Effectiveness of A person-centered and Culturally sensitive Course of Treatment in individuals with type 2 diabetes and non-Western backgrounds (the ACCT2 study): A pragmatic random-ized controlled trial protocol

Natasja Bjerre, Lene Christensen, Christina Hoeiberg, Cecilie Ottoson, Mie Klarskov Jensen, Nanna Marie Kildsig, Trine Kjeldgaard Moeller, Anne-Ditte Termannsen, Bettina Ewers, Britt Hollender-Schou, Rikke Molin, Ulla Bjerre-Christensen, Solveig May-Britt Jansen, Kamran Akram

Submitted to: JMIR Research Protocols
on: October 09, 2024

Table of Contents

Effectiveness of A person-centered and Culturally sensitive Course of Treatment in individuals with type 2 diabetes and non-Western backgrounds (the ACCT2 study): A pragmatic random-ized controlled trial protocol

Natasja Bjerre[1] PhD; Lene Christensen[2] MSc; Christina Hoeiberg[1] MSc; Cecilie Ottoson[1] MSc; Mie Klarskov Jensen[1] MSc; Nanna Marie Kildsig[1] MSc; Trine Kjeldgaard Moeller[1] MSc; Anne-Ditte Termannsen[1] MSc; Bettina Ewers[1] PhD; Britt Hollender-Schou[1] BA; Rikke Molin[1] MSc; Ulla Bjerre-Christensen[1] PhD; Solveig May-Britt Jansen[1] BA; Kamran Akram[1] PhD

[1]Copenhagen University Hospital - Steno Diabetes Center Copenhagen Herlev DK
[2]Municipality of Copenhagen Centre for Diabetes Copenhagen DK

Corresponding Author:
Natasja Bjerre PhD
Copenhagen University Hospital - Steno Diabetes Center Copenhagen
Borgmester Ib Juuls Vej 83
Herlev
DK

Abstract

Background: Individuals with non-Western backgrounds consistently exhibit a higher risk of type 2 diabetes (T2D) compared with ethnic Danes. Factors such as health behavior, limited healthcare access, and social determinants of health often contribute to this disparity. Culturally sensitive interventions are crucial, yet effective interventions for managing T2D in non-Western populations re-main limited.

Objective: This study examines the effect of a one-year person-centered and culturally sensitive intervention on improving glycemic control (HbA1c) among individuals with T2D and non-Western backgrounds. The secondary objectives are to improve diabetes management and overall well-being.

Methods: The present study is designed as a two-arm randomized controlled trial. 96 women and men with T2D (HbA1c?53 mmol/mol) speaking either Arabic, Turkish, or Urdu as their native language will be randomized for one year to an intervention group (person-centered and culturally sensitive course of treatment) or a control group (usual care) in a 1:1 ratio in Denmark. Assessments are scheduled at baseline and one year. The primary outcome is HbA1c while lipids, blood pressure, and patient-reported outcomes including well-being, diabetes management, health literacy, and use of and adherence to diabetes medication are secondary outcomes. Feasibility and satisfaction are evaluated using interviews. The study is approved by the Ethics Committee of the Capital Region of Denmark (H-23042245).

Results: A 5.0 mmol/mol (0.5%-DCCT) change in HbA1c is the minimally important difference, requiring 88 participants. To allow for uncertainties and dropouts, the total was increased to 96. As of October 2024, 70 participants have been recruited, with recruitment ongoing until March 2025. Data collection will continue until December 2025, with the first results expected by March 2026.

Conclusions: This study will contribute to the limited knowledge regarding the effects of person-centered and culturally sensitive treatment approaches for T2D in individuals with a non-Western background. The study employs a robust methodological design and will present an alternative avenue for man-aging T2D and improving overall well-being. The study offers valuable insights into the experiences of participants and healthcare professionals, including potential obstacles and strategies for implementation in outpatient clinics. Clinical Trial: Clinicaltrials.gov NCT06147245.

(JMIR Preprints 09/10/2024:67319)
DOI: https://doi.org/10.2196/preprints.67319

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

Please make my preprint PDF available to anyone at any time (recommended).

✓ **Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all u**

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain v

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="http

Original Manuscript

Effectiveness of A person-centered and Culturally sensitive Course of Treatment in individuals with type 2 diabetes and non-Western backgrounds (the ACCT2 study): A pragmatic randomized controlled trial protocol

Natasja Bjerre[1], Lene Christensen[2], Christina Høiberg Juul Nielsen[1], Cecilie Ottosson[1], Mie Klarskov Jensen[1], Nanna Marie Kildsig[1], Trine Kjeldgaard Møller[1], Anne-Ditte Termannsen[1], Bettina Ewers[1], Britt Hollender-Schou[1], Rikke Molin[1], Ulla Bjerre-Christensen[1], Solveig May-Britt Jansen[1], and Kamran Akram[1]

1. Copenhagen University Hospital - Steno Diabetes Center Copenhagen, Borgmester Ib Juuls Vej 83, 2730 Herlev, Denmark
2. Centre for Diabetes, Municipality of Copenhagen, 1620 Copenhagen, Denmark

Corresponding author:

Natasja Bjerre

Copenhagen University Hospital - Steno Diabetes Center Copenhagen,

Borgmester Ib Juuls Vej 83, 2730 Herlev, Denmark.

natasja.bjerre.martinsen@regionh.dk

Abstract

Introduction: Individuals with non-Western backgrounds consistently exhibit a higher risk of type 2 diabetes (T2D) compared with ethnic Danes. Factors such as health behavior, limited healthcare access, and social determinants of health often contribute to this disparity. Culturally sensitive interventions are crucial, yet effective interventions for managing T2D in non-Western populations remain limited.

Objectives: This study examines the effect of a one-year person-centered and culturally sensitive intervention on improving glycemic control (HbA1c) among individuals with T2D and non-Western backgrounds. The secondary objectives are to improve diabetes management and overall well-being.

Methods: The present study is designed as a two-arm randomized controlled trial. 96 women and men with T2D (HbA1c≥53 mmol/mol) speaking either Arabic, Turkish, or Urdu as their native language will be randomized for one year to an intervention group (person-centered and culturally sensitive course of treatment) or a control group (usual care) in a 1:1 ratio in Denmark. Assessments are scheduled at baseline and one year. The primary outcome is HbA1c while lipids, blood pressure, and patient-reported outcomes including well-being, diabetes management, health literacy, and use of and adherence to diabetes medication are secondary outcomes. Feasibility and satisfaction are evaluated using interviews. The study is approved by the Ethics Committee of the Capital Region of Denmark (H-23042245).

Results: A 5.0 mmol/mol (0.5%-DCCT) change in HbA1c is the minimally important difference, requiring 88 participants. To allow for uncertainties and dropouts, the total was increased to 96. As of October 2024, 70 participants have been recruited. Recruitment is ongoing until March 2025. Data collection will continue until December 2025, with the first results expected by March 2026.

Discussion: This study will contribute to the limited knowledge regarding the effects of person-centered and culturally sensitive treatment approaches for T2D in individuals with a non-Western

background. The study employs a robust methodological design and will present an alternative avenue for managing T2D and improving overall well-being. The study offers valuable insights into the experiences of participants and healthcare professionals, including potential obstacles and strategies for implementation in outpatient clinics.

Trial registration: Clinicaltrials.gov NCT06147245.

Keywords Immigrants; Migrants; Diabetes management; Ethnic minorities; Trial; Well-being; Public Health

Introduction

European studies have steadily indicated that immigrant groups born in non-Western countries are at a significantly higher risk of developing type 2 diabetes (T2D) when compared to the majority population [1-3]. In Denmark, immigrants from the Middle East exhibit a T2D incidence rate of 2.5 times higher than native Danes [4, 5] and increased risks of complications [2, 3, 6]. To this, individuals with non-Danish ethnic backgrounds have poorer glycemic control [7, 8], and a lower proportion receive diabetes monitoring and care within recommended intervals outlined in guidelines [7].

Individuals with non-Western backgrounds experience difficulties in managing their diabetes effectively. This is due to factors such as health behavior, access to healthcare, and social determinants as well as low health literacy, cultural norms, and language barriers that hinder access to and comprehension of information and treatment of diabetes [4, 9-13]. Other factors include misconceptions about diabetes, inadequate adherence to medication regimens, lifestyle factors, limited social support, and lack of cultural competencies among healthcare professionals (HCPs) [1, 13-16]. This emphasizes a need for culturally appropriate interventions to improve access to healthcare and support, but existing interventions often overlook these cultural considerations [17, 18].

Resnicow and Braithwaite [17] define cultural sensitivity as incorporating cultural characteristics, experiences, norms, values, behavioral patterns, beliefs, and environmental and social forces of a target population to design, deliver, and evaluate interventions. Despite interventions tailored for cultural minority groups that have shown positive effects on HbA1c [19, 20], limited knowledge exists on strategies for individuals with non-Western backgrounds in outpatient clinics [21-23]. This study aims to explore the effectiveness of a person-centered, culturally sensitive

intervention for individuals with T2D speaking Urdu, Arabic, or Turkish to improve glycemic control as well as diabetes management, health literacy, and overall well-being by utilizing a pragmatic randomized controlled trial (RCT) design [24, 25].

Methods

Objectives

The overall objective of this study is to examine the effect of a one-year person-centered and culturally sensitive intervention on alterations in glycemic control (HbA1c) among individuals with T2D and a non-Western background. Secondary objectives describe changes in cardiometabolic risk factors and patient-reported outcomes including well-being, diabetes management, health literacy, and adherence to diabetes medication.

Hypotheses

We hypothesize that a one-year person-centered and culturally sensitive intervention added to standard care will be superior for reducing HbA1c in individuals with T2D and non-Western backgrounds. Superiority will be claimed if the baseline corrected difference between the two groups is equal to, or surpass, the minimal important difference (5 mmol/mol) in favor of the intervention group, and if the P-value is <0.05.

Participants

Women and men, ≤75 years of age, with T2D whose native language is Urdu, Arabic, or Turkish will be considered eligible based on the specified inclusion and exclusion criteria.

Eligibility criteria

Inclusion and exclusion criteria are listed in Table 1.

Table 1. Inclusion and exclusion criteria

Inclusion criteria
Men and women speaking either Urdu, Arabic, or Turkish as their native language
Already in treatment at the outpatient T2D clinic at SDCC, Denmark
Having suboptimal glycemic control (HbA1c≥53 mmol/mol)
Individual treatment goal for HbA1c has not been achieved (in two consecutive measurements)
Exclusion criteria
Being over the age of 75 years at inclusion
Residing part-time in Denmark
Having disabilities inhibiting physical attendance
Having severe mental disorders
Markers of kidney function - estimated glomerular filtration rate (eGFR) below 30
General condition contraindicates continuing the study judged by the investigator or medical expert
Withdrawal of the informed consent
Other reasons determined by the investigator

Recruitment, screening, and consent

We plan to recruit 96 individuals with T2D who have a non-Western background from the outpatient T2D clinic at SDCC. During the latest visit at the usual course of treatment at SDCC, potential participants will receive a brief introduction to the ACCT2 study. If interested, potential participants will be met by a project worker who will provide an oral introduction and if interested, play an audio recording containing study information in Urdu, Arabic, or Turkish, depending on the participant's preference. All study participants will receive written study information in their native language. The information will be given in quiet surroundings at SDCC. The ability to bring one companion is allowed.

The project worker will have a written informed consent ready to sign and be available to address any questions. Participants may have at least 24 hours to consider participation. A participant folder containing the written study information and the written informed consent will be handed to

the potential participant, and a project worker will follow up with a phone call within a week. If the participant wishes to take part in the study, the written informed consent must be signed and forwarded to the project worker. By October 10th, 2024, 70 out of 96 participants were recruited. The recruitment process will continue until March 2025.

To ensure accessibility, all written information is translated into Urdu, Arabic, or Turkish by international standards [26]. Study participants are informed that they can always withdraw their commitment to participate. The individual participant's right not to know their data will be respected.

Randomization

After obtaining written informed consent, participants will be randomized to either the intervention or control group in a 1:1 ratio using block randomization (**Fig. 1**). Block randomization is used to secure an equal distribution of participants in the two groups, if the study for unexpected reasons should be terminated before inclusion of all participants, and further to account for potential seasonal confounding.

(Insert **Fig. 1.** Randomization)

Randomization will be performed by the investigator before the first visit using the randomization module in the software REDCap. The randomization list is created by a researcher not involved in the trial, who will be the sole person to access it throughout the trial. Should this person be unable to continue this function, a new person not involved in the trial will be appointed to store and access the sequence. Participants are recruited continuously.

Patient and public involvement

The intervention was developed in collaboration with the target group and HCPs from the outpatient

T2D clinic at SDCC. Overall, the ACCT2 study consists of three phases; 1) Needs assessment, 2) Intervention development and element testing, and 3) RCT.

Phase 1 (needs assessment) included interviews and workshops with individuals with T2D and non-Western backgrounds (n=18) and two workshops and individual interviews with HCPs (nurses, physicians, and dieticians) from the SDCC outpatient clinic (n=33). The findings from the needs assessment suggested adjustments in the standard course of treatment by focusing on 1) Extended time in consultations, 2) Use of technology for diabetes monitoring, 3) Awareness of language barriers, 4) Meeting the same HCP, 5) Use of accurate communication and dialogue tools, and 6) a need for increased levels of health literacy. A culturally sensitive approach of HCPs was also considered vital to increase understanding and engagement in diabetes management among the target group while emphasizing a whole-person approach rooted in individual everyday life.

Based on the results from the needs assessment and evidence from existing literature, a one-year intervention was designed to target the target group's needs. Visits in the intervention design were tested on three individuals speaking Urdu, Arabic, and Turkish as their native to test if the flow, content, and overall design match their needs. Tools and methods included in the intervention are partly inspired by the research-based diabetes self-management education, CUlturally Sensitive TOols and Methods for individuals with non-Western backgrounds (CUSTOM) [27, 28]. The RCT design is described in this study (phase 3). The SPIRIT reporting guidelines were applied [29].

RCT study design

The ACCT2 study is a one-year pragmatic randomized controlled parallel group open-label effectiveness trial including 96 individuals with T2D and non-Western backgrounds (**Fig. 2**). The intervention consists of six visits at SDCC. All visits are based on specific values and competencies of HCPs which are important in the organization, implementation, and completion of the intervention.

Values of the intervention

The intervention is based on a *person-centered approach* [30, 31]. A person-centered approach is characterized as a collaborative process between the participant and the HCP, wherein the participant's priorities, preferences, and needs are incorporated into decisions regarding their diabetes treatment. It focuses on understanding the patient's capacity and pace for change [30, 31], where cultural competence among HCPs is crucial. This includes adapting attitudes to individual needs and recognizing the implications of emotional, cultural, social, and psychological consequences [17]. Striking a balance, HCPs must acknowledge potential cultural differences without letting them dominate encounters. The intervention's visits consider individual circumstances, resources, expectations, and prerequisites for changes. Additionally, it aligns with the *Empowerment* treatment philosophy, where well-informed participants actively engage in diabetes management. The HCP's role is to support the participant in making decisions, achieving goals, and overcoming obstacles [32].

Study visits

The visits will be run by the same diabetes nurse and endocrinologist under the responsibility of the investigator. Visits with dieticians will be arranged if requested by participants (up to 60 min per visit). For logistical reasons, windows are allowed for the visits (± 30 days). A detailed visit flow is presented in Figure 2.

(Insert **Fig 2.** Visit flow)

Visit 1: The first visit, lasting 60 minutes, will involve meeting with a diabetes nurse. During this visit, the focus will be on introducing the participant to the course of treatment and to a continuous glucose monitor (CGM) (Freestyle Libre 2 sensor), which the participant will use for the following

two weeks. This will enable the participant to gain insight into personal glucose levels. Additionally, the nurse will provide information about T2D and its treatment and discuss everyday challenges and topics relevant to the participant.

Visit 2: The second visit, lasting 60 minutes, will involve the same diabetes nurse. The main aim is to talk about pattern identification obtained from the CGM sensor for the past two weeks to enhance knowledge of lifestyle factors contributing to stable or fluctuating glucose levels. The nurse will engage in a dialogue about the challenges participants face in everyday life. A new sensor will be applied to the participant for the upcoming two-week period.

Visit 3: During the third visit, lasting 45 minutes, the participant will meet with an endocrinologist. Patterns derived from the CGM sensor will be discussed to enhance participants' comprehension of unique glucose levels and determine if any changes or solutions discussed during the second visit have been implemented and proven effective in promoting more stable glucose levels. The endocrinologist will evaluate patterns of variation, e.g., focus on hypoglycemia, and make necessary adjustments in pharmacological treatment. The treatment plan will be negotiated with the participant providing information on the rationale for the change in treatment regimen and potential benefits and risks. Participants will also be guided to continue self-monitoring blood glucose according to individual plans.

Visit 4: During the fourth visit (2 x 30 minutes), the participant will meet with the same endocrinologist and diabetes nurse. The main purpose is to evaluate and follow up on the participant's everyday life with diabetes, medication usage, and individual questions/needs. The aim is to support the participant's positive experience with the treatment and lifestyle changes, address misperceptions, and reinforce the information provided. If necessary, the endocrinologist will adjust

the medication regimen.

Visit 5: During the fifth visit, lasting 30 minutes, the participant will meet with the same endocrinologist. The main purpose is to evaluate and follow up on the participant's medication usage and individual questions/needs. The aim is again to support the participant's positive experience with the treatment and lifestyle changes, address misperceptions, and reinforce the information provided. If necessary, the endocrinologist will adjust the medication regimen.

Visit 6: During the sixth visit (20 minutes + 30 minutes), the participant will again meet the same endocrinologist and diabetes nurse. The primary aim is to provide a comprehensive overview of the treatment progress and patterns obtained from the CGM sensor for the past two weeks. The participants will be instructed to apply the sensor at home two weeks before the last visit. If the participants prefer, they are booked for a short visit at SDCC with the diabetes nurse to apply the sensor. The last visit will serve as an opportunity to ask any questions, clarify doubts, or express any specific needs they may have.

Besides the six visits, participants will receive links to four short videos about T2D developed by the *Danish Diabetes Knowledge Center* at SDCC. The videos are translated into Urdu, Arabic, or Turkish and include knowledge on 1) What T2D is, 2) Complications associated with T2D, 3) Exercise and diabetes, and 4) Carbohydrates and diabetes (Videos can be found at: https://videncenterfordiabetes.dk/om-videncenter-for-diabetes/materialer/videoer). Participants in the intervention group may also have visits with e.g., a psychologist and podiatrist as a part of their usual course of treatment.

Control group

Participants in the control group will follow the standard course of treatment with regular visits with a physician, often an endocrinologist, and a nurse at the T2D outpatient clinic at SDCC 3-4 times/year (**Fig. 3**). These visits can both be in-person or virtual depending on the participant and HCPs preferences. The standard course of treatment also often includes visits with a podiatrist and eye screening and may include visits with a dietician and psychologist.

(Insert **Fig 3.** Standard course of treatment (1 year))

Outcomes

Primary outcome

The primary outcome is changes in HbA_{1c} (mmol/mol) from baseline to end of intervention (one year).

Secondary outcomes

The secondary exploratory outcomes encompass a range of metabolic and behavioral factors that may be linked to the intervention. These involve changes from baseline to end of intervention (one year), including plasma lipids, markers of kidney function, hormones involved in glucose metabolism, blood pressure, resting heart rate, CGM (time-in-range, time-above-range, time-below-range), body weight, and use of diabetes medication (**Table 2**).

Table 2. Data collection

Visits	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**
Clinical assessments						
HbA1c	x			x	x	x
Plasma lipids	x					x
Blood pressure and resting heart rate	x		x	x	x	x
Hormones involved in glucose metabolism	x					x

CGM		x	x			x
Markers of kidney function	x					x
Albumin creatinine ratio	x					x
Body weight	x					x
Use of diabetes medication	x					x
Questionnaires						
Sociodemographic characteristics	x					
Diabetes distress (PAID-5 scale) [33]	x					x
Well-being (WHO-5) [34]	x					x
Health literacy questionnaire (HLQ) (3 items) [35]	x					x
Diabetes management (PRO scheme diabetes) [36]	x					x
Medicine adherence (MARS-5) [37]	x					x
Acceptability, retention, and satisfaction [38]						x
Interviews						
Individual interviews *(subgroup of participants)*				x		x
Interviews with HCPs delivering the intervention				x		x

Clinical assessments

Blood samples

Blood samples are, as part of the regular treatment protocol at the outpatient clinic in SDCC, routinely taken before visits. The participant must arrive at the SDCC laboratory at least 70 minutes before V1 and V6 for non-fasting blood sampling from the antecubital vein, and urine analysis.

Continuous Glucose Monitoring (CGM)

CGM is initiated using the authorized FreeStyle Libre 2 device. Participants will be provided with detailed information about the device during V1 and it will be applied for two weeks. The monitoring will be repeated at V2 and again two weeks before V6. FreeStyle Libre 2 allows individuals to monitor glucose levels without routine fingerstick blood glucose testing. It is a small sensor worn on the skin, which measures glucose levels in the interstitial fluid to display real-time glucose readings. With features like trend arrows and built-in memory for data storage, FreeStyle Libre 2 supports

diabetes management and provides insights into glucose patterns to inform decisions about medication, diet, and lifestyle.

Blood pressure and resting heart rate

Blood pressure and resting heart rate are measured using approved and calibrated equipment (Microlife BP A3 Plus, Switzerland) and taken with the participant in a sitting position after a minimum of 10 min of rest, not talking during the measurement. Measurements are repeated three times separated by two-minute breaks to prevent artificially elevated blood pressure resulting from an unfamiliar and potentially stressful environment. A mean value is calculated.

Height and body weight

Height is measured with the participant's heels, buttocks, and upper back remaining in contact with the wall. Results are noted to the nearest 0.1 cm. Body weight is measured to the nearest 0.1 kg with the participant wearing indoor clothes and no shoes.

Questionnaires

Participants will fill in a baseline questionnaire and a questionnaire at the end of the intervention (see **Table 2**). Questionnaires will be answered during the 70-minute waiting time between blood samples before V1 and V6. A project worker will be present to address technical questions. Questionnaires are translated into Urdu, Arabic, or Turkish following international standards [26]. The following measures will be assessed at baseline alone: marital status, cohabitation status, social network, educational level, and occupation. Participants' acceptance of intervention is only explored in the questionnaire at the end of the intervention.

Interviews

Interviews will be conducted by a qualitative researcher with a sub-group of participants in the intervention group after the last visit. Participants' experiences during the intervention will be explored to examine experiences with the one-year intervention, possible improvements, and important factors for successful implementation into the clinical setting. HCPs delivering the intervention will also be interviewed about acceptability and experiences with intervention delivery in the clinical context.

Measurement of adherence

Adherence to the intervention is determined by calculating the number or percentage of visits, during the intervention, in which participants actively engage in all six scheduled visits. *Per protocol* is defined as ≥80% adherence.

Statistical considerations

Sample size calculation

A 5.0 mmol/mol (0.5%-DCCT) difference in changes was defined as the minimally important difference for the primary outcome, HbA1c. This resulted in the total number of participants required to enter and complete this two-arm, parallel-design trial of 88 participants. The sample size was estimated based on a general linear model equivalent to a repeated measure mixed model with two time points (Proc GLM-power, SAS 9.4, SAS institute, NC, USA). The estimation was based on the following conditions/assumptions: an allocation ratio of 1:1, alpha = 0.05, beta = 0.1, a mean HbA1c of 70 mmol/mol, a standard deviation for HbA1c at each timepoint of 14 mmol/mol [39, 40], and a correlation between repeated measures of 0.8 [41]. The total number of participants was multiplied by 1.1 to account for potential uncertainties in the conditions used in the power calculation and to account for potential dropouts, resulting in 96 participants.

Data management

Data will be entered directly into electronic case report forms (CRFs) using REDCap, licensed by the Capital Region of Denmark, or saved electronically. All forms are filled out during (or immediately after) each visit. Errors and corrections are logged as provided by the REDCap interface. For CGM, source data will be registered in a web-based software (LibreView).

Statistical analysis

An intention-to-treat analysis, encompassing all randomized participants, will be conducted upon completion of the last participant's final visit. A per-protocol analysis will be carried out, including participants who demonstrate compliance throughout the intervention. Data will be presented using standard descriptive statistics, with means and standard deviations (SD) for normally distributed data and medians with interquartile ranges for data not conforming to normal distribution. Changes from baseline and distinctions in delta values between groups will be assessed utilizing linear mixed-effects models, considering the outcome as a function of group, time, and the interaction between group and time, and accounting for a participant-specific random intercept. The adequacy of assumptions regarding normality and homogeneity of variances will be verified through graphical methods and data will be log-transformed for analysis and subsequently back-transformed for presentation. In cases where model assumptions are not met even after logarithmic transformation, non-parametric statistical tests will be employed. Statistically significant findings will be determined with a significance level of $P < 0.05$ (two-tailed). To assess the potential impact of missing data on the primary outcome, a sensitivity analysis will be conducted, involving multiple imputations with missing data at follow-up, which will be included in the imputation process with the control group. Results will be presented as estimated mean in changes, accompanied by 95% confidence intervals (CIs) and relevant p-values.

Ethics

The study has been approved by the Ethics Committee of the Capital Region of Denmark (H-23042245) and the Research Legal Affairs of the Capital Region of Denmark (P-2023-14503). The study will be conducted following the Declaration of Helsinki, and it complies with the Danish Data Protection Agency and the General Data Protection Regulation. Adequate blinding of all personal data during data processing and publication will be ensured. The participants are covered by the Patient Compensation Association according to the Danish Act on the Right to Complain and Receive Compensation within the Health Service.

Risk of harm

All equipment used in the study meets the requirement for patient safety and has previously been used in research projects. Participants will have blood samples taken before visits (max. 18 ml). The total amount of blood collected during the entire study period is at the same level as during the standard course of treatment and is considered safe.

Participants will not have any study-specific clinical measurements taken besides three times two weeks of CGM measurement. During the sensor placement, participants may experience minor and brief discomfort. The sensor is generally well-tolerated, and only a few potential discomforts are associated with its use. Few may experience mild skin irritation or redness where the sensor is inserted. There may be a slight discomfort during the insertion process, although it is generally brief. In rare cases, an allergic reaction to the sensor adhesive or materials may occur, leading to more significant skin irritation. It is also worth noting that the sensor needs to be replaced twice, which involves removing the old sensor and applying a new one, which can cause minor discomfort. However, these discomforts are small and temporary. A rare complication is a superficial skin

infection obtained in connection with penetration of the skin. The risk of so-called superficial phlebitis is minimized by following hygiene standards including double cleansing of the skin with an alcohol swab and using sterile materials. Superficial phlebitis is not dangerous. Medication will be reviewed and adjusted according to current clinical guidelines. Participants can contact the physician and diabetes nurse or use the hotline at SDCC about medical issues, e.g., concerns related to medication use.

Dissemination

Appointed researchers affiliated with SDCC will be granted access to data. The principal investigator will facilitate direct access to source data and documents for regulatory inspection. Since we anticipate no adverse effects associated with the intervention, recording of harm or side effects will be conducted. Positive and negative study results and inconclusive findings will be presented at conferences and published in international peer-reviewed journals. All co-authors are expected to adhere to the guidelines of the International Committee of Medical Journal Editors, and no professional writers will be involved in the writing process.

Results

By October 2024, 70 participants had been successfully enrolled in the study, with the recruitment phase scheduled to continue until March 2025. Efforts are underway to reach the target number of participants, ensuring the study achieves its full sample size. After the recruitment phase concludes, data collection will proceed until December 2025, allowing for comprehensive data gathering. Once data is collected, the research team will begin the analysis process, with the first results anticipated to be available by March 2026.

Discussion

Comparison with prior results

Despite the existing gaps in the literature, it is well-established that the target group faces an elevated risk of T2D [1-3], often attributed to factors like health behavior, limited healthcare access, social determinants of health, low health literacy, cultural norms, and language barriers [4, 9-16]. Our study aims to build on this understanding by employing several robust methodologies. The utilization of a scientifically rigorous design, power calculation for sample size estimation, and a replicable intervention are among the strategies employed. A control group allows for a meaningful comparison to 'usual care,' enhancing the reliability of our findings. Additionally, administering the intervention through the same HCPs ensures continuity in care and familiarity for participants, which may reduce dropout rates. A distinctive feature of our approach is the systematic involvement of the target group and HCPs in the intervention's design. By incorporating their insights into their needs, barriers, and potential solutions, we aim to create an intervention that better addresses their challenges than previous research. This tailored approach could lead to improved diabetes management, enhanced well-being, and reduce obstacles that typically hinder care within this high-risk population.

Strengths and limitations

The interdisciplinary nature of our study, coupled with feasibility assessments, offers valuable insights into the experiences of both participants and HCPs, shedding light on potential barriers and effective strategies for implementing the intervention in outpatient clinics. However, it is important to acknowledge certain limitations. The one-year duration of the trial restricts the exploration of long-term effects. Additionally, the broad inclusion criteria, while facilitating a more representative study population, may introduce heterogeneity in some secondary outcomes. Lastly, the inherent challenge of blinding participants poses a potential for performance bias which we cannot eliminate from the study design.

Conclusions

The intervention design, tailored to address the needs of both the target group and HCPs, is poised to maximize its potential for acceptability within the target group, particularly should the outcomes prove positive. This study is expected to provide knowledge translatable to clinical settings, with the anticipated clinical impact extending to the future development and implementation of interventions adapted to preferences, needs, and satisfaction.

Acknowledgments

We are truly grateful to all healthcare professionals and patients for sharing their experiences and needs during interviews and workshops and would like to thank them. Moreover, we thank PhD, MD Martin Bæk Blond for helping with the sample size calculation. This study was financed by an internal grant provided by Steno Diabetes Center Copenhagen.

Authors' contributions

NB, LC, SMJ, CH, UBC, and KA conceptualized the study and designed the intervention. NB drafted and registered the study protocol with the Ethics Committee of the Capital Region of Denmark. CO and NB registered the study at ClinicalTrials.gov and elaborated the first draft of the paper. NB led a content validation of the study materials, involving both the project and steering group. All authors contributed to the design and validation of the contents of the study and critically reviewed the manuscript for significant intellectual content. The final manuscript was reviewed, read, and approved by all authors.

Conflict of interest

SDCC is a hospital providing health services for the public health care system. The Novo Nordisk Foundation partly funds the research project and SDCC through unrestricted grants but does not have

economic interests in the study. The Novo Nordisk Foundation does not influence 1) study design; 2) collection, analysis, and interpretation of data; 3) writing of the study report or any publication; and 4) decision to submit the paper for publication. The investigators employed at SDCC will not benefit economically from conducting the study.

Data sharing

Data sharing does not apply to this study as no datasets were generated or analyzed.

Abbreviations

ACCT2: A person-centered and culturally sensitive course of treatment

CGM: Continuous glucose monitoring

HCPs: Healthcare professionals

RCT: Randomized controlled trial

T2D: Type 2 diabetes

SDCC: Steno Diabetes Center Copenhagen

References

1. Jervelund, S.S., et al., *Morbidity, self-perceived health and mortality among non-western immigrants and their descendants in Denmark in a life phase perspective.* Journal of Immigrant and Minority Health, 2017. **19**: p. 448-476.
2. Meeks, K.A., et al., *Disparities in type 2 diabetes prevalence among ethnic minority groups resident in Europe: a systematic review and meta-analysis.* Internal and emergency medicine, 2016. **11**: p. 327-340.
3. Ujcic-Voortman, J.K., et al., *Diabetes prevalence and risk factors among ethnic minorities.* The European Journal of Public Health, 2009. **19**(5): p. 511-515.
4. Andersen, G.S., et al., *Diabetes among migrants in Denmark: incidence, mortality, and prevalence based on a longitudinal register study of the entire Danish population.* Diabetes research and clinical practice, 2016. **122**: p. 9-16.
5. Wandell, P.E., A.C. Carlsson, and K.H. Steiner, *Prevalence of diabetes among immigrants in the Nordic countries.* Current diabetes reviews, 2010. **6**(2): p. 126-133.
6. Lanting, L.C., et al., *Ethnic differences in mortality, end-stage complications, and quality of care among diabetic patients: a review.* Diabetes care, 2005. **28**(9): p. 2280-2288.
7. Isaksen, A.A., et al., *Guideline-level monitoring, biomarker levels and pharmacological treatment in migrants and native Danes with type 2 diabetes: Population-wide analyses.* PLOS Global Public Health, 2023. **3**(10): p. e0001277.

8. Chrvala, C.A., D. Sherr, and R.D. Lipman, *Diabetes self-management education for adults with type 2 diabetes mellitus: a systematic review of the effect on glycemic control.* Patient education and counseling, 2016. **99**(6): p. 926-943.

9. Holmboe-Ottesen, G. and M. Wandel, *Changes in dietary habits after migration and consequences for health: a focus on South Asians in Europe.* Food & nutrition research, 2012. **56**(1): p. 18891.

10. Stronks, K. and A.E. Kunst, *The complex interrelationship between ethnic and socio-economic inequalities in health.* Journal of Public Health, 2009. **31**(3): p. 324-325.

11. Montesi, L., M.T. Caletti, and G. Marchesini, *Diabetes in migrants and ethnic minorities in a changing world.* World journal of diabetes, 2016. **7**(3): p. 34.

12. Spallek, J., H. Zeeb, and O. Razum, *What do we have to know from migrants' past exposures to understand their health status? a life course approach.* Emerging themes in epidemiology, 2011. **8**(1): p. 1-8.

13. Majeed-Ariss, R., et al., *A systematic review of research into black and ethnic minority patients' views on self-management of type 2 diabetes.* Health Expect, 2015. **18**(5): p. 625-42.

14. Zeh, P., et al., *Cultural barriers impeding ethnic minority groups from accessing effective diabetes care services: a systematic review of observational studies.* Diversity and equality in health and care, 2014. **11**(1): p. 9-33.

15. Kim, J.E., *Factors Related to Diabetes Self-Care among Immigrants in the United States: A Scoping Review.* Research in Community and Public Health Nursing, 2023. **34**(2): p. 171-182.

16. Andersen, A.M.J., et al., *Acquisition, application, and distribution of health literacy from culturally sensitive type 2 diabetes education among Arabic-Speaking migrants in Denmark: A longitudinal qualitative analysis.* Scandinavian Journal of Caring Sciences, 2023.

17. Resnicow, K. and R.L. Braithwaite, *Cultural sensitivity in public health.* 2001.

18. Navodia, N., et al., *Culturally tailored self-management interventions for South Asians with type 2 diabetes: A systematic review.* Canadian Journal of Diabetes, 2019. **43**(6): p. 445-452.

19. Goff, L.M., et al., *Healthy Eating and Active Lifestyles for Diabetes (HEAL-D), a culturally tailored self-management education and support program for type 2 diabetes in black-British adults: a randomized controlled feasibility trial.* BMJ Open Diabetes Research and Care, 2021. **9**(1): p. e002438.

20. Attridge, M., et al., *Culturally appropriate health education for people in ethnic minority groups with type 2 diabetes mellitus.* Cochrane Database of Systematic Reviews, 2014(9).

21. Khunti, K., et al., *Educational interventions for migrant South Asians with Type 2 diabetes: a systematic review.* Diabetic Medicine, 2008. **25**(8): p. 985-992.

22. Zou, P. and M. Parry, *Strategies for health education in North American immigrant populations.* International nursing review, 2012. **59**(4): p. 482-488.

23. Garad, R.M., *Health literacy driving health engagement in the pluralist context of migrant health in Australia*. 2017, Deakin University.

24. Eik Bjerre, Klaus Brasso, and J. Midtgaard, *Pragmatiske studier er vigtige for medicinsk forskning.* Ugeskr Læger, 2015. **177**: p. V10140571.

25. Gamerman, V., T. Cai, and A. Elsäßer, *Pragmatic randomized clinical trials: best practices and statistical guidance.* Health Services and Outcomes Research Methodology, 2019. **19**: p. 23-35.

26. Chaves, F.F., et al., *Translation, cross-cultural adaptation and validation of the Diabetes Empowerment Scale–Short Form.* Revista de saude publica, 2017. **51**.

27. Hempler, N.F., N.I. Christensen, and D.H. Laursen, *Koncept for uddannelse målrettet etniske minoriteter med type 2 diabetes: Fokus på værdier, kompetencer og værktøjer.* 2018.

28. Hempler, N.F., et al., *Improving Health and Diabetes Self-Management in Immigrants with Type 2 Diabetes Through a Co-Created Diabetes Self-Management Education and Support*

Intervention. Journal of community health, 2023. **48**(1): p. 141-151.

29. Chan, A.-W., et al., *SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials.* Bmj, 2013. **346**.
30. Stenov, V., et al., *The potential of a self-assessment tool to identify healthcare professionals' strengths and areas in need of professional development to aid effective facilitation of group-based, person-centered diabetes education.* BMC Medical Education, 2017. **17**(1): p. 1-11.
31. Pulvirenti, M., J. McMillan, and S. Lawn, *Empowerment, patient centred care and self-management.* Health expectations, 2014. **17**(3): p. 303-310.
32. Funnell, M.M. and R.M. Anderson, *Empowerment and self-management of diabetes.* Clinical diabetes, 2004. **22**(3): p. 123-128.
33. McGuire, B., et al., *Short-form measures of diabetes-related emotional distress: the Problem Areas in Diabetes Scale (PAID)-5 and PAID-1.* Diabetologia, 2010. **53**: p. 66-69.
34. Topp, C.W., et al., *The WHO-5 Well-Being Index: a systematic review of the literature.* Psychotherapy and psychosomatics, 2015. **84**(3): p. 167-176.
35. Osborne, R.H., et al., *The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ).* BMC public health, 2013. **13**: p. 658.
36. PRO sekretariatet, *PRO-spørgeskemabank 'Diabetes'*. 2023, Sundhedsdatastyrelsen: København S.
37. Chan, A.H.Y., et al., *The medication adherence report scale: a measurement tool for eliciting patients' reports of nonadherence.* British journal of clinical pharmacology, 2020. **86**(7): p. 1281-1288.
38. Nicolaisen, A., P. Qvist, and A.K. Fallesen *Spørgeskema om PatientOplevet kvalitet i Tværsektorielle forløb (SPOT): Et udviklingsprojekt.* 2016.
39. Wing, R.R., et al., *Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes.* The New England journal of medicine, 2013. **369**(2): p. 145-154.

40. Redmon, J.B., et al., *Effect of the look AHEAD study intervention on medication use and related cost to treat cardiovascular disease risk factors in individuals with type 2 diabetes.* Diabetes care, 2010. **33**(6): p. 1153-1158.

41. O'Neil, P.M., et al., *Randomized controlled trial of a nationally available weight control program tailored for adults with type 2 diabetes.* Obesity, 2016. **24**(11): p. 2269-2277.

Supplementary Files

Figures

Fig. 1. Randomization.

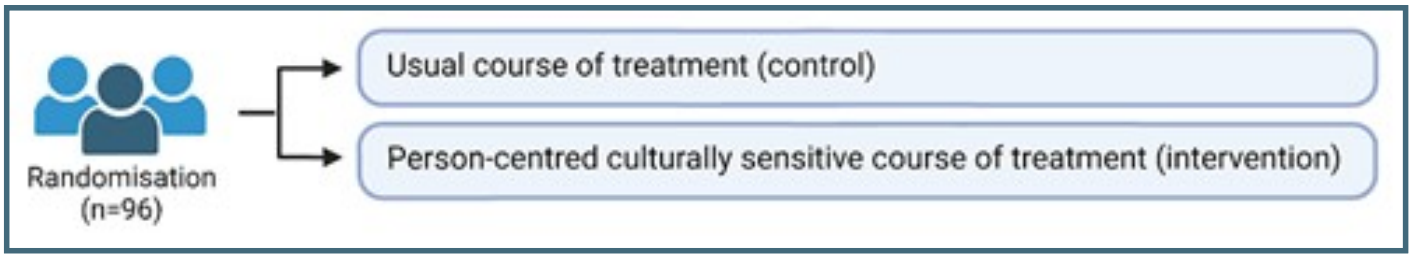

Fig 2. Visit flow.

Fig 3. Standard course of treatment 1 year.