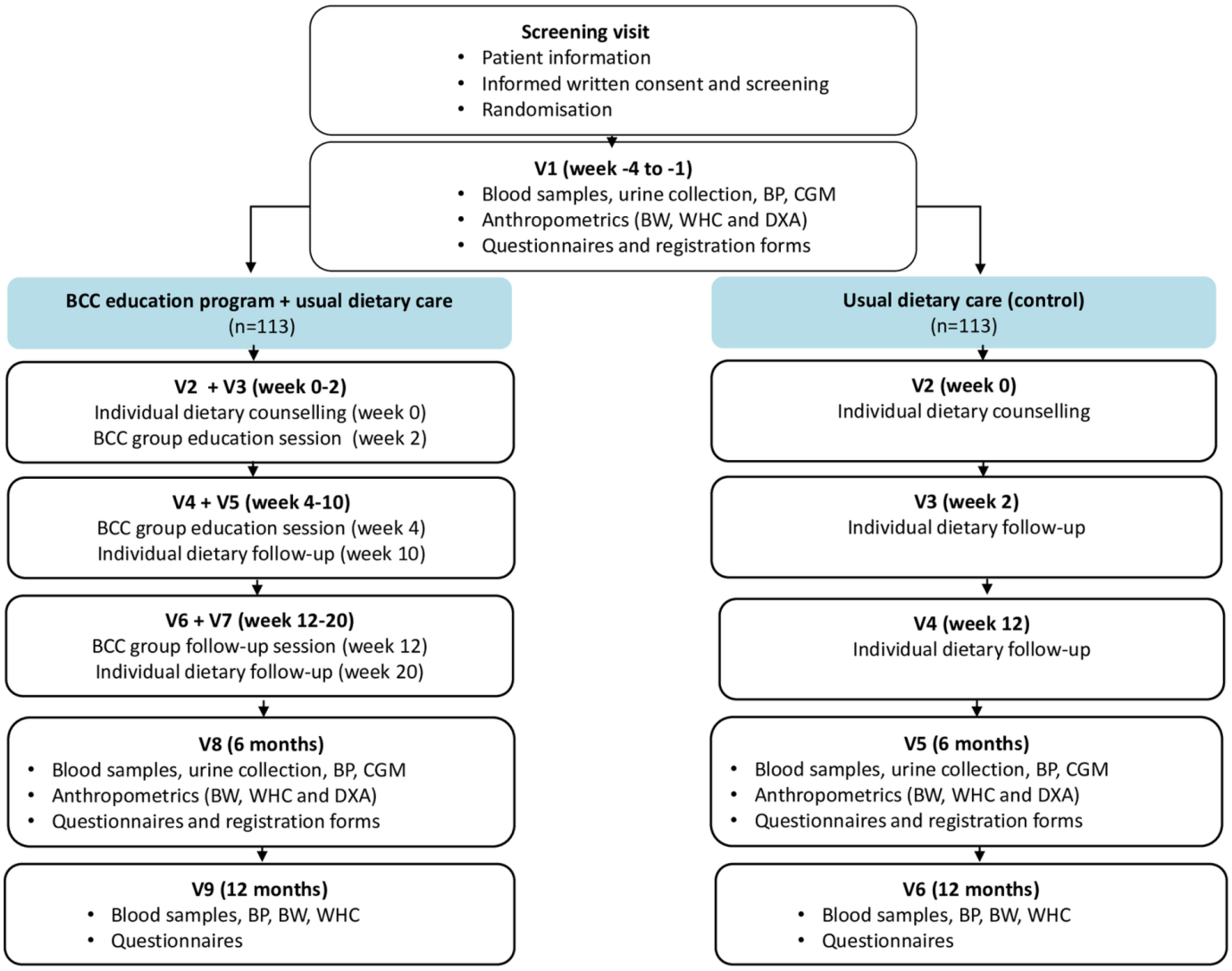


**Figure 2** Schematic diagram of the intervention. BCC, basic carbohydrate counting; BP, blood pressure; BW, body weight; CGM, continuous glucose monitoring; DXA, dual-energy X-ray absorptiometry; V, visit; WHC, waist-hip circumference.

a key challenge for most dietary interventions. Nutrition therapy is a fundamental part of diabetes self-management education and support to help empower and support people in managing their diabetes to improve glycaemic control.[2] This may be accomplished by including skills training and social support for maintaining dietary changes. Evidence suggest that a hands-on, learning-by-doing approach (problem-based and experience-based patient education) can support the development of food skills in general and improve diet quality in particular.[26] Adding group-based dietary approaches to individual lifestyle counselling has also been found to improve dietary habits.[27] Similarly, adding diabetes self-management approaches to the diabetes education has led to lower dropout rates, increased self-efficacy and improved HbA1c in people with T2D.[28] One study also found that perceived competence in managing diabetes as predicted by the degree to which people experienced the healthcare climate to be autonomy supportive and the perceived competence predicted HbA1c.[29]

The sparse scientific knowledge about the effect of group approaches with practiced-focused nutrition education and the BCC concept underlines the need for investigating and evaluating this in a practice-based group educational approach and examining the effect on improved metabolic control in people with T2D.

## AIM

The aim is to examine the effectiveness of a group-based dietitian-led practise-focused educational approach for dietary self-management compared with the standard nutrition education on glycaemic control in people with T2D.

## Methods and analysis

### Study design

The study is as a randomised controlled intervention trial with a parallel-group design (figure 1).

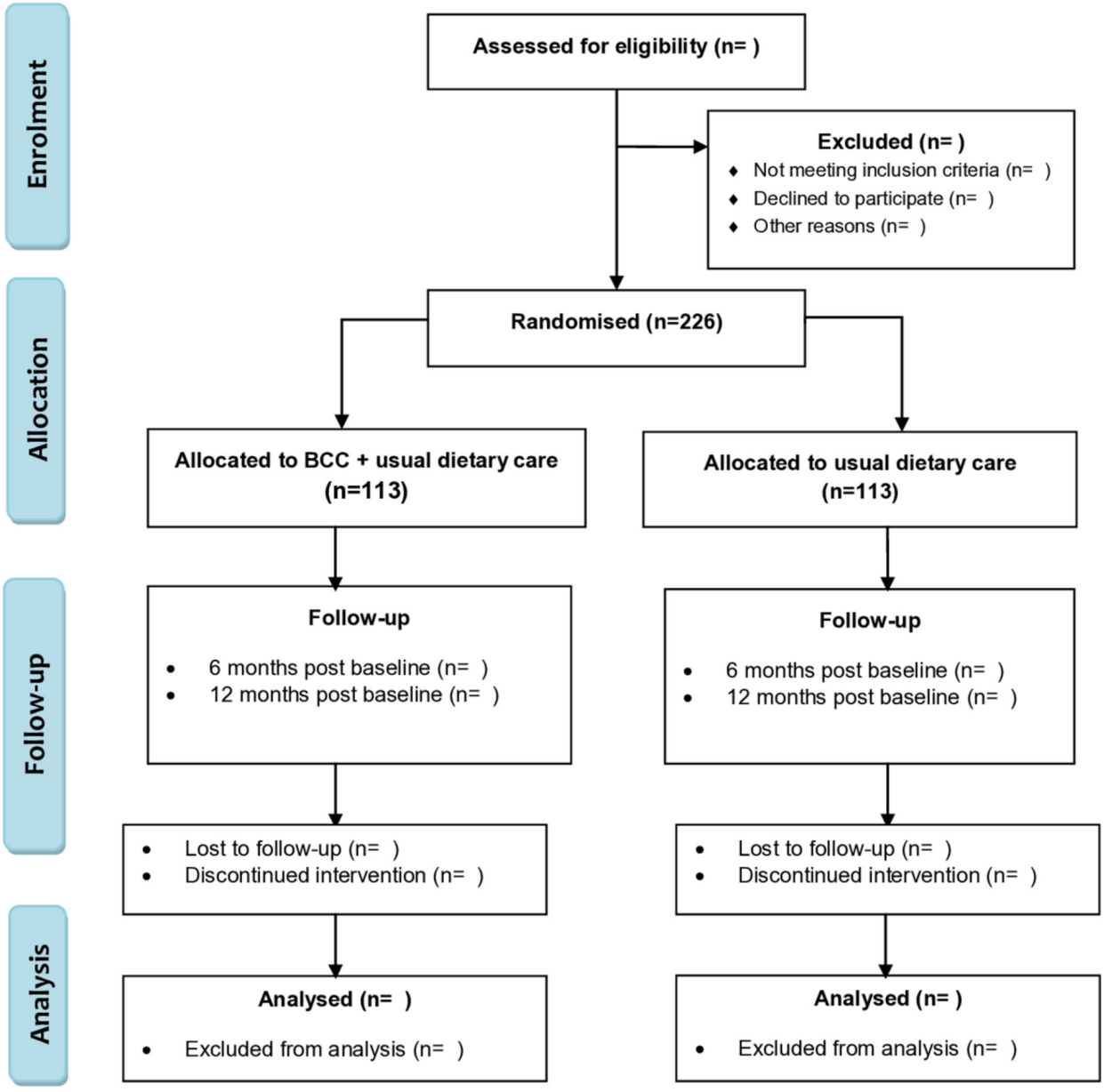


**Figure 3** Study flow diagram. The planned flow of participants through the stages of the study. BCC, basic carbohydrate counting.

For each participant, the study duration is 12 months and includes up to nine visits at the study site (figure 2). All participants will be instructed to maintain their habitual lifestyle in all other aspects than their diet, for example, keeping the same level of physical activity as habitually during the study period. All participants will be instructed to follow their regular diabetes care in the hospital, which usually includes 4 yearly visits with a diabetologist (endocrinologist) and 1 yearly consultation with a diabetes nurse. Participants will be instructed not to receive any further dietary education during the study period. Close relatives can participate in the dietary education in both study groups if the participant needs support to manage dietary changes.

The study flow is presented in figure 3. The study follows the guidelines of Standard Protocol Items for Randomised Trials.

### Setting

The study will be carried out at the outpatient clinic at Steno Diabetes Centre Copenhagen (SDCC) in Gentofte, Denmark.

### Recruitment and consent

As a temporary supplementary treatment initiative, SDCC offers courses in BCC for people with T2D treated at SDCC. Participants for the current study will be recruited among people signing up for these courses or people directly referred to one of the courses or the study by a healthcare professional (diabetologist, diabetes nurse or dietitian) from SDCC. A course administrator at SDCC will contact all interested or referred people by telephone and provide information about the study. In addition, potential study participants will be recruited through information on sdcc.dk and other electronic media or

patient-related networks. If the person is interested in the study, the person will receive the written information by mail or email. If interested in study participation, the study investigator/study personnel will schedule a personal meeting for oral information, offering the possibility of bringing a confidant. The person will be given time to discuss any questions and will be informed that he/she has at least 24 hours to decide on participation in the study. If the person decides to participate in the study, the person and the study investigator/study personnel will sign the written informed consent, and the investigator/study personnel will perform a screening. If all inclusion criteria are fulfilled and none of the exclusion criteria are met, the person will be included in the study and randomised to one of the groups. People who decline to participate or do not meet the inclusion criteria will continue their usual care in an outpatient diabetes clinic and will be offered to participate on a BCC course if they still wish to do so. Participants will be informed that participation is voluntary, and that they may withdraw their consent at any time.

### Inclusion criteria

People with T2D between 18 and 75 years with a diabetes duration of at least 12 months and baseline HbA1c of 53–97 mmol/mol treated with diet or any glucose-lowering medication are eligible for the study.

### Exclusion criteria

People are excluded if they have other types of diabetes than T2D, are practising carbohydrate counting as judged by the investigator, have a low daily intake of carbohydrates (defined as below 25 E% or 100 g/day), have participated in a BCC group programme within the last 2 years, use an automated bolus calculator, have gastroparesis, have uncontrolled medical issues affecting dietary intake as judged by the investigator or a medical expert. Women who are pregnant or breastfeeding or have plans of pregnancy within the study period are also excluded. Furthermore, people who are either participating in other clinical studies or are unable to understand the informed consent and the study procedures will be excluded.

### Randomisation

Participants eligible for inclusion in the study will be randomly allocated in a 1:1 ratio to one of the two groups (BCC or control) using a computer-generated randomisation in the software program *REDCap*. The randomisation is done by stratifying participants based on sex (male or female), BMI (<30 or ≥30 kg/m$^2$) and HbA1c (<70 or ≥70 mmol/mol) at baseline. The randomisation is done in blocks to ensure an equal number of participants in each group.

### Intervention group

Participants will receive education in BCC in addition to the standard outpatient nutrition education as described for the control group. The BCC programme consists of two sessions of 3 hours and a follow-up group session of 2 hours. The BCC programme uses trained dietitians following a planned curriculum which include experience-based learning with problem-solving exercises, hands-on activities, short theoretical presentations, discussions of motivational aspects and coping strategies. The BCC programme integrates peer modelling, skills development, goal setting, observational learning and social support into the programme content and activities. The training includes identifying carbohydrates in food, reading carbohydrate tables, calculating the carbohydrate content from food labels, tables and applications (app) for smartphones, and use of a personalised carbohydrate plan with guiding suggestions for daily intake of carbohydrates at meals based on personal dietary recordings including plasma glucose measurements. An app from the Danish Diabetes Association (*Diabetes og Kulhydrattælling*. The Danish Diabetes Association's app, Pragma soft A/S, available in Google Play and App Store 12/2014, Free) will be introduced to support estimation and calculation of carbohydrates.

### Control group

Participants randomised to the control group will receive current standard outpatient nutrition education in T2D. This includes individual guidance by a trained dietitian, with one initial 60-min dietary counselling session and two individual 30-min follow-up session. The individual guidance is based on the overall treatment goal and the defined personal dietary goals for behavioural change according to personal preferences. Dietary guidance includes topics such as healthy dietary habits and weight loss approaches for replacement of energy-dense foods with low energy-dense foods or special attention to carbohydrate quality (eg, glycaemic index and dietary fibre intake), fat quality and other dietary recommendations according to personal needs.

### Data collection

All study data will be collected at three visits with clinical examination (baseline, after 6 and 12 months). Data will be obtained from a self-reported questionnaire, electronic medical records and the physical examinations conducted by the study investigator or study personnel. All questionnaire data will be collected electronically using the software system *REDCap* according to local standards for research projects in the capital region of Denmark. In addition, all sources will be registered in this database. Data generated and stored for specific equipment (eg, dual-energy X-ray absorptiometry (DXA) data stored in the DXA scanner software database), electronic medical data (blood and urine measurements, glucose-lowering and lipid-lowering medicine), data from iPro2 a continuous glucose monitor (CMG) using software from Medtronic (Northridge, Carolina, USA) to download CGM measurements, dietary data on total energy and nutrients based calculations from the software system *Vitakost* will be added to the database in *REDCap* on an ongoing basis and at the end of study.

Table 1 Schematic overview of outcomes measured

| Week no. from start of intervention | -4 to -1 wk | 3 mo | 6 mo | 12 mo |
|---|---|---|---|---|
| HbA1c | X | X | X | X |
| Plasma lipids | X | | X | X |
| Body weight | X | | X | X |
| Height | X | | | |
| Waist and hip circumference | X | | X | X |
| Blood pressure | X | | X | X |
| Blood samples, fasting | X | | X | X |
| Urine samples for 4 days* | X | | X | |
| Glucose variability (CGM) including PG diary for 6 days* | X | | X | |
| Body composition (DXA) | X | | X | |
| Prescribed lipid-lowering and glucose-lowering medication | X | | X | X |
| F: Dietary registration for 4 days* | X | | X | |
| Q: Diet-related quality of life | X | | X | X |
| Q: Perceived Competencies in Diabetes | X | | X | X |
| Q: Health-Care Climate | X | | X | |
| Q: Carbohydrate estimation accuracy | X | | X | X |
| Q: Mathematical literacy | X | | X | X |
| Q: Demographic data | X | | | |
| Q: Physical activity | X | | X | X |

*Measured in the days following the study visits.
CGM, continuous glucose monitoring; d, day; DXA, dual-energy X-ray absorptiometry; F, forms; mo, months; PG, plasma glucose; Q, questionnaire; wk, weeks.

The primary outcome is the difference in mean HbA1c or mean amplitude of glycaemic excursions (MAGE) from baseline to end of the intervention (6 months) between and within each of the two study groups (BCC and control). MAGE is used as a measure of glycaemic variability to capture mealtime-related glucose excursions. MAGE has been associated with coronary artery disease independent of HbA1c.[30 31]

A schematic overview of outcomes measurements is presented in table 1.

Secondary outcomes are listed below:

*Clinical parameters*: Body weight, body composition (measured by DXA), waist and hip circumference, blood pressure, type and dose of prescribed glucose-lowering and lipid lowering medication, other parameters of plasma glucose variability including % of time in range (3.9–10.0 mmol/L), % time spent in hypoglycaemia (<3.9 mmol/L), % time spent in hyperglycaemia (>10.0 mmol/L) and SD of mean plasma glucose assessed from CGM measurements. Percentages of time in ranges (target, hypoglycaemia and hyperglycaemia) according to the described thresholds have been recommended by a large expert group in an international consensus report on the use of CGM.[32]

*Blood and urine samples:* HbA1c (after 12 weeks and 12 months), low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, very-low-density lipoprotein cholesterol, total cholesterol, free fatty acids and triglycerides, alanine aminotransferase, urine albumin/creatinine ratio and urinary biomarkers based on three daily midstream urine spots collected for 4 days.

*Patient-reported outcomes:* Diet-related quality of life, perceived competencies in diabetes, healthcare climate, carbohydrate estimation accuracy, mathematical literacy skills, physical activity and demographic questions. The six questionnaires used are:

*Diabetes Diet-Related Quality of Life (DDRQOL) questionnaire:* The DDRQOL is a 31-item scale which has been validated in people with diabetes.[33] The scale is designed to determine patient satisfaction with the diet, the degree of daily life and social life limitations due to dietary changes, and the impact of food insecurity on dietary adherence and self-management due to limited financial resources. A forward translation and cultural adaption of the DDRQOL questionnaire was done by a Japanese-Danish interpreter with a background as a clinical dietitian and an expert panel of six clinical dietitians working with diabetes. This was followed by a pilot testing by 10 people with diabetes.

*Perceived Competencies in Diabetes Scale (PCS)*: The PCS is a validated scale[34] which includes four items that reflect participants' feelings of competence about engaging in a healthier behaviour and participating in a nutritional education programme. Forward and backward linguistic translation from English to Danish has been done according to standard procedures in 2001 under the guidance of Professor Vibeke Zoffmann.

*Healthcare Climate Questionnaire (HCCQ)*: The HCCQ chosen in this study is a 5-item short form of the originally validated 15-item measure that assesses people's perceptions of the degree to which dieticians are autonomy supportive versus controlling in providing dietary treatment.

*Carbohydrate Photographic Questionnaire (CPQ)*: The CPQ is an electronic questionnaire assessing skills in correct estimation of portion sizes of 11 commonly eaten high-carbohydrate foods. The CPQ has been developed and validated against real food in 87 people with diabetes (Schouw N, Skouboe AG, Bruun JM, Ewers B. Validation Data Based on a Web-BasedPhotographic Questionnaire for Assessment of Skills in Estimating CarbohydratePortion Sizes in Adults with Type 1 Diabetes. Data-in-Brief. *J Clin Nutr Food Sci.* 2019; 2:1:54-56).

*Mathematical Literacy Questionnaire*: A 10-item test with modified questions from the nutrition domain of the *Diabetes Numeracy Test* (DNT)[35] was designed and feasibility tested to investigate mathematical literacy including

numeracy skills (addition, subtraction, division and multiplication) which are essential for understanding numbers and applying mathematical skills in daily life, for example, for calculating carbohydrates.

*International Physical Activity Questionnaire Short Form (IPAQ SF)*: The Danish version of the IPAQ SF[36] will be used to assess changes in level of physical activity during the study period.

Self-reported demographic questions include level of education, occupation, marital status, household composition and yearly income.

*Dietary data:* Four days of weighed dietary food records collected at baseline and 6 months after baseline. Dietary records will be calculated using the software system *Vitakost* (Vitakost Aps, Kolding) where nutrient and energy calculations are based on the Danish national food database. The dietary food records are used to estimate total energy intake (kJ/day), intake of carbohydrates, protein and fat (g/day and g/meal), added sugar (g/day) and total dietary fibre intake (g/day).

*Baseline data (from the electronic medical record)*: Type of diabetes, gender, age, smoking status, medical conditions, total number of visits at a diabetologist and diabetes nurse and dietician during the study period.

### Data analysis plan

The trial in ongoing. The recruitment started in October 2018 and is expected to be completed by October 2021.

### Sample size calculation

A power calculation was conducted based on the primary outcome measures HbA1c and MAGE. Allowing for an estimated dropout rate of 30% and subgroup analyses, the sample size was planned to include a total of 226 people in the study (113 in each arm). This was based on a sample size calculation which suggested that including 87 participants in each of the study groups would give 80% power to detect a difference in change in HbA1c of 3.0 mmol/mol between the BCC group and the control group with a 5% significance level using a two-sided test and an estimated SD of 7 mmol/mol. The used SD and dropout rate were based on previous BCC courses at SDCC where mean changes and SD of HbA1c after 6 months were calculated based on completers with T2D. MAGE has only been used as an outcome measure of glucose variability in a few randomised controlled dietary intervention studies of people with diabetes,[37 38] showing differences in changes in MAGE up to 4.8 mmol/L (SD 1.0) after a 12-week carbohydrate counting intervention,[37] but is regularly used in other clinical studies evaluating glucose variability. By including 113 participants in each study group, we will have a power of 80% (alpha level of 0.05) in a two-sided test to detect a difference in the change in MAGE during the intervention period (6 months) of ≥0.30 mmol/L (SD 0.7 mmol/L) between the two study groups.

### Statistical methods

Analysis and reporting of the study results will follow the CONSORT (Consolidated Standards of Reporting Trials) guidelines for reporting parallel group randomised trials.[39] Results will be presented as means (SD) for normally distributed variables and as medians (IQR) for non-normally distributed variables.

Paired samples t-test will be used to compare baseline data between and within the two study groups for normal data and Wilcoxon signed-rank test for non-normal data. Mixed-effect models will be used to test differences in outcomes from baseline to follow-up to take repeated measurements into account. If model assumptions cannot be met even after logarithmic transformation, non-parametric tests will be used. Examinations of the relevant diagnostic plots, including QQ-plots, will be used to evaluate normality of the residuals.

The baseline demographics as well as clinical and diabetes-related characteristics of the intervention and the control groups will be presented and compared. The average changes between baseline and 6 months, and 12 months in primary and secondary outcomes will be calculated for each of the groups. Intention-to-treat (ITT) analysis will be performed as the primary analysis on all primary and secondary outcomes after the last participant has ended participation. Missing values will be handled with a last observation carried forward approach for ITT analysis with the use of the multiple imputation approach in a sensitivity analysis. Per-protocol analysis will only be performed in case of sensitivity testing. Metabolic patterns will be tested with multivariate statistics. Adjustment for relevant confounders will be performed including adjustment for the stratified variables. Heterogeneity in responsiveness to the interventions will be tested by dividing each intervention group into smaller groups based on data distribution (medians) or clinically meaningful cut-points. Two-sided tests will be used. P values of <0.05 are considered significant. The statistical programs SPSS version 22 and SAS 7.1 will be used for data analysis.

### Patient and public involvement

People with T2D were involved in developing the educational content of the programme in BCC. People with T2D were not involved in setting the research questions or the outcome measures, nor were they involved in developing the study design. Information may be disseminated to the public via any media coverage of study findings.

## ETHICS AND DISSEMINATION

The study will be conducted in accordance with the ethical principles in the Declaration of Helsinki and to the regulations for Good Clinical Practice to the extent that this is relevant for non-medical studies. The study has been approved by the Ethics Committee of the Capital Region, Copenhagen (#H-18014918), has been approved for data storage by the Danish Data Protection Agency (journal no. VD-2018–233, I-suite no 6474) and has been registered at ClinicalTrials.gov (NCT03623139).

All health-related matters and sensitive personal data will be handled in accordance with the Danish 'Act on Processing of Personal Data'. All health-related matters and sensitive personal data (blood test results and so on) will be depersonalised. All participants will be given a study number referring to their personal information, which will be stored securely and separately. Data will be stored in coded form for 10 years after the last participant has attended the last visit, after which the data will be fully anonymised.

Data are owned by the investigators who are responsible for publishing the results. Positive and negative as well as inconclusive study results will be published by the investigators in international peer-reviewed journals, and all co-authors must comply with the Vancouver rules. BE will be responsible for writing the first draft of the manuscript based on the main study results as a first author under the guidance of TV and JMB. The study results will be presented at relevant national and international scientific conferences and meetings and will be published in international peer-reviewed scientific journals.

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**Contributors** BE conceived the original idea for this trial, planned the study design, performed the sample size calculations and wrote the first draft of the protocol manuscript. TV and JMB provided valuable input regarding trial design, planning and analytical considerations, and edited the first draft of the protocol manuscript. All authors approved the final version of the clinical trial protocol. BE is the principle investigator and is responsible for correspondence with all authorities regarding the study and is responsible for the data collection (recruitment, screening and clinical study examinations), overall monitoring the trial and for conducting the statistical analyses. TV and JMB are supervisors and coinvestigators of this trial. Should any safety concerns arise during the conduct of the study, these will be brought to the attention of TV and JMB by BE and will be carefully reviewed.

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**Competing interests** None declared.

**Patient consent for publication** Not required.

**Provenance and peer review** Not commissioned; externally peer reviewed.



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