Psychometric evaluation of the summary of diabetes self-care activities measure in Ghanaian adults living with type 2 diabetes

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ABSTRACT

Aims: We evaluated the content validity, factorial structure, internal consistency, construct validity, and floor and ceiling effects of the SDSCA among Ghanaian persons with type 2 diabetes.

Methods: The summary of diabetes self-care activities measure (SDSCA) was administered to 187 adults living with type 2 diabetes from three diabetes clinics.

Results: A confirmatory factor analysis maintained the four factor structure of the SDSCA. However, two items, 3 (fruit and vegetable servings) and 4 (red meat or full-fat dairy products) had factor loadings of 0.26 and 0.16 respectively. The model also had a statistical power of 0.72 (below acceptable criteria). Modification of the model by removing item 4 resulted in an improved revised model with a power of 0.82. Construct validity was found for the exercise and diet subscales of the SDSCA but not for the self-monitoring of blood glucose and foot care subscales. The internal consistency of the SDSCA measure was 0.68, below acceptable criteria for internal consistency. No floor effects were present but the exercise subscale had ceiling effects.

Conclusion: The SDSCA measure had content validity, maintained its multidimensionality and met the criteria for floor effects but not for construct validity, internal consistency and ceiling effects. The SDSCA measure may require improvements to evaluate self-care behaviours of adult type 2 diabetes patients in Ghana and probably in other sub-Saharan countries.

1. Introduction

Approximately 30 million people in Africa had diabetes, more than half of which live in sub-Saharan Africa and estimated to rise by 162% by the year 2045 [1,2]. More than 90% of all cases of diabetes globally and in the sub-region is type 2 diabetes [1,2]. The sub-Sharan region has the highest prevalence of undiagnosed diabetes in the world (69.2%) and 6% of all mortality is attributed to diabetes [2]. In Ghana, a sub-Saharan African country, the prevalence of diabetes increased from 0.3% in 1986 to 3.6% in 2017 [2–4].

Patients with type 2 diabetes are expected to follow a number of recommended self-care behaviours [5–7]. These self-care behaviours include regular participation in physical activity, healthy eating, weight management, self-monitoring of blood glucose (SMBG), and adherence to medications [8]. Evidence indicates that regular participation in these self-care behaviours may result in improved glycaemic control, reduced risk of developing diabetes complications, improved quality of life and dietary habits [5,9–12].

Given the significant role of self-care behaviours in improving health outcomes of type 2 diabetes patients, a brief, valid and reliable instrument to assess diabetes self-care behaviours is necessary. Such instruments are useful to both clinicians and other healthcare professionals who provide care to diabetes patients and for researchers interested in evaluating the effectiveness of interventions to improve diabetes self-care behaviours [13].

The Summary of Diabetes Self-Care Activities (SDSCA) measure [13], is arguably the most widely used self-report instrument for assessing self-care behaviours in adult diabetes patients [13,14]. The original version comprised 12-items assessing five components of diabetes self-care [15]: general diet, specific diet, exercise, medication taking, and blood glucose testing. A review of seven studies by the authors [13] of the SDSCA resulted in the addition of items for foot care and smoking status. The revised version comprised 11 core items and an expanded list of 14 additional items yielding a total of 25 items [13]. However, due to little or no data on the reliability and validity of the additional items [13], the authors recommend using the 11-item revised SDSCA measure. Furthermore, the revised version of the SDSCA does not include items on medication because they had strong ceiling effects and low test-retest reliability [13]. According to the authors [13], strengths of the 11-item revised SDSCA measure include its brevity and ease of use in both clinical and research settings and evidence for its validity and reliability.

The psychometric properties of the revised SDSCA measure has been evaluated among diabetes populations in Europe [13,14], Asia [16,17] and African Americans [13,18]. Using a cut-off point of 0.50, Toobert et al [13] reported an average inter-item correlations of 0.47 which they described as acceptable in a sample of 7 individual studies. The rest of the studies except one (alpha = 0.62) [14] showed adequacy of internal consistency with Cronbach's alphas between 0.74 and 0.93 [16,17]. However, psychometric properties of the SDSCA are yet to be investigated among type 2 diabetes patients in a sub-Saharan African context despite being used to assess self-care behaviours in this setting [19]. It is important to assess the psychometric properties of the SDSCA measure among a sub-Saharan African type 2 diabetes patient population because of the socio-cultural, socio-economic, and ethnic and health system differences between African populations and other populations.

This study aimed to assess content validity, factorial structure, internal consistency, construct validity, and floor and ceiling effects of the SDSCA measure in adult Ghanaian type 2 diabetes patients.

2. Methods

2.1. Participants and procedure

2.1.1. Content validity

Semi-structured interviews were conducted with type 2 diabetes patients recruited from weekly diabetes clinics from three hospitals in the Tamale Metropolis, Ghana. Tamale is approximately 500 km North of Accra, Ghana's capital city. These clinics undertake weekly diabetes clinics to provide diabetes care to patients, who come from both urban and rural settings. Participants were either asked to read the items of the SDSCA measure or listen carefully to the items translated to them in the local dialect by a research assistant. Using an interview guide, they were then asked to comment on the ease of use of the SDSCA measure, clarity of its items, readability of the items, understanding and relevance of the items to diabetes self-care. Research assistants had the option of probing further to clarify comments. All interviews were conducted by a research assistant who recorded the interviews digitally and transcribed them verbatim.

2.1.2. Psychometric evaluation of the SDSCA measure

To assess the internal consistency, construct validity, and floor and ceiling effects of the SDSCA measure, it was administered to another group of type 2 diabetes patients recruited from these hospitals. Patients were eligible to participate if they had a confirmed diagnosis of type 2 diabetes or self-reported a healthcare professional diagnosis of type 2 diabetes or were identified by the healthcare professional as seeking care for type 2 diabetes and were registered with the specific hospital and had sought care from its diabetes clinic at least twice during the last 12 months. Patients were not eligible if they were: identified by the healthcare professional as having type 1 diabetes; or were younger than 18 years of age and/or were diagnosed with diabetes before the age of 30 years. Trained research assistants visited the hospitals on scheduled diabetes clinic days to collect data. While patients waited for their medical consultation, the research assistants approached them to introduce the study and seek their consent to participate. Consenting participants were given a self-completed paper survey. For those who could not read nor write in English, trained research assistants assisted them to complete the survey by verbally translating the questions into their respective local dialects. This occurred for less than 10% of the participants.

The research was approved by the research department of the Tamale Teaching Hospital, the Ethics Committee of the School of Allied Health Science of the University for Development Studies, Ghana and the Human Research Ethics Committee of the University of Newcastle, Australia. All data collection procedures were completed during May 2015 to June 2017.

2.2. Measures

2.2.1. Summary of diabetes self-care activities measure
As shown in Table 1, the SDSCA consists of 11 items assessing participants' frequency during the last 7 days or month of engaging in diabetes self-care behaviours including diet (general and specific), exercise, self-monitoring of blood glucose (SMBG), foot care and smoking status. Participants are asked to indicate the number of days on which the respective self-care behaviour was performed using an eight point Likert scale (0–7). The greater the number of days reported for a behaviour the better the self-care. The first ten items are summed to correspond with the four subscales: diet (items 1–4), exercise (items 5–6), SMBG (items 7–8) and foot care (items 9–10). The eleventh item, which investigates tobacco use by assessing the number of cigarettes smoked per day [13,20], was not included in the factor analysis because it is one item which is consistent with previous studies investigating the psychometric properties of the SDSCA measure [14,21,22].

2.2.2. Demographic characteristics
Demographic characteristics such as age (continuous), gender, duration of diabetes since diagnosis (years), family history of diabetes (yes/no), educational status (years), marital status (married and not married) and religious status (Christianity, Islamic and African traditional religion) were self-reported.

2.3. Statistical analysis

IBM SPSS and AMOS 23.0 were used to perform all data analysis. Means and standard deviations were used to describe continuous variables while frequencies and percentages were used to present categorical data. Confirmatory factor analysis (CFA) was undertaken to confirm the four factor structure of the SDSCA measure using AMOS version 23.0. CFA evaluates the extent to which the data fits into a predetermined and constructed model [23]. The maximum likelihood (ML) estimation method with bootstrapping was used. As recommended by Nevitt and Hancock [24], bootstrap samples were placed at 250. A bias-corrected interval of 95% confidence level was set. To determine model fit the Bollen-Stine bootstrap p was adopted together with Chi-Square to determine model fit [25]. Bollen-Stine estimates fit without normal theory limitations, and p > 0.05 was considered indicative of model fit [25]. Other model fit indices adopted were goodness-of-fit index (GFI), normed fit index (NFI), and a comparative fit index (CFI) [26]. The parsimonious normed fit index (PNFI), Tucker Lewis index (TLI), root mean square residual (RMR) and a root mean square error of approximation (RMSEA) were also calculated. For the GFI, CFI, TLI, NFI and PNFI indices, values ≥0.90 were considered acceptable model fit [27–30]. RMR values of ≤0.05 and RMSEA values of ≤0.06 represent acceptable model fit [28,29,31]. Sampling adequacy was determined using Kaiser-Meyer-Olkin (KMO) test and Bartlett's test of sphericity. A sample size is deemed adequate if the value of KMO is ≥ 0.5 (Kaiser, 1974) [32]. Post-hoc power analysis for RMSEA was performed using Preacher and Coffman online statistical power calculator [33] based on an alternative RMSEA of 0.08 at an alpha value of 0.05. A power ≥0.80 was considered adequate [34].

To assess the construct validity of the SDSCA measure we compared subscale scores by participant educational levels using one-way analysis of variance. Previous studies conducted among diabetes populations in sub-Saharan Africa have found level of education to be associated with adherence to self-care behaviours [19,35]. We thus hypothesised a positive correlation between number of years in formal education and participants' adherence to diabetes self-care behaviours scores. Construct validity was acceptable if ≥75% of the hypotheses were supported [36]. Pearson correlation analysis was thus conducted.

Internal consistency of the SDSCA measure was determined using Cronbach's alpha [37]. To determine the influence of each of the individual items on the internal consistency of the total score, item-total correlations were computed. This provides an assessment of the correlation between an item and the sum of the rest of the items in the scale. Values >0.2 are considered acceptable [37]. To determine Cronbach's alpha if an item is deleted, Cronbach's alpha was computed with the removal of each item in turn.

To determine floor and ceiling effects the proportion of participants with the lowest and highest scores respectively were calculated. Floor and ceiling effects were present for factors for which >15% of participants obtained the lowest or highest score, respectively [36].

3. Results

3.1. Content validity

Of the 27 patients approached, 23 completed an interview. During the semi-structured interviews the majority of the participants found all the items of the SDSCA measure to be clear and unambiguous; readable and understandable, and easy to use. They also found the items to be relevant to their diabetes self-care behaviours. Only two participants had difficulty understanding the phrase 'full-fat dairy products' which is used in item 4. Participants' required further explanation of this phrase to enable them determine their adherence to this self-care behaviour. Participants also found the response options to be appropriate.

3.2. Psychometric evaluation

3.2.1. Demographics
One hundred and ninety patients from the 201 patients who were approached consented to participate in the study and

Table 1 – The revised version of the SDSCA measure.	
Item	Description
Diet	
Q1	How many of the last SEVEN DAYS have you followed a healthful eating plan?
Q2	On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?
Q3	On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?
Q4	On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?
Exercise	
Q5	On how many of the last SEVEN DAYS did you participate in at least 30 min of physical activity? (Total minutes of continuous activity, including walking).
Q6	On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?
SMBG	
Q7	On how many of the last SEVEN DAYS did you test your blood sugar?
Q8	On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?
Foot care	
Q9	On how many of the last SEVEN DAYS did you check your feet?
Q10	On how many of the last SEVEN DAYS did you inspect the inside of your shoes?
Smoking status	
Q11	Have you smoked a cigarette—even one puff—during the past SEVEN DAYS? 1. No 2. Yes. If yes, how many cigarettes did you smoke on an average day?

187 (93%) surveys contained sufficient data for inclusion in the analysis. Participants had a mean (SD) age of 54.83 (13.32) years; were mainly female (72.2%, n = 135), had a mean duration of diabetes of 5.43 (4.92) years, and only 2 participants reported smoking with an average of 5.00 ± 1.00 cigarettes per week. The majority of participants were married (64%, n = 120), had low level of education (75%, n = 140) followed the Islamic religion (84%, n = 154) and 38.5% had a family history of diabetes.

3.2.2. Factorial structure using confirmatory factor analysis

Applying the KMO measure of sample adequacy, an overall index of 0.576 was obtained, making factor analysis appropriate. Bartlett's test of sphericity had an approximated Chi-Square of 657.43, p < 0.001, also indicative of the sample being appropriate for factor analysis. Confirmatory Factor Analysis was conducted to confirm the four factor structure of the SDCSA measure. With an X^2 value of 36.97 (p = 0.15), degrees of freedom of 29 and a Bollen-Stine p = 0.287. The model had a goodness-of-fit index of 0.96, a normed fit index of 0.94 and a comparative fit index of 0.98. In addition, the model had a parsimonious normed fit index of 0.61; a Tucker Lewis index of 0.98; a root mean square residual of 0.18, a root mean square error of approximation of 0.04 and model power of 0.72. Correlations between the factors were generally low ranging from 0.07 to 0.34. The model is displayed in Fig. 1, along with the latent variable correlations, standardised parameter estimates and squared multiple correlations.

Although, majority of the indices showed a good fit, the power of the model did not meet acceptable criteria. We thus evaluated the factor loadings of each of the items and item 4 had a very low factor loading of 0.16. Theoretically, we also noted from the content validity that participants found it difficult to understand some terms used in item 4. We thus proceeded to test an alternative model (Shown in Fig. 2) in which item 4 was deleted. The revised model had an X^2 value of 22.72 (p = 0.359), degrees of freedom of 21 and Bollen-Stine p = 0.482. With a power of 0.82 (indicative of adequate power), the revised model had a goodness-of-fit index of 0.97, a normed fit index of 0.96 and a comparative fit index of 1.00. In addition, the model had a parsimonious normed fit index of 0.56; a Tucker Lewis index of 1.00; a root mean square residual of 0.14 and a root mean square error of approximation of 0.02.

3.2.3. Internal consistency

The overall Cronbach's alpha value of the SDSCA measure was 0.68 with the values of the subscales ranging from 0.61 to 0.84 (Shown in Table 2).

The mean scores of the individual items, item-total statistics and internal consistency if an item is deleted is shown in Table 3. Apart from items 4, 7 and 8, the deletion of any other item resulted in a decrease of the Cronbach's alpha of the SDSCA measure. Item 4 had the lowest item-total correlation of 0.04 and the internal consistency of the SDSCA measure improved to 0.71 following its removal. Also, the deletion of items 7 and 8 resulted in the improvement of the Cronbach's alpha of the SDSCA measure to 0.69.

3.2.4. Construct validity

Table 4 presents the construct validity of the subscales of the SDSCA measure. Except for the SMBG subscale, the diet, exercise and foot care subscales were significantly associated with the number of years participants spent schooling.

3.2.5. Floor and ceiling effects

As shown in Table 5, only the exercise subscale had a ceiling effect with >15% of the sample obtaining the highest possible score. There were no floor effects.

4. Discussion

This is the first study to evaluate the psychometric properties of the SDSCA measure in a type 2 diabetes population in sub-Saharan Africa. It provides information about the psychometric properties of the SDSCA measure in an area where the prevalence of diabetes is rising and outcomes are generally poor [2]. We found that the SDSCA measure met the recommended criteria for content validity as it measured what it was designed to assess [36]. Nonetheless, revision of the phrase "full-fat dairy products" to a more familiar phrase in the Ghanaian context such as 'full milk products' may improve patients' understanding of this item.

The findings among these type 2 diabetes patients having low levels of education; frequently being female; reporting general low use of tobacco and being middle-aged are similar to those of previous studies conducted in Ghana and other parts of Africa [4,19,38–48]. Our finding that majority of the diabetes patients practiced the Islamic religion differ from studies from other parts of Ghana [3,4,38] but similar to those previously reported from the study setting [49]. The differences may be due to the fact that the study setting is dominated by those who practice the Islamic religion [50]. Consistent with previous studies [14,22], the four factor structure of the SDSCA measure was maintained using the model fit indices to demonstrate acceptable level of internal consistency. Although the four factor structure of the SDSCA measure was maintained, item 4 (red meat or full-fat dairy products) had an extremely low factor loading consistent with previous studies [14,21,22]. In addition, the power of the model did not also meet acceptable criteria. In theory, par-
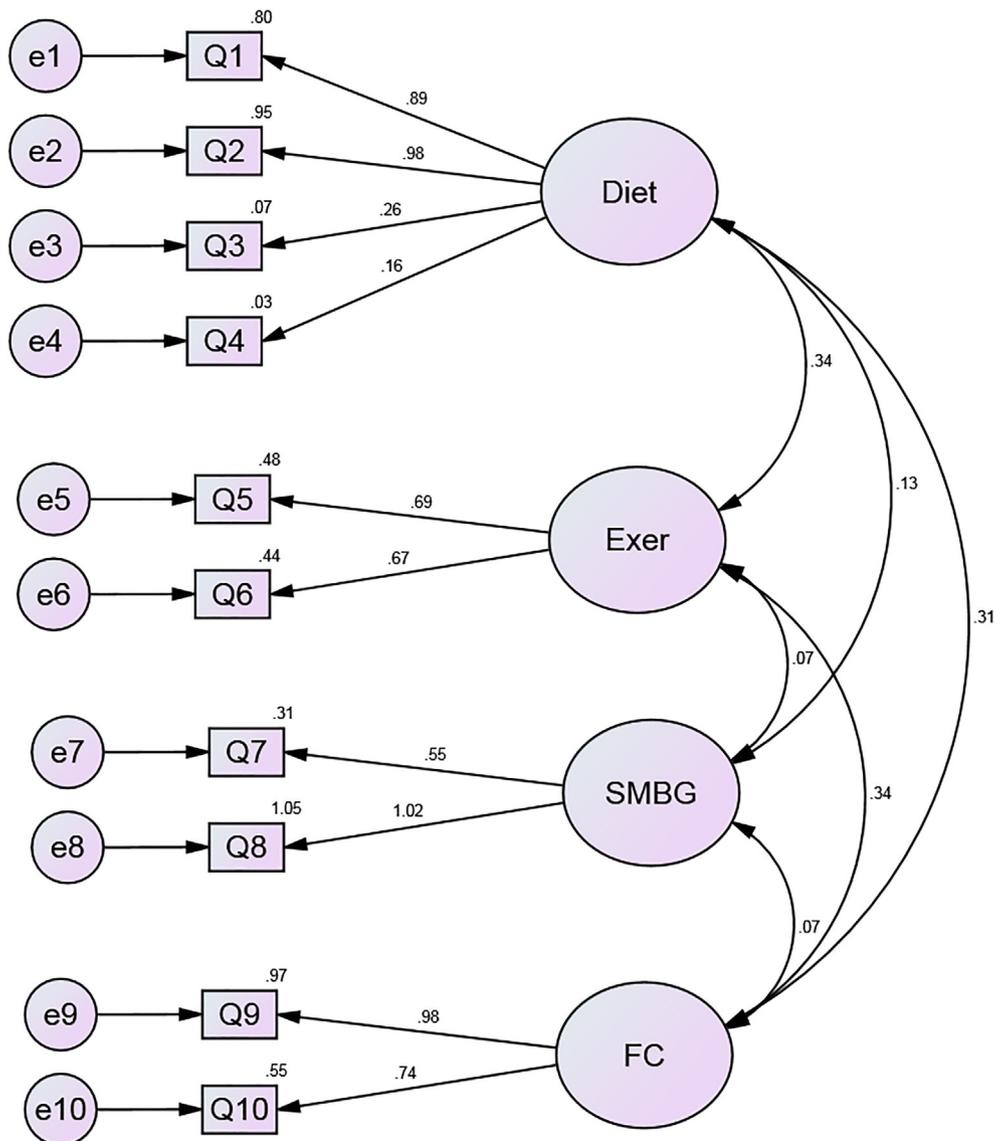

Fig. 1 – CFA model of the SDSCA measure including factor loadings, squared correlations and latent variable correlations. Exer = Exercise; SMBG = Self-monitoring of blood glucose; and FC = Foot care.
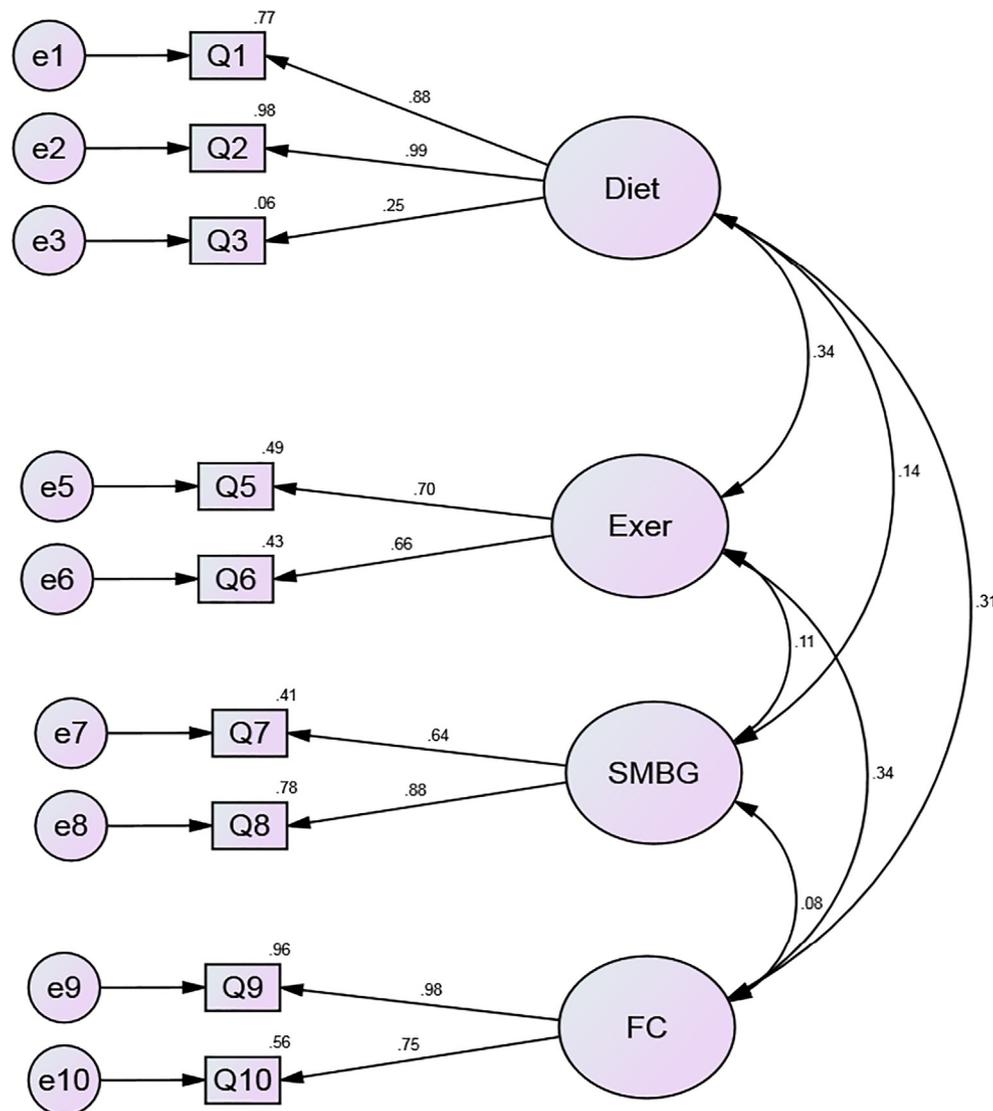
Fig. 2 – Revised CFA model of the SDSCA measure including factor loadings, squared correlations and latent variable correlations. Exer = Exercise; SMBG = Self-monitoring of blood glucose; and FC = Foot care.

ticipants also had difficulty understanding item 4, providing us further justification to revise the model by removing item 4. The revised model without item 4 showed improvements of the χ^2 value, model fit indices and model power. Our findings are similar to those of Kamradt et al in which authors reported improvements of the relevant model fit indices and the X^2 value of a revised model of the SDSCA measure [14] after removing item 4 in a psychometric evaluation of the SDSCA measure among German type 2 diabetes patients. Revision of item 4 by replacing dairy products with full milk products may help improve its factor loading.

The low factor loading of item 3 (fruits and vegetables) could be because these adult Ghanaian type 2 diabetes patients may have found it difficult to understand, interpret and quantify serving sizes due to the lack of uniformly accepted portion sizes in Ghana [51] for estimation of how much food is eaten. Generally, vegetables are not eaten alone but included in thicken soups and stews making it difficult for the participant to estimate portion/serving sizes. In addition,

the size of kitchen utensil (i.e. ladle) that is used to fetch soups or stews vary in households. Notwithstanding the low factor loading of item 3 (fruits and vegetables), we did not remove item 3 to modify the model because we did not have theoretical justification to do so. For CFA, decisions as to which models should be assessed should be hypothesis-driven, based on strong empirical evidence, informed by theoretical knowledge and therefore, should not be entirely data driven or solely on the basis of modification indices to realise an acceptable goodness of fit [52].

Overall, the low correlations between the factors in both models demonstrate the multidimensional nature of the sub-scales of the SDCSA measure. This finding suggests that self-care activities are independent of each other [14,22].

Another important finding was that the SDSCA measure did not meet acceptable criteria for construct validity [36]. However, the exercise, diet and foot care subscales met the hypothesis and differentiated adherence by number of years participants spent schooling. Despite not meeting the criteria

Table 2 – Cronbach alpha values for the revised SDSCA.

Domain	Items	Cronbach's alpha
Diet	1–4	0.61
Exercise	5–6	0.63
SMBG	7–8	0.72
Foot care	9–10	0.84
Overall	**1–10**	**0.68**

Table 3 – Mean (SD) item scores, item-total statistics and internal consistency in case of deletion.

Item	Mean (SD) item scores	Corrected item-total correlation	Cronbach's alpha if item deleted
Q1	4.79 (2.09)	0.45	0.65
Q2	3.94 (1.97)	0.54	0.63
Q3	3.25 (2.11)	0.29	0.68
Q4	5.63 (1.67)	**0.04**	**0.71**
Q5	4.19 (2.31)	0.46	0.64
Q6	4.98 (2.00)	0.38	0.66
Q7	2.17 (0.71)	**0.13**	0.69
Q8	2.12 (0.65)	**0.17**	0.69
Q9	3.02 (2.16)	0.49	0.64
Q10	2.43 (1.99)	0.44	0.65

Items with corrected item-total correlation <0.2 is in bold.

Table 4 – Construct validity of the SDSCA measure subscales with number of years in school.

	Diet	Exercise	SMBG	Foot care
Number of years in school	0.199[**]	0.182[*]	0.115	0.165[*]
Diet		0.229[**]	0.105	0.234[**]
Exercise			0.104	0.258[**]
SMBG				0.058

[**] Correlation is significant at the 0.01 level (2-tailed).
[*] Correlation is significant at the 0.05 level (2-tailed).

for construct validity we note our limitation that we only conducted four tests, and thus recommend that future research is needed to assess further the construct validity of this scale by assessing differences between other known groups.

Although the Cronbach's alpha coefficients of the SDSCA were found to be lower than some of the more commonly recommended criteria for assessing internal reliability [37], they were similar to previous studies assessing the reliability of the SDSCA scale, with previous alphas ranging from 0.62 to 0.69 [14,21,22]. As the Cronbach's alpha coefficients are influenced by the number of items in a scale it is possible that the low number of items in each of the subscales of the SDSCA may be influencing the low alpha coefficient seen here. However, as the lowest Cronbach's alpha value was found for the diet subscale, which contains 4 items, it is also likely that the reliability of this scale is also in need of improvement. Furthermore, low alpha coefficient value of the SDSCA measure once again demonstrates the multidimensional nature of the SDSCA and the independence of the individual self-care activities as reported by authors of the SDSCA and other researchers [13,14,53]. For example, a patient reporting high adherence to foot care may not report high adherence for diet, exercise or SMBG. Importantly, item 4 had an extremely low-item-subscale and item-total correlation contributing to the low internal consistency of the SDSCA measure and the diet sub-scale. This finding is consistent with previous reports [14,21,54]. Authors of the SDSCA measure have also reported similar difficulties regarding item 4 and the internal consistency of the SDSCA measure [13]. These findings suggest that the reliability issues of the SDSCA measure may not be unique to the Ghanaian context but may exist in other context/settings around the world.

Items 7 and 8 which constitute the exercise subscale had item-total correlation lower than 0.2, contributing to the low internal consistency of the subscale and that of the entire SDSCA measure. Revision of these items may be necessary as previous studies have reported findings similar to ours [14,54]. Also, addition of more items into the SDSCA may also help improve its internal consistency.

Ceiling effects were present for the exercise subscale of the SDSCA which may affect the responsiveness of the SDSCA measure [36]. There were no floor effects for any SDSCA subscale.

This study is not without limitations. In assessing our sample adequacy using KMO, a cut of value of 0.5 was used as originally classified by Kaiser as a borderline of acceptability [32]. We however recognize that some authors use >0.6 as acceptable level of KMO. Our value of 0.5 may suggest that the factorability of the items could be improved. There is also the need for future studies to use larger samples. This study did not assess measurement error and test-retest reliability thus the stability of the SDSCA measure on this sample of type 2 diabetes patients is unknown. The cross-sectional design also made it impossible to assess the predictive validity of the SDSCA measure. Nonetheless our findings present information about the performance of the SDSCA on a sample of

Table 5 – Floor and ceiling effects of the subscales of the SDSCA measure.

	Diet	Exercise	SMBG	Foot care
Mean (SD)	4.40 (1.52)	4.78 (2.09)	2.15 (0.65)	2.86(2.16)
Median (Min-Max)	4.53 (0.50–7.00)	4.63 (1.00–7.00)	2.00 (1.00–7.00)	2.17 (1.00–7.00)
Floor – Frequency (% with lowest possible score)	0 (0)	0 (0)	0 (0)	0 (0)
Ceiling – Frequency (% with highest possible score)	5 (2.7%)	40 (21.4%)	1 (0.5%)	18 (9.6%)

diabetes patients from sub-Sharan Africa that may be relevant to future studies evaluating adherence to self-care behaviours in these populations.

5. Conclusion

The multidimensionality of the SDSCA measure was maintained and it met the acceptable criteria for content validity, and floor effects but not for construct validity, and ceiling effects. Accordingly, although the SDSCA measure could be an important tool for assessing self-care behaviours in Ghanaian adult type 2 diabetes patients it requires further development which includes, but is not limited, to the revision of items 3 and probably the removal of item 4 and development of its construct validity. Further validation studies of the SDSCA in this population is also needed.

Ethics approval and consent to participate

Ethical approval for this study was granted by the research Department of the Tamale Teaching Hospital, the Ethics Committee of the School of Allied Health Sciences of the University for Development Studies and the Human Research Ethics Committee of the University of Newcastle. The data was handled anonymously and confidentially.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Authors' contribution

VM conceived and designed the study, performed data analysis, interpretation, and drafting of manuscript; ZOA collected data; FT, NAJ & CP jointly undertook critical revision of the manuscript. All authors approved the manuscript for publication.

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Declarations of interest

None.

Appendix A.   Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2019.02.004.

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