

A Mixed-methods Approach to Understanding the Perspectives, Experiences and Attitudes of Cognitive Behavioral Therapy for African American Patients with Type-2 Diabetes: A Randomized Parallel Design Pilot Study

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1 **A Mixed-methods Approach to Understanding the Perspectives, Experiences and Attitudes**
2 **of Cognitive Behavioral Therapy for African American Patients with Type-2 Diabetes: A**
3 **Randomized Parallel Design Pilot Study**

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40 **Abstract:**

41

42 Background: African American (AA) adults are 60% more likely to be diagnosed with diabetes
43 mellitus (DM) and experience more complications than non-Hispanic White adults. Cognitive
44 behavioral therapy (CBT) is a technique that combines traditional care with cognitive and
45 psychosocial techniques. We aimed to assess the effects of CBT integrated with motivational
46 interviewing (MI) on glycemic control in AA participants and understand their perspectives,
47 attitudes, and experiences toward CBT.

48

49 Methods: Using a randomized, parallel design pilot study (web-based group vs in-person group),
50 20 participants aged ≥ 18 years, identifying as AA, and having a glycosylated hemoglobin
51 (HbA1c) $> 8\%$, were recruited. CBT was administered in six sessions over three months.
52 Participants completed baseline and follow-up assessments on measures for diabetes control
53 (HbA1c), self-efficacy, generalized anxiety, depression, perceived stress, health-related quality
54 of life and cognitive ability. Post-CBT focus groups were conducted to determine patient
55 perspectives regarding the intervention.

56

57 Results: Fourteen participants completed the study, their mean HbA1c improved from 8.5% to
58 7.7%. The Diabetes Distress Scale demonstrated decreased distress overall ($t(26)=2.6$; p -
59 $value=0.02$). The Generalized Anxiety Disorder Scale demonstrated decreased generalized
60 anxiety for all participants ($t(26)=2.2$; $p=0.04$). Themes identified in focus groups included: (1)
61 intervention group social support through information sharing; (2) mental health and personal
62 identities in diabetes understanding and management; (3) receptivity to CBT/MI Intervention
63 positively impacts self-efficacy through improved health literacy.

64 Conclusion: Group-based CBT intervention for type 2 DM care was positively received by AA
65 participants and helped improve diabetes control, as demonstrated by the change in HbA1c.
66 There were additional benefits of social support through group interactions and a stronger sense
67 of self-efficacy due to health education. A comprehensive treatment plan like CBT, may be
68 useful in promoting healthy diabetes self-management.

69

70 Trial registration: This trial is registered at ClinicalTrials.gov with the identifier NCT03562767.

71 *Registered 19 June 2018,*

72 *<https://clinicaltrials.gov/ct2/show/NCT03562767?term=NCT03562767&draw=2&rank=1>*

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75 **Key Words:**

76 1) African American 2) Type 2 Diabetes 3) Cognitive Behavioral Therapy

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87 **Key Messages Regarding Feasibility:**

88 1) What uncertainties existed regarding the feasibility?

89 At the start of the trial, investigators were concerned about the feasibility of using a technology-
90 based intervention in an older age group- in terms of both, access and uptake. Another concern
91 was the level of comfort among participants during discussions pertaining to their medical
92 condition and barriers in achieving optimal health.

93 2) What are the key feasibility findings?

94 This study demonstrated that technology was not a barrier for participation and retention of study
95 participants. It indicated that group and web-based interventions were feasible and acceptable.

96 3) What are the implications of the feasibility findings for the design of the main study?

97 Future studies with a larger sample size, exploring the acceptability and effects of cognitive
98 behavior therapy on diabetes mellitus control in African American people, are feasible.

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105 **Background:**

106 In 2018, about 10% of the total US population was estimated to have diabetes mellitus (DM) (1).
107 According to the Centers for Disease Control and Prevention, diabetes has been documented to
108 have a disproportionate impact on the African American (AA) population of the United States
109 (2). AA adults are 1.7 times more likely to develop diabetes as non-Hispanic White adults and
110 twice as likely to die from diabetes (2). These disparate diabetes outcomes have been linked to
111 traditional risk factors such as obesity and lower socioeconomic status (SES), as well as risk
112 factors attributed to the environment and lifestyle choices of AA adults (3).

113 AA adults are more likely to receive a physician diagnosis of DM, have worse glycemic control
114 and have more DM-related complications compared to non-Hispanic White adults (4-7). Risk
115 factors for DM are also more prevalent in the AA population, such as a 1.3 times greater
116 likelihood of obesity when compared to Non-Hispanic White adults (8). Other related risk factors
117 seen in the AA population at higher rates include, hypertension, high cholesterol levels and
118 smoking. Additionally, depression, anxiety and diabetes-related specific concerns are common
119 comorbidities in people with DM (9-11). The relationship between DM and these co-morbidities
120 is complex, since they are thought to influence each other and are affected by biological and
121 psychosocial pathways (12). The interaction between DM and related comorbidities adds a
122 complex behavioral aspect of diabetes management, since it requires tasks with self-care
123 components such as activity, diet, adherence and compliance with treatment regimens, self-
124 monitoring of glucose levels, and making and keeping healthcare appointments.

125

126 Further aggravating the impact of type 2 diabetes on AA adults are racial discrimination and low
127 SES. These two factors are respectively associated with poorer health outcomes and a greater
128 prevalence of diabetes (13, 14). Even after accounting for factors related to socioeconomic
129 position, access to healthcare and severity of disease, these racial/ethnic differences in glycemic
130 control persist (5, 6). The greater risk and diabetes burden in AA patients suggests a need for
131 tailoring interventions in this high-risk group.

132

133 Psychological interventions such as cognitive behavioral therapy (CBT) have been shown as
134 effective for overcoming behavioral barriers related to self-care and improve glycemic control
135 among people with diabetes. CBT combines traditional care with cognitive and psychosocial
136 techniques to address thoughts, beliefs, and behaviors detrimental to self-care and replace them
137 with more helpful thoughts and behaviors. CBT has previously been used to account for
138 depression in diabetes care and assess biological markers of diabetes along with behavioral
139 outcomes of diabetes management (15, 16). Systemic reviews of CBT-based interventions on
140 glycemic control have found that CBT may be beneficial in improving glycemic control and
141 other aspects of psychological health, such as depression (17, 18). Furthermore, since non-
142 compliance is one of the most commonly cited reasons for CBT-based therapy failure (19), we
143 believed that modifying our CBT approach by integrating Motivational Interviewing (MI) into
144 the delivery of the intervention would support participants' engagement. Engagement is a
145 foundational pillar of MI, in the process of learning, and applying CBT content. Therefore, we
146 integrated MI into this intervention as a delivery process to encourage patients' acceptance
147 and motivation to practice CBT skills that promote healthy lifestyle choices.

148 There are no studies that have examined the effects of an integrated CBT/MI intervention in a
149 group-based format among AA patients and examined its effects with uncontrolled diabetes. Our
150 pilot study aimed to assess the efficacy of this CBT/MI intervention related to glycemic control
151 in AA participants and understand their experience and assess their perspectives and attitudes
152 toward this CBT/MI intervention.

153 **Methods:**

154 Study design and setting: The LIGHT (Lifestyle Intervention Guidance for a Healthier
155 Tomorrow) study was a randomized, parallel design pilot clinical trial. It was conducted at the
156 Dunwoody Family Medicine Clinic, Emory University, Atlanta, GA in 2019. The participants
157 were administered a behavioral intervention (CBT) program, from March 2019- May 2019, with
158 the administration of initial study scales shortly before beginning the study in March of 2019 and
159 the collection of follow-up data in May of 2019. It used a mixed methods approach with
160 quantitative and qualitative study methods to assess glycemic control, perspectives, experiences
161 and attitudes of AA patients with diabetes mellitus. The trial was registered at ClinicalTrials.gov
162 (identifier: NCT03562767).

163

164 Study population: (Figure 1) Participants were recruited from primary care clinics by various
165 study staff at Emory through phone calls or letters. Eligibility criteria for this study included, age
166 ≥ 18 years, fluency in English, identifying as AA and, having a glycosylated hemoglobin
167 (HbA1c) level of over 8% (an indicator of uncontrolled diabetes mellitus). Participants were
168 excluded if they did not have internet access, used insulin pumps, were pregnant, actively
169 misused substances (including alcohol) and had visual or physical impairments that did not allow

170 them to complete study activities. Participants were followed-up for a three-month period. From
171 the initial 20 participants who were recruited, 14 participants completed the study with 7 in each
172 intervention group. The six study participants who did not complete the study either failed to
173 attend a sufficient number of intervention sessions or were missed follow-up visits for post-study
174 data collection. All participants provided informed consent and research activities were approved
175 by the Emory Institutional Review Board.

176

177 Cognitive behavior therapy intervention: Participants were randomized using computer
178 generated random numbers to one of two CBT/MI formats - a web-based and an in-person
179 format. Both formats had six 1-hour sessions, every 2 weeks for three months, focusing on food
180 planning education (15 minutes) and culturally specific CBT presentations and interactive
181 activities (45 minutes). The in-person format allowed for group interaction which was limited in
182 the web format. The inclusion of both formats in a study assessing CBT is a novel technique.
183 This intervention was led by a licensed psychologist who had extensive experience providing
184 CBT and MI treatment to African American patients. This individual is a member of the
185 Motivational Interviewing Network of Trainers (MINT). As a MINT member, this psychologist
186 is experienced in training clinicians to support participants' engagement and motivation to make
187 health behavior changes, including implementing CBT skills. The licensed psychologist trained
188 the study facilitator using the Motivational Interviewing Treatment Integrity Coding Manual
189 (MITI) 4.2.1 (20). Using the coding manual's evaluation standards to
190 determine competence, the study facilitator was determined to have met a "good" (highest
191 category) threshold of clinician competence and proficiency in applying MI.

192

193 Evidence suggests that, in general, adapted interventions outperform non-adapted interventions,
194 and are preferred by African American populations (21, 22). Thus, we determined that
195 developing behavioral health interventions for MCI-related cognitive and functional decline in
196 ways that are culturally relevant to African American patients was important. To access expertise
197 in cultural tailoring, we worked with an African American clinical psychologist and researcher
198 who had expertise in both CBT and the cultural-adaptation of evidence-based interventions for
199 African American patients. The intervention team received implicit bias training, lectures, and
200 ongoing consultation from our cultural tailoring content expert in order to learn about
201 sociocultural considerations relevant to African American people and increase awareness of
202 microaggressions that are commonly overlooked or dismissed (23). Bi-weekly, the cultural
203 tailoring content expert met virtually with the intervention team to provide feedback on drafts of
204 each module. The goal of this feedback was to understand cultural considerations and strategies
205 for integrating African American cultural values into the intervention.

206

207 Quantitative assessments: At baseline and during follow-up, participants were administered
208 paper-based survey questionnaires that collected information on demographics. They also
209 answered surveys on self-efficacy, generalized anxiety severity, depression severity, perceived
210 stress, health-related quality of life (HRQoL), and cognitive ability. Sociodemographic
211 information of interest included age, gender, education level, and marital status, all of which
212 were self-reported. Participant body mass index (BMI) was used to determine obesity status
213 (normal weight, overweight, obese). Additionally, glycosylated hemoglobin (HbA1c)
214 information was obtained for all participants from Electronic Medical Records and Point of Care
215 Testing, at baseline and during follow-up.

216 The measure of self-efficacy was collected using the Self-Management Resource Center's Self
217 Efficacy for Diabetes scale (24). This 8-item scale assesses self-efficacy in diabetes self-
218 management. A score closer to 10 is indicative of greater self-efficacy. The Diabetes Distress
219 Scale is a 17-item, 6-point Likert, scale that evaluates the severity of emotional distress
220 experienced by a person with diabetes (25). It provides an overall score and one for each of the
221 following dimensions: emotional burden, regimen distress, interpersonal distress and physician
222 distress. The patient's responses associated with each of the four dimensions were summed then
223 divided by the number of items in the given dimension. The mean of the responses to all 17
224 items was calculated to determine the overall distress experienced. A mean score of 3 (moderate
225 distress) or higher is serves as the indicator for clinical attention for study participants.

226 Generalized anxiety in the two weeks prior to the scale's administration was assessed using the
227 Generalized Anxiety Disorder (GAD) Scale- 7 (26). It assesses the degrees to which participants
228 feel anxious, nervous or restless. A higher score indicates greater severity of anxiety. The Patient
229 Health Questionnaire (PHQ)-9 scale assesses the severity of depression, a higher score is
230 indicative of greater severity of depression (27). The Perceived Stress Scale (PSS) was used to
231 assess the extent to which participants identify situations in their life as stressful, within the past
232 month (28). A higher score suggests greater perceived stress. Health-Related Quality of Life
233 (HQRoL) was assessed using the RAND-36 survey (29). It is a scale which assesses eight health
234 concepts: physical functioning, role limitations caused by physical health problems, role
235 limitations caused by emotional problems, social functioning, emotional well-being,
236 energy/fatigue, pain and general health perceptions (29). Each of these health concepts are
237 scored continuously (0-100), higher scores suggest a more positive perception of HRQoL. The
238 Montreal Cognitive Assessment (MoCA) scale screens for cognitive dysfunction and assesses

239 different cognitive domains through performance of twelve different tasks (30). A sum of item
240 scores is used to determine cognitive ability, a score of ≥ 26 is considered 'normal.'

241 Qualitative assessments: Following the CBT/MI intervention, focus group sessions were
242 conducted to evaluate the receptivity of the CBT/MI intervention among participants through
243 semi-structured focus group discussion (FGD). Based on the intervention format to which they
244 were randomized, participants were assigned to separate focus groups- one focus group for the
245 web-based intervention and one group for the in-person intervention. These sessions were 25
246 minutes in length and were conducted in-person in one of Emory University Healthcare System
247 Dunwoody clinic's conference rooms. The sessions were audio recorded by the interviewer and
248 there was a student collaborator present as a notetaker during each session.

249 The Diffusion of Innovations theoretical framework was used in designing the interview guide
250 found in Appendix A. This model is designed to communicate new knowledge to members of
251 target groups through four main elements: innovation, communication channels, social system
252 and time (31, 32). The innovation being assessed is the Cognitive Behavioral Therapy through
253 web-based and in-person intervention formats. Communications channels were the culturally
254 tailored materials presented to participants during the study. The social system is the target
255 population: Black or African American patients with type-2 diabetes. The time is the
256 incorporation of the study over a six-session intervention time frame. The Diffusion of
257 Innovations model helped incorporate these key elements into the interview guide to
258 theoretically frame the information garnered from study participants.

259 The focus group discussion questions aimed to capture participants' perspectives, attitudes, and
260 experiences with the CBT/MI intervention. The post-study focus group session evaluated study

261 acceptability and cultural congruence of the CBT/MI intervention through semi-structured group
262 discussions. The focus groups aimed to assess compatibility, complexity, observability, and
263 relative advantage of a culturally tailored CBT/MI for AA patients. It also aimed to assess the
264 cultural sensitivity of the study.

265

266 Data analysis:

267 Quantitative analysis: Baseline characteristics of study participants were assessed using t-tests
268 and chi-square tests, as needed. Baseline and follow-up assessments of quantitative scales were
269 assessed for change in scores. This was done among the overall study population as well as by
270 intervention group. For continuous scales, paired t-test were used to assess change and for
271 categorical scales, chi-square tests were used. Statistical significance was set at an alpha level of
272 .05. Quantitative analyses were performed on SAS 9.4 M software.

273

274 Qualitative analysis: Audio-recordings were transcribed and imported into the MAXQDA
275 analysis software. For each transcript, initial memos were developed to obtain familiarity of
276 information in each interview. This was followed by development of a codebook containing
277 names and definitions of codes and sub-codes that were developed. The codebook can be
278 accessed in Appendix B. The transcripts were then coded by a student collaborator at the Rollins
279 School of Public Health, who's coding techniques were discussed with the team and approved.
280 Once coded, the codes and coded segments were reviewed to develop overarching themes
281 describing related codes. Overarching themes were determined by assessing coding co-
282 occurrence and proximity of codes through the MAXQDA code map function. A preliminary
283 code map (Figure 2) was used to assess co-occurrence and coding similarities of all codes. The

284 subsequent code maps (Figures 3-5) were derived from the preliminary code map to determine
285 the thematic threads of the study. Themes were further developed by exploring differences and
286 similarities in perspectives expressed in each intervention group. A second cycle of coding was
287 completed by reviewing matrices of related codes and by comparing and contrasting themes
288 between the two intervention groups. Quotes were identified that illustrated identified themes.

289 **Results:**

290

291 Participant characteristics: (Table 1)

292 Participants had a mean age of 56 ± 9.4 years, 79% identified as women ($n=11$). About half the
293 participants had a college degree or higher and half reported being currently unmarried. The
294 mean duration since a diagnosis of diabetes was 13 ± 5.3 years. BMI measurements categorized
295 64% of participants as obese. Demographic information can be found on table 1.

296 Quantitative results: (Table 2)

297 The Self Efficacy for Diabetes scale results demonstrated a statistically insignificant decrease in
298 scores for all participants, with a baseline mean score of 7.2 and a follow-up mean score of 7.1
299 ($t(26)=0.26$; $p\text{-value}=0.80$). The in-person and web-based groups also had statistically
300 insignificant decreases in mean group scores for self-efficacy, as demonstrated in table 2. The
301 Diabetes Distress Scale demonstrated decreased distress overall, from a mean at baseline of 2.5
302 to a follow-up mean of 2.0 ($t(26)=2.6$; $p\text{-value}=0.02$), and in each of the four dimensions it
303 assesses; emotional burden, regimen distress, physician distress, and interpersonal distress. The
304 physician distress and interpersonal distress did not have statistically significant differences
305 between baseline and follow-up mean scores. The emotional burden dimension had a statistically
306 significant decrease in mean scores, with a baseline mean score of 2.9 and a follow-up mean

307 score of 2.3 ($t(26)=2.6$; $p\text{-value}=0.02$). In-person participants also had a statistically significant
308 decrease in emotional burden mean scores, as demonstrated in table 2. The regimen distress
309 dimension had a statistically significant decrease in mean scores, with a baseline mean score of
310 3.1 and a follow-up mean score of 2.6 ($t(26)=2.6$; $p\text{-value}=0.02$). The web-based group also had
311 a statistically significant decrease in regimen distress mean scores, as shown in table 2. The
312 Generalized Anxiety Disorder Scale had a statistically significant decrease in anxiety from mild
313 anxiety to low anxiety for all participants, with a mean baseline score of 6.3 and a follow-up
314 mean score of 4.2 ($t(26)=2.2$; $p\text{-value}=0.04$). The Generalized Anxiety Scale did not yield
315 statistically significant differences in the in-person and web-based groups, as demonstrated in
316 table 2. Depression, as assessed by the PHQ-9 questionnaire, decreased by the end of the study
317 but was not statistically significant for the study cohort and each intervention group (table 2).
318 Similarly, there was a statistically insignificant decrease in perceived stress levels in the study, as
319 assessed by the Perceived Stress Scale (table 2). More specifically, the in-person group had an
320 increase in perceived stress (13.3 to 15.4) while the web format participants had a decrease in
321 perceived stress (17.0 to 13.6). The only HRQoL domain of the RAND-36 survey that
322 demonstrated a statistically significant increase was the pain health concept. A statistically
323 significant increase for this health concept was demonstrated for participants overall as well as
324 the in-person group. The overall mean score increased from 51 at baseline to 70 at follow-up
325 ($t(26)= -3.8$; $p\text{-value}= 0.002$), and the in-person group mean score increased from 39 at baseline
326 to 64 at follow-up ($t(26)= -0.28$; $p\text{-value}= 0.01$). Most of the remaining health concepts had
327 increased mean scores from baseline to follow-up assessments, although these differences were
328 not statistically significant (table 2). In the paired t-test analyses, participant mean HbA1c
329 improved from 8.5% at baseline to 7.7% during follow-up ($t(26) =0.4$, $p\text{-value}=0.08$) (table 2).

330

331 Qualitative results:

332 Themes identified from the qualitative data included: (1) intervention group social support
333 through information sharing; (2) mental health and personal identities in diabetes understanding
334 and management; (3) receptivity to CBT/MI Intervention positively impacts self-efficacy
335 through improved health literacy.

336

337 *Intervention Group Social Support Through Information Sharing:* Participants in both
338 intervention formats emphasized the importance of participating in the intervention as a means of
339 social support which required intentional engagement with the intervention materials and
340 between participants of the intervention. Two general ideas were expressed pervasively in the
341 transcripts: 1) participants benefit most by sharing and receiving information 2) participants were
342 reassured by knowing that they were not alone in treating their diabetes. For this thematic thread,
343 social support and information sharing was linked to interactions within study groups but did not
344 extend outside of the group. Reflections of the participants demonstrated perceptions of the
345 importance of being open to the experiences of others and that day-to-day behaviors could be
346 influenced by the information learned from group interactions. In seeking support from focus
347 group members, the sentiment that participants were in a community where they could be
348 understood was an important thematic thread. Participants were reassured by the communal
349 experience of navigating diabetes management with others also inspired by the success they
350 shared as a group. This sentiment was clearly expressed by one participant who stated, “I hear
351 [somebody’s] victory so that encourages me.” The sense of belonging mirrored the effect of
352 information sharing, as participants were willing to adjust behaviors to improve diabetes

353 management. The support gained from a shared experience spurred participant to treat their
354 diabetes in novel ways with the new information gained. Participants were in a space where they
355 felt comfortable enough to honestly share instances of unhealthy behaviors, which illustrates the
356 supportive environment that was promoted by the CBT/MI intervention. Instead of being
357 criticized by fellow group members for admitting unhealthy behaviors, participants were instead
358 encouraged to “do it in moderation.” Promoting moderation as a mechanism for more sustainable
359 behavioral change was often mentioned in the transcripts and encouraged among participants to
360 limit the intake of unhealthy foods. The community formed by study participants also provided
361 study group members with accountability and positive reinforcement. One participant stated, “I
362 know I was [going to] feel accountable when we had the meeting [...] it definitely inspired me to
363 do better,” clearly demonstrating the promotion of sustained behavioral change due to group
364 accountability. The code map that illustrates the visuospatial relation of the codes which
365 informed this thematic thread can be found in figure 3.

366

367 *Mental Health and Personal Identities in Diabetes Understanding and Management: Study*
368 participants emphasized that the stresses associated with being AA or Black were unique. One
369 participant stated, “African Americans may have some life stressors that other classes may not
370 have.” Identifying the stressors associated with race was an important step in understanding
371 underlying influences that contribute to effective behavioral changes. Race was not the only
372 pertinent identity that participants discussed in relation to diabetes management. One participant
373 discussed how costs associated with proper diabetes management was linked to socioeconomic
374 position when he stated, “The whole management [...] between medications and equipment [...]
375 [...]in terms of healthy eating [...] It can become taxing on the pocketbook.” The costs associated

376 with proper diabetes management can impact beneficial behavioral changes when considering
377 SES. Participant mental health also impacted their perception of diabetes. The mental health
378 challenges of managing diabetes were shown to be linked to a lack of effective strategies of
379 managing diabetes with reflections of how the CBT/MI intervention improved management
380 techniques. Their reflections demonstrated that mental health was negatively impacted by having
381 diabetes, which improved with the CBT/MI intervention. Having a social network of people
382 living with diabetes contributed positively to their outlook on diabetes management as this
383 provided an outlet of negative emotions and an improved perspective of diabetes. Ultimately, a
384 participant's reflection revealed that "the intervention [...] made me realize that I wasn't the only
385 one," emphasizing the importance of having a community to lean on. The code map that
386 illustrates the visuospatial relation of the codes which informed this thematic thread can be found
387 in figure 4.

388 *Receptivity to CBT/MI Intervention Positively Impacts Self-Efficacy through Improved Health*
389 *Literacy:* Receptivity captured the positive dimensions of how study participants received study
390 materials. The sentiment that positive reception was essential to a more successful participation
391 experience was shared by many study participants. The positive reception of study materials with
392 an improved outlook on living with diabetes resulted in participants retaining health information
393 thus improving health literacy. Improved health literacy was most readily observed when a
394 participant said, "You can go at it a different route, cause now you have more knowledge about
395 what you're dealing with", identifying the benefit of health literacy to diabetes management. As
396 a result, participant self-efficacy improved as they accepted and applied the knowledge shared
397 with them. The intervention also increased awareness to life stressors to promote healthy coping
398 strategies beneficial to diabetes management, thus providing another mechanism to maintain a

399 positive outlook; informed decision making. There was a cyclical trend of the positive reception
400 of information which allowed participants to retain the learned information to be self-efficacious
401 and apply it toward positive health outcomes. Per their reflections, participants were able to
402 “recognize the problem [...] apply those things they learned,” and were “prepared to deal with
403 the situation” following the CBT/MI intervention. The code map that illustrates the visuospatial
404 relation of the codes which informed this thematic thread can be found in figure 5.

405

406 **Discussion:**

407 This study evaluated the feasibility and acceptability of a cognitive behavior therapy intervention
408 among African American patients with type-2 Diabetes mellitus. It additionally explored the
409 experiences of African Americans with type 2 diabetes and captured their perspectives
410 concerning Culturally Tailored CBT/MI as an intervention technique in managing their diabetes.
411 An analysis was performed to determine how the intervention was received by participants and
412 quantitative baseline and follow-up data was analyzed to determine if positive or negative
413 perceptions were supported by health-related assessment tools. The study was conducted by
414 independently assessing qualitative and quantitative data to gain an understanding of the
415 implications CBT/MI interventions have for Black or African American people in the U.S. A
416 grounded theory approach allowed the study team to explore how the information gleaned from
417 the independent analysis of the quantitative and qualitative data could better inform study
418 findings when considered concurrently. Results of the concurrent analysis illuminated two core
419 concepts: 1) disease perception and perspectives on quality of life are interrelated 2) social
420 support gained from CBT/MI interventions relate to perceived distress associated with diabetes
421 management. This concurrent analysis revealed that a group-based CBT/MI intervention for type

422 2 DM care was feasible, acceptable, and positively received by AA participants. There were
423 benefits of social support through group interactions and a stronger sense of self-efficacy due to
424 health education.

425

426 Core Concept: Quality of Life and Disease Perceptions

427 Participants reported increased mean scores, from baseline to follow-up assessments, in seven of
428 the eight health concepts of the HRQoL scale. The concept of pain had a statistically significant
429 increase, during follow-up, for the overall group and the in-person intervention group. This is
430 indicative of more positive perceptions of HRQoL in relation to pain associated with DM. The
431 RAND-36 Emotional problems/ limitations health concept is the only HRQoL health concept to
432 differentially demonstrate decreased HRQoL overall and in both intervention groups. When
433 coupled with the results of the depression scale there exists a congruence in the observed trend in
434 which participants have decreased health-related emotional capacity with mild levels of
435 depression. These mixed results for HRQoL were particularly intriguing and warranted further
436 consideration.

437 Concurrent analysis of the data emphasized the importance of considering how the unique
438 stresses of being AA, expressed in the qualitative data, interacts with the quantitative mental
439 health and HRQoL data. Participant awareness of their daily stresses, influenced by their racial
440 identity, assisted in developing coping mechanisms that aid in diabetes management and may
441 improve their perceived HRQoL. Awareness of these stresses may conversely lead to cynicism
442 that can contribute to other mental health concerns and perception of decreased HRQoL. The
443 literature emphasizes that diabetes-related distress and depression can contribute to low glycemic
444 control, treatment adherence behaviors and self-management (15-17). However, research on

445 social networks and diabetes management has shown that the quality of an individual's social
446 network could be an indicator of improved health outcomes in diabetes management (33). The
447 qualitative data indicated that providing a space with social support which disseminated pertinent
448 health information could mitigate the mental health difficulties participants faced. Therefore, the
449 community created in the respective intervention groups may have been beneficial to participant
450 health outcomes during the study.

451 Sociological factors are also essential in holistically considering disparate health outcomes for
452 AA adults with type 2 diabetes. Self-reported experiences of racial discrimination have been
453 associated with poorer health outcomes in type 2 diabetes (13). The effects of SES have also
454 been shown to be associated with the prevalence of type 2 diabetes in the AA community (14).
455 The literature cites a strong inverse relationship between SES and diabetes incidence, citing that
456 as income and educational level decrease the diabetes risk increases two-fold (34). Therefore,
457 sociological factors independent of patient behavior may contribute to poor health outcomes. By
458 gaining a better understanding of life stressors associated with their race and socioeconomic
459 position, participants were able to develop better coping strategies to manage their diabetes,
460 further facilitated by their open-mindedness to behavioral change. The study's qualitative data
461 demonstrated the importance of SES in considering the costs associated with proper diabetes
462 management. The associated additional costs result in higher levels of stress due to the added
463 financial burden of diabetes care. The interaction of participant identities and stress when
464 considering behavioral change to improve diabetes outcomes was identified as a quintessential
465 aspect of understanding the perspectives of AA patients.

466 As a group, participants held each other accountable to improve diabetes management while
467 bolstering mental health support in the community that participants created with one another.
468 The intervention offered participants a skillset to cope with the stress of diabetes management
469 and have an active role in improving their quality of life. While there may have been an
470 improved outlook on disease management, the stresses associated with daily diabetes
471 management for an AA person may still contribute to a decreased emotional capacity to cope
472 with diabetes in terms of mental health. Finding a community of support may help with the
473 diminished emotional capacity observed in the study.

474

475 Core Concept: Emotional Burden, Distress & Social Network Support

476 The DDS demonstrated decreased distress overall and in each of the scale's four dimensions:
477 Emotional Burden, Physician Distress, Regimen Distress, and Interpersonal distress. Emotional
478 Burden and Regimen Distress had scores greater than or equal to the clinically meaningful
479 threshold of 3 at baseline and, subsequent scores that decreased to levels below this threshold.
480 These results suggest that the CBT/MI intervention appeared to lower distress associated with
481 the diabetes management regimen, which could be more effective on a web-based platform.
482 Similarly, the intervention may be beneficial in alleviating distress associated with the emotional
483 burden of diabetes, more so in an in-person setting.

484 It is important to note that a major documented comorbid factor to diabetes is depression. Studies
485 have shown that depression and diabetes are likely to occur together twice as frequently as would
486 be predicted simply by chance (10). The incidence of depression has also been documented to be
487 24% higher in people with diabetes (35). Not only are diabetes and depression more like to occur
488 together, but they have also been shown to exacerbate symptoms. Epidemiological studies have

489 demonstrated that the association between the two illnesses is bidirectional, which means that
490 diabetes can impact the patient's psychological well-being while depression can impact the
491 severity of diabetes symptoms (36, 37). More specifically, people with diabetes have longer
492 lasting depressive episodes that occur more often than those in the general population (3). The
493 group-based design of the CBT/MI intervention was beneficial to patients who experienced the
494 comorbid effects of diabetes and depression by providing a space to promote proper diabetes
495 management and social support. The Mental Health, Personal Identities and Diabetes
496 Management theme revealed that participants had positive outlooks when in a social network of
497 similar experiences. Group members demonstrated a level of comfort such that, they shared
498 unhealthy eating behaviors. In turn, the group's response was to approach diabetes treatment
499 with a mindset of moderation, which was crucial in supporting participants.

500 Positive reinforcement and group accountability fostered candid conversations among group
501 members and enabled participants to build a social support system. Health literacy disparities
502 were addressed through provision of health information from a trained health professional.
503 Participant receptivity of study material was essential in addressing disparities in health literacy.
504 An integrative review of the self-management of type 2 diabetes indicated that the perspectives
505 and participation of patients is vital in the continued success of properly treating type 2 diabetes
506 (38). The participants' willingness to learn and apply study information allowed them to retain
507 the CBT/MI intervention to bolster their self-efficacy. Past research has also shown that
508 combining medical nutrition therapy and self-management education improved patient outcomes
509 with significant weight loss, HbA1c reduction, and a decrease in cholesterol levels (39). Further
510 research exploring the impact of diabetes self-management education demonstrated improved
511 self-care, improved self-efficacy and lower levels of psychological distress (40). AA participants

512 also demonstrated better health status with their improved psychological distress (40). Therefore,
513 promoting self-efficacy through this CBT/MI intervention was an appropriate approach to
514 address the psychological distress associated with diabetes management.

515 Group member accountability and participant receptivity may have contributed to the decreased
516 regimen distress observed in this setting of social support. Creating a communal component to
517 diabetes management may be an effective method to improving the outlook of AA adults and
518 mitigate the associated distress stemming from living with diabetes as a member of this racial
519 group.

520

521 Strengths and Limitations: The study had a number of strengths. It presented a novel approach of
522 provision of CBT/MI in two forms- an in-person format and a web-based format which has not
523 been attempted previously. The study addressed a significant gap in existing literatures by
524 explicitly considering the perspectives of AA adults in chronic disease management. The study
525 revealed unique aspects of health education and chronic disease management through the
526 CBT/MI intervention, to aid participants in promoting positive health outcomes. The study
527 provided participants knowledge about psychological, behavioral, psychosocial, and social
528 determinants of health for a more holistic treatment plan. Participants were empowered through
529 information sharing and in finding social support among other study participants.

530 Our study was a pilot study but experienced loss to follow-up, potentially resulting in selection
531 bias. This may affect the depth and richness of the data collected through the focus group
532 discussions. Participants were provided the surveys to fill out on their own and assured
533 anonymity. However, there is still a possibility that the self-reported data may have social
534 desirability bias as they related to concepts of mental health, which is often stigmatized.

535 Hemoglobin A1C was measured for a few participants using a point of care test which may have
536 introduced measurement error. While the difference in mean hemoglobin A1C scores was not
537 significant, the data does indicate some promise for future studies. The information from focus
538 groups may have come from participants who are more likely to actively engage with the study
539 and may have resulted in an unintentional bias to be introduced toward more positive reflections.

540

541 **Conclusion:**

542 The study demonstrated that CBT/MI based group intervention was feasible and acceptable in
543 AA with uncontrolled type 2 diabetes. A CBT/MI based group intervention led to positive
544 changes in glycemic control (change in HbA1c from 8.5% to 7.7%), distress and anxiety
545 associated with diabetes mellitus. Our focus group analyses showed the benefits of social support
546 through intervention group interactions, and a stronger sense of participant self-efficacy due to
547 health education and information sharing, Study results supported prior findings that
548 mental/psychological health is an important factor in diabetes treatment and management,
549 supporting the idea that diabetes is a multifactorial disease. Given the complex array of
550 interacting components to diabetes, a more comprehensive treatment plan, like CBT/MI, may be
551 useful in promoting healthy diabetes self-management. Future studies should consider expanding
552 the study's sampling frame to include a wider range of the AA population and similar tailored
553 interventions targeting other marginalized groups. This approach would diversify the lived
554 experiences of participants and provide more robust data to better understand how to support
555 diabetes management in the AA community.

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559 **List of Abbreviations:**

560 African American (AA)

561 Diabetes mellitus (DM)

562 Cognitive behavioral therapy (CBT)

563 Motivational Interviewing (MI)

564 Glycosylated hemoglobin (HbA1c)

565 Socioeconomic status (SES)

566 Body Mass Index (BMI)

567 Generalized Anxiety Disorder (GAD)

568 Patient Health Questionnaire (PHQ)-9 (PHQ-9)

569 Perceived Stress Scale (PSS)

570 Health-Related Quality of Life (HRQoL)

571 Focus group discussion (FGD)

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579 **Declarations**

580 All manuscripts must contain the following sections under the heading 'Declarations':

- 581 • Ethics approval and consent to participate: This study was reviewed and approved by the
582 Institutional Review Board, Emory University. Participation in the study was voluntary
583 and informed consent was obtained from all participants, prior to participation.
- 584 • Consent for publication: Not applicable
- 585 • Availability of data and materials: Data can be made available on request, pending
586 institutional and funding agency guidelines.
- 587 • Competing interests: No competing interests.
- 588 • Funding: This work was supported by P30DK111024, Georgia Diabetes Translation Research
589 Center
- 590 • Authors' contributions: RC performed the analysis and drafted the manuscript. VS drafted
591 and reviewed the manuscript. RM reviewed and provided critical feedback on the
592 manuscript. AO designed the intervention and supervised its implementation. AK is the
593 principal investigator and supervised the design and conduct of the study.
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Figure 1: Participant flow diagram

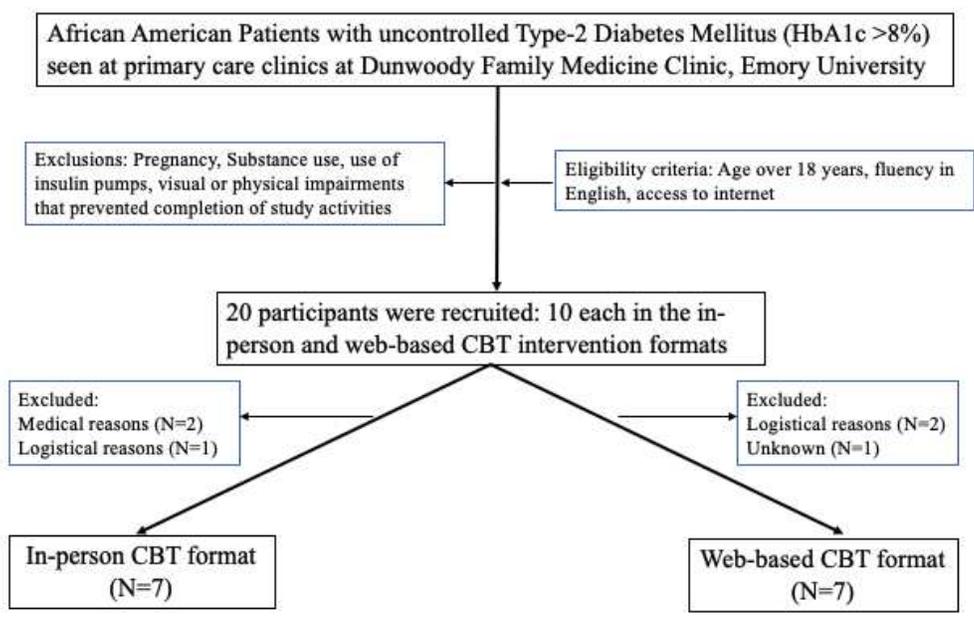


Figure 2: Preliminary Code Map for Qualitative Analysis (Code Map 1)

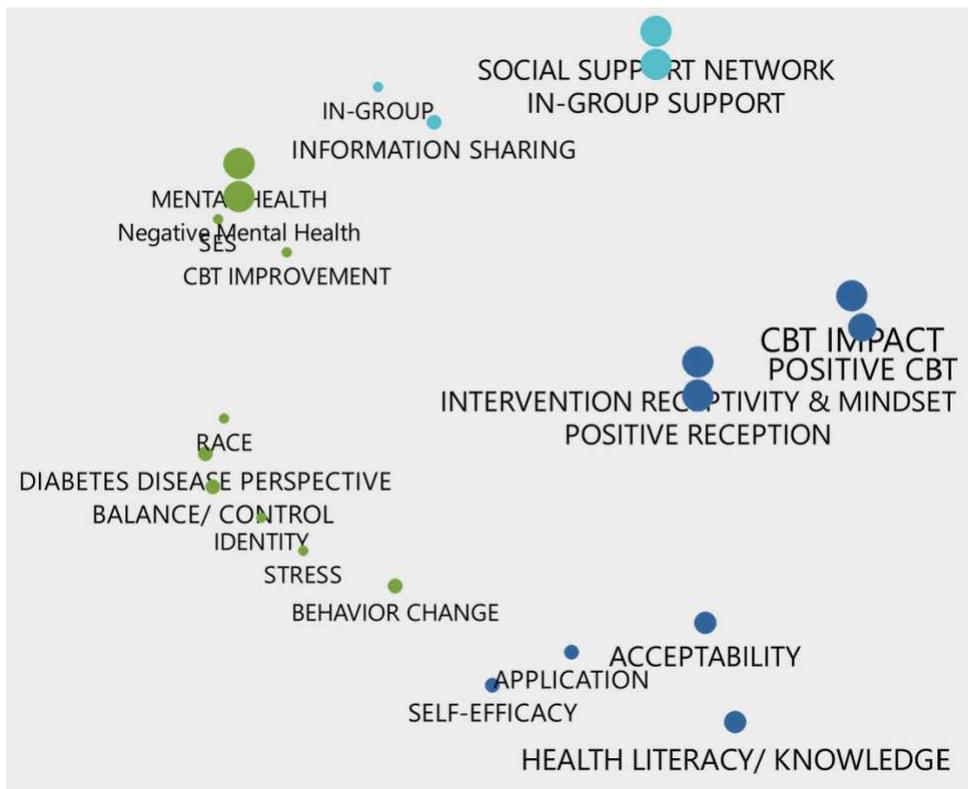


Figure 3: Social Support and Information Sharing (Code Map 2)

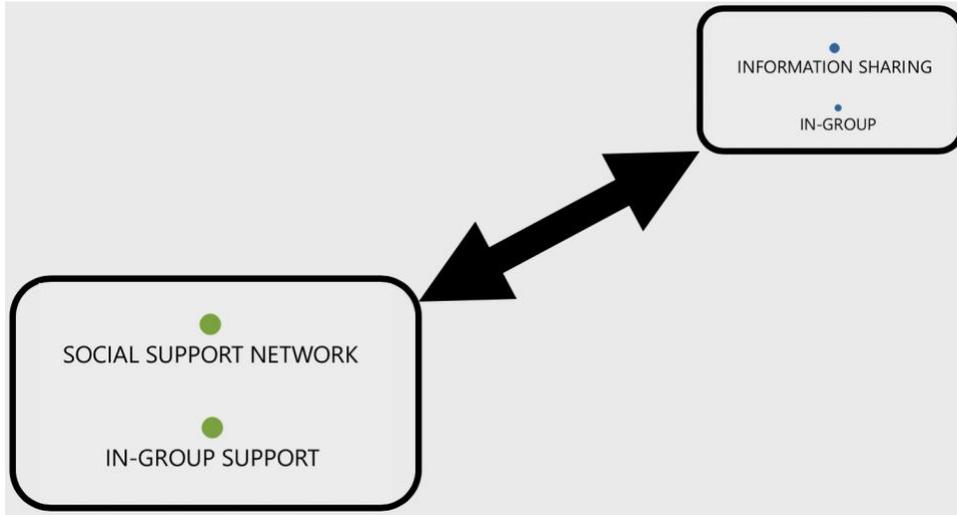


Figure 4: Disease Perception, Mental Health and Identities (Code Map 3)

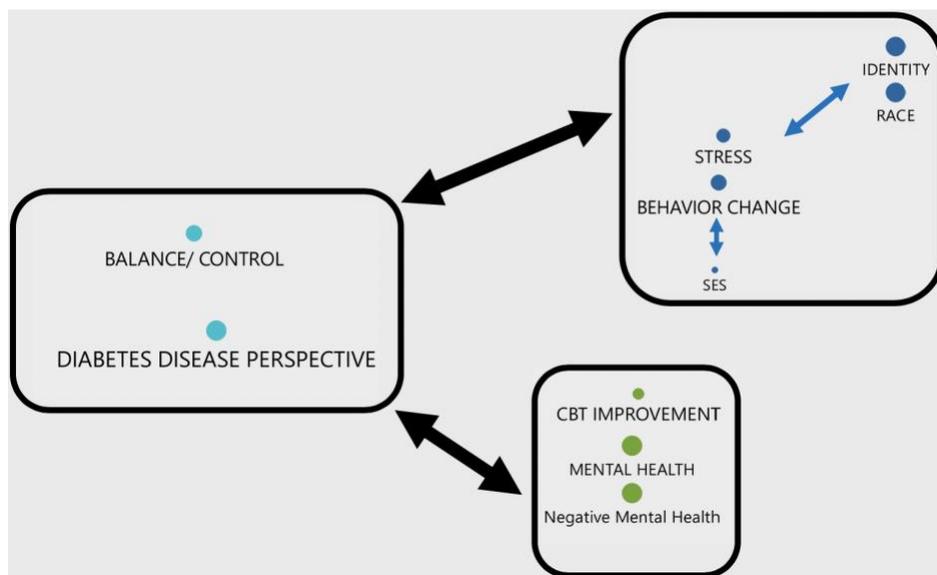


Figure 5: Receptivity, Impact and Health Literacy (Code Map 4)

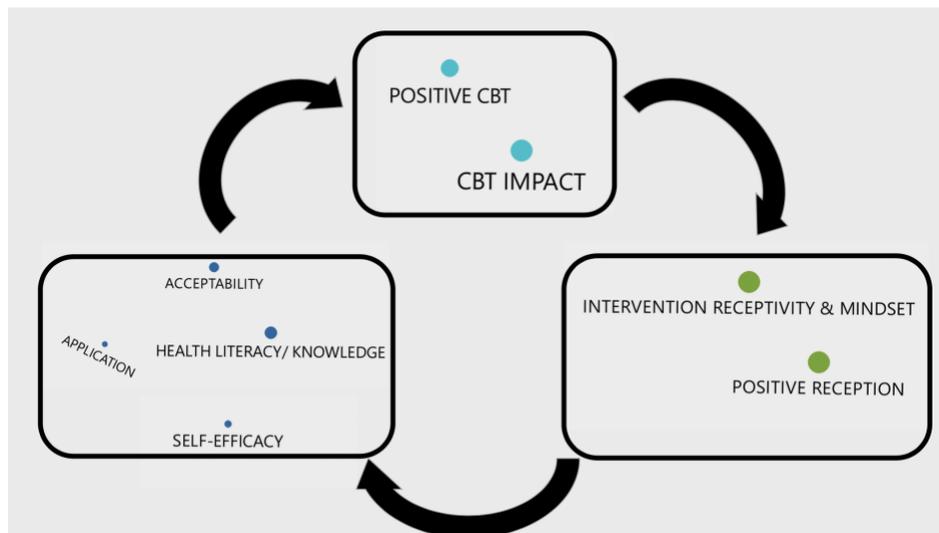


Table 1: Participant characteristics at study baseline (N=14)

Characteristic	Category	Frequency (N)	Percent (%)	Mean	Frequency (N) By Group		Percent (%) By Group		Mean		Standard Error (In-Person/ Web)	95% CI (In-Person/ Online)	P-value (In-Person/ web)
		All Participants	All Participants	All Participants	In-Person	Web	In-Person	Web	In-Person	Web			
Age (Years)	> 55	5	36	56.43	4	1	57	14	52	60.86	4.53	(-0.98, 18.78)	0.07
	55 +	9	64		3	6	43	86					
Number of Years with Diabetes	0 -> 5	2	14	13.30	0	2	0	29	14.86	11.5	2.82	(-9.51, 2.80)	0.26
	6 -> 10	2	14		1	1	14	14					
	11 -> 15	5	36		3	2	43	29					
	16 -> 20	4	29		2	2	29	29					
	20 -> 25	1	7		1	0	14	0					
Weight Status	Normal (BMI 18.5-24.9)	2	14	33.42	1	1	14	14	35.77	31.07	4.39	(-14.26,4.86)	0.31
	Overweight (BMI 25.0-29.9)	3	21		1	2	14	29					
	Obese (BMI >= 30.0)	9	64		5	4	71	57					
Gender	Man	3	21	(-)	2	1	29	14	(-)	(-)	(-)	(-)	(-)
	Woman	11	79		5	6	71	86					
Marital Status	Single	7	50	(-)	4	3	57	43	(-)	(-)	(-)	(-)	(-)
	Married	4	29		1	3	14	43					
	Divorced	3	21		2	1	29	14					
Highest Level of Education	Less than a college degree	7	50	(-)	3	4	43	57	(-)	(-)	(-)	(-)	(-)
	College Degree or More	7	50		4	3	57	43					

Abbreviations: BMI: body mass index, CI: confidence interval

Table 2: Quantitative scales score- pre (baseline) and post (follow-up) cognitive behavioral therapy intervention

Scales	T2DM Mean at Baseline	T2DM Mean at Follow-Up	t(26)	P-value	Max Score
SMRC Self-Efficacy					
All Participants (n=14)	7.21	7.10	0.26	0.80	10
In-Person (n=7)	7.34	7.43	-0.16	0.88	
Online (n=7)	6.94	6.77	0.47	0.65	
DDS Total					
All Participants (n=14)	2.46	1.95	2.62	0.02 *	6
In-Person (n=7)	2.35	1.74	1.98	0.09	
Online (n=7)	2.57	2.15	1.60	0.16	
DDS- Emotional Burden					
All Participants (n=14)	2.94	2.28	2.59	0.02 *	6
In-Person (n=7)	3.00	2.00	2.66	0.04 *	
Online (n=7)	2.89	2.56	1.00	0.35	
DDS- Physician Distress					
All Participants (n=14)	1.70	1.14	1.80	0.09	6
In-Person (n=7)	1.39	1.07	1.12	0.31	
Online (n=7)	2.00	1.21	1.42	0.21	
DDS- Regimen Distress					
All Participants (n=14)	3.11	2.55	2.6	0.02 *	6
In-Person (n=7)	2.71	2.11	1.47	0.19	
Online (n=7)	3.51	2.99	2.80	0.03 *	
DDS- Interpersonal Distress					
All Participants (n=14)	1.66	1.38	1.03	0.32	6
In-Person (n=7)	2.00	1.33	1.92	0.10	
Online (n=7)	1.33	1.43	-0.25	0.81	
GAD-7					
All Participants (n=14)	6.36	4.21	2.22	0.04 *	21
In-Person (n=7)	7.14	6.00	0.80	0.45	
Online (n=7)	5.57	2.43	2.42	0.05	
PHQ-9					
All Participants (n=14)	6.64	6.36	0.26	0.80	27
In-Person (n=7)	7.29	7.71	-0.35	0.74	
Online (n=7)	6.00	5.00	0.52	0.62	
PSS					
All Participants (n=14)	15.14	14.5	0.32	0.76	40
In-Person (n=7)	13.29	15.43	-1.37	0.22	
Online (n=7)	17.00	13.57	0.95	0.38	
RAND 36-Physical Functioning					
All Participants (n=14)	62.14	66.43	-0.90	0.39	100
In-Person (n=7)	53.57	60.00	-1.19	0.28	
Online (n=7)	70.71	72.86	-0.26	0.80	

RAND 36-Physical Problems Limitations					
All Participants (n=14)	58.93	61.61	-0.28	0.79	100
In-Person (n=7)	42.86	57.14	-0.88	0.41	
Online (n=7)	75.00	66.07	0.92	0.39	
RAND 36-Emotional Problems Limitations					
All Participants (n=14)	69.05	61.91	0.67	0.51	100
In-Person (n=7)	66.66	57.14	0.79	0.46	
Online (n=7)	71.43	66.67	0.26	0.80	
RAND 36- Energy/Fatigue					
All Participants (n=14)	47.14	52.86	-0.99	0.34	100
In-Person (n=7)	45.71	58.57	-1.44	0.20	
Online (n=7)	48.57	66.67	0.21	0.84	
RAND 36- Emotional Wellness					
All Participants (n=14)	74.00	74.29	-0.08	0.94	100
In-Person (n=7)	77.71	74.86	0.55	0.60	
Online (n=7)	70.29	73.71	-0.66	0.53	
RAND 36- Social Functioning					
All Participants (n=14)	61.61	75.00	-2.03	0.06	100
In-Person (n=7)	50.00	69.64	-1.66	0.15	
Online (n=7)	73.21	80.36	-1.19	0.28	
RAND 36- Pain					
All Participants (n=14)	51.07	70.00	-3.78	<0.01 *	100
In-Person (n=7)	39.29	64.29	-3.43	0.01 *	
Online (n=7)	62.86	75.71	-1.95	0.10	
RAND 36- General Health					
All Participants (n=14)	55	55.71	-0.13	0.90	100
In-Person (n=7)	52.86	55.71	-0.30	0.77	
Online (n=7)	57.14	55.71	0.25	0.81	
MOCA					
All Participants (n=14)	25.29	26.21	-1.34	0.20	30
In-Person (n=7)	25.14	25.71	-0.55	0.60	
Online (n=7)	25.43	26.71	-1.33	0.23	
HbA1c					
All Participants	8.5%	7.7%	0.4	0.08	
* Statistically significant difference indicated by a p-value less than 0.05.					

Appendix A: Interview Guide

Key Questions: Compatibility, Complexity, Observability and Relative Advantage of a Culturally Tailored Cognitive Behavior intervention (CT-CB) for African American patients

1. What was your experience with the cognitive behavioral therapy intervention?
 - a. *Probe: What did you like about it? What didn't you like about it?*
2. Have you ever participated in a similar intervention? Please tell us more.
 - a. *Probe: Did you prefer aspects of the other intervention more? Less? How about this intervention?*
3. What was confusing about the cognitive behavioral therapy intervention? What didn't make sense to you?
 - a. *Probe: What about it was confusing? How could we have better communicated with you?*
4. How has the cognitive behavioral therapy intervention impacted how you manage your diabetes, if at all?
 - a. *Probe: Did you feel like you had more control of your diabetes? Did you feel like you had less control of your diabetes?*
5. How did the material presented from the therapy align with your daily activities?
 - a. *Probes: Is it easy to incorporate? What is difficult to incorporate? How would it have been easier to make it as part of your daily life? Have you done something like this before?*

Key Questions: Cultural Sensitivity of the Study

1. How could the study improve in making the intervention and experience more comfortable for African American patients?
 - a. *Probe: Did you ever feel uncomfortable? Why?*
2. How did study staff make you feel during the intervention?
 - a. *Probe: Words of encouragement? Attitudes? Demographics?*
3. How did the staff account for your beliefs and identity when presenting the intervention material?
 - a. *Probe: Words? Actions? Intervention specific components?*

Closing Questions/ Conclusion

1. If you could advise other African American patients on how to navigate these experiences what would you say?
2. Do you have any final thoughts you would like to share?

Appendix B: Code System

Code #	Code	Sub-code	Definition	Example quotes
1	DIABETES DISEASE PERSPECTIVE		How participants view diabetes as a disease and how they describe it when discussing the intervention. Discussions about how diabetes relates to them are also useful.	“This whole experience is just a rollercoaster. Every day you do everything right, you take your blood sugar levels and it’s all over the map”
1.1		BALANCE/ CONTROL	When participants discuss dealing with aspects of their lives in relation to diabetes. Reference could be to diabetes as a disease, navigating the learning curve of diabetes, or managing diabetes.	“Sometimes I’m good, sometimes I’m not so good. Sometimes the experiences are good, sometimes they’re not good.”
1.2		BEHAVIOR CHANGE	Mention of action taken to improve self-management of diabetes which include a behavioral change by participants.	“In my life I found out that I have a lot more power to choose what I do”
2	IDENTITY		Any mention of how participants view themselves or how society may view them.	“many of us could relate to it, you know, we’ve experience it or we’re living it”
2.1		SES	Experiences that participants describe which are related to the individual’s socioeconomic status (positive or negative). This may include costs of treatment and living expenses.	“It can become, it can become taxing on the pocketbook”
2.2		RACE	Any mention of race as a social construct, whether related to personal identity of the participant or in relation to society in general.	“So, this disease impacts African Americans somewhat differently based on culture”
3	HEALTH LITERACY/ KNOWLEDGE		Mention of information learned from the CBT intervention.	“You know, the materials made you think about things that you hadn’t thought about”
4	COPING		Mentions of how participant has been able to handle the stresses of diabetes management.	“that particular session did have an effect on what I ate during that stressful situation”

5	INFORMATION SHARING		Sharing of information with others concerning diabetes management and coping mechanisms.	“I learned a lot of information from each and every one of them”
5.1		IN-GROUP	Sharing of information in a given treatment group.	“And we learned some things from each other [Group members verbally agreeing]”
5.2		PUBLIC	Discussions of disseminating information to the public.	“They gotta get it out. In, you know, be it in spurts or increments”
6	SELF-EFFICACY		Reflections on how participants have acted to improve their health when managing their diabetes as a result of the information learned from the CBT/MI intervention.	“So, I specifically went to the store and started buying vegetables instead of buying other things”
7	ACCEPTABILITY		Mentions of how well received the information was by the group and how they believe it would be received by other African American/ Black people.	“I think the materials were really helpful.”
7.1		APPLICATION	Mention of acceptability of material that leads to application of learned material.	“Umm, problem solving, you know, um, and just kind of trying to give you options and things to think about, uh, day-to-day”
8	AGREEMENT		When participants express that they have had the same, or similar, experiences. Verbal and non-verbal cues in transcript should be coded.	“I think because I feel like it’s more people that are around that are going through some of the same things.”
8.1		CULTURAL AGREEMENT	Having the same cultural background or similarity in cultural practices.	No Data Coded.
8.2		TREATMENT AGREEMENT	When participants express similar experiences in relation to treatment (good or bad)	“They’ve been eye opening. They’ve been, they’ve been very direct [Other participant: Mhm hmm] and it’s kind of made me think out of the box”
9	SOCIAL SUPPORT NETWORK		Any mention of being encouraged or finding refuge from others.	“We really had a great group”

9.1		IN-GROUP SUPPORT	Encouragement or refuge from the intervention group.	“Well the intervention made me feel like, well I’m not the only one”
9.2		AT-HOME/ SOCIETAL SUPPORT	Encouragement or refuge from people outside of intervention group.	No Data Coded.
10	MENTAL HEALTH		Any indication of psychological status from study participants.	“I feel a reduction in my life, and does it ever get any better?”
10.1		POSITIVE MENTAL HEALTH	Any indication of positive experiences related to the patient's state of mind and diabetes management.	“help you evolve, you know, into a better person. So, it’s been, it’s been real good.”
10.2		NEGATIVE MENTAL HEALTH	Any mention of desperation or loss of hope from participants.	“I would say depressed sometimes.”
11	STRESS		Any mention of psychological or emotional distress from participants.	“And something that really just “stress me out , and automatically I would’ve went to eating something that, you know, people say comfort food or whatever. [
12	INTERVENTION RECEPTIVITY & MINDSET		Discussions about how well received study materials and intervention was by participants and what their state of mind was.	“It’s making me feel like I can grow, you know, dealing with them and they’ve changed a lot of things, you know, as far as medication and all.”
12.1		POSITIVE RECEPTION	Discussions of when intervention materials were well received.	“One thing it helped me with is periodically I know I was gonna feel accountable when we had the meeting, so it kind of inspired me to do better”
12.2		NEGATIVE RECEPTION	Discussions of when intervention materials were not well received.	No Data Coded.
13	ENVIRONMENTAL & ECOLOGICAL FACTORS		Discussions about how participant environment affected the use of materials from the study intervention by participants.	“Go to a cooking class and learn how to make the foods that you like in a different way”

14	CBT/MI IMPACT		Any mention of how CBT/MI has contributed to treatment of disease or how the information has been received by participants.	
14.1		POSITIVE CBT/MI	How CBT/MI has contributed to participants positively.	“It was helpful.”
14.2		NEGATIVE CBT/MI	How CBT/MI has contributed to participants negatively.	No Data Coded.
14.3		CBT/MI IMPROVEMENT	How CBT/MI can be improved.	“I think that we could’ve gotten suggestions. Recipes or things to avoid.”

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [ReportingChecklist.pdf](#)