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Community-Based Culturally Tailored Education Programs for Black Adults with Cardiovascular Disease, Diabetes, Hypertension, and Stroke: A Systematic Review Protocol

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Community-Based Culturally Tailored Education Programs for Black Adults with Cardiovascular Disease, Diabetes, Hypertension, and Stroke: A Systematic Review Protocol

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Abstract:

Introduction: Chronic conditions and stroke disproportionately affect Black adults in communities all around the world due patterns of systemic racism, disparities in care, and lack of resources. Culturally-tailored programs can meet the needs of the communities they serve, including Black adults who tend to have reduced access to postacute services. To address unequal care received by Black communities, a shift to community-based programs that deliver culturally-tailored programs may give an alternative to a healthcare model which reinforces health inequities. However, community-based culturally-tailored programs (CBCT) are relatively understudied but show promise to improve the delivery of services to marginalized communities. The objectives of this review are to: (i) synthesize key program characteristics and outcomes of CBCT programs that are designed to improve health outcomes in Black adults with cardiovascular disease, hypertension, diabetes, or stroke and (ii) identify which of the five categories of culturally appropriate programs from Kreuter and colleagues have been used to implement CBCT programs.

Methods and Analysis: This is a protocol for a systematic review that will search MEDLINE, EMBASE and CINAHL databases to identify studies of CBCT programs for Black adults with cardiovascular disease, hypertension, diabetes, or stroke between 2000-2021. Two reviewers will assess each study to determine if the studies meet the inclusion criteria and any disagreements will be resolved by a third reviewer. Data will be extracted using a customized data extraction form developed based on the Joanna Briggs Institute Manual for Evidence Synthesis to identify essential program characteristics and Kreuter's five strategies of culturally appropriate interventions to determine the number and type of strategies used for each program included in

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2
3 the review. AMSTAR will be used to evaluate the articles included in the study. The aggregated
4 data will be presented through textual description of program characteristics and outcomes.
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7 **Ethics and Dissemination:** This systematic review protocol does not require ethics approval
8 without the inclusion of human participants and will use studies who have previously obtained
9 informed consent. The systematic review findings will be disseminated in a peer-reviewed
10 journal and used to inform future research of JF and HS.
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15 **Trial registration:** PROSPERO CRD42021245772
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17 **Keywords:** Cultural competence, Chronic disease, Culturally-tailored, Intervention
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19 **Protocol Word Count:** 2,634
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27 **Strengths & Limitations:**

- 28 ● This systematic review contributes to the current literature by including multiple
29 conditions greatly impacting the lives of Black adults and allows researchers to see key
30 characteristics of CBCT programs across conditions rather than a single one.
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- 33 ● Two independent reviewers will be used in abstract screening and full text screening to
34 reduce the risk of bias with a potential for a third reviewer to address any disagreements.
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- 37 ● Due to varying terminology used to describe CBCT programs, relevant articles may be
38 missed during the literature search.
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Background

The aging population combined with medical advances have enabled people to live longer, but the proportion of people living with chronic diseases and/or with the effects of a stroke has been increasing.¹ This is particularly so for Black adults (defined in this review as individuals of African descent) who experience a higher incidence and severity of stroke and their odds of cardiovascular disease, hypertension, and diabetes is greater than White individuals.²⁻⁵ Chronic conditions, including cardiovascular disease, hypertension and diabetes not only increase the risk of additional health events, such as a stroke, but also reduce functional status, health-related quality of life, social and psychological functioning, and productivity of those living with these chronic conditions.⁶ Sharing a greater burden of these conditions has effects that extend beyond poorer physical health; these conditions can be amplified by socio-economic disparities among Black communities limiting access to the resources required for improved health.^{7,8}

Numerous studies have demonstrated that Black adults receive poorer disease prevention and management care from the health system.⁹⁻¹¹ For example, medical advances in identification and treatment of cardiovascular diseases have resulted in decreased incidence of and mortality from cardiovascular disease at a population-wide level. However, cardiovascular disease rates among Black adults remain high as a result of poor disease management among Black communities.⁹ Furthermore, Bonow & colleagues have found that racialized communities experience a higher frequency of undiagnosed risk factors that stem from disparities in access to care and health literacy. Black adults experience poorer health outcomes from chronic health conditions than White adults.^{12,13} Moreover, Odonkor & colleagues noted that “Black individuals were less likely to receive care that was concordant with clinical guidelines per the reported literature.”¹⁴

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3 Health disparities among Black communities have been recognized for decades, but
4 specific programs meant to address them have yet to become a priority within the medical field.¹⁵
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6 Although it is not a predominant intervention strategy, a growing body of literature have called
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8 for culturally-tailored community-based (CBCT) programs to reduce health disparities and
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10 improve health outcomes for racialized communities.^{15,16} CBCT programs “provide context and
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12 meaning to the message about a given health problem or behavior” to a specific group of people
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14 based on the group's shared “cultural values, beliefs, and behaviors.”¹⁷ They do so by taking into
15
16 account specific factors, including social–cultural (e.g., ethnic–cultural values, racially
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18 discriminatory social policies), community (e.g., institutional racism), and familial factors (e.g.,
19
20 differential acculturation) that can cause health disparities among specific communities.¹⁸ CBCT
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22 programs can be used to provide services to marginalized communities who may not receive the
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24 same levels of support from the healthcare system.¹⁹ In particular, they can be used to improve
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26 the health outcomes of Black Adults who have been diagnosed with hypertension and
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28 diabetes.^{20–23}
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35 Kreuter and colleagues have outlined five strategies for designing and implementing
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37 culturally-tailored programs,¹⁵ which can serve as a valuable framework for understanding and
38
39 comparing CBCT programs. The five strategies include: (1) peripheral strategies, (2) evidential
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41 strategies, (3) linguistic strategies, (4) constituent-involving strategies, and (5) sociocultural
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43 strategies.¹⁶ Peripheral strategies entail creating program materials featuring images and text
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45 meant for the target cultural group. Evidential strategies employ data to highlight the impacts of
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47 specific conditions on participants who are from a specific group. Linguistic strategies develop
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49 the program around the linguistic capabilities of participants using their native language or basic
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51 everyday vernacular. Constituent-involving strategies involve members of a target community to
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3 develop insights and cultural awareness in program development.¹⁵ Socio-cultural strategies
4 recognize the impact of social and cultural characteristics in community health practices and
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6 leverage them to provide context into the issues facing these communities.
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10 A common practice in CBCT programs is to involve community members in program
11 design. Designing CBCT programs with input and developmental insights from cultural groups
12 that they intend to serve allows the programs to target relevant barriers and challenges, and
13 resources to be applied where most needed.^{15,16} CBCT programs have shown promising impacts
14 on chronic disease awareness, condition management, medication adherence, program
15 satisfaction, condition specific knowledge, psychosocial factors, and health intervention
16 strategies among Black communities.²³⁻²⁸ However, the design and structure, and operational
17 definition of CBCT programs varies considerably from program to program, making them
18 difficult to compare. Thus, the purpose of this systematic review is to understand the design,
19 structure and definition of CBCT programs that have been used to improve health outcomes in
20 Black adults with cardiovascular disease, hypertension, diabetes, or stroke using Kreuter and
21 colleagues framework.
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41 **Review Questions**

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43 We will address the following questions in this review:
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46 (1) What are key program characteristics and outcomes of CBCT programs that are designed
47 to improve health outcomes in Black adults with cardiovascular disease, hypertension,
48 diabetes, or stroke?
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52 (2) Which of the five categories of culturally appropriate programs, as identified by Kreuter
53 and colleagues, have been used in CBCT programs for Black adults with cardiovascular
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disease, hypertension, diabetes, or stroke, and how have they been implemented in these programs?

Methods

This review will follow the procedures outlined in the Preferred Reporting Items of Systematic Review of Interventions and Meta-Analyses (PRISMA) 2020 statement and has been registered with the International Prospective Register of Systematic Reviews (CRD42021245772).

Search Strategy

To access published materials, a comprehensive search strategy will be conducted within the following electronic databases: Medline, Embase (OvidSP), and Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCOhost). These particular databases were selected as they focus on health-related literature and include community-based interventions, which will allow us to locate the most relevant articles. Concepts relating to i) *community based or culturally-tailored education*) and ii) *cardiovascular disease, hypertension, diabetes, or stroke* and iii) *Black Adults* (e.g. “African continental ancestral group”) will be searched for within the selected databases. The use of the search term “African continental ancestral group” was meant to broaden the search outside of just the American context while also recognizing Black adults as a heterogeneous population connected by a shared ancestry. A comprehensive search strategy will be created with assistance from EMU, an Information Scientist (see Appendix A for the full search strategy for Medline). The studies will be limited to articles published in the English-language. The search, which was conducted on September 30, 2021 in Medline had generated 627 articles.

Inclusion Criteria

Detailed inclusion criteria can be found in Table 1.

Table 1. Inclusion Criteria

<p>Black Adults (≥18 years of age) Possible Terms: -African American -Black Canadian -Black British -Afro-Caribbean -Afro-Brazilians -Afro- (other countries of Central or South America)</p>	<p>Other Terms for Title Abstract Screening -Minorities -Visible Minority -People of Color -Racialized -Ethnic Minority</p>
<p>Community-Based (CB) -CB approach brings people together with the intention of sharing knowledge, experiences, and to develop a common understanding²⁹ -Members of the community have roles in the intervention</p>	<p>Culturally-Tailored -Culturally Appropriate -Culturally Competent -Culturally Adapted -Cultural Targeting</p>
<p>Program includes at least one of the 5 Strategies of Culturally Appropriate Programs (1) peripheral strategies; (2) evidential strategies; (3) linguistic strategies; (4) constituent-involving strategies; and, (5) sociocultural strategies</p>	<p>At least One Education Component Examples: -Diet/ Nutrition -Medication adherence -Behavioral -Exercise -Self-Management -Health Literacy -Strategy (term) -self-management (term)</p>
<p>Participant has Cardiovascular Disease/Hypertension/ Diabetes/ Stroke</p>	<p>Existing Program</p>
<p>Patient Focused -Program developed for Patients rather than Clinicians</p>	<p>Published 2000-2021</p>
<p>English Studies Only</p>	<p>Study Type & Designs -Primary Source -Any Empirical Study Design</p>

Study design

We will include published empirical studies of any study design that gather evidence from a CBCT program for Black adults with cardiovascular disease, hypertension, diabetes, or stroke. The use of primary source studies will provide an opportunity for reviewers to extract data from the original source and ensure data specific to our topic of interest will be recorded. The inclusion of quantitative and qualitative data will allow us to generate an understanding of the effects of CBCT programs on health outcomes using quantitative data as well as patient-reported outcomes by the target community through qualitative inquiry.

Setting

No restrictions will be placed on the country in which the program occurred. However, this review will limit to programs that take place in the community setting (i.e. outside of a hospital setting).

Participants

The participants in this review will be Black adults (≥ 18 years of age) with hypertension, cardiovascular disease, diabetes, or stroke.

Intervention

This review will include programs which deliver culturally-tailored education to the Black adults with cardiovascular disease, hypertension, diabetes, or stroke. The education should relate to the management of one of these conditions (i.e. hypertension, cardiovascular disease, diabetes, or stroke). To be considered culturally-tailored, the intervention must include at least one of the following culturally appropriate strategies outlined by Kreuter and colleagues: (1) peripheral

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3 strategies, (2) evidential strategies, (3) linguistic strategies, (4) constituent-involving strategies,
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5 and (5) sociocultural strategies.
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7 8 **Type of Outcome Measure** 9

10 As the intent of this review is to inform the design and structure of future programs, all outcome
11 measurements will be reported in this systematic review, including participant-level (e.g. health-
12 related outcomes, health literacy, medication adherence, psychosocial measurements) as well as
13 program-level outcome measures (e.g. program adherence, satisfaction).
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19 **Study Records** 20

21 22 **Search Methods** 23

24 The search will be conducted by the lead author (JF) and Information Specialist (EMU) on the
25 relevant databases. To ensure we maximize our results, we will hand search the reference lists of
26 included studies.
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31 32 **Selection Process** 33

34 All articles identified from the search will be uploaded into Covidence, a reference management
35 software. Duplicates will be removed in Covidence. The titles and abstracts of the identified
36 articles will be independently screened by two reviewers based on the inclusion criteria (see
37 Table 1). However, prior to beginning title and abstract screening, interrater reliability with title
38 and abstract screening among the researchers will be tested using a random sample of 50 articles.
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46 A Kappa score of ≥ 0.80 will be deemed acceptable as it indicates almost perfect agreement
47 amongst the research team.³⁰
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Once studies are identified for the full-text screening, a similar process will be followed
with two reviewers deciding if inclusion or exclusion criteria. All articles excluded at the full-
text review will be categorized based on predefined terms to document the reasoning behind the

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3 exclusion. To resolve any discrepancies between reviewers during title/abstract and full-text
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5 review, meetings will be held at regular intervals to discuss disagreements and reach a team
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8 consensus.
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10 **Data Items and Collection Process**

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12 For each article, one researcher will complete a data extraction form to record: program names,
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14 study participants, setting, study design, duration, evaluation measure, intervention, outcome,
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16 outcome measurements and study results, to summarize the existing data.^{15,31,32} A customized
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18 data extraction form will be created based on the Joanna Briggs Institute Manual for Evidence
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20 Synthesis to identify essential program characteristics³² and Kreuter's five strategies of culturally
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22 appropriate interventions to determine the number and type of strategies used for each program
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24 included in the review.¹⁶
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28 **Quality Appraisal**

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30 Quality assessment and risk of bias will be evaluated independently by two researchers using
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32 AMSTAR: A Measurement Tool to Assess Systematic Reviews³³ for all articles included in the
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34 systematic review to note the quality and detect any bias present in the study. This tool is
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36 appropriate for this review as it demonstrates substantial interrater agreement and has acceptable
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38 reliability, construct validity, and feasibility.³⁴
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43 **Data Synthesis**

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45 This systematic review of the literature will aggregate data from all studies that have used CBCT
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47 programs to improve health outcomes of Black adults with diabetes, hypertension,
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49 cardiovascular disease, or stroke using a thematic analysis.³⁵ A textual description of key
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51 program characteristics (e.g. populations served, type of intervention) and outcomes of each
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53 program will be provided. Following this, an inductive thematic analysis will be used to identify
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3 similarities and differences among and within programs.³⁵ A deductive thematic analysis using
4 Kreuter and colleagues' five categories of cultural appropriateness (i.e. peripheral, evidential,
5 linguistic, constituent-involving, and sociocultural) will be used to determine how many, which
6 and how these components have been used within the design and delivery of culturally-tailored
7 education programs.¹⁶ These insights will inform the creation of recommendations that can guide
8 the design and implementation of future CBCT programs for Black communities.
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17 **Discussion**

20 This systematic review will generate comprehensive insights into CBCT programs for Black
21 adults with cardiovascular disease, hypertension, diabetes, or stroke. The recognition of
22 significant health inequities within racialized communities presents a major gap in the current
23 healthcare system where new possibilities must be explored to reduce this gap. The current
24 healthcare system has done little to incorporate cultural values, beliefs, practices, customs, diets,
25 and religious views in the development of programs for racialized communities, instead
26 programs are built with a one-size-fits-all approach that do not address the specific issues
27 impacting the target community. CBCT programs differ from a one-size-fits-all approach by
28 acknowledging cultural differences in health experiences and intend to address the barriers
29 facing culturally diverse communities to improve overall health with the assistance of the
30 community members. As CBCT programs are becoming more popular, more attention must be
31 directed to the valuable lessons that can be learned from existing CBCT programs and applied to
32 future CBCT programs.
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50 This review will not be without limitations. First, given variability within the literature of
51 terminology that has been used to describe CBCT programs, there is a potential we may miss
52 relevant articles. Second, based on the heterogeneity within study designs and outcomes included
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3 in this review, we will be unable to perform a meta-analysis and therefore unable to determine
4 the effectiveness of these programs. Third, to ensure contextual relevance of programs, we have
5 restricted articles published within the last twenty years; however, we recognize that limiting the
6 study date may exclude relevant articles published before this date. Fourth, for feasibility and
7 resource constraints, we decided to limit inclusion of articles to those available in English;
8 however we may miss potentially relevant literature. Lastly, to ensure we generate
9 recommendations based on high quality evidence, we have limited this review to published
10 articles, and as a result we will be unable to capture programs introduced within gray literature
11 sources. Nonetheless, this review will highlight valuable insights into CBCT programs.
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23 **Conclusion**

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25 Health inequities experienced by Black communities stem from a long history of systemic
26 racism, differential treatment, and neglect from medical institutions. While health disparities are
27 recognized as an issue within medicine, little has been done to shift the focus of medical research
28 to solutions that are tailored to meet the specific needs of racialized communities. New models of
29 care must be prioritized and researched to identify possible solutions to health inequities facing
30 Black communities. CBCT programs do present a possible path forward to improve the health of
31 racialized communities with messaging that is tailored to their specific cultural needs and
32 encourages a deeper level of ownership over the type of care they receive. CBCT interventions
33 must be assessed to determine the effectiveness of addressing health disparities in the interest.
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47 **Ethics and Dissemination**

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49 This systematic review protocol does not require ethics approval without human participants.
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51 The review will be an aggregate of published studies that focus on CBCT rather than developing
52 a CBCT program. The systematic review findings will be disseminated in a peer-reviewed
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3 journal with an interest addressing health inequities faced in the Black community. The
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5 intention of the authors is to use the review findings to disseminate potential strategies to
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8 develop culturally tailored programming within community-based organizations.
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10 **Declarations**

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13 **Authors' contributions:** JF conceptualized the project and wrote the original protocol draft. JF,
14
15 HS, and OP developed methodology, wrote, reviewed, and edited the protocol. EMU assisted in
16
17 the creation of the search strategy and ran the search. MLAN contributed to the
18
19 conceptualization of the project and provided supervision over the scope of the project.
20
21

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23
24 public, commercial or not-for-profit sectors.
25

26
27 **Competing interests:** The authors declare that they have no competing interests.
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For peer review only

Appendix A: Full search strategy for Medline

Medline OVID Search from September 30, 2021			
#	Searches	Results	Comment
1	african continental ancestry group/ or african americans/	91690	
2	(african adj2 american*).ti,ab,kf.	51564	
3	or/1-2	112373	Ethnic group terms
4	Culturally Competent Care/	1887	
5	cultural diversity/ or Cultural Characteristics/	28371	
6	cultural competency/	6048	
7	(cultural* adj2 adapted).ti,ab,kf.	1661	
8	(cultural* adj2 competen*).ti,ab,kf.	5244	
9	(cultural* adj2 tailor*).ti,ab,kf.	1216	
10	or/4-9	39177	Culturally competent terms
11	self care/ or blood glucose self-monitoring/ or self administration/ or self medication/	57615	
12	exp Cardiovascular Diseases/	2528700	
13	glucose metabolism disorders/ or exp diabetes mellitus/ or exp glycosuria/ or exp hyperglycemia/ or exp hyperinsulinism/ or exp hypoglycemia/	554001	
14	aftercare/ or exp rehabilitation/	3237982	
15	or/11-14	292	Chronic Disease rehabilitation terms
16	3 and 10 and 15	431544	Base set 1
17	attitude to health/ or health knowledge, attitudes, practice/ or "treatment adherence and compliance"/ or "patient acceptance of health care"/ or patient compliance/ or medication adherence/ or no-show patients/ or patient dropouts/ or patient participation/ or patient satisfaction/ or patient preference/ or treatment refusal/ or vaccination refusal/	173976	Health attitude terms

18	consumer health information/ or health literacy/ or health promotion/ or healthy people programs/ or weight reduction programs/ or patient education as topic/	377	Consumer health terms
19	3 and 15 and 17 and 18 [**Base set 7 Attitudes and Ethnic Groups and Diseases and patient education**]	641	Base set 2
20	16 or 19	627	Final results

For peer review only

BMJ Open

Community-Based Culturally Tailored Education Programs for Black Adults with Cardiovascular Disease, Diabetes, Hypertension, and Stroke: A Systematic Review Protocol of Primary Empirical Studies

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-059883.R1
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Primary Subject Heading:	Health services research
Secondary Subject Heading:	Public health
Keywords:	General diabetes < DIABETES & ENDOCRINOLOGY, Hypertension < CARDIOLOGY, STROKE MEDICINE

SCHOLARONE™
Manuscripts

Community-Based Culturally Tailored Education Programs for Black Adults with Cardiovascular Disease, Diabetes, Hypertension, and Stroke: A Systematic Review Protocol of Primary Empirical Studies

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Abstract:

Introduction: Chronic conditions and stroke disproportionately affect Black adults in communities all around the world partly due to patterns of systemic racism, disparities in care, and lack of resources. Culturally tailored programs can potentially meet the needs of the communities they serve, including Black adults who may experience reduced access to postacute services. To address unequal care received by Black communities, a shift to community-based programs that deliver culturally tailored programs may give an alternative to a healthcare model which reinforces health inequities. The objectives of this review are to: (i) synthesize key program characteristics and outcomes of CBCT programs that are designed to improve health outcomes in Black adults with cardiovascular disease, hypertension, diabetes, or stroke and (ii) identify which of the five categories of culturally appropriate programs from Kreuter and colleagues have been used to implement CBCT programs.

Methods and Analysis: This is a protocol for a systematic review that will search MEDLINE, EMBASE and CINAHL databases to identify studies of CBCT programs for Black adults with cardiovascular disease, hypertension, diabetes, or stroke between 2000-2021. Two reviewers will assess each study based on the inclusion criteria and any disagreements will be resolved by a third reviewer. Data will be extracted using a customized data extraction form to identify program characteristics and the strategies used to develop culturally appropriate programs. AMSTAR will be used to evaluate the articles included in the study. The aggregated data will be presented through textual descriptions of program characteristics and outcomes.

Ethics and Dissemination: This systematic review protocol does not require ethics approval without the inclusion of human participants and will use studies that have previously obtained informed consent. The systematic review findings will be disseminated in a peer-reviewed

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3 journal and used to inform future research led by JF and HS.
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5 **Trial registration:** PROSPERO CRD42021245772
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7 **Keywords:** Cultural competence, Chronic disease, culturally tailored, Intervention
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10 **Protocol Word Count:** 3,078
11

12 **Strengths & Limitations:**

13

- 14 ● This systematic review contributes to the current literature by including multiple
15 conditions that greatly impact the lives of Black adults and will allow researchers to
16 identify key characteristics of CBCT programs across conditions rather than targeting a
17 single condition.
18
- 19 ● Two independent reviewers will complete abstract and full text screening with a third
20 reviewer to address any disagreements and reduce the risk of bias.
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- 22 ● Due to varying terminology used to describe CBCT programs, relevant articles may be
23 missed during the literature search.
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Background

The aging population combined with medical advances have enabled people to live longer, but the proportion of people living with chronic diseases and/or with the effects of a stroke has been increasing.¹ This is particularly so for Black adults (defined in this review as individuals of African descent) who experience a higher incidence and severity of stroke and their odds of cardiovascular disease, hypertension, and diabetes is greater than White individuals.²⁻⁵ Chronic conditions, including cardiovascular disease, hypertension and diabetes not only increase the risk of additional health events, such as a stroke, but also reduce functional status, health-related quality of life, social and psychological functioning, and productivity of those living with these chronic conditions.⁶ Sharing a greater burden of these conditions has effects that extend beyond poorer physical health; these conditions can be amplified by socio-economic disparities among Black communities limiting access to the resources required for improved health.^{7,8}

Numerous studies have demonstrated that Black adults receive poorer disease prevention and management care from the health system.⁹⁻¹¹ For example, medical advances in the identification and treatment of cardiovascular diseases have resulted in decreased incidence of and mortality from cardiovascular disease at a population-wide level. However, cardiovascular disease rates among Black adults remain high as a result of poor disease management among Black communities.⁹ Furthermore, Bonow & colleagues have found that racialized communities experience a higher frequency of undiagnosed risk factors that stem from disparities in access to care and health literacy.¹² Black adults experience poorer health outcomes from chronic health conditions than White adults.^{12,13} Moreover, Odonkor & colleagues noted that “Black individuals were less likely to receive care that was concordant with clinical guidelines per the reported literature.”¹⁴

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3 Health disparities among Black communities have been recognized for decades, but
4 specific programs meant to address them have yet to become a priority within the medical field.¹⁵
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6 Although it is not a predominant intervention strategy, a growing body of literature have called
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8 for culturally tailored community-based (CBCT) programs to reduce health disparities and
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10 improve health outcomes for racialized communities.^{15,16} They do so by taking into account
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12 specific factors, including social-cultural (e.g., ethnic-cultural values, racially discriminatory
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14 social policies), community (e.g., institutional racism), and familial factors (e.g., differential
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16 acculturation) that can cause health disparities among specific communities.¹⁷ CBCT programs
17
18 can be used to provide services to marginalized communities who may not receive the same
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20 levels of support from the healthcare system.¹⁸ In particular, they can be used to improve the
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22 health outcomes of Black Adults who have been diagnosed with hypertension and
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24 diabetes.^{19–22}
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31 For this review, a ‘community-based’ refers to an intervention delivered within a
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33 community setting (e.g. an individual’s home, healthcare clinic)²³ that brings people together
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35 with the intention of empowering members of the community to share their own knowledge and
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37 experience to develop a common understanding to address common problems faced by
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39 communities.²⁴ Multiple terms have been used, sometimes interchangeably, to describe
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41 interventions that take culture (e.g. “culturally appropriate,” “culturally targeted,” and “culturally
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43 relevant”); in this review culturally tailored is used to refer to ‘recognition of a group’s cultural
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45 values, beliefs and behaviors’ as indispensable context to addressing specific health problems
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47 impacting a specific ethnic community.²⁵ The combination of community-based and culturally
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49 tailored allows for the empowerment of individuals living within communities to use their
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3 cultural values, beliefs, and behaviors to inform programs and interventions to address health
4 issues in their community.
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8 Multiple frameworks^{26–28} exist to evaluate and develop interventions based on the
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10 cultural characteristics of the communities the interventions are meant to serve. While many of
11 these frameworks outline similar approaches, concepts and ideas, the culturally appropriate
12 framework developed by Kreuter et al. provides evaluation tools for surface level cultural
13 characteristics (e.g. materials), deep structure cultural characteristics (e.g. language) and socio-
14 cultural issues facing target communities.¹⁶ Kreuter and colleagues have outlined five strategies
15 for designing and implementing culturally tailored programs,¹⁵ which can serve as a valuable
16 framework for understanding and comparing CBCT programs. The five strategies include: (1)
17 peripheral strategies, (2) evidential strategies, (3) linguistic strategies, (4) constituent-involving
18 strategies, and (5) sociocultural strategies.¹⁶ Peripheral strategies entail creating program
19 materials featuring images and text meant for the target cultural group. Evidential strategies
20 employ data to highlight the impacts of specific conditions on participants who are from a
21 specific group. Linguistic strategies develop the program around the linguistic capabilities of
22 participants using their native language or basic everyday vernacular. Constituent-involving
23 strategies involve members of a target community to develop insights and cultural awareness in
24 program development.¹⁵ Socio-cultural strategies recognize the impact of social and cultural
25 characteristics in community health practices and leverage them to provide context into the
26 issues facing these communities.¹⁶
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49 A common practice in CBCT programs is to involve community members in program
50 design. Designing CBCT programs with input and developmental insights from cultural groups
51 that they intend to serve allows the programs to target relevant barriers and challenges, and
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resources to be applied where most needed.^{15,16} CBCT programs have shown promising impacts on chronic disease awareness, condition management, medication adherence, program satisfaction, condition specific knowledge, psychosocial factors, and health intervention strategies among Black communities.^{22,29–33} However, the design, structure, and operational definition of CBCT programs varies considerably from program to program, making them difficult to compare. Thus, the purpose of this systematic review is to understand the design, structure and definition of CBCT programs that have been used to improve health outcomes in Black adults with cardiovascular disease, hypertension, diabetes, or stroke using Kreuter and colleagues' framework.

Review Questions

We will address the following questions in this review:

- (1) What are key program characteristics and outcomes of CBCT programs that are designed to improve health outcomes in Black adults with cardiovascular disease, hypertension, diabetes, or stroke?
- (2) Which of the five categories of culturally appropriate programs, as identified by Kreuter and colleagues, have been used in CBCT programs for Black adults with cardiovascular disease, hypertension, diabetes, or stroke, and how have they been implemented in these programs?

Methods

This review will follow the procedures outlined in the Preferred Reporting Items of Systematic Review of Interventions and Meta-Analyses (PRISMA) 2020 statement and has been registered with the International Prospective Register of Systematic Reviews (CRD42021245772).

Search Strategy

To access published materials, a comprehensive search strategy will be conducted within the following electronic databases: Medline, Embase (OvidSP), and Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCOhost). These particular databases were selected as they focus on health-related literature and include community-based interventions, which will allow us to locate the most relevant articles. Concepts relating to i) *community based or culturally tailored education*, ii) *cardiovascular disease, hypertension, diabetes, or stroke*, and iii) *Black Adults* (e.g. “African continental ancestral group”) will be searched for within the selected databases. The use of the search term “African continental ancestral group” was meant to broaden the search outside of just the American context while also recognizing Black adults as a heterogeneous population connected by shared ancestry. A comprehensive search strategy will be created with assistance from EMU, an Information Scientist (see Appendix A for the full search strategy for Medline). No language restrictions will be applied to the search strategy. The preliminary search, which was conducted on September 30, 2021 in Medline, had generated 627 articles.

Inclusion Criteria

Detailed inclusion criteria can be found in Table 1.

Table 1. Inclusion Criteria	
<p>Black Adults (≥ 18 years of age) Possible Terms: -African American -Black Canadian -Black British -Afro-Caribbean -Afro-Brazilians -Afro- (other countries of Central or South America)</p>	<p>Other Terms for Title Abstract Screening -Minorities -Visible Minority -People of Color -Racialized -Ethnic Minority</p>

Community-Based (CB) -CB approach brings people together with the intention of sharing knowledge, experiences, and to develop a common understanding ²⁴ -Members of the community have roles in the intervention	Culturally Tailored -Culturally Appropriate -Culturally Competent -Culturally Adapted -Cultural Targeting
Program includes at least one of the 5 Strategies of Culturally Appropriate Programs (1) peripheral strategies; (2) evidential strategies; (3) linguistic strategies; (4) constituent-involving strategies; and, (5) sociocultural strategies	At least One Education Component Examples: -Diet/ Nutrition -Medication adherence -Behavioral -Exercise -Self-Management -Health Literacy -Strategy (term) -self-management (term)
Participant has Cardiovascular Disease/Hypertension/ Diabetes/ Stroke	Existing Program
Patient Focused -Program developed for Patients rather than Clinicians	Published 2000-2021
English Studies Only	Study Type & Designs -Primary Source -Any Empirical Study Design

Study design

We will include published empirical studies of any study design that gather evidence from a CBCT program for Black adults with cardiovascular disease, hypertension, diabetes, or stroke. Empirical studies are any study “obtaining direct, observable information from the world, rather than, for example, by theorising, or by reasoning, or by arguing from first principles.”³⁴ The key concept from this definition is the “observable information from the world” that is found from empirical studies (e.g. pilot studies, randomized control trials, cohort studies, qualitative

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3 interviews, surveys) and not from opinion letters, commentaries protocols, or intervention
4 descriptions.³⁵ The use of primary source studies will provide an opportunity for reviewers to
5 extract data from the original source and ensure data specific to our topic of interest will be
6 recorded. The inclusion of quantitative and qualitative data will allow us to generate an
7 understanding of the effects of CBCT programs on health outcomes using quantitative data as
8 well as patient-reported outcomes by the target community through qualitative inquiry. Our
9 research team decided to limit to empirical published studies to effectively address our research
10 aims. We have excluded gray literature due to lack of peer-review and the variable quality and
11 inconsistent reporting of program outcomes.

22 **Setting**

23
24 No restrictions will be placed on the country in which the program occurred. However, this
25 review will limit to programs that take place in the community setting (i.e. outside of a hospital
26 setting).

27 **Participants**

28 The participants in this review will be Black adults (≥ 18 years of age) with hypertension,
29 cardiovascular disease, diabetes, or stroke.

30 **Intervention**

31 This review will include programs which deliver culturally tailored education to Black adults
32 with cardiovascular disease, hypertension, diabetes, or stroke. Thus, studies focused on
33 prevention will not be included in this systematic review. The education should relate to the
34 management of one of these conditions (i.e. hypertension, cardiovascular disease, diabetes, or
35 stroke). To be considered culturally tailored, the intervention must include at least one of the
36 following culturally appropriate strategies outlined by Kreuter and colleagues: (1) peripheral
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3 strategies, (2) evidential strategies, (3) linguistic strategies, (4) constituent-involving strategies,
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5 and (5) sociocultural strategies.
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7 8 **Type of Outcome Measure** 9

10 As the intent of this review is to inform the design and structure of future programs, all outcome
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12 measurements will be reported in this systematic review, including participant-level (e.g. health-
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14 related outcomes, health literacy, medication adherence, psychosocial measurements) as well as
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16 program-level outcome measures (e.g. program adherence, satisfaction).
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19 20 **Patient and Public Involvement** 21

22 While the researchers recognize the importance of patient and public involvement in the research
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24 process, we will not engage with patients or the public in completing this systematic review.
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27 28 **Study Records** 29

30 31 **Search Methods** 32

33 The search will be conducted by the lead author (JF) and Information Specialist (EMU) on the
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35 relevant databases. To ensure we maximize our results, we will hand search the reference lists of
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37 included studies.
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39 40 **Selection Process** 41

42 All articles identified from the search will be uploaded into Covidence, a reference management
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44 software. Duplicates will be removed in Covidence. The titles and abstracts of the identified
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46 articles will be independently screened by two reviewers based on the inclusion criteria (see
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48 Table 1). However, prior to beginning title and abstract screening, interrater reliability with title
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50 and abstract screening among the researchers will be tested using a random sample of 50 articles.
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52 A Kappa score of ≥ 0.80 will be deemed acceptable as it indicates almost perfect agreement
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54 amongst the research team.³⁶
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3 Once studies are identified for the full-text screening, a similar process will be followed
4 with two reviewers deciding if inclusion or exclusion criteria. All articles excluded in the full-
5 text review will be categorized based on predefined terms to document the reasoning behind the
6 exclusion. To resolve any discrepancies between reviewers during title/abstract and full-text
7 review, meetings will be held at regular intervals to discuss disagreements and reach a team
8 consensus.
9

16 **Data Items and Collection Process**

17 For each article, one researcher will complete a data extraction form to record: program names,
18 study participants, setting, study design, duration, evaluation measure, intervention, outcome,
19 outcome measurements and study results to summarize the existing data.^{15,37,38} A customized
20 data extraction form will be created based on the Joanna Briggs Institute (JBI) Manual for
21 Evidence Synthesis,³⁷ TIDIER guidelines to identify essential program characteristics (Tidier
22 guidelines),³⁹ and Kreuter's five strategies of culturally appropriate interventions to determine
23 the number and type of strategies used for each program included in the review.¹⁶
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35 **Quality Appraisal**

36 Quality assessment and risk of bias will be evaluated independently by two researchers using
37 AMSTAR: A Measurement Tool to Assess Systematic Reviews⁴⁰ for all articles included in the
38 systematic review to note the quality and detect any bias present in the study. This tool is
39 appropriate for this review as it demonstrates substantial interrater agreement and has acceptable
40 reliability, construct validity, and feasibility.⁴¹
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50 **Data Synthesis**

51 This systematic review of the literature will aggregate data from all studies that have used CBCT
52 programs to improve health outcomes of Black adults with diabetes, hypertension,
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3 cardiovascular disease, or stroke using a thematic analysis.⁴² A textual description of key
4 program characteristics (e.g. populations served, type of intervention) and outcomes of each
5 program will be provided. Following this, an inductive thematic analysis will be used to identify
6 similarities and differences among and within programs.⁴² A deductive thematic analysis using
7 Kreuter and colleagues' five categories of cultural appropriateness (i.e. peripheral, evidential,
8 linguistic, constituent-involving, and sociocultural) will be used to determine how many, which
9 and how these components have been used within the design and delivery of culturally tailored
10 education programs.¹⁶ These insights will inform the creation of recommendations that can guide
11 the design and implementation of future CBCT programs for Black communities.
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24 **Discussion**

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27 This systematic review will generate comprehensive insights into CBCT programs for Black
28 adults with cardiovascular disease, hypertension, diabetes, or stroke. The recognition of
29 significant health inequities within racialized communities presents a major gap in the current
30 healthcare system where new possibilities must be explored to reduce this gap. The current
31 healthcare system has done little to incorporate cultural values, beliefs, practices, customs, diets,
32 and religious views in the development of programs for racialized communities, instead
33 programs are built with an one-size-fits-all approach that do not address the specific issues
34 impacting the target community. CBCT programs differ from a one-size-fits-all approach by
35 acknowledging cultural differences in health experiences and intend to address the barriers
36 facing culturally diverse communities to improve overall health with the assistance of the
37 community members. As CBCT programs are becoming more popular, more attention must be
38 directed to the valuable lessons that can be learned from existing CBCT programs and applied to
39 future CBCT programs.
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3 This review will not be without limitations. First, given variability within the literature of
4 terminology that has been used to describe CBCT programs, there is a potential we may miss
5 relevant articles. Second, based on the heterogeneity within study designs and outcomes included
6 in this review, we will be unable to perform a meta-analysis and therefore unable to determine
7 the effectiveness of these programs. Third, to ensure contextual relevance of programs, we have
8 restricted articles published within the last twenty years; however, we recognize that limiting the
9 study date may exclude relevant articles published before this date. Fourth, for feasibility and
10 resource constraints, we decided to limit inclusion of articles to those available in English (i.e.
11 articles will be excluded during title/abstract screening); however, we may miss potentially
12 relevant literature. Fifth, the focus of this review will be on interventions designed and developed
13 for people living with the target condition rather than prevention. Future research should explore
14 studies that focus specifically on culturally tailored prevention programs and interventions.
15 Lastly, to ensure we generate recommendations based on high quality evidence, we have limited
16 this review to published articles, and as a result we will be unable to capture programs
17 introduced within gray literature sources. While gray literature is not deemed necessary to
18 answer our questions, omitting gray literature may introduce publication bias,⁴³ and it could be a
19 valuable resource for future research (e.g. informing intervention development). Nonetheless,
20 this review will highlight valuable insights into CBCT programs.
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44 **Conclusion**

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47 Health inequities experienced by Black communities stem from a long history of systemic
48 racism, differential treatment, and neglect from medical institutions. While health disparities are
49 recognized as an issue within medicine, little has been done to shift the focus of medical research
50 to solutions that are tailored to meet the specific needs of racialized communities. New models of
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3 care must be prioritized and researched to identify possible solutions to health inequities facing
4 Black communities. CBCT programs do present a possible path forward to improve the health of
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6 racialized communities with messaging that is tailored to their specific cultural needs and
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8 encourages a deeper level of ownership over the type of care they receive. CBCT interventions
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10 must be assessed to determine the effectiveness of addressing health disparities in the interest.
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14 **Ethics and Dissemination**

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17 This systematic review protocol does not require ethics approval without human participants.

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20 The review will be an aggregate of published studies that focus on CBCT rather than developing
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22 a CBCT program. The systematic review findings will be disseminated in a peer-reviewed
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24 journal with an interest addressing health inequities faced in the Black community. The intention
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26 of the authors is to use the review findings to disseminate potential strategies to develop
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28 culturally tailored programming within community-based organizations.
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31 **Declarations**

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34 **Authors' contributions:** JF conceptualized the project and wrote the original protocol draft. JF,
35
36 HS, and OP developed methodology, wrote, reviewed, and edited the protocol. EMU assisted in
37
38 the creation of the search strategy and ran the search. MLAN contributed to the
39
40 conceptualization of the project and provided supervision over the scope of the project.
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44 **Funding Statement:** This research received no specific grant from any funding agency in the
45
46 public, commercial or not-for-profit sectors. HS holds the March of Dimes Canada Paul J. J.
47
48 Martin Early Career Professorship.
49

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51 **Competing interests:** The authors declare that they have no competing interests.
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Table 1. Inclusion Criteria	
<p>Black Adults (≥18 years of age) Possible Terms: -African American -Black Canadian -Black British -Afro-Caribbean -Afro-Brazilians -Afro- (other countries of Central or South America)</p>	<p>Other Terms for Title Abstract Screening -Minorities -Visible Minority -People of Color -Racialized -Ethnic Minority</p>
<p>Community-Based (CB) -CB approach brings people together with the intention of sharing knowledge, experiences, and to develop a common understanding²⁴ -Members of the community have roles in the intervention</p>	<p>Culturally Tailored -Culturally Appropriate -Culturally Competent -Culturally Adapted -Cultural Targeting</p>
<p>Program includes at least one of the 5 Strategies of Culturally Appropriate Programs (1) peripheral strategies; (2) evidential strategies; (3) linguistic strategies; (4) constituent-involving strategies; and, (5) sociocultural strategies</p>	<p>At least One Education Component Examples: -Diet/ Nutrition -Medication adherence -Behavioral -Exercise -Self-Management -Health Literacy -Strategy (term) -self-management (term)</p>
<p>Participant has Cardiovascular Disease/Hypertension/ Diabetes/ Stroke</p>	<p>Existing Program</p>
<p>Patient Focused -Program developed for Patients rather than Clinicians</p>	<p>Published 2000-2021</p>
<p>English Studies Only</p>	<p>Study Type & Designs -Primary Source -Any Empirical Study Design</p>

Appendix A: Full search strategy for Medline

Medline OVID Search from September 30, 2021			
#	Searches	Results	Comment
1	african continental ancestry group/ or african americans/	91690	
2	(african adj2 american*).ti,ab,kf.	51564	
3	or/1-2	112373	Ethnic group terms
4	Culturally Competent Care/	1887	
5	cultural diversity/ or Cultural Characteristics/	28371	
6	cultural competency/	6048	
7	(cultural* adj2 adapted).ti,ab,kf.	1661	
8	(cultural* adj2 competen*).ti,ab,kf.	5244	
9	(cultural* adj2 tailor*).ti,ab,kf.	1216	
10	or/4-9	39177	Culturally competent terms
11	self care/ or blood glucose self-monitoring/ or self administration/ or self medication/	57615	
12	exp Cardiovascular Diseases/	2528700	
13	glucose metabolism disorders/ or exp diabetes mellitus/ or exp glycosuria/ or exp hyperglycemia/ or exp hyperinsulinism/ or exp hypoglycemia/	554001	
14	aftercare/ or exp rehabilitation/	3237982	
15	or/11-14	292	Chronic Disease rehabilitation terms
16	3 and 10 and 15	431544	Base set 1
17	attitude to health/ or health knowledge, attitudes, practice/ or "treatment adherence and compliance"/ or "patient acceptance of health care"/ or patient compliance/ or medication adherence/ or no-show patients/ or patient dropouts/ or patient participation/ or patient satisfaction/ or patient preference/ or treatment refusal/ or vaccination refusal/	173976	Health attitude terms
18	consumer health information/ or health literacy/ or health promotion/ or healthy people programs/ or weight reduction programs/ or patient education as topic/	377	Consumer health terms

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19	3 and 15 and 17 and 18 [**Base set 7 Attitudes and Ethnic Groups and Diseases and patient education**]	641	Base set 2
20	16 or 19	627	Final results

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PRISMA 2020 Checklist

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Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	p. 1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	p. 2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	p. 4-7
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	p. 7
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	p. 8-9
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	p. 8
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	p. 8
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	p. 11-12
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	p. 12
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	p. 11
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	p. 10-11
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	p. 12
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	N/A
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	p. 12-13
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	p. 12-13
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	N/A
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	N/A
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	p. 12



PRISMA 2020 Checklist

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Section and Topic	Item #	Checklist item	Location where item is reported
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	N/A
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	N/A
Study characteristics	17	Cite each included study and present its characteristics.	N/A
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	N/A
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	N/A
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	N/A
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	p. 13
	23b	Discuss any limitations of the evidence included in the review.	p. 14
	23c	Discuss any limitations of the review processes used.	p. 14
	23d	Discuss implications of the results for practice, policy, and future research.	p. 14-15
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	p. 3
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	N/A
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	p. 1
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	p. 15
Competing interests	26	Declare any competing interests of review authors.	p. 15
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	N/A

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71

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BMJ Open

Community-Based Culturally Tailored Education Programs for Black Adults with Cardiovascular Disease, Diabetes, Hypertension, and Stroke: A Systematic Review Protocol of Primary Empirical Studies

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-059883.R2
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Primary Subject Heading:	Health services research
Secondary Subject Heading:	Public health
Keywords:	General diabetes < DIABETES & ENDOCRINOLOGY, Hypertension < CARDIOLOGY, STROKE MEDICINE

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Manuscripts

Community-Based Culturally Tailored Education Programs for Black Adults with Cardiovascular Disease, Diabetes, Hypertension, and Stroke: A Systematic Review Protocol of Primary Empirical Studies

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Abstract:

Introduction: Chronic conditions and stroke disproportionately affect Black adults in communities all around the world partly due to patterns of systemic racism, disparities in care, and lack of resources. Culturally tailored programs can potentially meet the needs of the communities they serve, including Black adults who may experience reduced access to postacute services. To address unequal care received by Black communities, a shift to community-based programs that deliver culturally tailored programs may give an alternative to a healthcare model which reinforces health inequities. The objectives of this review are to: (i) synthesize key program characteristics and outcomes of CBCT programs that are designed to improve health outcomes in Black adults with cardiovascular disease, hypertension, diabetes, or stroke and (ii) identify which of the five categories of culturally appropriate programs from Kreuter and colleagues have been used to implement CBCT programs.

Methods and Analysis: This is a protocol for a systematic review that will search MEDLINE, EMBASE and CINAHL databases to identify studies of CBCT programs for Black adults with cardiovascular disease, hypertension, diabetes, or stroke between 2000-2021. Two reviewers will assess each study based on the inclusion criteria and any disagreements will be resolved by a third reviewer. Data will be extracted using a customized data extraction form to identify program characteristics and the strategies used to develop culturally appropriate programs. AMSTAR will be used to evaluate the articles included in the study. The aggregated data will be presented through textual descriptions of program characteristics and outcomes.

Ethics and Dissemination: This systematic review protocol does not require ethics approval without the inclusion of human participants and will use studies that have previously obtained informed consent. The systematic review findings will be disseminated in a peer-reviewed

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3 journal and used to inform future research led by JF and HS.
4

5 **Trial registration:** PROSPERO CRD42021245772
6

7 **Keywords:** Cultural competence, Chronic disease, culturally tailored, Intervention
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10 **Protocol Word Count:** 3,078
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12 **Strengths & Limitations:**

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15 ● This systematic review contributes to the current literature by including multiple
16 conditions that greatly impact the lives of Black adults and will allow researchers to
17 identify key characteristics of CBCT programs across conditions rather than targeting a
18 single condition.
19
- 20 ● Two independent reviewers will complete abstract and full text screening with a third
21 reviewer to address any disagreements and reduce the risk of bias.
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- 23 ● Due to varying terminology used to describe CBCT programs, relevant articles may be
24 missed during the literature search.
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Background

The aging population combined with medical advances have enabled people to live longer, but the proportion of people living with chronic diseases and/or with the effects of a stroke has been increasing.¹ This is particularly so for Black adults (defined in this review as individuals of African descent) who experience a higher incidence and severity of stroke and their odds of cardiovascular disease, hypertension, and diabetes is greater than White individuals.²⁻⁵ Chronic conditions, including cardiovascular disease, hypertension and diabetes not only increase the risk of additional health events, such as a stroke, but also reduce functional status, health-related quality of life, social and psychological functioning, and productivity of those living with these chronic conditions.⁶ Sharing a greater burden of these conditions has effects that extend beyond poorer physical health; these conditions can be amplified by socio-economic disparities among Black communities limiting access to the resources required for improved health.^{7,8}

Numerous studies have demonstrated that Black adults receive poorer disease prevention and management care from the health system.⁹⁻¹¹ For example, medical advances in the identification and treatment of cardiovascular diseases have resulted in decreased incidence of and mortality from cardiovascular disease at a population-wide level. However, cardiovascular disease rates among Black adults remain high as a result of poor disease management among Black communities.⁹ Furthermore, Bonow & colleagues have found that racialized communities experience a higher frequency of undiagnosed risk factors that stem from disparities in access to care and health literacy.¹² Black adults experience poorer health outcomes from chronic health conditions than White adults.^{12,13} Moreover, Odonkor & colleagues noted that “Black individuals were less likely to receive care that was concordant with clinical guidelines per the reported literature.”¹⁴

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3 Health disparities among Black communities have been recognized for decades, but
4 specific programs meant to address them have yet to become a priority within the medical field.¹⁵
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6 Although it is not a predominant intervention strategy, a growing body of literature have called
7
8 for culturally tailored community-based (CBCT) programs to reduce health disparities and
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10 improve health outcomes for racialized communities.^{15,16} They do so by taking into account
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12 specific factors, including social-cultural (e.g., ethnic-cultural values, racially discriminatory
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14 social policies), community (e.g., institutional racism), and familial factors (e.g., differential
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16 acculturation) that can cause health disparities among specific communities.¹⁷ CBCT programs
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18 can be used to provide services to marginalized communities who may not receive the same
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20 levels of support from the healthcare system.¹⁸ In particular, they can be used to improve the
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22 health outcomes of Black Adults who have been diagnosed with hypertension and
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24 diabetes.^{19–22}
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31 For this review, a ‘community-based’ refers to an intervention delivered within a
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33 community setting (e.g. an individual’s home, healthcare clinic)²³ that brings people together
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35 with the intention of empowering members of the community to share their own knowledge and
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37 experience to develop a common understanding to address common problems faced by
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39 communities.²⁴ Multiple terms have been used, sometimes interchangeably, to describe
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41 interventions that take culture (e.g. “culturally appropriate,” “culturally targeted,” and “culturally
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43 relevant”); in this review culturally tailored is used to refer to ‘recognition of a group’s cultural
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45 values, beliefs and behaviors’ as indispensable context to addressing specific health problems
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47 impacting a specific ethnic community.²⁵ The combination of community-based and culturally
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49 tailored allows for the empowerment of individuals living within communities to use their
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3 cultural values, beliefs, and behaviors to inform programs and interventions to address health
4 issues in their community.
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8 Multiple frameworks^{26–28} exist to evaluate and develop interventions based on the
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10 cultural characteristics of the communities the interventions are meant to serve. While many of
11 these frameworks outline similar approaches, concepts and ideas, the culturally appropriate
12 framework developed by Kreuter et al. provides evaluation tools for surface level cultural
13 characteristics (e.g. materials), deep structure cultural characteristics (e.g. language) and socio-
14 cultural issues facing target communities.¹⁶ Kreuter and colleagues have outlined five strategies
15 for designing and implementing culturally tailored programs,¹⁵ which can serve as a valuable
16 framework for understanding and comparing CBCT programs. The five strategies include: (1)
17 peripheral strategies, (2) evidential strategies, (3) linguistic strategies, (4) constituent-involving
18 strategies, and (5) sociocultural strategies.¹⁶ Peripheral strategies entail creating program
19 materials featuring images and text meant for the target cultural group. Evidential strategies
20 employ data to highlight the impacts of specific conditions on participants who are from a
21 specific group. Linguistic strategies develop the program around the linguistic capabilities of
22 participants using their native language or basic everyday vernacular. Constituent-involving
23 strategies involve members of a target community to develop insights and cultural awareness in
24 program development.¹⁵ Socio-cultural strategies recognize the impact of social and cultural
25 characteristics in community health practices and leverage them to provide context into the
26 issues facing these communities.¹⁶
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49 A common practice in CBCT programs is to involve community members in program
50 design. Designing CBCT programs with input and developmental insights from cultural groups
51 that they intend to serve allows the programs to target relevant barriers and challenges, and
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resources to be applied where most needed.^{15,16} CBCT programs have shown promising impacts on chronic disease awareness, condition management, medication adherence, program satisfaction, condition specific knowledge, psychosocial factors, and health intervention strategies among Black communities.^{22,29–33} However, the design, structure, and operational definition of CBCT programs varies considerably from program to program, making them difficult to compare. Thus, the purpose of this systematic review is to understand the design, structure and definition of CBCT programs that have been used to improve health outcomes in Black adults with cardiovascular disease, hypertension, diabetes, or stroke using Kreuter and colleagues' framework.

Review Questions

We will address the following questions in this review:

- (1) What are key program characteristics and outcomes of CBCT programs that are designed to improve health outcomes in Black adults with cardiovascular disease, hypertension, diabetes, or stroke?
- (2) Which of the five categories of culturally appropriate programs, as identified by Kreuter and colleagues, have been used in CBCT programs for Black adults with cardiovascular disease, hypertension, diabetes, or stroke, and how have they been implemented in these programs?

Methods

This review will follow the procedures outlined in the Preferred Reporting Items of Systematic Review of Interventions and Meta-Analyses (PRISMA) 2020 statement and has been registered with the International Prospective Register of Systematic Reviews (CRD42021245772).

Search Strategy

To access published materials, a comprehensive search strategy will be conducted within the following electronic databases: Medline, Embase (OvidSP), and Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCOhost). These particular databases were selected as they focus on health-related literature and include community-based interventions, which will allow us to locate the most relevant articles. Concepts relating to i) *community based or culturally tailored education*, ii) *cardiovascular disease, hypertension, diabetes, or stroke*, and iii) *Black Adults* (e.g. “African continental ancestral group”) will be searched for within the selected databases. The use of the search term “African continental ancestral group” was meant to broaden the search outside of just the American context while also recognizing Black adults as a heterogeneous population connected by shared ancestry. A comprehensive search strategy will be created with assistance from EMU, an Information Scientist (see Appendix A for the full search strategy for Medline). No language restrictions will be applied to the search strategy. The preliminary search, which was conducted on September 30, 2021 in Medline, had generated 627 articles.

Inclusion Criteria

Detailed inclusion criteria can be found in Table 1.

Table 1. Inclusion Criteria	
<p>Black Adults (≥ 18 years of age) Possible Terms: -African American -Black Canadian -Black British -Afro-Caribbean -Afro-Brazilians -Afro- (other countries of Central or South America)</p>	<p>Other Terms for Title Abstract Screening -Minorities -Visible Minority -People of Color -Racialized -Ethnic Minority</p>

Community-Based (CB) -CB approach brings people together with the intention of sharing knowledge, experiences, and to develop a common understanding ²⁴ -Members of the community have roles in the intervention	Culturally Tailored -Culturally Appropriate -Culturally Competent -Culturally Adapted -Cultural Targeting
Program includes at least one of the 5 Strategies of Culturally Appropriate Programs (1) peripheral strategies; (2) evidential strategies; (3) linguistic strategies; (4) constituent-involving strategies; and, (5) sociocultural strategies	At least One Education Component Examples: -Diet/ Nutrition -Medication adherence -Behavioral -Exercise -Self-Management -Health Literacy -Strategy (term) -self-management (term)
Participant has Cardiovascular Disease/Hypertension/ Diabetes/ Stroke	Existing Program
Patient Focused -Program developed for Patients rather than Clinicians	Published 2000-2021
English Studies Only	Study Type & Designs -Primary Source -Any Empirical Study Design

Study design

We will include published empirical studies of any study design that gather evidence from a CBCT program for Black adults with cardiovascular disease, hypertension, diabetes, or stroke. Empirical studies are any study “obtaining direct, observable information from the world, rather than, for example, by theorising, or by reasoning, or by arguing from first principles.”³⁴ The key concept from this definition is the “observable information from the world” that is found from empirical studies (e.g. pilot studies, randomized control trials, cohort studies, qualitative

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3 interviews, surveys) and not from opinion letters, commentaries protocols, or intervention
4 descriptions.³⁵ The use of primary source studies will provide an opportunity for reviewers to
5 extract data from the original source and ensure data specific to our topic of interest will be
6 recorded. The inclusion of quantitative and qualitative data will allow us to generate an
7 understanding of the effects of CBCT programs on health outcomes using quantitative data as
8 well as patient-reported outcomes by the target community through qualitative inquiry. Our
9 research team decided to limit to empirical published studies to effectively address our research
10 aims. We have excluded gray literature due to lack of peer-review and the variable quality and
11 inconsistent reporting of program outcomes.
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23 **Setting**

24 No restrictions will be placed on the country in which the program occurred. However, this
25 review will limit to programs that take place in the community setting (i.e. outside of a hospital
26 setting).
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33 **Participants**

34 The participants in this review will be Black adults (≥ 18 years of age) with hypertension,
35 cardiovascular disease, diabetes, or stroke.
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40 **Intervention**

41 This review will include programs which deliver culturally tailored education to Black adults
42 with cardiovascular disease, hypertension, diabetes, or stroke. Thus, studies focused on
43 prevention will not be included in this systematic review. The education should relate to the
44 management of one of these conditions (i.e. hypertension, cardiovascular disease, diabetes, or
45 stroke). To be considered culturally tailored, the intervention must include at least one of the
46 following culturally appropriate strategies outlined by Kreuter and colleagues: (1) peripheral
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3 strategies, (2) evidential strategies, (3) linguistic strategies, (4) constituent-involving strategies,
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5 and (5) sociocultural strategies.
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7 8 **Type of Outcome Measure** 9

10 As the intent of this review is to inform the design and structure of future programs, all outcome
11 measurements will be reported in this systematic review, including participant-level (e.g. health-
12 related outcomes, health literacy, medication adherence, psychosocial measurements) as well as
13 program-level outcome measures (e.g. program adherence, satisfaction).
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18 19 **Patient and Public Involvement** 20

21 While the researchers recognize the importance of patient and public involvement in the research
22 process, we will not engage with patients or the public in completing this systematic review.
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26 27 **Study Records** 28

29 30 **Search Methods** 31

32 The search will be conducted by the lead author (JF) and Information Specialist (EMU) on the
33 relevant databases. To ensure we maximize our results, we will hand search the reference lists of
34 included studies.
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38 39 **Selection Process** 40

41 All articles identified from the search will be uploaded into Covidence, a reference management
42 software. Duplicates will be removed in Covidence. The titles and abstracts of the identified
43 articles will be independently screened by two reviewers based on the inclusion criteria (see
44 Table 1). However, prior to beginning title and abstract screening, interrater reliability with title
45 and abstract screening among the researchers will be tested using a random sample of 50 articles.
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48 A Kappa score of ≥ 0.80 will be deemed acceptable as it indicates almost perfect agreement
49 amongst the research team.³⁶
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3 Once studies are identified for the full-text screening, a similar process will be followed
4 with two reviewers deciding if inclusion or exclusion criteria. All articles excluded in the full-
5 text review will be categorized based on predefined terms to document the reasoning behind the
6 exclusion. To resolve any discrepancies between reviewers during title/abstract and full-text
7 review, meetings will be held at regular intervals to discuss disagreements and reach a team
8 consensus.
9

16 **Data Items and Collection Process**

17 For each article, one researcher will complete a data extraction form to record: program names,
18 study participants, setting, study design, duration, evaluation measure, intervention, outcome,
19 outcome measurements and study results to summarize the existing data.^{15,37,38} A customized
20 data extraction form will be created based on the Joanna Briggs Institute (JBI) Manual for
21 Evidence Synthesis,³⁷ TIDIER guidelines to identify essential program characteristics (Tidier
22 guidelines),³⁹ and Kreuter's five strategies of culturally appropriate interventions to determine
23 the number and type of strategies used for each program included in the review.¹⁶
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36 **Quality Appraisal**

37 Quality assessment and risk of bias will be evaluated independently by two researchers using
38 AMSTAR: A Measurement Tool to Assess Systematic Reviews⁴⁰ for all articles included in the
39 systematic review to note the quality and detect any bias present in the study. This tool is
40 appropriate for this review as it demonstrates substantial interrater agreement and has acceptable
41 reliability, construct validity, and feasibility.⁴¹
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50 **Data Synthesis**

51 This systematic review of the literature will aggregate data from all studies that have used CBCT
52 programs to improve health outcomes of Black adults with diabetes, hypertension,
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3 cardiovascular disease, or stroke using a thematic analysis.⁴² A textual description of key
4 program characteristics (e.g. populations served, type of intervention) and outcomes of each
5 program will be provided. Following this, an inductive thematic analysis will be used to identify
6 similarities and differences among and within programs.⁴² A deductive thematic analysis using
7 Kreuter and colleagues' five categories of cultural appropriateness (i.e. peripheral, evidential,
8 linguistic, constituent-involving, and sociocultural) will be used to determine how many, which
9 and how these components have been used within the design and delivery of culturally tailored
10 education programs.¹⁶ These insights will inform the creation of recommendations that can guide
11 the design and implementation of future CBCT programs for Black communities.
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24 **Discussion**

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27 This systematic review will generate comprehensive insights into CBCT programs for Black
28 adults with cardiovascular disease, hypertension, diabetes, or stroke. The recognition of
29 significant health inequities within racialized communities presents a major gap in the current
30 healthcare system where new possibilities must be explored to reduce this gap. The current
31 healthcare system has done little to incorporate cultural values, beliefs, practices, customs, diets,
32 and religious views in the development of programs for racialized communities, instead
33 programs are built with an one-size-fits-all approach that do not address the specific issues
34 impacting the target community. CBCT programs differ from a one-size-fits-all approach by
35 acknowledging cultural differences in health experiences and intend to address the barriers
36 facing culturally diverse communities to improve overall health with the assistance of the
37 community members. As CBCT programs are becoming more popular, more attention must be
38 directed to the valuable lessons that can be learned from existing CBCT programs and applied to
39 future CBCT programs.
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This review will not be without limitations. First, given variability within the literature of terminology that has been used to describe CBCT programs, there is a potential we may miss relevant articles. Second, based on the heterogeneity within study designs and outcomes included in this review, we will be unable to perform a meta-analysis and therefore unable to determine the effectiveness of these programs. Third, to ensure contextual relevance of programs, we have restricted articles published within the last twenty years; however, we recognize that limiting the study date may exclude relevant articles published before this date. Fourth, for feasibility and resource constraints, we decided to limit inclusion of articles to those available in English (i.e. articles will be excluded during title/abstract screening); however, we may miss potentially relevant literature. Fifth, the focus of this review will be on interventions designed and developed for people living with the target condition rather than prevention. Future research should explore studies that focus specifically on culturally tailored prevention programs and interventions. Lastly, to ensure we generate recommendations based on high quality evidence, we have limited this review to published articles, and as a result we will be unable to capture programs introduced within gray literature sources. While gray literature is not deemed necessary to answer our questions, omitting gray literature may introduce publication bias,⁴³ and it could be a valuable resource for future research (e.g. informing intervention development). Nonetheless, this review will highlight valuable insights into CBCT programs.

45 **Conclusion**

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Health inequities experienced by Black communities stem from a long history of systemic racism, differential treatment, and neglect from medical institutions. While health disparities are recognized as an issue within medicine, little has been done to shift the focus of medical research to solutions that are tailored to meet the specific needs of racialized communities. New models of

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3 care must be prioritized and researched to identify possible solutions to health inequities facing
4 Black communities. CBCT programs do present a possible path forward to improve the health of
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6 racialized communities with messaging that is tailored to their specific cultural needs and
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8 encourages a deeper level of ownership over the type of care they receive. CBCT interventions
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10 must be assessed to determine the effectiveness of addressing health disparities in the interest.
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14 **Ethics and Dissemination**

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17 This systematic review protocol does not require ethics approval without human participants.

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20 The review will be an aggregate of published studies that focus on CBCT rather than developing
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22 a CBCT program. The systematic review findings will be disseminated in a peer-reviewed
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24 journal with an interest addressing health inequities faced in the Black community. The intention
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26 of the authors is to use the review findings to disseminate potential strategies to develop
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28 culturally tailored programming within community-based organizations.
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31 **Declarations**

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34 **Authors' contributions:** JF conceptualized the project and wrote the original protocol draft. JF,
35
36 HS, and OP developed methodology, wrote, reviewed, and edited the protocol. EMU assisted in
37
38 the creation of the search strategy and ran the search. MLAN contributed to the
39
40 conceptualization of the project and provided supervision over the scope of the project.
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42

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45
46 public, commercial or not-for-profit sectors. HS holds the March of Dimes Canada Paul J. J.
47
48 Martin Early Career Professorship.
49

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51 **Competing interests:** The authors declare that they have no competing interests.
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Appendix A: Full search strategy for Medline

Medline OVID Search from September 30, 2021			
#	Searches	Results	Comment
1	african continental ancestry group/ or african americans/	91690	
2	(african adj2 american*).ti,ab,kf.	51564	
3	or/1-2	112373	Ethnic group terms
4	Culturally Competent Care/	1887	
5	cultural diversity/ or Cultural Characteristics/	28371	
6	cultural competency/	6048	
7	(cultural* adj2 adapted).ti,ab,kf.	1661	
8	(cultural* adj2 competen*).ti,ab,kf.	5244	
9	(cultural* adj2 tailor*).ti,ab,kf.	1216	
10	or/4-9	39177	Culturally competent terms
11	self care/ or blood glucose self-monitoring/ or self administration/ or self medication/	57615	
12	exp Cardiovascular Diseases/	2528700	
13	glucose metabolism disorders/ or exp diabetes mellitus/ or exp glycosuria/ or exp hyperglycemia/ or exp hyperinsulinism/ or exp hypoglycemia/	554001	
14	aftercare/ or exp rehabilitation/	3237982	
15	or/11-14	292	Chronic Disease rehabilitation terms
16	3 and 10 and 15	431544	Base set 1
17	attitude to health/ or health knowledge, attitudes, practice/ or "treatment adherence and compliance"/ or "patient acceptance of health care"/ or patient compliance/ or medication adherence/ or no-show patients/ or patient dropouts/ or patient participation/ or patient satisfaction/ or patient preference/ or treatment refusal/ or vaccination refusal/	173976	Health attitude terms
18	consumer health information/ or health literacy/ or health promotion/ or healthy people programs/ or weight reduction programs/ or patient education as topic/	377	Consumer health terms

19	3 and 15 and 17 and 18 [**Base set 7 Attitudes and Ethnic Groups and Diseases and patient education**]	641	Base set 2
20	16 or 19	627	Final results

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Pg. 1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Pg. 3
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Pg. 1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Pg. 15
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Pg. 1
Support:			
Sources	5a	Indicate sources of financial or other support for the review	Pg. 15
Sponsor	5b	Provide name for the review funder and/or sponsor	Pg. 15
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Pg. 15
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	Pg. 4-7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Pg. 7
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Pg. 8-9
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Pg. 8
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Pg. 8
Study records:			

Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Pg. 12
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Pg. 11-12
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Pg. 12
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources) any pre-planned data assumptions and simplifications	Pg. 9-11
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Pg. 11
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Pg. 12
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	Pg. 12-13
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Pg. 12-13
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Pg. 12
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Pg. 12

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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