UNIVERSIDADE ESTADUAL DE MONTES CLAROS

Thaísa Soares Crespo

Propriedades psicométricas e interpretabilidade de instrumento de avaliação da literacia em saúde entre pessoas com diabetes assistidas na atenção primária à saúde e sua associação com cognição e parâmetros bioquímicos

Montes Claros - Minas Gerais

2021

Thaísa Soares Crespo

Propriedades psicométricas e interpretabilidade de instrumento de avaliação da literacia em saúde entre pessoas com diabetes assistidas na atenção primária à saúde e sua associação com cognição e parâmetros bioquímicos

Tese apresentada ao Programa de Pós-graduação em Ciências da Saúde (PPGCS) da Universidade Estadual de Montes Claros (UNIMONTES), como parte das exigências para a obtenção do título de Doutora em Ciências da Saúde.

<u>Área de Concentração</u>: Saúde Coletiva.

<u>Orientador</u>: Prof. Dr. Sérgio Henrique Sousa Santos.
<u>Coorientadora</u>: Profª. Drª. Andrea Maria Eleutério de Barros Lima Martins.

Montes Claros - Minas Gerais

2021

UNIVERSIDADE ESTADUAL DE MONTES CLAROS - UNIMONTES

Reitor: Antônio Alvimar Souza

Vice-reitora: Ilva Ruas Abreu

Pró-reitora de Pesquisa: Clarice Diniz Alvarenga Corsato

Coordenadoria de Acompanhamento de Projetos: Virgílio Mesquita Gomes

Coordenadoria de Iniciação Científica: Sônia Ribeiro Arrudas

Coordenadoria de Inovação Tecnológica: Sara Gonçalves Antunes de Souza

Pró-reitor de Pós-graduação: André Luiz Sena Guimarães

Coordenadoria de Pós-graduação Lato-sensu: Marcos Flávio Silveira Vasconcelos D'Angelo

Coordenadoria de Pós-graduação Stricto-sensu: Marcelo Perim Baldo

PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS DA SAÚDE

Coordenador: Alfredo Maurício Batista de Paula

Coordenador Adjunto: Renato Sobral Monteiro Júnior

ALUNA: THAÍSA SOARES CRESPO

TÍTULO DO TRABALHO: "Propriedades psicométricas e interpretabilidade de instrumento de avaliação da literacia em saúde entre pessoas com diabetes assistidas na atenção primária à saúde e sua associação com cognição e parâmetros bioquímicos"

BANCA (MEMBROS TITULARES)	ASSINATURAS
Prof. Dr. Sérgio Henrique Sousa Santos - Orientador	
Profª. Drª. Andrea Maria Eleutério de Barros Lima Martins	
Profª. Drª. Varéria Mafra Cota	
Prof. Dr. João Marcus Oliveira Andrade	
Prof. Dr. Carlos Eduardo Mendes D'angelis	
Prof.ª Dr.ª Maria Tereza Carvalho Almeida	
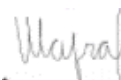
BANCA (SUPLENTES)	ASSINATURAS
Prof.ª Dr.ª Marise Fagundes Silveira	
Prof.ª Dr.ª Rosângela Ramos Veloso Silva	

[X] APROVADO(A)   **[   ] REPROVADO(A)**

Foram anos de hipóteses e vieses entremeados à arte de ser mãe

A você, Alice, que de pequenina se fez grande, dedico este trabalho.

A você, minha filha, dedico também cada batida do coração e todas as palavras que compõem

a poesia da vida.

AGRADECIMENTOS

A Deus,

Por estar acima e além de qualquer teoria

Por ser o Dono de todas as páginas.

Ao descompassado coração,

Por ensinar sobre a urgência de viver

Por sentir e viver o amor que primeiro cresceu

E só depois brotou.

Aos familiares,

Especialmente ao irmão amado

Por ser no mais além da vida e da morte

O eterno professor da perseverança e paciência.

Ao companheiro de nós e de laços,

Pela história de amor e amizade

Por entender os rabiscos

Por aceitar as páginas em branco.

Aos melhores amigos,

A flor do deserto e o bonsai

Por serem oásis

Por serem gigantes

Doutores do verdadeiro saber

Donos da minha amizade.

Aos orientadores,

Por serem imprescindíveis em capítulos da minha vida

Por serem verdadeiras pontes entre os abismos do conhecimento

E a busca por sabedoria e humanidade.

Aos professores,

Por gentilmente aceitarem participar da banca de defesa

Por partilharem experiências

Por engrandecerem e iluminarem o trabalho.

Aos pacientes,

Por serem o motivo maior da busca pelo melhor

Por acolherem a arte baseada em ciência

Por darem significado à ciência do amor

E no amor

A desmedida pode ser a medida certa

Só o que é demais

É que é o bastante.

Aos acadêmicos,

De ontem, hoje e amanhã

Por alimentarem meu desejo de capinar e plantar e colher.

Aos meus literatos preferidos,

Por respeitarem os *outliers*

Por compreenderem que "graças aos 5%"

Ainda estamos aqui

Tentando fazer do mundo um lugar melhor!

O cuidado está na ponta da agulha

Na luva que protege

Na mão que sutura

A esperança está no traço do lápis

Na escrita que borda

Na borracha que apaga

Entre versos que falam

E silêncio que cala

Escuta, palavra e ponto.

O amor está em todas as teses

Nos lugares inesperados

Nas inesperadas horas

Horas que não esperam

Cuidado, esperança, amor

Com eles estou

Entre presença, palavra e ponto.

A brotar, a tecer

Entre linhas e letras

Entremeios

Dos acontecimentos que sou.

Thaísa Crespo, 2021

RESUMO

O diabetes é uma doença metabólica progressiva e faz parte das doenças não transmissíveis, as quais constituem sete das dez principais causas de óbitos no mundo de acordo com a Organização Mundial de Saúde. Segundo a Federação Internacional de Diabetes, a estimativa para o ano 2045 é de que o número de pessoas com diabetes poderá atingir 693 milhões, com impacto nas esferas sociais e econômicas, principalmente nos países de baixa e média renda. O controle metabólico no diabetes depende não só do uso de medicamentos, mas também de cuidados referentes à dieta e aos exercícios físicos. Logo, o autocuidado é fundamental no manejo da doença para minimização da morbimortalidade. Em virtude dessas características, o diabetes é um modelo elegível de doença crônica para o estudo da Literacia em Saúde (LS) nos desfechos clínicos e para formulação de políticas de promoção da equidade em saúde. A LS abrange o conhecimento, a motivação e a competência para acessar, compreender, avaliar e aplicar as informações de saúde a fim de fazer julgamentos e propiciar a tomada de decisões com relação ao autocuidado, sendo extensiva ao âmbito comunitário, social, cultural, econômico e político. De modo inclusivo e integrativo, a LS desponta como medida essencial para atender às desafiadoras demandas de saúde na sociedade moderna. Apesar da relevância, as evidências científicas sobre a LS e sua aplicabilidade permanecem escassas e deficitárias principalmente em subgrupos populacionais como os idosos e os de baixa renda. Nos idosos, o diabetes interage e predispõe a processos demenciais como os decorrentes de doença vascular e doença de Alzheimer, acelerando o declínio cognitivo. Portanto, faz-se necessário o desenvolvimento e validação de instrumentos que contemplem de forma abrangente os domínios da LS. Em cenários clínicos e em pesquisa, instrumentos válidos e confiáveis podem contribuir para a identificação de fatores de risco modificáveis que, ao atuarem de modo bidirecional, retroalimentam a limitação da literacia, cuja complexidade precisa ser alvo de estudos que auxiliem as políticas públicas de saúde. A presente tese é um recorte do "Projeto Health Literacy" que incluiu uma população com diabetes assistida por profissionais da Estratégia de Saúde da Família em Montes Claros - MG. Trata da validação de constructo (validade estrutural e teste de hipóteses), bem como da interpretabilidade do instrumento "Alfabetização em Saúde para Diabéticos" (ASD) destinado à avaliação da LS entre pessoas com diabetes assistidas na Atenção Primária à Saúde. As análises estatísticas demonstraram a confiabilidade e a validade de constructo do instrumento na população estudada, inferindo adequação para aplicação em cenários de pesquisa e em serviços de saúde que prestam

assistência a pessoas com diabetes. Também ficou evidenciado que uma maior acessibilidade às informações sobre o diabetes tende a melhorar as outras competências da literacia, a qual está associada com condições cognitivas, características sociodemográficas e parâmetros bioquímicos. Posteriormente, utilizando o Mini-Exame do Estado Mental e instrumentos de LS diabetes-específicos, foi avaliada a condição cognitiva de idosos com diabetes e a LS com relação à adesão medicamentosa, atividade física e nutrição, além de correlacioná-la a fatores sociodemográficos e bioquímicos. Nesse subgrupo, a LS foi correlacionada à cognição e às condições sociodemográficas (idade, renda e escolaridade). Logo, o uso de instrumentos para avaliação da LS e da condição cognitiva pode contribuir para incrementar medidas que visem o cuidado integral dos idosos com diabetes, melhorando a efetividade do manejo da doença. Portanto, o trabalho metodológico de avaliação das propriedades psicométricas do ASD em pessoas com diabetes acrescido de correlações com a cognição e condições sociodemográficas colabora para enfatizar a importância do uso de instrumentos como ferramentas para a elaboração de estratégias de prevenção de doenças, minimização de complicações e promoção da saúde.

Palavras-chave: Letramento em Saúde. Diabetes Mellitus. Cognição. Psicometria. Confiabilidade e Validade.

ABSTRACT

Diabetes is a progressive metabolic disease, being part of the noncommunicable diseases, which according to the World Health Organization, comprise seven of the ten main death causes worldwide. According to the Diabetes International Federation, the estimates for 2045 is that the number of people with diabetes may reach 693 million, with impacts on the social, and economic scenarios, especially in low and middle-income countries. The metabolic control in diabetes relies not only on the medication's use but also on the diet and physical activity lifestyles. Therefore, the self-care is fundamental in the disease management to minimize the associated morbimortality. In this perspective, diabetes is an eligible model of chronic disease for the study of health literacy (HL) on the clinical outcomes, and for the formulation of public policies aimed to promote health equity. The HL embraces the knowledge, the motivation, and the competence to access, comprehend, evaluate, and apply the health information to encourage judgments and decision-making regarding self-care, being extended to the community, social, cultural, economic, and political scope. In an inclusive and integrative way, HL emerges as an essential measure to meet the challenging health demands in modern society. Despite the relevance, scientific evidence on HL and its applicability remains scarce and faulty, mainly among the elderly, and low-income population subgroups. In the elderly, diabetes interacts and predisposes to dementia processes as resulting from vascular disease, and Alzheimer's disease, accelerating the cognitive decline. Therefore, the development and validation of instruments that comprehensively contemplate the HL domains, are necessary. In clinical and research scenarios, valid and reliable instruments may contribute to the identification of modifiable risk factors that, by acting bidirectionally, feedback the limitation of literacy, from which complexity needs to be the target of studies that support public health policies. The present study is an excerpt from the "Health Literacy Project", and included a population with diabetes assisted by professionals from the Family Health Strategy in Montes Claros – MG. It comprises a construct validation (structural validity and hypothesis test), as well as the "Health Literacy for Diabetics" (HLD) instrument interpretability, which is designated to assess the health literacy (HL) among individuals with diabetes assisted in the Health Primary Care. The statistical analysis demonstrated the instrument construct reliability and validity in the studied population, inferring suitability for application in research, and health services that assist patients with diabetes. It was also evidenced that a greater accessibility to information on diabetes tends to improve other literacy skills, which is related to cognitive conditions,

sociodemographic characteristics, and biochemical parameters. Subsequently, the cognitive condition, and HL of elderly with diabetes and their relation with medication adherence, physical activity, nutrition, sociodemographic, and biochemical factors were evaluated by using the Mini-Mental State Examination and diabetes-specific HL instruments. In this subgroup, HL was correlated with cognition and sociodemographic conditions (age, income, and educational level). Therefore, the use of instruments to evaluate HL and cognitive condition may contribute to the improvement of measures based on the comprehensive care of elderly with diabetes, enriching the disease management effectiveness. In this perspective, the HLD psychometric properties evaluation in individuals with diabetes, in addition to correlations with the cognition and sociodemographic conditions collaborates to emphasize the importance of using instruments as tools for the elaboration of strategies for disease prevention, minimization of complications, and health promotion.

LISTA DE ILUSTRAÇÕES

LISTA DE ABREVIATURAS E SIGLAS

3-brief-SQ	3-brief Screening Questions
ASD	Alfabetização em Saúde entre Diabéticos
ASHN-D	Alfabetização em Saúde quanto aos Hábitos Nutricionais entre Diabéticos
ASPAF-D	Alfabetização em Saúde quanto à Prática de Atividades Físicas entre Diabéticos
AASAM-D	Alfabetização em Saúde quanto à Adesão Medicamentosa entre Diabéticos
CEP-UNIMONTES	Comitê de Ética e Pesquisa da Universidade Estadual de Montes Claros
CNPq	Conselho Nacional de Desenvolvimento Científico e Tecnológico
COSMIN	Consensus-based Standards for the selection of health Measurement Instruments
DKN	The Diabetes Knowledge Assessment
DM1	Diabetes *Mellitus* tipo 1
DM2	Diabetes *Mellitus* tipo 2
DNT	Diabetes Numeracy Test
ESF	Estratégia de Saúde da Família
HbA1C	Hemoglobina Glicada
HEALS	The Health Literacy Scale
IDF	Internacional Diabetes Federation
LAD	Literacy Assessment for Diabetes
LS	Letramento em Saúde
METER	Medical Term Recognition Test
MSFHL	Multidimensional Screener of Functional Health Literacy

NVS	Newest Vital Sign
OMS	Organização Mundial da Saúde
PPGCS	Programa de Pós-Graduação em Ciências da Saúde
REALM	Rapid Estimate of Adult Literacy in Medicine
SAC	Scientific Advisory Committee
SAHLPA	Short Assessment of Health Literacy for Portuguese-Speaking Adults
SAHLSA	Short Assessment of Health Literacy for Spanish Adults
SILS	Single Item Literacy Screener
SKILLD	Spoken Knowledge in Low Literacy Patients with Diabetes
SUS	Sistema Único de Saúde
TCLE	Termo de Consentimento Livre e Esclarecido
TOFHLA	Test of Functional Health Literacy in Adults
UNIMONTES	Universidade Estadual de Montes Claros

APRESENTAÇÃO

Esta tese está de acordo com as normas de formatação em vigor preconizada pelo Programa de Pós-Graduação em Ciências da Saúde (PPGCS) - Universidade Estadual de Montes Claros (UNIMONTES), Montes Claros - MG, que recomenda a apresentação de uma primeira seção com a introdução, os objetivos do trabalho, a revisão de literatura (opcional) e a metodologia (opcional). A segunda seção apresenta os produtos, sendo que os artigos foram redigidos seguindo as normas do periódico escolhido para a submissão do artigo 1 (*The Science of Diabetes Self-Management and Care - Formerly known as The Diabetes Educator Journal)* e publicação do artigo 2 (*IBRO Reports*), incluindo a lista de referências utilizadas especificamente nos artigos. A terceira seção é composta por considerações finais e referências das citações utilizadas na introdução. As referências estão adaptadas do *International Committee of Medical Journals Editors* (Vancouver). No Apêndice está incluído o artigo *"Psychometric properties of an oral health literacy scale for people living with diabetes"*. Esse artigo foi elaborado por membros da equipe do "Projeto Health Literacy" e submetido no periódico Journal of Public Health Dentistry (coautoria). Anexos estão incluídos após as referências, nos quais constam o Parecer Consubstanciado do Comitê de Ética em Pesquisa, o Termo de Consentimento Livre e Esclarecido (TCLE), o Termo de Concordância da Instituição para participação em pesquisa e a norma do periódico para elaboração e submissão de artigos (artigo 2). Detalhes sobre a formatação preconizada e normalização adotada podem ser obtidos no endereço eletrônico www.ppgcs.unimontes.br - Universidade Estadual de Montes Claros. PPGCS - "Manual de orientação para elaboração de dissertação e tese", elaborado pelas professoras Drª. Ana Cristina de Carvalho Botelho, Drª. Andrea Maria Eleutério de Barros Lima Martins, Drª. Cristina Andrade Sampaio, Drª. Desirée Sant'Ana Haikal, Drª. Maisa Tavares de Souza Leite, Drª. Raquel Conceição Ferreira e Drª. Sibele Nascimento de Aquino. Montes Claros; 2014.

Trata-se de um recorte do projeto de pesquisa, financiado pelo CNPq, intitulado "Avaliação do impacto de ações educativas nos níveis de alfabetização em saúde entre idosos cadastrados na Estratégia Saúde da Família: um ensaio randomizado" e denominado "Projeto Health Literacy". Este projeto foi submetido ao Comitê de Ética e Pesquisa da Unimontes (CEP-UNIMONTES), tendo parecer de aprovação para realização do estudo, sob o nº 1.461.818/2014 (CAEE: 54417616.1.0000.5146). Uma vez aprovado, houve garantia aos sujeitos amostrais e às

instituições envolvidas na pesquisa da preservação dos dados, da confidencialidade e sigilo das informações relativas à identidade civil e jurídica.

SUMÁRIO

1 INTRODUÇÃO

1.1 Diabetes

O diabetes é uma doença metabólica progressiva caracterizada por níveis séricos elevados de glicose quando não tratada, o que predispõe a efeitos deletérios sistêmicos e em órgãos-alvo, aumentando o risco de doenças cardiovasculares, cerebrovasculares, renais, neurológicas, oftalmológicas, dentre outras (1, 2). O diabetes faz parte das doenças crônicas não degenerativas, as quais constituem sete das dez principais causas de óbitos no mundo de acordo com as Estimativas Globais de Saúde da Organização Mundial de Saúde (OMS) entre os anos 2000 e 2019 (1). Nesse período, as mortes por diabetes aumentaram 70% globalmente, com um aumento de 80% das mortes no gênero masculino (1). Segundo a *International Diabetes Federation* (IDF), há aproximadamente 422 milhões de pessoas vivendo com diabetes em todo o mundo, com projeção de atingir 693 milhões de pessoas em 2045, além de que 1,6 milhão de mortes são diretamente atribuídas a essa doença a cada ano, com consequências deletérias nas esferas sociais e econômicas e nos sistemas de saúde, principalmente nos países de baixa e média renda (1). Além disso, estima-se que 49,7% das pessoas com diabetes não têm o diagnóstico da doença (3). Em 2019, o número de pessoas com diabetes no Brasil foi estimado em 16,5 milhões, sendo o país com maior prevalência de diabetes na América Latina (4). As regiões norte e nordeste do Brasil concentram menores taxas de diabetes em comparação com o sudeste, tendo maior prevalência em áreas mais urbanizadas (5). Ademais, indivíduos com escolaridade até o ensino fundamental incompleto ou até 8 anos de escolaridade possuíam maior percentual de diabetes no país (9,6%) (5). No município de Montes Claros – MG, estudo estimou a prevalência autorreferida de diabetes em 4,5% da população nos anos 2010 e 2011, sendo maior em indivíduos idosos, em concordância à média nacional (6). Por outro lado, estudo evidenciou que, apesar do aumento da prevalência de pessoas com diabetes, o número de internações hospitalares relativas a complicações dessa doença reduziu nos últimos 20 anos em decorrência da expansão da cobertura da Atenção Primária em Saúde de Montes Claros (7). Paralelamente, outro estudo demonstrou que a Unidade Básica de Saúde foi o principal local de acesso ao sistema de saúde pelos indivíduos com diabetes (5). O sistema público de saúde brasileiro vigente foi implantado a partir de 1990 como Sistema Único de Saúde (SUS). O SUS é organizado de forma descentralizada, de modo que o primeiro contato do indivíduo com o sistema seja na Atenção Primária conforme a Estratégia de Saúde da Família (ESF). Essa

estratégia abrange equipes de saúde da família e atua em determinadas áreas geográficas com populações adscritas de 2000 a 3500 pessoas (8).

A distinção entre os dois tipos mais prevalentes (tipo 1 e tipo 2) tem sido definida com base na idade de início da doença, no grau de perda da função das células beta pancreáticas, no perfil de resistência insulínica, na presença de autoanticorpos e na necessidade de insulinoterapia. Entretanto, nenhuma dessas características distingue inequivocamente um tipo de diabetes do outro nem considera integralmente todos os fenótipos da doença (2). A etiopatogenia é heterogênea e inclui déficit na secreção e/ou na ação da insulina, bem como distúrbios do metabolismo de proteínas, carboidratos e lipídios (2). O diabetes tipo 1 (DM1) é uma condição crônica na qual o pâncreas produz pouca ou nenhuma insulina devido à destruição das células beta pancreáticas, não sendo prevenível conforme o conhecimento científico atual (1). O tipo mais comum é o diabetes tipo 2 (DM2) que geralmente afeta adultos e cuja prevalência tem aumentado de modo significativo em todos os países independentemente de suas condições socioeconômicas. Nesse caso, a secreção insuficiente de insulina está associada à resistência insulínica e sua fisiopatologia, na maior parte das vezes, envolve o sobrepeso e a obesidade, que são considerados os mais importantes fatores de risco para o desenvolvimento da doença (1, 4, 9).

1.1.1 Diabetes e envelhecimento

O risco de desenvolver diabetes tipo 2 aumenta com a obesidade, com o aumento percentual de gordura corporal na região abdominal, com o sedentarismo e também com o envelhecimento (10). Apesar das evidências demonstrarem a tendência do aumento da longevidade, esse fato não implica necessariamente em acréscimo de anos de vida saudável. Em 2019, a expectativa de vida foi de seis anos a mais do que no ano 2000, com uma média global de mais de 73 anos em 2019 em comparação com aproximadamente 67 anos no ano 2000 (1). Porém, as incapacidades decorrentes das doenças crônicas, dentre elas o diabetes, a doença de Alzheimer e outras formas de demência, estão em ascensão e contribuem para a perda de anos de vida saudável e para as principais causas de morte no mundo (1). Nas pessoas mais idosas (> 70 anos), o diabetes interage e predispõe a outros processos demenciais como doença vascular e doença de Alzheimer, o que acelera o declínio cognitivo (11-14). Os déficits cognitivos possuem elevada prevalência, com estimativa de 42 milhões de indivíduos no mundo em 2020 e 81 milhões no mundo em 2040, sendo que o aumento nesses índices pode estar associado à

prevalência crescente de diabetes (15). Estudos demonstram maior prevalência de déficits cognitivos em pessoas idosas com intolerância à glicose ou diabetes não tratado, com comprometimento principalmente da memória verbal e da velocidade de processamento das informações (11, 16). O controle glicêmico inadequado está associado ao comprometimento da função executiva cerebral independentemente da idade e de lesões em órgãos-alvo, contribuindo com a redução da flexibilidade cognitiva e a incapacidade em tomada de decisões (16, 17). O início precoce da doença, o inadequado controle da glicemia, a presença de lesões micro e macro vasculares e de outros fatores como depressão, doenças cardiovasculares e cerebrovasculares contribuem para agravar os déficits cognitivos nessa faixa etária (11, 12). Além disso, estudos demonstram que o declínio da função cognitiva em idosos com diabetes prejudica a alfabetização em saúde nessa população, independentemente da educação e de outros fatores de confusão (18). Ademais, com a senescência, ocorrem mudanças no organismo que interferem nos processos de farmacocinética e farmacodinâmica, o que torna os idosos mais vulneráveis aos efeitos adversos de medicações. Nesse sentido, sociedades médicas estabelecem metas diferenciadas para o controle glicêmico em idosos com diabetes, com níveis de hemoglobina glicada (HbA1C) variando de acordo com as condições clínicas e sociais, capacidade funcional, tempo de doença, presença de comorbidade, presença de complicações da doença e expectativa de vida (19, 20). Contudo, o manejo dos pacientes com diabetes não se limita apenas ao incremento dos parâmetros bioquímicos. Nessa população, além do controle glicêmico inadequado predispondo à disfunção cognitiva, existe alta incidência de deficiências funcionais, incluindo déficits auditivos e visuais, histórico de quedas e dificuldades de realização de atividades da vida diária (21). Pessoas com diabetes também são mais susceptíveis a doenças bucais, como as periodontais, e é possível observar uma relação de retroalimentação entre o diabetes e as doenças odontológicas (22). Um controle glicêmico não adequado afeta os tecidos bucais de modo similar à fisiopatologia do diabetes em outros sistemas orgânicos (23). É biologicamente plausível que a inflamação crônica consequente a alterações bucais tenha impacto no controle do diabetes. Associações significativas independentes entre inflamação periodontal, status glicêmico e complicações do diabetes foram evidenciadas (22, 24). Torna-se relevante, então, contemplar individualmente as necessidades específicas do tratamento da doença, o rastreamento e a detecção de outras síndromes geriátricas, assim como visar a prevenção de complicações, a minimização das limitações impostas pela doença e a reabilitação, com consequente melhora da qualidade de vida (25, 26).

1.1.2 Rastreamento e diagnóstico precoce do declínio cognitivo nos pacientes com diabetes

Os déficits cognitivos são considerados fatores de risco para o incremento da morbimortalidade nos pacientes idosos com diabetes, já que a adesão medicamentosa e a adesão a outros cuidados necessários ao manejo da doença poderão estar comprometidas (27). Embora não existam evidências para dar suporte à realização de rastreio cognitivo em todos os idosos, faz-se necessário o diagnóstico dos declínios cognitivos em suas fases iniciais (28, 29). Para rastreamento e diagnóstico precoce, o Mini-Exame do Estado Mental (MEEM) é o instrumento mais utilizado na avaliação inicial da cognição. Esse teste analisa as áreas de orientação, memória, atenção, nomeação, obedecer aos comandos, escrita e habilidade visuoespacial (30-32). A identificação precoce do declínio cognitivo pode desencadear ações preventivas para minimizar riscos (33) e garantir uma maior chance de sucesso na abordagem de fatores potencialmente reversíveis (34, 35). O conhecimento do diagnóstico de demência permite aos profissionais de saúde um manejo mais apropriado das comorbidades (36) e aos familiares um entendimento mais preciso sobre as alterações cognitivas e comportamentais observadas, minimizando o risco de conflitos e facilitando a implantação de estratégias adaptativas (37). O diagnóstico precoce permite ao próprio paciente uma melhor compreensão de seus sintomas, dando-lhe a segurança de que medidas apropriadas estão sendo tomadas (38). E, por conseguinte, nas fases mais iniciais das demências é mais fácil conseguir o engajamento do paciente em estratégias de tratamento não-farmacológico, como treinamento cognitivo, atividade física e socialização (39, 40). Nesse contexto, demonstrou-se que os pacientes com diabetes, ao participarem de seus próprios cuidados, causam um impacto positivo na evolução da doença. Mesmo assim, a adesão ao tratamento é baixa e desafiadora quando associada com alterações cognitivas, sendo necessária uma abordagem sistemática, multifacetada e integrada para promoção de práticas adequadas de autocuidado em longo prazo (25).

1.2 Literacia em saúde

1.2.1 Conceito e importância da literacia em saúde

A partir de uma revisão sistemática e integrativa de definições e modelos conceituais, foi proposto por Sørensen *et al.* uma concepção abrangente de literacia em saúde (LS) (41). A LS engloba o conhecimento, a motivação e as competências para acessar, compreender, avaliar e aplicar as informações de saúde a fim de fazer julgamentos e propiciar a tomada de decisões na vida cotidiana com relação à prevenção de doenças, atenção e promoção da saúde como exposto

na figura 1 (41). Pessoas literatas em saúde têm conhecimento e capacidade de assumir a responsabilidade de cuidar da própria saúde bem como influenciar nos cuidados de saúde de seus familiares e de sua comunidade, entendendo o contexto não só do autocuidado mas também toda dimensão social, cultural, econômica e política da LS (42). Portanto, conceitualmente, a LS integra as dimensões médicas e de saúde pública, sendo essencial para atender às complexas demandas de saúde na sociedade moderna. Apesar da relevância do assunto e da crescente atenção às suas competências pelos formuladores de políticas de saúde, pesquisadores e profissionais da área, as informações sobre a LS permanecem escassas e os níveis de literacia diferem significativamente até mesmo em países desenvolvidos (41, 43). A LS envolve atividades de educação e comunicação direcionadas para a melhoria das condições de saúde. Entretanto, mostra-se deficitária principalmente nos subgrupos populacionais de baixa renda, baixa escolaridade e idosos. Nessa perspectiva, a percepção da importância do impacto social na LS implica em um desafio para as políticas e práticas que visam o desenvolvimento de estratégias de promoção da equidade em saúde (43). Incrementar a LS significa muito mais do que transmitir informações, desenvolver habilidades de leitura e melhorar o acesso a consultas médicas. À medida que o acesso às informações de saúde, a capacidade de avaliá-las e aplicá-las de modo eficaz são ampliados, é possível alcançar o empoderamento tanto no nível do autocuidado quanto no nível comunitário. E, para alcançar esse objetivo, é preciso dar ênfase às políticas de educação e às formas pessoais de comunicação baseadas na realidade da comunidade, com foco em preparar melhor as pessoas para superar as barreiras estruturais à saúde (44). Nesse sentido, além da dimensão individual e do contexto médico, o modelo prototípico desenvolvido por Nutbeam, descreve três tipologias da LS: literacia funcional, literacia interativa (comunicativa) e literacia crítica em saúde. Elas representam níveis de conhecimento e habilidades que apoiam maior autonomia e empoderamento pessoal na tomada de decisões bem como um conhecimento progressivamente maior em saúde que se estende desde a gestão da saúde pessoal aos determinantes sociais de saúde (44, 45). A LS funcional remete às habilidades básicas de leitura e escrita necessárias cotidianamente. A LS interativa refere-se às habilidades cognitivas e de alfabetização mais avançadas que, juntamente com as habilidades sociais, permitem uma participação ativa em situações cotidianas, buscando e atribuindo significado às informações obtidas a partir de diferentes meios de comunicação, o que possibilita a aplicação apropriada de acordo com as circunstâncias. Por fim, a LS crítica refere-se às habilidades cognitivas mais avançadas que, juntamente com as habilidades sociais, podem ser aplicadas para analisar criticamente as informações e usá-las para exercer maior controle sobre eventos e situações da vida (33).

Portanto, por intermédio da LS, impactos na promoção da saúde são percebidos a partir de diferentes esferas hierárquicas de intervenções desde os comportamentos pessoais (por exemplo, tabagismo, escolhas alimentares, atividade física, uso de álcool e drogas ilícitas) até os estruturais e os sociais (por exemplo, qualidade de vida, independência funcional e equidade). Assim, a LS visa o melhor conhecimento e compreensão dos determinantes da saúde, mudança de atitudes e motivações comportamentais, além de melhorar a alta eficácia relativa às tarefas recomendadas, o que pode levar a uma melhora da qualidade de vida e à redução da morbimortalidade. Além disso contempla esforços para superar barreiras estruturais à saúde através da participação ativa em comunidade, empoderamento comunitário, opinião pública e normas sociais. Políticas públicas de saúde e práticas organizacionais, incluindo mudanças legislativas, como, por exemplo, o controle do tabaco e os programas de promoção de alimentação saudável implantados em alguns países, podem ser alcançadas. Nesse contexto, a educação e a comunicação em saúde são fundamentais para a LS e, consequentemente, para o empoderamento pessoal e melhores resultados da promoção da saúde (46).

Figura 1 - Modelo teórico de literacia em saúde apresentado por Sørensen *et al.*, 2012
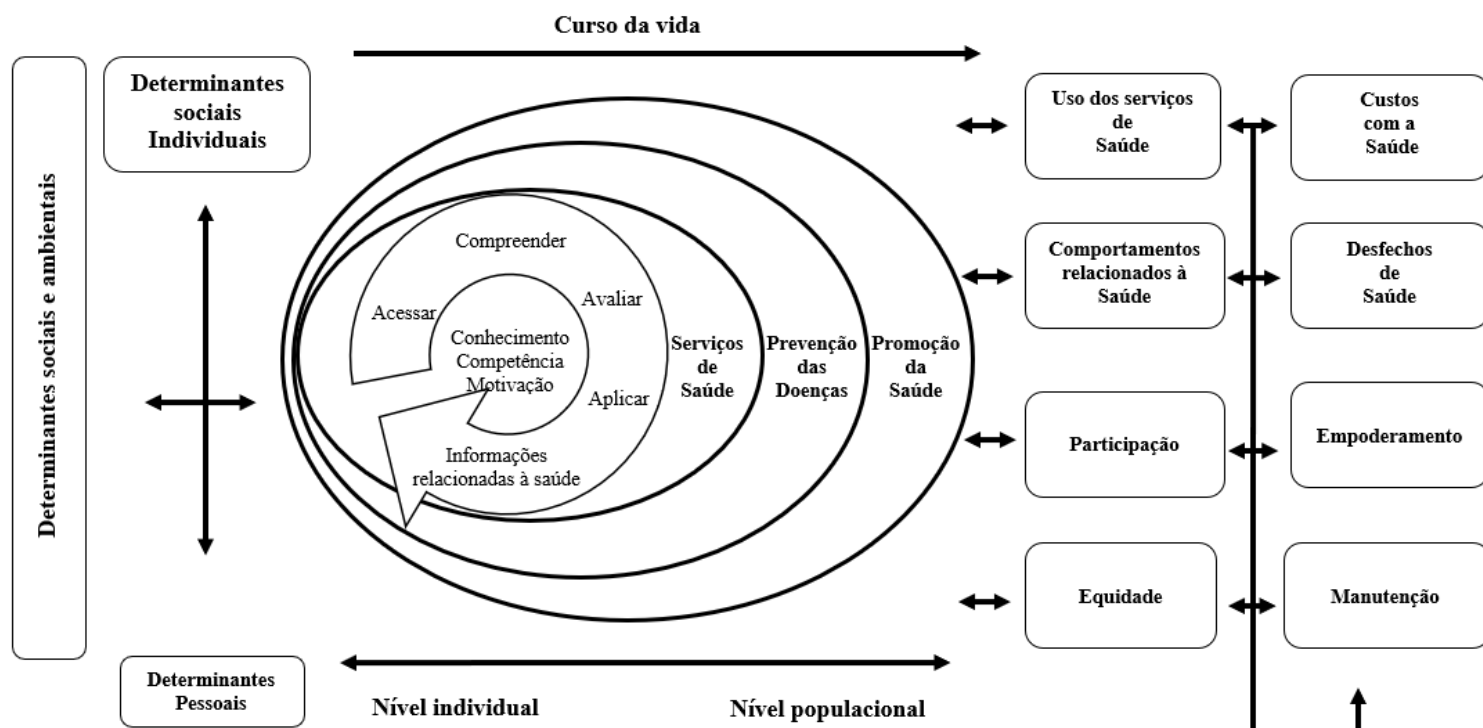
Fonte: Modificado de Sørensen *et al.*, 2012

1.2.2 Literacia em saúde em pessoas com diabetes

Pessoas vivendo com diabetes necessitam de procedimentos contínuos e extensivos de autocuidado, incluindo a autorregulação da dieta (escolhas alimentares e tamanho das porções), monitorização dos níveis séricos de glicose, exercícios físicos regulares, administração de medicamentos de acordo com as doses prescritas e a posologia, cuidado com os pés e controle do estresse (47). Esse autocuidado tem um papel fundamental no sucesso do tratamento do diabetes. Nesse contexto, a LS adequada inclui o conjunto de habilidades importantes para o manejo da própria doença, abrangendo conhecimentos culturais, capacidade de ouvir e falar, capacidade de ler e escrever e habilidade de usar números (48). Em virtude dessas características, o diabetes é um modelo de doença crônica para o estudo da influência da LS no controle de desfechos clínicos e laboratoriais (49). Estudos demonstram que a autoeficácia do cuidado do diabetes não difere significativamente com os níveis de literacia funcional. Por outro lado, a literacia interativa e crítica tem correlações positivas significativas com a autoeficácia, o que sugere que níveis mais avançados de LS estão estreitamente mais relacionados a uma melhor eficácia no controle da doença (50, 51). Entretanto, pacientes com baixa LS

experimentam dificuldade no entendimento das informações em saúde e são menos predispostos a expressar suas dúvidas aos profissionais de saúde, resultando em um automanejo precário da doença (52). A LS adequada é importante para obtenção de melhores desfechos em pacientes com diabetes e para melhor compreensão de potenciais barreiras ao autocuidado e aos comportamentos de promoção da saúde (53). Alguns trabalhos não evidenciaram associação entre o controle glicêmico e a LS nos seus diversos domínios (54-56), ao passo que outros demonstraram uma relação entre LS inadequada e pior controle glicêmico por efeito direto (48, 57, 58) ou indireto por meio do conhecimento em diabetes (59). Osborn *et al.* avaliaram efeitos de possíveis fatores determinantes do controle glicêmico em idosos e observaram que a LS não teve um efeito direto sobre o controle glicêmico, porém teve um efeito indireto por meio do suporte social, reforçando a hipótese de que a LS pode estar relacionada indiretamente ao autocuidado e na melhora de parâmetros bioquímicos através do suporte social (60). Schillinger *et al*. demonstraram associação entre LS e lesões em órgãos-alvo, como retinopatia e acidente vascular encefálico (48), o que não ficou demonstrado em trabalhos de outros autores (55, 57). Revisão sistemática realizada por Al Sayah *et al*. incluiu estudos que avaliaram a relação entre LS, controle glicêmico e lesões de órgãos-alvo como complicação da doença. Os resultados observados foram inconsistentes e a heterogeneidade não permitiu inferência estatística (61). O baixo nível de literacia em saúde bucal dos pacientes com diabetes está associado a um maior número de doenças periodontais e piores desfechos da doença (22, 62). A melhora da literacia em saúde bucal de pacientes com diabetes concomitantemente ao incremento da prevenção primária, ao acesso aos serviços odontológicos e à qualidade do atendimento, contribui para reduzir os custos e as desigualdades na saúde bucal (63). Estudo demonstrou consenso entre as conceituações multidimensionais da LS e concordância quanto aos instrumentos para aferição da LS. Todavia, demonstrou escassez de correlação da LS a desfechos em saúde e autoeficácia, à diferença de gêneros, ao custo-efetividade de intervenções e à influência do ambiente organizacional (53). Destaca-se também a numeracia como importante elemento da LS, já que se refere às habilidades em aplicar as informações numéricas em tarefas específicas fundamentais para os pacientes com diabetes, tais como dosagem de medicamentos e mensuração dos níveis de glicose e de outros parâmetros bioquímicos (53).

A LS como um constructo multidimensional emerge, portanto, como um importante determinante do automanejo no diabetes (41, 64). A LS, principalmente quando combinada com o foco na prevenção e na saúde integrativa, é uma das abordagens mais promissoras para o avanço da saúde pública (65).

1.3 Instrumentos para avaliação da literacia em saúde

1.3.1 Características dos instrumentos de avaliação da literacia em saúde

Na literatura são encontrados instrumentos com diferentes enfoques para avaliar a LS em pacientes com diabetes (64). Os instrumentos apresentam pontos fortes e fracos em função do escopo de aferição, estrutura e propriedades de validade (61). É importante conhecer os itens, os objetivos, os domínios, as formas de avaliação e as propriedades desses instrumentos para selecioná-los de acordo com sua aplicabilidade em ambientes clínicos e/ou de pesquisa. Estudos sobre as propriedades de medida fornecem evidências acerca da qualidade dos instrumentos e resultados podem contribuir para subsidiar mudanças da prática do cuidado (66). A estrutura, o modo e a duração da aplicação bem como as propriedades de medição afetam a aplicabilidade desses instrumentos em ambientes clínicos e de pesquisa (61).

É possível categorizar os instrumentos de LS como instrumentos de avaliações genéricas ou instrumentos específicos de determinadas patologias, por exemplo os que avaliam a LS no diabetes. Os instrumentos também podem ser classificados de acordo com a avaliação direta ou indireta de habilidades da literacia (61, 64, 67). Os instrumentos categorizados em medidas diretas avaliam o desempenho dos indivíduos nas habilidades da LS e os de medida indireta são baseados no autorrelato dessas habilidades. Medidas indiretas autoaplicadas ou aplicadas pelo profissional de saúde parecem ser mais úteis nos campos clínicos e de pesquisa porque são menos influenciados pelo viés da coleta de dados (por exemplo, capacidade de escrita, concentração e visão) (53).

1.3.2 Instrumentos genéricos para avaliação da literacia em saúde e instrumentos diabetes-específicos

1.3.2.1 *Rapid Estimate of Adult Literacy in Medicine*

Instruções médicas, materiais de educação, formulários de consentimento e questionários de autorrelato são, muitas vezes, repassados aos pacientes com pouca consideração às suas habilidades de leitura que raramente são testadas em ambientes médicos. O *Rapid Estimate of Adult Literacy in Medicine* (REALM) foi desenvolvido como uma ferramenta de rastreamento rápido para auxiliar os médicos na identificação de pacientes com habilidades de leitura

deficitárias e para estimar os níveis de leitura dos pacientes. O REALM é um instrumento para avaliar a alfabetização no quesito da leitura em cuidado primário, educação em saúde e pesquisas médicas, com tempo de aplicação e pontuação de três a cinco minutos (68). A versão original é composta de 125 palavras relacionadas à saúde, que devem ser reconhecidas e lidas em voz alta, em ordem ascendente de dificuldade. Em caso de acerto, cada palavra pronunciada corretamente contribui com um ponto no escore (68). Posteriormente, foi desenvolvida e validada uma versão revisada mais curta do REALM (REALM-R), com menor tempo dispendido à sua aplicação (um a dois minutos, se aplicado por uma pessoa com um treinamento mínimo) (69). Apesar do amplo uso em publicações e de ser conhecida como a ferramenta mais facilmente aplicada para avaliar a alfabetização em saúde na língua inglesa, o REALM pode subestimar ou superestimar a habilidade de leitura e apresenta limitações, já que se restringe a avaliar a pronúncia de termos médicos, sem que sejam avaliadas outras habilidades como compreensão das palavras e numeracia. Entretanto, existem dificuldades na triagem de alfabetização na versão em espanhol cuja particularidade ortográfica (correspondência fonema-grafema) implica que a leitura oral pode não refletir a real compreensão do vocábulo, não permitindo diferenciar o nível de alfabetização em espanhol (70).

1.3.2.2 *Test of Functional Health Literacy in Adults*

O *Test of Functional Health Literacy in Adults* (TOFHLA) é um instrumento desenvolvido para avaliar o alfabetismo funcional em saúde e foi criado com a intenção de ampliar os domínios de avaliação do alfabetismo em saúde (71). Analisa um maior número de âmbitos em alfabetismo funcional, consistindo em um teste de compreensão de leitura de 50 itens (habilidade de ler e entender termos e situações comumente encontradas nos ambientes de saúde) e um teste de habilidade numérica de 17 itens, com duração de até 22 minutos para sua aplicação (71). Devido ao tempo demorado de aplicação, o que dificulta seu uso na rotina médica, foi desenvolvido por Baker *et al.* uma versão abreviada do TOFHLA, reduzindo os itens de compreensão de leitura e de numeracia e abreviando para, aproximadamente, 12 minutos o tempo máximo de aplicação (72). O TOFHLA é um dos testes de alfabetismo em saúde mais utilizados em pesquisas, com traduções e validações em várias línguas (73-76). A versão curta do TOFHLA (S-TOFHLA) também foi aplicada em estudo brasileiro, o qual demonstrou que 32,4% das pessoas da amostra apresentavam déficits em alfabetização e numeracia e esse percentual aumentou para 51,6% entre os idosos (≥ 65anos) (77). Trabalho posterior validou o S-TOFHLA para a língua portuguesa ao ser usada em uma amostra de idosos

brasileiros, reforçando sua aplicabilidade em pesquisas e ambientes clínicos para rastreamento de inadequações de alfabetização em saúde no nosso país (78).

1.3.2.3 *Short Assessment of Health Literacy for Portuguese-Speaking Adults*

O *Short Assessment of Health Literacy for Portuguese-Speaking Adults* (SAHLPA) é uma versão brasileira adaptada do *Short Assessment of Health Literacy for Spanish-Speaking Adults* (SAHLSA) e que foi validada por Apolinário *et al*. em 2012. A concepção do SAHLSA, por sua vez, foi baseada no REALM, mas além do teste de reconhecimento de palavras, incorpora um teste de compreensão usando questões de múltipla escolhas elaboradas por um painel de especialistas, superando assim as dificuldades de tradução para a língua espanhola e sendo validado como instrumento de avaliação de alfabetismo funcional (78-80). A versão original é composta por 50 itens (SAHLSA-50) e considera-se que 43 seja o ponto de corte para definir alfabetismo em saúde (79). Posteriormente, com a intenção de facilitar a aplicabilidade clínica, foi publicada uma versão curta com 18 itens. Nessa versão, um número de acertos menor ou igual a 14 itens é classificado como inadequado alfabetismo em saúde e pontuação de 15 a 18 configura um adequado alfabetismo em saúde (80). A vantagem do SAHLPA é ser de fácil e rápida aplicabilidade e, de modo distinto do REALM, avalia tanto o reconhecimento através da pronúncia quanto a compreensão de termos usados em saúde. Acredita-se que o seu uso seja mais apropriado em populações de países em desenvolvimento, já que avalia funções mais rudimentares ligadas ao alfabetismo em saúde, podendo tornar sua aplicação possível em indivíduos de baixa escolaridade (78).

1.3.2.4 "Alfabetização em Saúde entre Diabéticos"

Em 2018, Martins *et al*. baseados no modelo teórico de LS proposto por Sørensen (41), no SAHLPA (78) e no **CO**nsensus-based **S**tandards for the selection of health **M**easurement **IN**struments (COSMIN) (81-83) criaram o "Alfabetização em Saúde entre Diabéticos" (ASD) (84) que, de modo inédito, avalia todos os domínios da LS em pacientes com diabetes. Inicialmente com 150 itens, foi condensado para uma versão com 30 itens divididos em cinco partes. A primeira parte é composta por dez perguntas que aferem o acesso, compreensão, avaliação e aplicação de conhecimentos sobre a alfabetização em diabetes, incluindo perguntas que avaliam a frequência com que os indivíduos têm acesso a informações sobre diabetes e de que modo ocorre a compreensão, avaliação e aplicação desses conhecimentos, evidenciando ou não o empoderamento das pessoas na escolha de comportamentos saudáveis. A segunda parte afere o acesso à informação sobre o diabetes repassada por profissionais e/ou por outras pessoas

(médico, enfermeiro, cirurgião-dentista, agente de saúde e outros). A terceira parte avalia a qualidade dos assuntos relacionados ao diabetes que os indivíduos têm acesso (conceito e complicação do diabetes, uso de medicamentos, atividade física, alimentação, fumo, bebida alcóolica e pé diabético). A quarta parte afere o acesso a informações sobre o diabetes através da leitura (receitas médicas, bulas de medicamentos, jornal, revista, cartaz, *outdoor*, panfleto / *folder* / cartilha, internet e outra forma de acesso). A quinta parte verifica os meios através dos quais o indivíduo ouve e/ou assiste as informações sobre diabetes (televisão, rádio, internet, filmes / cinema e outros). Na segunda, terceira, quarta e quinta partes, além do acesso, o instrumento tem como objetivos avaliar a frequência desses acessos, a capacidade de avaliação, de compreensão e de aplicação das informações acessadas. O ASD é válido quanto ao seu conteúdo, apresenta um bom nível de confiabilidade (84) e é o único questionário diabetes-específico que inclui detalhadamente as fontes de acesso, os profissionais de saúde e pessoas que transmitem as informações e os tópicos abordados. O presente estudo, dentre outros objetivos, visa o trabalho metodológico de validação de constructo e interpretabilidade desse instrumento.

1.3.2.5 *Newest Vital Sign*

O *Newest Vital Sign* (NVS) é um instrumento de triagem rápido, criado por Weiss *et al*., que avalia a leitura e a compreensão por meio de seis perguntas sobre a interpretação de um rótulo de alimento. O teste permite a avaliação de habilidades numéricas, incluindo cálculo de percentagens. O NVS é adequado para uso como triagem rápida para alfabetização inadequada em atenção primária à saúde (85). Ainda não foi traduzido e validado para a língua portuguesa.

1.3.2.6 *Medical Term Recognition Test*

Desenvolvido em 2009, o *Medical Term Recognition Test* (METER) é um instrumento breve e autoaplicável para avaliar o nível de alfabetização em saúde. Foi validado originalmente na língua inglesa e seu objetivo é facilitar a aplicabilidade com relação ao tempo dispendido (aplicado em aproximadamente 2 minutos). É uma medida rápida e prática de alfabetização para uso em ambientes clínicos (86). Posteriormente, foi adaptado culturalmente e validado para a língua portuguesa, avaliando a alfabetização em saúde na população portuguesa por meio de identificação correta de palavras relacionadas à área da saúde e de termos fictícios que apresentam semelhanças fonêmicas com palavras relacionadas à saúde, mas não constituem palavras. A alfabetização adequada é definida como pontuação de, pelo menos, 35/40 palavras e 18/30 em termos fictícios. Após a adaptação transcultural, mostrou validade e confiabilidade

como instrumento de aferição de alfabetização em saúde em adultos portugueses e em pesquisas de associações de alfabetismo com desfechos em saúde (87). Como o REALM, baseia-se apenas na identificação de palavras e no conhecimento do vocabulário (69), não contemplando o conceito amplo de LS que trata do acesso à informação, da compreensão e avaliação da informação e também da aplicação da informação obtida (41).

1.3.2.7 *Literacy Assessment for Diabetes*

O *Literacy Assessment for Diabetes* (LAD) é um instrumento de avaliação de LS diabetes-específico desenvolvido e validado na língua inglesa e consta de 60 palavras (LAD-60) graduadas em dificuldade crescente e que funciona como um teste de reconhecimento de palavras (88). Avalia a capacidade do paciente de pronunciar termos comuns nas clínicas e de ler instruções de autocuidado. É confiável e válido para aferir a alfabetização em adultos com diabetes e pode ser aplicado em tempo menor ou igual a três minutos (88). Estudo demonstrou adaptação transcultural satisfatória para a versão em português do Brasil, podendo ser usado como instrumento de triagem na identificação dos níveis de alfabetização em saúde. As 60 palavras são distribuídas em três listas de 20 palavras que devem ser lidas em voz alta pelo entrevistado diante do entrevistador e, dessa forma, o escore pode variar de 0 a 60 (89).

1.3.2.8 *Brief Diabetes Knowledge Test*

Desenvolvido em 1997, o *Brief Diabetes Knowledge Test* é um dos instrumentos mais utilizados na literatura no contexto do diabetes e que mostra relação significativa com alfabetismo em saúde aferido pelo S-TOFHLA (90). Caracteriza-se por ser um teste de conhecimento sobre diabetes com dois componentes: um teste geral de 14 itens e uma subescala de uso de insulina de 9 itens. Quando aplicado em população com diabetes tipo 1 e em população com diabetes tipo 2, as pontuações foram maiores para o grupo com diabetes tipo 1 no teste geral e na subescala de uso da insulina e, para ambas as amostras, as pontuações aumentaram à medida que os anos de educação formal completados aumentaram. Os pacientes que receberam educação sobre diabetes pontuaram mais do que os que não receberam.

1.3.2.9 *Diabetes Numeracy Test*

O *Diabetes Numeracy Test* (DNT) foi desenvolvido com base na premissa de que habilidades matemáticas são fundamentais no controle do diabetes. São habilidades necessárias na interpretação de dosagens glicêmicas, administração de medicamentos (orais e/ou insulina),

especificidades dietéticas e outras tarefas. A partir dessa percepção, Huizinga *et al.* desenvolveram o DNT, sendo o primeiro instrumento específico de aferição de habilidades numéricas necessárias ao autocuidado do diabetes, podendo ser usado para fins clínicos e de pesquisa (91). A versão original constava de 43 itens, com avaliação dicotômica da resposta (correto ou incorreto) e com o escore final dado por uma medida intervalar de 0 a 100%. Levou em média 33 minutos para ser respondida e foi significativamente correlacionada com educação, renda, alfabetização, habilidades matemáticas e conhecimento sobre diabetes. Posteriormente, foi criada uma versão reduzida de 15 itens, comparativamente adequada e mais eficiente quanto ao dispêndio de tempo (DNT-15) (91). White *et al.* validaram a versão em espanhol do DNT-15 (56), o qual ainda não foi adaptado e validado para a língua portuguesa.

1.3.2.10 *The Diabetes Knowledge Assessment* (DKN) e *ADKnowl*

The Diabetes Knowledge Assessment (DKN) é um instrumento desenvolvido especificamente para avaliação de conhecimento em pacientes com diabetes. Envolve leitura e baseia-se em escala mais complexa, com aplicabilidade clínica limitada principalmente para indivíduos com baixa escolaridade (92). A *ADKnowl* também é um instrumento complexo de avaliação do conhecimento relacionado ao diabetes que foi desenvolvido para mensurar a extensão e natureza dos déficits de conhecimento do paciente e do profissional de saúde, alertando que deficiências específicas entre os profissionais de saúde podem ser a causa de alguns déficits de conhecimento do paciente. Está indicado principalmente em um contexto de avaliação contínua. A afirmação como "frutas frescas podem ser consumidas livremente com pouco efeito sobre os níveis de glicose no sangue" e a compreensão acerca do fato de ser aconselhável aparar as unhas no formato do dedo dos pés, bem como sobre prevenção de hipoglicemia e de cetoacidose diabética, dentre outros, são usados na aferição do conhecimento dos pacientes e dos profissionais da saúde (93).

1.3.2.11 *Spoken Knowledge in Low Literacy Patients with Diabetes*

Em 2005, Rothman *et al.* desenvolveram *Spoken Knowledge in Low Literacy Patients with Diabetes* (SKILLD) que é um instrumento de conhecimento para pacientes com diabetes tipo 2 e baixos níveis de alfabetização (94). É composto por 10 perguntas relacionadas ao conhecimento em diabetes, formuladas em linguagem simples, com nível de dificuldade adequado para indivíduos de baixa escolaridade. Por ser aplicado verbalmente, o SKILLD testa parâmetros independentes da capacidade de leitura e permite ao entrevistado explicar as

respostas com suas próprias palavras. O desempenho do SKILLD foi comparado ao status socioeconômico, nível de alfabetização, duração do diabetes e hemoglobina glicada e revelou déficits de conhecimento significativos associados ao controle glicêmico (94). Em 2016, o SKILLD foi traduzido e adaptado para a língua portuguesa e, nessa versão, foi validado para avaliar conhecimentos em diabetes em idosos de baixa escolaridade, sendo considerado de boa aplicabilidade, já que o dispêndio de tempo é pouco e independe da capacidade de leitura (95).

1.3.2.12 Instrumentos que avaliam outros domínios da literacia em saúde e instrumentos com perguntas rápidas para avaliação da literacia em saúde

Considerando a abrangência da LS, foram desenvolvidos instrumentos que avaliam domínios além do alfabetismo funcional e da numeracia em saúde. Em 2008, Ishikawa *et al.* criaram um instrumento que avalia os três domínios da LS (funcional, interativo e crítico) em pacientes com diabetes tipo 2 (50). Cada domínio é avaliado por meio de cinco itens com perguntas sobre dificuldade para ler instruções ou folhetos fornecidos por hospitais ou farmácias (avaliação funcional), sobre a extensão do que extrai e consegue comunicar a partir das informações recebidas referentes ao diabetes desde o momento do diagnóstico (avaliação comunicativa) e sobre a análise crítica das informações relacionadas ao diabetes e se as utiliza para a tomada de decisões (avaliação crítica) (50). Além disso, características sociodemográficas e clínicas, conhecimento sobre diabetes, comportamentos acerca de busca de informações e autoeficácia foram avaliados por meio de um questionário de autorrelato e de revisão de prontuários eletrônicos. Altos escores na avaliação foram associados a um maior conhecimento sobre a doença e maior autocuidado, sem que fossem estabelecidos pontos de corte para determinar a literacia em saúde inadequada (50). Em 2018, Lee *et al.* desenvolveram um instrumento curto de literacia em diabetes, em língua coreana, contemplando aspectos de informação, numeracia e comunicação em LS, composto por apenas 14 itens pontuados em uma escala Likert de 5 pontos, exibindo propriedades psicométricas satisfatórias (96). Ainda no contexto do diabetes, podemos destacar instrumentos com domínios específicos como Alfabetização em Saúde quanto aos Hábitos Nutricionais entre Diabéticos (ASHN - D) (97), Alfabetização em Saúde quanto à Prática de Atividades Físicas entre Diabéticos (ASPAF - D) (98), Alfabetização em Saúde quanto à Adesão Medicamentosa entre Diabéticos (AASAM - D) (99) e Letramento em Saúde Bucal entre pessoas com Diabetes (LSBD) que foi desenvolvido por membros da equipe do "Projeto Health Literacy" e submetido ao periódico *Journal of Public Health Dentistry* (Apêndice).

Entre os instrumentos que avaliam a LS por meio de perguntas rápidas, destaca-se o modelo proposto por Chew *et al.* em 2004, o *3-brief Screening Questions (3-brief SQ)*, composto por três breves questões com o objetivo de triar, de modo prático, pacientes com baixo nível de alfabetização em saúde (100). As perguntas são as seguintes: "Com que frequência você tem ajuda de terceiros para a leitura de materiais hospitalares?" "Quão confiante você está no preenchimento de formulários médicos sem auxílio?" e "Com que frequência você tem problemas de aprendizado sobre condições médicas devido a dificuldades no entendimento de informações escritas?" (89). O *Single Item Literacy Screener* (SILS) é outro instrumento de triagem cujo objetivo é identificar a limitação na capacidade de leitura por meio de apenas uma pergunta: "Com que frequência você tem alguém para auxiliá-lo quando lê instruções, panfletos ou material escrito pelo médico?". Por meio da pergunta, identificam-se os pacientes que precisam de ajuda na leitura de materiais relacionados à saúde. O SILS tem um desempenho moderadamente bom em identificar a incapacidade de leitura em adultos e permite que os profissionais da área direcionem avaliações adicionais de LS prioritariamente para aqueles que mais precisam (55). Apesar da praticidade dos instrumentos de perguntas rápidas, esses testes não demonstraram boa sensibilidade na triagem de indivíduos com alfabetismo em saúde limítrofe (55, 100). Apolinário *et al.* desenvolveram, no ano 2014, o instrumento denominado *Multidimensional Screener of Functional Health Literacy* (MSFHL), combinando perguntas de triagem e características demográficas (escolaridade, escolaridade da mãe e ocupação principal no decorrer da vida - braçal ou não braçal) para avaliar a alfabetização funcional em saúde. As questões referem-se à frequência de uso do computador, dificuldade de escrita que já tenha impedido de conseguir um emprego melhor e dificuldade de leitura das legendas ao assistir um filme estrangeiro. O MSFHL demonstrou superioridade em relação ao nível educacional para classificar com melhor acurácia o nível de alfabetização funcional em saúde (101).

1.4 Elaboração de instrumentos adequados ou de novas versões de avaliação da literacia em saúde

A partir da conceituação inclusiva e integrativa de Sørensen, o letramento em saúde emerge como uma das abordagens mais promissoras para o avanço da saúde pública, sendo essencial para atender às desafiadoras demandas de saúde na sociedade moderna (41, 65). Com a ampliação das competências da LS, a utilidade dos instrumentos de aferição da LS necessita ser reconsiderada (41, 65). Embora estudos relacionem os baixos níveis de educação e de LS com o agravamento de problemas de saúde, má utilização dos serviços de saúde, maiores barreiras ao manejo da doença e morte precoce, os instrumentos de aferição da complexa

dimensão da LS apresentam uma evolução contínua, porém incompleta (65). Os instrumentos mais frequentemente utilizados contemplam os tópicos da LS de modo estreito, como, por exemplo a avaliação das habilidades na leitura e pronúncia de uma lista de termos médicos (69), a compreensão e as habilidades de numeracia (71) e, no entanto, não abordam outras habilidades importantes como a comunicação verbal, a navegação no sistema de saúde e a tomada de decisão relacionada à saúde (61).

Nesse contexto, o desenvolvimento de instrumentos para a avaliação da LS, com focos específicos, em populações específicas e com validação estatística de seus constructos, permite a inferência de adequação metodológica e possibilidade de aplicabilidade em cenários clínicos e/ou em pesquisas direcionadas à melhoria das condições de saúde (66). E, sendo a educação e a comunicação fundamentais ao letramento em saúde, o uso desses instrumentos pode contribuir para a identificação de variáveis modificáveis que, ao atuarem de modo bidirecional, retroalimentam as deficiências do letramento, cuja complexidade precisa ser alvo de pesquisas que contribuam para o desenvolvimento de estratégias de prevenção de doenças e de promoção da saúde (43).

Conhecer os referenciais para avaliação das propriedades de medidas em saúde é importante não só para a escolha dos instrumentos, mas também para a elaboração de novos instrumentos

ou apresentação de novas versões (66). Segundo o *Scientific Advisory Committee* (SAC), os atributos e critérios indispensáveis aos instrumentos são: modelo conceitual e de medição, confiabilidade, validade, responsividade, interpretabilidade, formas alternativas, traduções e adaptações culturais (102). Os pesquisadores devem considerar padrões para fazer inferências com relação às propriedades psicométricas dos instrumentos e à qualidade metodológica dos estudos. Um estudo Delphi, de consenso internacional e multidisciplinar conduzido por 43 especialistas, padronizou conceitos para avaliar as propriedades de medida e qualidade metodológica dos trabalhos e teve como produto o ***CO**nsensus-based **S**tandards for the selection of health **M**easurement **IN**struments* (COSMIN), o qual explicita concordância sobre taxonomia, terminologia e definições das propriedades de medida para desfechos de saúde (83, 103). O COSMIN visa auxiliar a escolha de instrumentos adequados tanto na prática clínica quanto na pesquisa e estabelece um conjunto composto por quatro domínios que medem a qualidade de um instrumento: três domínios para estimativas da confiabilidade, validade e responsividade e um domínio para a avaliação da interpretabilidade conforme demonstrado na figura 2 (82, 104).

Figura 2 Qualidades de um instrumento de acordo com o **CO**nsensus-based **S**tandarts for the selection of health **M**easurement **IN**struments (COSMIN)
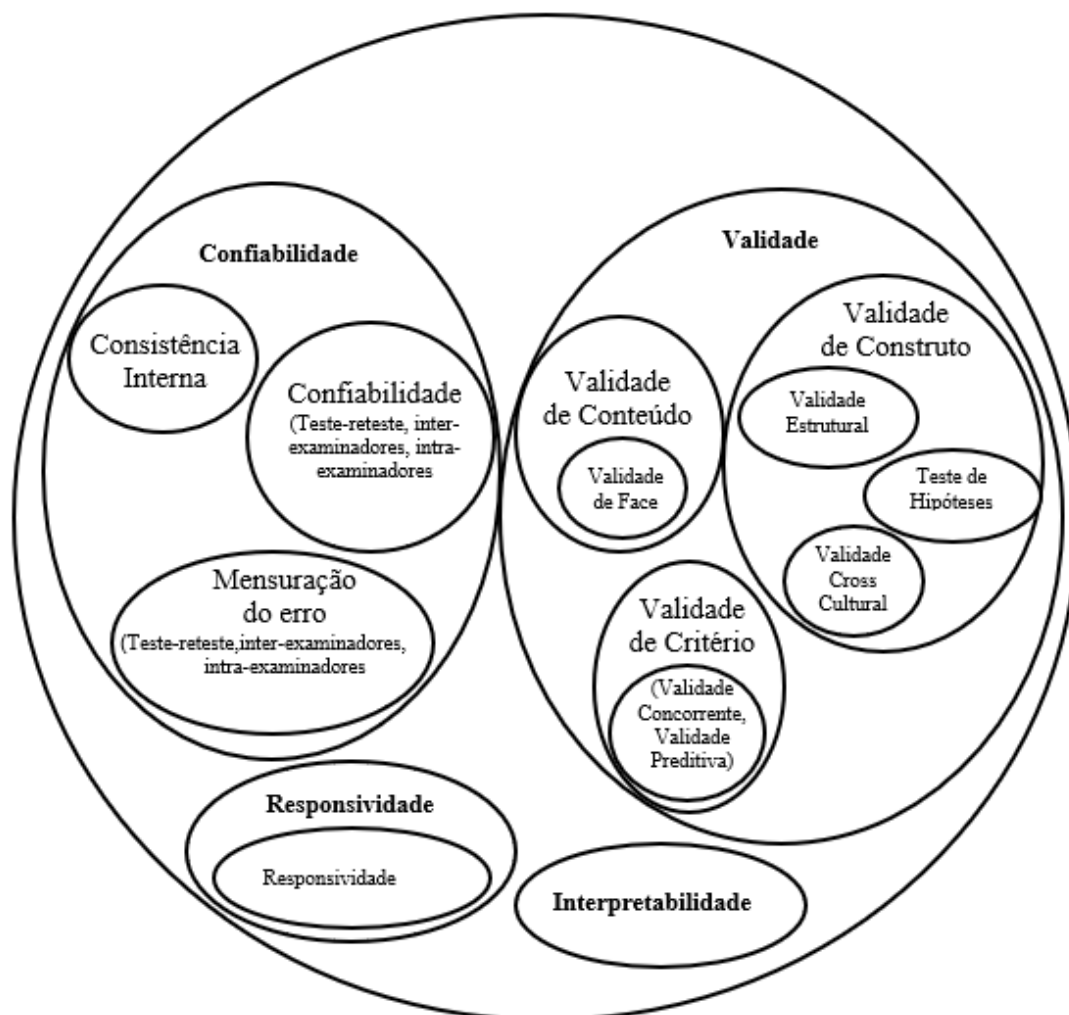
Fonte: Modificado de Mokkink *et al.*, 2010

A confiabilidade e a validade são consideradas as principais propriedades de medida dos instrumentos e não são totalmente independentes (66). A confiabilidade (ou fidedignidade) se refere à capacidade de reproduzir um resultado de forma consistente no tempo e no espaço, livre de erro de medida, pressupondo o controle dos erros aleatórios e sistemáticos. Pode também ser aferida a partir de observadores diferentes, indicando aspectos sobre coerência, precisão, equivalência e homogeneidade. Refere-se, principalmente, à estabilidade, à consistência interna e à equivalência de uma medida. A validade de um instrumento de medida se refere à propriedade de um instrumento medir com precisão o que propõe, devendo ser determinada com relação a uma questão particular, uma vez que se discorre sobre uma

população definida. A validade é subdividida em validade de conteúdo (validade de face), de constructo (validade estrutural, teste de hipóteses e validade transcultural) e de critério (validade concorrente e preditiva). A responsividade relaciona-se à capacidade de um instrumento detectar mudanças no constructo a ser medido considerando o tempo. Para avaliar a mudança de escore ao longo do tempo, dois métodos bastante utilizados são o teste t e o tamanho do efeito; sendo que o teste t assume que as observações têm uma distribuição normal (Gaussiana), porém, quando a amostra é pequena, nem sempre é possível verificar se essa suposição é correta. Por fim, a interpretabilidade é relativa ao grau de inferência dos resultados qualitativos e valores quantitativos de um constructo elaborado a partir da avaliação de um evento relacionado à saúde, não sendo considerada uma propriedade de medida (66, 82, 105, 106).

2 OBJETIVOS

2.1 Objetivo geral

- Explorar as propriedades psicométricas do instrumento "Alfabetização em Saúde para Diabéticos" na avaliação de literacia em saúde entre pessoas com diabetes cadastradas na Estratégia de Saúde da Família e a importância da condição cognitiva nos idosos com diabetes.

2.2 Objetivos específicos

- Avaliar a validade estrutural e confiabilidade do instrumento "Alfabetização em Saúde para Diabéticos" aplicado em pacientes com diabetes usuários do Sistema Único de Saúde.
- Interpretar a associação dos níveis de literacia em saúde com variáveis sociodemográficas e clínicas entre pessoas com diabetes, por meio da aplicação do questionário "Alfabetização em Saúde para Diabéticos".
- Correlacionar variáveis sociodemográficas e clínicas com condições cognitivas entre pessoas idosas com diabetes.
- Correlacionar a literacia em saúde relativa à adesão medicamentosa, atividade física e estado nutricional com as condições cognitivas entre pessoas idosas com diabetes.

3 PRODUTOS CIENTÍFICOS GERADOS

Conforme as recomendações do Programa de Pós-Graduação em Ciências da Saúde, os resultados do presente estudo estão apresentados em forma de produtos científicos:

3.1 **Artigo 1**: *Exploring the health literacy on diabetes: psychometric properties of a newly scale and effect on biochemical parameters*, submetido no periódico *The Science of Diabetes Self-Management and Care - Formerly known as The Diabetes Educator Journal.*

3.2 **Artigo 2**: *Adherence to medication, physical activity and diet among older people living with diabetes mellitus: Correlation between cognitive function and health literacy*, publicado no periódico IBRO Reports. Referência: Crespo TS, Andrade JMO, Lelis DF, Ferreira AC, Souza JGS, Martins AMEBL, Santos SHS. Adherence to medication, physical activity and diet among older people living with diabetes mellitus: Correlation between cognitive function and health literacy. IBRO Rep. 2020 Jul 8; 9:132-137. Doi: 10.1016/j.ibror.2020.07.003. PMID: 33336106; PMCID: PMC7733141.

3.1 ARTIGO 1

EXPLORING THE HEALTH LITERACY ON DIABETES: PSYCHOMETRIC PROPERTIES OF A NEWLY SCALE AND EFFECT ON BIOCHEMICAL PARAMETERS

Running title: Exploring the health literacy on diabetes

Thaísa S. Crespo[1,2], João G. S. Souza[3,4], Alice C. Ferreira[1], Sérgio H. S. Santos[1,5], Andrea M. E. B. L. Martins[1,6]

[1] Laboratory of Health Sciences, Montes Claros State University, Montes Claros, Minas Gerais, Brazil.

[2] Department of Physiopathology, Center of Health and Biological Sciences, Montes Claros State University, Montes Claros, Minas Gerais, Brazil.

[3] Dental Science School (Faculdade de Ciências Odontológicas, FCO), Montes Claros, Brazil; Piracicaba Dental School, University of Campinas, Piracicaba, Brazil.

[4] Dental Research Division, Guarulhos University, Guarulhos, Brazil.

[5] Institute of Agricultural Sciences. Food Engineering College, Federal University of Minas Gerais (UFMG), Minas Gerais, Brazil; Montes Claros, Minas Gerais, Brazil.

[6] Department of Dentistry, Center of Health and Biological Sciences, Montes Claros State University, Montes Claros, Minas Gerais, Brazil.

Corresponding author:

Thaísa S. Crespo, Department of Physiopathology, Center of Health and Biological Sciences, Montes Claros State University (UNIMONTES), Montes Claros, Minas Gerais, Brazil.

Campos Universitário Prof. Darcy Ribeiro, Av. Prof. Ruy Braga, s/n - Vila Mauriceia, Montes Claros, Minas Gerais, 39401-089, Brazil.

E-mail: thaisacrespo@gmail.com

ABSTRACT

Purpose: The purpose of this study is to evaluate the health literacy (HL) competencies (access, understand/appraise, and apply) using a newly developed scale and the association biochemical profile among people living with diabetes.

Methods: Diabetes was diagnosed by biochemical parameters. Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA) estimated the construct validity of the scale. Statistical models estimated the association of HL with socioeconomic, biochemical, and physical and cognitive parameters.

Results: 341 people living with diabetes were included. 91.9% received information related to diabetes. EFA showed a proper factorial fit (KMO=0.919) and the items were loaded in three factors: access, understand/appraise, and apply. CFA confirmed the fit of the model (λ^2/df of 2.09; RMSEA of 0.061). High levels of access of information related to diabetes led to a higher apply level self-reported. However, a high apply level was not associated with better biochemical profile ($p<0.05$), including the dosage of glycated hemoglobin. Higher HL level related to medication adherence and physical activity was correlated to lower insulin levels ($p<0.05$).

Conclusion: The developed scale showed proper psychometric properties. A high HL level was not associated with a better biochemical profile.

Practical implication: Health information for people living with diabetes should focus on specific risk factors for the disease or behaviors that modulate biochemical parameters.

Keywords: Diabetes mellitus, health literacy, health.

1 INTRODUCTION

The increasing burden of noncommunicable chronic diseases worldwide is the main cause of morbidity and mortality currently [1] and, therefore, it is a threat to global health. Among them, diabetes, a chronic disease triggered by genetic and environmental factors characterized by the progressive loss of β-cell mass and/or function which shows clinically as a hyperglycemia condition [2,3], affects more than 460 million people worldwide [3]. Although diabetes diagnosis, treatment, and prevention have advanced significantly [4], this disease is still among the top 10 causes of death globally and its prevalence is projected to increase drastically more than 50% until 2045 [3]. Diabetes has been related to poor quality of life [5], high need for medical care [6], complications and association with others chronic diseases, such as cardiovascular problems [7].

Interestingly, type 2 diabetes, which represents ≈90% of cases, is preventable since its main risk factors are related to body conditions, such as physical inactivity, diet and overweight [3,8]. Even among diagnosed patients, these conditions need to be controlled as part of treatment to avoid complications related to diabetes [3]. Therefore, it is expected that people living with diabetes have access to information about the disease to develop skills and abilities to may change harmful behaviors and apply self-care/self-management [8], which is described by the health literacy concept.

Health literacy (HL) has been described as individual abilities to access information related to health and critically understand/appraise it and applies on own situation, making appropriate health decisions [9]. Therefore, HL considers multiple personal skills and not only simple abilities, such as reading or numeracy [10]. In fact, a previous systematic review

suggested that a proper HL conceptual model should consider the following types of competencies: Access, ability to obtain information regarding health; Understand and Appraise, ability to comprehend and evaluate the health information and Apply, ability to use this information and improve health conditions or behavior [11]. Therefore, it is expected that evaluations regarding HL related to diabetes consider these competencies.

Since inadequate HL may lead to reduce adherence to the treatment and increase mortality rates [12], self-management skills among people living with diabetes (i.e., adequate diet and physical activity) are expected as part of diabetes care to control complications/outcomes related to the disease [8]. In fact, HL and, consequently, enhanced self-care have been associated with improved glycemic control [13] and medication adherence [14]. Previous studies evaluated the HL among people living with diabetes and a high variation on HL prevalence between 7-80% has been reported [13,15,16], which may be explained by the differences in the tools used [16]. Moreover, there is no consensus about the use of low HL as a suitable screening to improve self-management and health behavior related to diabetes [17], but it could be enhanced by HL scales that consider properly its competencies. Some HL related to diabetes scales have been developed with properly psychometric properties, but it has considered mainly the access of information or "understand/appraise'' factor [18-20] and confirmatory factor analysis, which is used to check the 'fit' of developed model [21], was not considered [18]. Additionally, since health professionals should improve access to information and high HL [22], the different sources/professionals that provide information about diabetes has not been widely considered by previous scales.

Moreover, although an enhanced biochemical profile has been associated with HL among people living with diabetes [13], a systematic review suggested that this relationship still a gap in the knowledge and needs to be better understood [23]. Therefore, we evaluated the construct validity of newly HL related to diabetes scale that was developed [24] considering

proper competencies: access, understand/appraise, and apply. Additionally, the association of high HL level with a better biochemical profile among people living with diabetes was estimated. It is expected that people with high HL levels show improved biochemical parameters as a consequence of proper self-management.

2 MATERIALS AND METHODS

2.1 Ethical aspects

The study was carried out respecting the ethical principles of National Health Council Resolution 196/96, in accordance with the Helsinki Declaration. The survey was approved and registered by the National Commission for Research Ethics (CONEP) (protocol / CAAE: 54417616.1.0000.5146).

2.2 Design, sampling and diabetes diagnosis

A cross-sectional study was carried out among individuals diagnosed with diabetes and attended by the public health service of a medium-sized municipality (estimated population: 400,000 inhabitants) in the southeastern region of Brazil.

The participants were selected by sampling for infinite population considering a p value of 0.5, q=0.5, E=0.053, Z value=1.96, non-response rate of 10% and confidence level of 10 (n=341). For this, two health care centers from the primary health care in the city were randomly selected among the 73 centers. These two centers represent 7 health teams from public health system in the city. Then, individuals (more than 18 years) from these centers were invited to participate in the study until achieve the sample number previously established.

Diabetes diagnosis was conducted according to the American Diabetes Association, using one of the following tests: fasting plasma glucose $\geq$126 mg/dL, 2 hours of plasma glucose

(PG) ≥ 200 mg/dL during an oral glucose tolerance test (OGTT), glycated hemoglobin (A1C) ≥ 6.5%, or in patients with classic symptoms of hyperglycemia or hyperglycemic crisis a random plasma glucose ≥ 200 mg/dL [25].

All individuals eligible were interviewed by a researcher, examined and blood draw executed.

2.3 Health Literacy related to diabetes scale

The Health Literacy in Diabetes (HLD) scale (known as "*Alfabetização em Saúde para Diabéticos*") was developed based on the Health Literacy theoretical model [11] to evaluate the access, understand/appraise and apply of information related to diabetes. The developed scale considered 10 questions and some psychometric properties were evaluated previously showing a suitable content validity and reliability (Kappa ≥0.60) [24].

The following three initial overall questions were considered/applied but not included in the scale: "Have you received any information about diabetes?"; "When was the last time that you received information about diabetes?"; and "How is the frequency that you receive information about diabetes?". These three questions were used to characterize the overall access of information about diabetes (Table S1).

The HLD developed scale initially considered the different characteristics of information related diabetes. First the individuals were asked about who provided information about diabetes (doctor, dentist, nurse, health care agent and others). Then, they were asked about the topic of information, considering factors that affect diabetes (diabetes, complications, medicines/drugs, physical activity, nutrition, tobacco and alcohol). Moreover, questions about the source of information were considered (television, internet, radio, billboard, flyer, newspaper, magazine, poster, medicine leaflet and medical prescription). Thus, all these questions were used to develop three main questions about the access: information provider,

topic of information and source of information. Therefore, the questions of each category were summed and categorized according with quintile. The following questions – 7 questions - in the scale were developed to measure understand/appraise and application of information. These questions asked about the understanding of the information, the possibility of classifying it as more or less important, the possibility of identifying the quality and veracity of the information, the evaluation of the advantages and the disadvantages of different treatments for diabetes and if the interviewee incorporated / practiced information on a daily basis, maintaining an appropriate behavior considering the information received about diabetes.

2.4 Factor analysis

The factorial structure of the HLD scale was analyzed by Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA). Initially, EFA was conducted to check the latent dimensions of scale. Since HL theoretical model [11] considering the access, understand/appraise and apply factors was used to develop the scale, it was also considered to define the number of factors in the EFA. Initially, matrix correlation was analyzed to identify any correlation ($p<0.05$) among the items in the scale. The Bartlett test and the Kaiser–Meyer–Olkin (KMO) measure were used to check whether the items were adequate to perform factor analysis. Then, the communalities were analyzed to identify the variance of each item in relation to the all scale (>0.5). Varimax orthogonal rotations were used to check the factors considered and the variance explained by the selected components was evaluated to identify the items in each factor (higher values grouped). Cronbach's Alpha was used to check the internal consistency of each factor and the total scale.

After that, CFA was conducted to confirm and establish the factorial model. For this, the quality of model was evaluated by the ratio between chi-square (χ^2) value and the number of degrees of freedom – values lower than 5 mean a suitable model. The goodness of factorial

model was evaluated using the following parameters: Root Mean Square Error of Approximation (RMSEA) (suitable when lower than 0.05), Goodness-of-fit (GFI) (>0.90 means a suitable model), Comparative Fit Index (CFI) and the Tucker–Lewis index (TLI) (>0.90 indicate a good fit). Convergent validity was estimated by Average Variance Extracted (AVE) and Composite Reliability (CR). AVE values ≥ 0.5 and CR ≥ 0.7 were considered adequate [26,27]. Internal consistency was estimated using Cronbach's Alpha.

To evaluate each factor (latent variable) identified separately all items (questions) attributed in each factor (according with variances) were summed to determine a score (cut-off) for each one. For this, each factor constructed was dichotomized according with the lower limit of confidence interval as cutoff and categorized as "low" and "high" level of condition/outcome. Therefore, it can be used in any sample considering the lower limit of confidence interval. The overall HL considering the 10 items was also summed and categorized as mentioned above.

2.5 Individuals profile – socioeconomic, biochemical and psychological/physical measures

Considering each factor generated by factor analysis as dependent variable (outcome), the associated factors with the "high" (better) condition were identified to determine the profile of individuals with HL related to diabetes. The following socioeconomic and diabetes description variables were considered as independent variables: sex, age, skin color / ethnicity, civil status, schooling, number of people with diabetes at home and speeding money with medication.

Biochemical parameters were also evaluated. For this, a blood draw was conducted after 8 hours of fasting to determine serum levels of: HDL (high density lipoproteins), LDL (low density lipoproteins), glucose, glycated hemoglobin, insulin, triglycerides and urea levels. All analyses were performed at the same laboratory. Glucose measurement was performed using

the enzymatic colorimetric method, with values between 70 and 99 mg/dL as reference. The measurement of glycated hemoglobin was performed by high-performance liquid chromatography (HPLC). Insulin level was checked by chemiluminescence method. HDL, LDL, glucose, triglycerides and urea were measured by enzymatic method (Wiener CB350i). Data were expressed as mean and standard deviation.

Physical condition was evaluated by waist circumference and expressed as mean and standard deviation. The quality of life of patients with diabetes was evaluated by the scale Diabetes-39 [28]. All items of scale were summed and the impact of at least one item was considered with impact in the quality of life. Cognitive function was evaluated by the Mini-Mental State Examination (MMSE) [29], which evaluate five areas of cognitive function: orientation, immediate memory, attention and calculation, language and verbal construction. The total score ranges from 0 (impaired) to 30 (normal) and the variable was considered quantitatively. The gender differences in terms of HL factors were also considered.

The evaluation of literacy in terms of nutritional habits was done through the application of an instrument (questionnaire) called Nutritional Literacy among people with Diabetes (NLD) whose interpretability is made by identifying and counting the correct answers for 24 combinations of 3 words each. For each combination of words, the individual should indicate the right one related to diabetes. All right questions were summed and considered quantitatively [30].

Same approach was used for HL regarding the practice of physical activity, using the "Health Literacy on the Practice of Physical Activities Among Diabetics" (HLPPA-D) questionnaire, [31] and drug adherence among people living with diabetes, using the "Health Literacy Regarding Drug Adherence Among Diabetics" (HLDA-D) questionnaire, each one with 18 questions [32,33].

2.6 Statistics

SPSS 20.0 (IBM) software was used for EFA, descriptive, bivariate and multiple analyses. AMOS SPSS (IBM) software was used for CFA. Initially, descriptive analysis was conducted to estimate absolute frequency (n), the relative frequency (%) and average and standard deviation for quantitative variables. Bivariate analyses were carried out using the ǀ2-test. Variables with p value equal or lower than 0.2 were considered in multiple models. Subsequently, the adjusted multilevel model was estimated by Logistic regression, and only variables with a significance level of 5% (p≤0.05) were maintained. *Odds ratio* and 95% confidence interval were estimated. Pearson correlations were conducted to evaluate the relation between each factor of HL scale, as well physical activity, nutritional status and drug adherence HL with biochemical parameters. Factor analysis and parameters were described above. For CFA, all individuals with any missing information were excluded and this sample was also considered for bivariate and multiple analysis.

3 RESULTS

341 individuals were diagnosed with diabetes and included in the study. Socioeconomic characteristics of the sample were described in the Table 1. Among them, the most of individuals received information related to diabetes (91.9%) (Table S1). Interestingly, the sample evaluated mainly has had access to this type of information frequently, every month (31.5%) or 6 months (31.1%) (Table S1). It is may explained by the characteristic of sample that was recruited from a health care center from the Brazilian health system which is mainly based on the prevention of diseases. In overall, a good pattern of HL was identified among the individuals evaluated, with higher prevalence to the best conditions for all questions used to develop the HL scale (Table S2).

Table 1 – Multiple analyses of independent variables associated (p<0.05) to high level of health literacy related to diabetes scale considering each factor (access, understand/appraise and apply).

Variables	High Access		High Understand/ Appraise		High Apply		High total HL	
	OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
Skin color/ethnicity								
White	1							
Black/Brown/ Asian/ Indigenous	2.69 (1.41-4.26)	0.004						
Civil status								
In a relationship	1							
Single	0.42 (0.23-0.77)	0.005						
Schooling (years)				<0.001			1.18 (1.09-1.27)	<0.001
	1.13 (1.04-1.22)	0.002	1.16 (1.08-1.26)					
Spending money with medication								
No					1			
Yes					1.88 (1.09-3.24)	0.021		
HDL	0.97 (0.95-0.99)	0.005						
LDL					0.99 (0.98-1.00)	0.016		
Insulin					0.96 (0.93-1.00)	0.050		
Cognitive condition	1.15 (1.02-1.29)	0.019	1.24 (1.11-1.39)	<0.001			1.14 (1.03-1.27)	0.009

OR – odds ratio. 95% IC – 95% confidence interval.

Table S1 (supplemental material) – Descriptive analysis of socioeconomic variables and overall questions related to health literacy scale regarding access to information. n=341. SD – standard deviation.

Variable	Average (SD)
Age (years)	61.2 (±11.8)
Schooling (years)	7.6 (±4.4)

	%
Gender	
Men	31,8
Women	68,2

Skin color/ ethnicity

White	29,9
Asian	5,1
Black	14,7
Brown	45,5
Indigenous	0,9
Do not know	3,9

Civil status

Single	12,1
Married	55,9
Common-law marriage	3,6
Widowed	18,7
Divorced	9,7

Have you received information about diabetes?

No	8.1
Yes	91.9

When was the last time you received information about diabetes?

Never	8.1
More than 2 years	14.6
In the last 2 years	4.9
Last year	16.9
Last 6 months	25.3
Last month	30.2

How often do you receive information about diabetes?

Never	8.9
More than 2 years	8.5
2 years	3.9
1 year	16.1
6 months	31.1
A month	31.5

Table S2 (supplemental material) – Description of the questions in the Health Literacy for

Diabetes scale.

HLD	Absolute frequency	Relative frequency
Quantity of professionals that provided information about diabetes		
Never received information	35	11,0
1	100	31,4
2	76	23,9
3	63	19,8
4	41	12,9
5	3	0,9

Quantity of topics discussed in the information about diabetes

Never received information	30	9,5
Until 3	27	8,5
4	36	11,4
5	41	12,9
6	49	15,5
7	134	42,3

Quantity of sources that provided information about diabetes

Never received information	47	14,7
1	46	14,4
2 to 3	78	24,5
4 to 5	65	20,4
6	29	9,1
7 to 10	54	16,9

Did you understand the information about diabetes that you received?

Never received information	27	8,4
Did not understand	3	0,9
Understood a little	22	6,9
Understood partially	53	16,6
Understood almost everything	60	18,8
Understood everything	155	48,4

Can you categorize the information about diabetes that you received as less or more important?

Never received information	27	8,5
I can not	23	7,2
I can with too much difficulty	9	2,8
I can with difficulty	25	7,8
I can with some difficulty	41	12,9
I can easily	194	60,8

Can you identify the quality of information about diabetes that you received?

Never received information	27	8,5
I can not	22	6,9
I can with too much difficulty	11	3,5
I can with difficulty	27	8,5
I can with some difficulty	29	9,1
I can easily	201	63,4

Can you evaluate whether the information about diabetes that you received are false or true?

Never received information	27	8,5
I can not	23	7,3
I can with too much difficulty	12	3,8
I can with difficulty	24	7,6
I can with some difficulty	46	14,6
I can easily	184	58,2

Can you evaluate the advantages and disadvantages of the different treatments for diabetes considering the information that you received?

Never received information	27	8,4

I can not	38	11,9
I can with too much difficulty	13	4,1
I can with difficulty	23	7,2
I can with some difficulty	49	15,3
I can easily	170	53,1

Do you apply in your daily life the information that you received about diabetes?

Never received information	27	8,4
Never	13	4,0
Rarely	19	5,9
Occasionally	106	33,0
Frequently	69	21,5
Always	87	27,1

Do you keep a properly behavior considering the information about diabetes that you received?

Never received information	27	8,4
Never	8	2,5
Rarely	25	7,8
Occasionally	95	29,7
Frequently	60	18,8
Always	105	32,8

Information from doctor

No	43	13,4
Yes	277	86,6

Information from nurse

No	205	64,1
Yes	115	35,9

Information from dentist

No	256	79,8
Yes	65	20,2

Information from health care agent

No	178	55,6
Yes	142	44,4

Information from any professional

No	293	91,3
Yes	28	8,7

Information about what is diabetes

No	75	23,4
Yes	246	76,6

Information about complications

No	71	22,1
Yes	250	77,9

Information about medicine

No	65	20,3
Yes	255	79,7

Information about physical activity

No	71	22,1
Yes	250	77,9

Information about diet

No	45	14,1

Yes	274	85,9
Information about tobacco		
No	127	39,7
Yes	193	60,3
Information about alcohol		
No	123	38,4
Yes	196	61,3
Access to information by prescription		
No	207	64,7
Yes	113	35,3
Access to information by medicine leaflet		
No	196	61,3
Yes	124	38,8
Access to information by folder		
No	196	61,3
Yes	124	38,8
Access to information by magazine		
No	179	55,9
Yes	141	44,1
Access to information by newspaper		
No	248	77,3
Yes	73	22,7
Access to information by billboard		
No	283	88,4
Yes	37	11,6
Access to information by flyer		
No	193	60,1
Yes	128	39,9
Access to information by Internet		
No	232	72,3
Yes	89	27,7
Access to information by TV		
No	88	27,4
Yes	233	72,6
Access to information by radio		
No	236	73,5
Yes	85	26,5

3.1 Access, understand/appraise and apply competencies identified by factor analysis

The developed HL related to diabetes scale was evaluated regarding factor analysis considering the conceptual model proposed by Sørensen1 *et al*., 2012 [11]. Therefore, in the EFA was checked whether the three factors proposed (access, understand/appraise and apply) and each item loaded on the factors could be identified as designed. The 10 items of scale and considering 3 conceptual factors showed a KMO value of 0.919 and *Barllett* test with p-value <0.001, showing a properly factorial fit for the matrix data. Cronbach's Alpha test for the scale considering all items was of 0.936, suggesting an optimal internal consistency. The Varimax rotation showed that three items (1, 2, 3) were loaded (variance >0.6) on the first factor (access); five items (4, 5, 6, 7, 8) loaded on the second factor (understand/appraise); and two items (9, 10) on the third factor (apply) and it explained 81.2% of cumulative variance that means (Fig. 1A). Therefore, the items in the developed HL related to diabetes scale were loaded in the right factor, and the scale was able to explain 81.2% of the conceptual model to evaluate the access, understand/appraise and apply. Moreover, each factor showed a good internal consistency with Cronbach's Alpha test between 0.7-0.9 and communalities among the items between 0.5-0.9 (Fig. 1A).

Then, CFA was conducted to confirm the factorial structure identified by EFA using 3 factors (Fig. 1B). CFA confirmed the fit of model by the following results: x^2/df of 2.09; RMSEA of 0.061 (95% confidence interval 0.04-0.08); CFI of 0.986; TLI of 0.980; and GFI of 0.955. The model presents AVE values of 0.5250 and CR of 0.964. All these tests confirmed an optimal fit and quality of the proposed model. Therefore, the items in the developed HL related to diabetes scale were in fact loaded in three factors to evaluate the access, understand/appraise and apply of HL.

A)

|	Factor 1	Factor 2	Factor 3	Communalities	Cronbach's alpha
ACCESS					
1 – Quantity of professionals/people who provided information related to diabetes.	**0.674**	0.225	0.154	0.528	
2 – Quantity of topics discussed in the information related to diabetes.	**0.751**	0.318	0.335	0.778	
3 – Quantity of sources used to obtain information related to diabetes.	**0.848**	0.297	0.116	0.820	0.788
UNDERSTAND/APPRAISE					
4 – Did you understand the information received related to diabetes?	0.294	**0.692**	0.461	0.778	
5 – Are you able to classify the importance of information received related to diabetes?	0.326	**0.831**	0.281	0.875	
6 – Are you able to judge the quality of information received related to diabetes?	0.280	**0.819**	0.323	0.853	
7 – Are you able to evaluate if the information received related to diabetes is true or false?	0.334	**0.842**	0.256	0.886	
8 – Are you able to evaluate the advantages and disadvantages of information received related to diabetes?	0.267	**0.828**	0.205	0.799	0.947
APPLY					
9 – Do you apply in you daily life the information received related to diabetes?	0.203	0.319	**0.874**	0.906	
10 – Can you keep a properly behavior considering the information received related to diabetes?	0.241	0.323	**0.861**	0.904	0.910
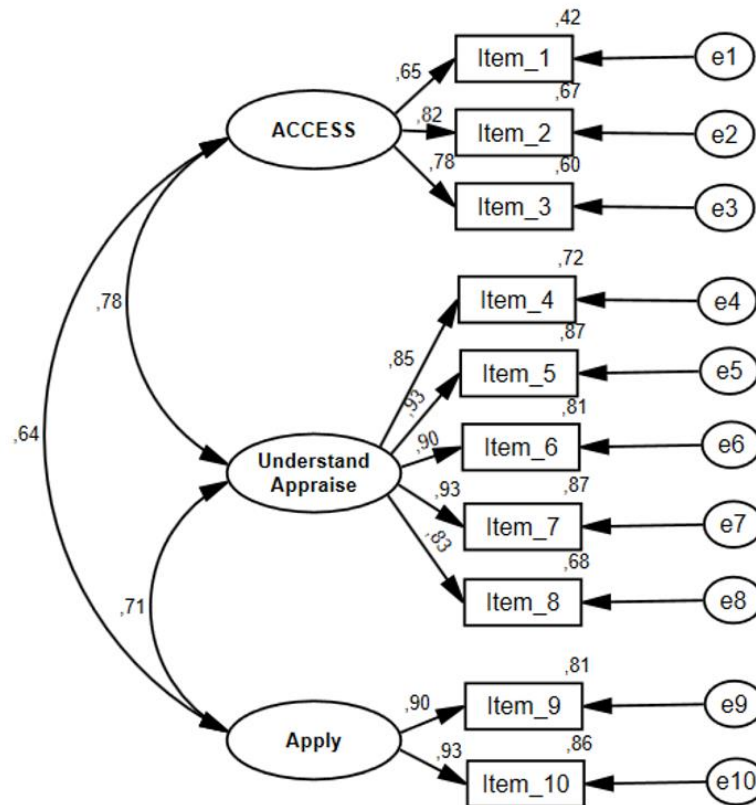
Figure 1- **(A)** Exploratory factor analysis (EFA) of health literacy related to diabetes scale according with factors identified. n=341. **(B)** Confirmatory factor analysis (CFA) of health literacy related to diabetes scale according with factors identified (latent variables) and items/questions.

3.2 High access to information promotes understand/appraise and apply factors self-reported but better HL profile did not change biochemical profile

The items in each factor considered (access, understand/appraise and apply) were grouped (summed) and dichotomized according with lower limit of 95% confidence interval as "low" and "high" level. 60-70% of individuals had a high level of access to information, understand/appraise and apply (Fig. 2A). Therefore, a high level of HL related to diabetes was identified in the sample evaluated, since the information received was understood and applied, according with individuals' answers. In fact, people living with diabetes who had high access to information also reported a higher understand/appraise and apply (Fig. 2B). Considering the components of "access'' factor where the questions were formed considering different providers and sources, a higher number of sources to information can lead to a higher understand/appraise and apply and, therefore, should be considered by HL scales.

Although a high prevalence of HL was found among people living with diabetes, the results suggest that it did not change biochemical profile related to diabetes. No difference was identified for all biochemical and physical parameters among people considered with low and high HL apply factor (Fig. 2C). These results suggest that may some information has not been properly applied in the daily life to change harmful behaviors or these informations were focused in others topics. However, higher HL related to physical activity and medication adherence was significantly correlated to lower insulin level (Fig. 2D). Despite the significance of this finding, insulin dosage has a minor relevance for patients who already have a diagnosis of diabetes and their values vary according to the duration of the disease and the use of medications for the treatment of diabetes, especially exogenous insulin and insulin secretagogues [34].
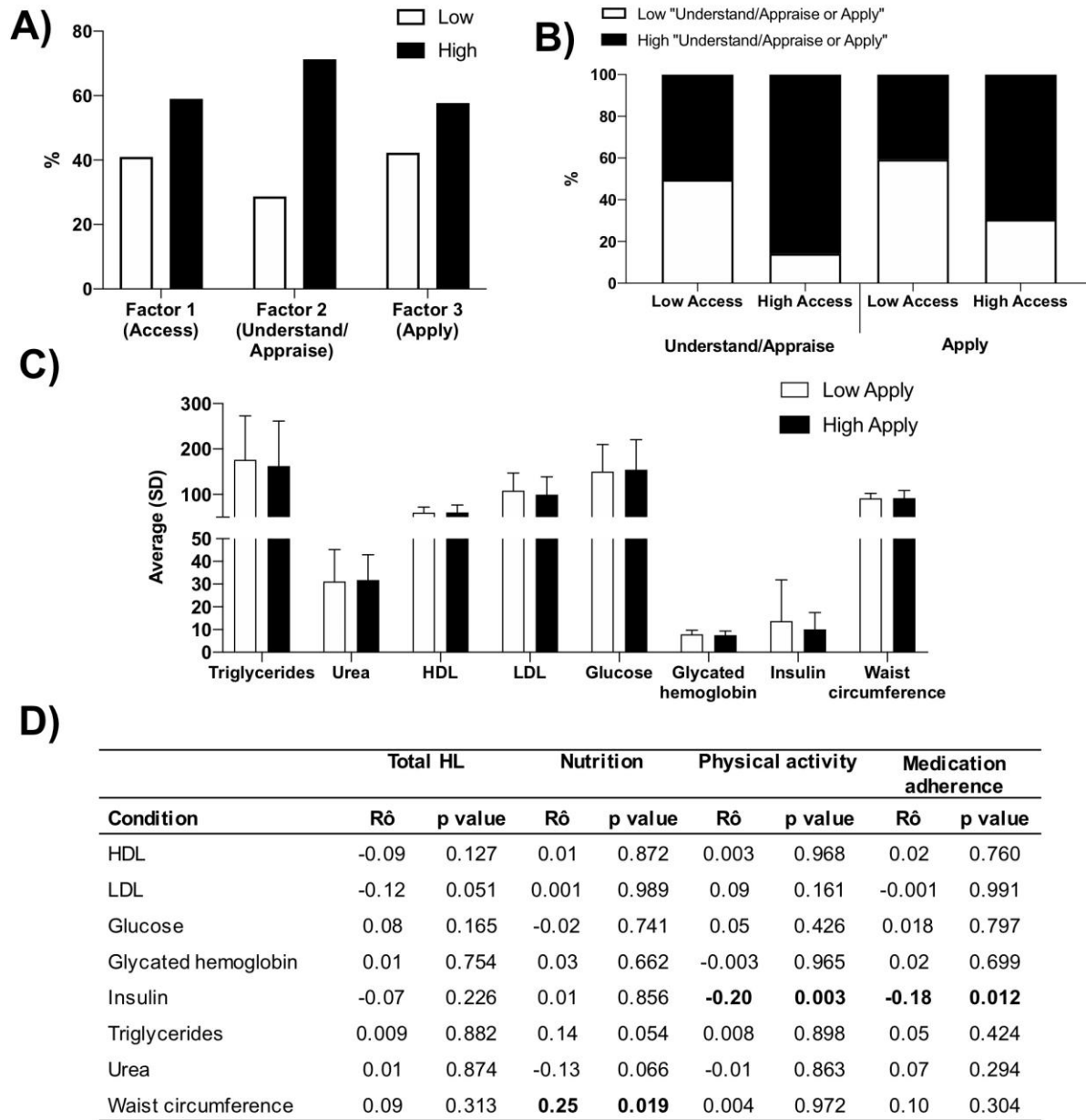
Figure 2 – (A) Percentage of low and high level of health literacy related to diabetes in each factor identified (access, understand/appraise and apply); (B) Percentage of low and high levels of understand/appraise and apply factor among individuals with low and high access of information (factor) related to diabetes. **(C)** Average (SD) of biochemical parameters and physical conditions of individuals evaluated. SD - standard deviation. LDL - Low Density Lipoproteins; HDL - High Density Lipoproteins. **(D)** Correlation between biochemical and

Condition	Total HL		Nutrition		Physical activity		Medication adherence	
	Rô	p value	Rô	p value	Rô	p value	Rô	p value
HDL	-0.09	0.127	0.01	0.872	0.003	0.968	0.02	0.760
LDL	-0.12	0.051	0.001	0.989	0.09	0.161	-0.001	0.991
Glucose	0.08	0.165	-0.02	0.741	0.05	0.426	0.018	0.797
Glycated hemoglobin	0.01	0.754	0.03	0.662	-0.003	0.965	0.02	0.699
Insulin	-0.07	0.226	0.01	0.856	**-0.20**	**0.003**	**-0.18**	**0.012**
Triglycerides	0.009	0.882	0.14	0.054	0.008	0.898	0.05	0.424
Urea	0.01	0.874	-0.13	0.066	-0.01	0.863	0.07	0.294
Waist circumference	0.09	0.313	**0.25**	**0.019**	0.004	0.972	0.10	0.304

physical parameters with total HL related to diabetes scale and HL related to nutritional status, physical activity and medication adherence.

3.3 Patient profile with high level of HL related to diabetes

Considering the total HL scale and factors identified (access, understand/appraise and apply), we also evaluated the variables associated with the high HL level to identify the profile of people living with diabetes and high HL. In the bivariate analysis, independent variables related to socioeconomic conditions, characterization of diabetes costs, biochemical parameters, physical/cognitive conditions and quality of life were considered (Table S3); and variables with p value lower than 0.2 were considered in the multiple models.

In the multiple model (logistic regression) was identified that high access was associated (p>0.05) with: skin color / ethnicity, schooling, HDL level and cognitive condition (Table 1). The high understand/appraise was associated (p>0.05) with schooling and cognitive condition (Table 1). Additionally, the high apply was associated with spending money with medication, LDL and insulin levels (Table 1). With regard to the elderly, Medical Societies have defined the establishment of goals for glycemic control in patients in this age group. According to the American Geriatrics Society (AGS), a glycemic target with A1C between 7.5% and 8% should be sought in healthy elderly people with a life expectancy greater than 10 years, which can be reduced to 7.0% to 7, 5% depending on the clinical and social conditions of each person. However, for those who have a higher number of complications related to diabetes, disabilities, longer illness time and shorter life expectancy, the target can be raised to levels between 8% and 9% of A1C [35]. The IDF and the American Diabetes Association defined glycemic targets depending on individual characteristics, varying between 7.5% A1C, 8% or 8.5% [3,36]. Therefore, in our sample, although the statistical significance of HL as a way of increasing

glycemic control by reducing A1C levels is not evident, most patients presented A1C values within reference limits recommended by relevant medical societies. The high total HL level was associated (p>0.05) with: schooling and cognitive condition (Table 1). In summary, these results suggest that educational status and cognitive condition may favor a better HL level, showing higher access to information and understanding/appraising, which was expected. Moreover, high apply level was higher among people which spending money with medication and, therefore, it may suggest the adherence to medication.

Table S3 (supplemental material) – Bivariate analyses of independent variables in relation to the developed scale considering high level of health literacy in each factor (access, understand/appraise, apply).

Variables	High Access	High Understand/Appraise	High Apply	High Total HL
	OR	OR	OR	
Sex				
Male	1	1	1	1
Female	0.47[#]	0.70	1.08	0.69[#]
Age (years)	0.97[#]	0.97[#]	1.02[#]	0.97[#]
Skin color / ethnicity				
White	1	1	1	1
Black/Brown/Asian/Indigenous	1.74[#]	0.75	0.91	0.99
Civil status				
In a relationship	1	1	1	1
Single	0.37[#]	0.87	0.97	0.79
Schooling (years)	1.16[#]	1.25[#]	1.03	1.23[#]
Number of people with Diabetes at home	0.93	0.97	1.00	0.92
Spending money with medication				
No	1	1	1	1
Yes	1.22	1.19	1.80[#]	1.20
Triglycerides	1.00[#]	1.00	0.99	1.00
Urea	1.00	0.99	1.00	0.99
HDL	0.98[#]	1.01	1.00	1.00
LDL	0.99	0.99[#]	0.99[#]	0.99
Glucose	1.00	1.00[#]	1.00	1.00[#]
Glycated hemoglobin	1.07	1.05	0.90[#]	1.04
Insulin	1.00	0.99	0.97[#]	0.99

Waist circumference	0.99	0.98	0.99	1.00
Cognitive condition	1.21[#]	1.36[#]	1.07[#]	1.27[#]
Quality of life				
Low	1	1	1	1
High	0.97	0.58[#]	0.75	0.76
HL Nutrition	1.23[#]	1.17[#]	0.98	1.17[#]
HL Physical activity	1.22[#]	1.34[#]	1.03	1.29[#]
HL Medication adherence	1.16[#]	1.25[#]	0.98	1.24[#]

OR – Odds Ratio. # - p <0.20. HL – Health literacy

3.4 Gender differences in the level of HL related to diabetes

Since previous systematic review highlighted the needed to evaluate gender differences in the levels of HL related to diabetes [23], it was considered. A higher proportion of men had high access factor level, compared to women (p=0.003, by chi-square test) (Fig. 3A). However, a similar proportion of high understand/appraise and apply was identified for both genders (Fig. 3A). Considering the better level of high access among men, the specific source/provider of information between the genders was characterized. In overall, men showed higher levels of access to information in all sources/providers, compared to women (Fig. 3B), except for health care agent provider. Altogether, these data suggest a higher HL related to diabetes level for men, compared to women, and mainly in relation to access to information.
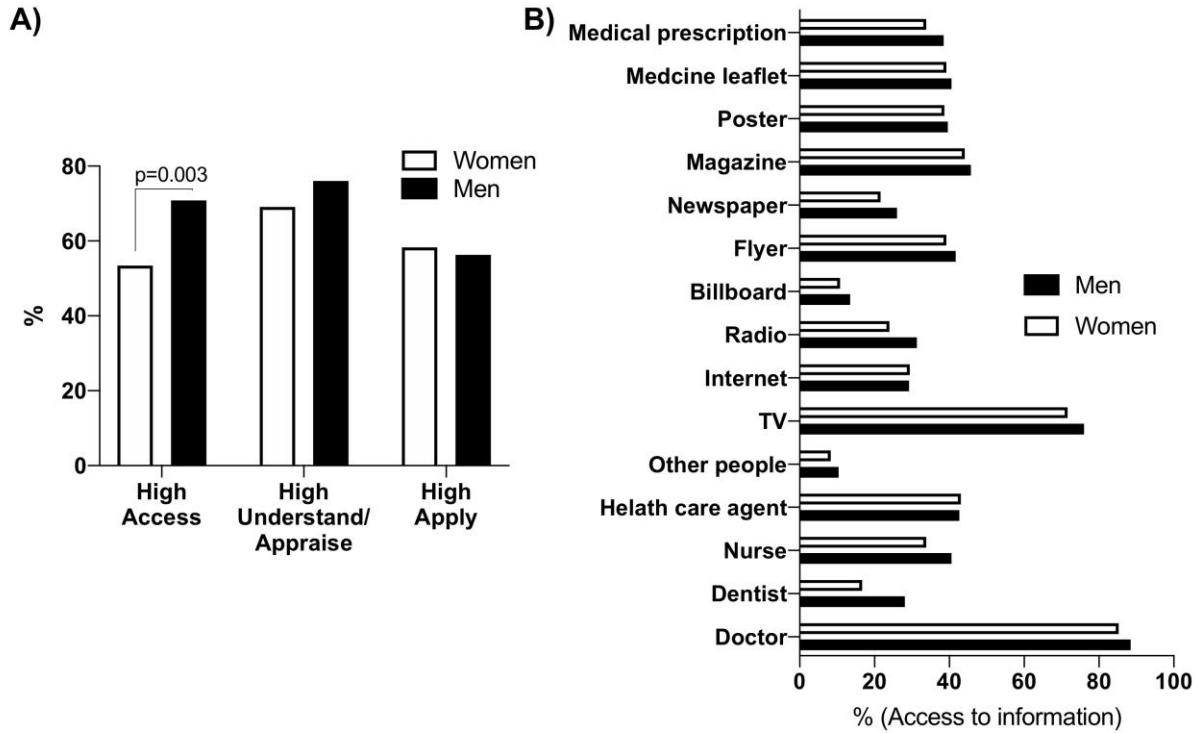
Figure 3 – (A) Distribution of high level of health literacy related to diabetes in each factor according with gender. (B) Level of access to information considering each provider or source according with gender.

4 DISCUSSION

Although HL concept still been debated in the literature, it is mainly described as individual cognitive skills and abilities applied in a medical context in relation the access to information which when understood is applied to promote health outcomes [11]. Since diabetes treatment is mainly based on self-care to avoid complications and to reduce risk factors [8], HL context is extremely important to improve quality of life and life expectancy of people living with diabetes. Here, we showed a developed HL related to diabetes scale, which consider as factorial structure the following competencies: access, understand/appraise and apply. The validity construct conducted by EFA and CFA confirmed the optimal fit of proposed model

according with the items loaded in each factor. Acceptable values for convergent validity were identified showing the quality of proposed model. Interestingly, as novelty, in our scale the access factor was developed considering the different sources of information, as well professionals/people who could provide any information related to diabetes and topics discussed in this information. In fact, people who reported high levels of access also reported high understand/appraise and apply. Therefore, to achieve a high HL on diabetes may it is necessary to increase the quantity of sources and professionals/people responsible to provide this information and, consequently, it may drive toward an enhanced understand/appraise and apply profile. However, high apply did not led to a better biochemical profile which suggest that HL self-reported may not affect directly clinical outcomes or the quality and content of information needs to be enhanced according with patients needed. Even for individuals that received information about diabetes, understood and evaluate it as important (appraise), it is a personal choice to apply in the daily life. Moreover, contextual determinants and social context may not favor the application of some behavior to change health outcomes. Results from multiples analysis showed that different variables are associated to a high HL on diabetes considering each factor, and it could be considered to enhance this process (i.e., cognitive condition associated to access and understand/appraise factors).

Clinical trials have shown that educational interventions to improve self-care among people living with diabetes affect positively health outcomes [37-39], such as physical activity and vegetable intake [37]. Moreover, these interventions also promote knowledge, emotional adaptation and self-efficacy to overcome barriers [39]. In this context, HL is a proper indicator of how these interventions are understood and applied in the daily life. For this, HL scale should consider all these factors (access, understand/appraise and apply). Although previous scales have considered mainly a wide evaluation of understand/appraise process [18,19], the apply factor is necessary to identify whether the information received has been used to improve self-

care and health outcomes. Additionally, educational interventions, which also consider frequent contact with the individuals and increased number of sessions to provider information, can reduce significantly the incidence rate of diabetes [40]. Therefore, whether an increased number of providers (professionals/people) and sources of information is considered, a higher HL related to diabetes is expected. Then, as novelty we considered in the access factor different sources of information which could provide any information related to diabetes; and we also included among overall questions in the developed scale a specific one to evaluate the frequency that this type of information has been received.

The factor analysis is used to determine the factorial structure of scale, exploring the characteristics of instrument and whether the items support the theoretical model considered [21]. Our scale was developed based on HL conceptual model proposed by Sørensen *et al.*, 2012 [11], and competencies suggested by the model (access, understand/appraise and apply) were confirmed as factors in the developed scale in an optimal fit. Therefore, the proposed scale is able to collect information related to access, understand/appraise and apply of HL on people living with diabetes.

The multiple models evaluated here by regression logistic analysis may suggest the profile of patients with high HL related to diabetes. In fact, educational interventions have to be designed to fit patients' profile, such as resources, culture and lifestyle [11]. Even socio-cultural environment affects the implementation of self-care in diabetes and, therefore, there is interplay between individual and contextual determinants to promote HL [41]. Considering these aspects, professionals could promote patient empowerment, which describes the ability to help patients to discover their capacities and to be responsible on own health decisions [42]. Interestingly, the high access level was higher among people with skin color and ethnicity black/brown/Asian/indigenous. Although some racial inequalities related to diabetes prevalence and rates of complications have been reported [43], our results suggest that a high

level of access to information has been provided for this group, but it was may affected by Brazilian health system context which is based on reduced inequalities related to health care. In contrast, high level of access and understand/appraise was associated with better schooling (years) and cognitive condition. Since low literate people has reported difficulties to understand/appraise the decision process [44] and poor cognitive condition has been associated to inadequate HL [45], we expected that both conditions could favor the access and, mainly, the understand/appraise factor and it needs to be further investigated by interventional studies.

HL related to diabetes has been associated with higher medication adherence [14]. In fact, high apply was associated with spending money with medication. This result suggests that may the main application done by the participants with high HL level was medication adherence. Therefore, information related to diabetes should also focus on others factors which affects diabetes treatment and to avoid complications, such as diet and physical activity. These results also highlight that HL related to diabetes should consider the complex factors that affect the disease and the quality of information is necessary to achieve a properly HL profile. Although LDL and insulin level were associated with high apply, OR values (±1.0) shows that these biochemical factors do not affect apply and it was significantly confirmed. Surprisingly, in relation to gender difference the access to information was higher for men. Although women experience more health issues than men [46], even for diabetes [47], a higher access to health care is expected for women [48]. Therefore, we expected a better profile for women compared to men. However, this result suggests that HL related to diabetes must be improved among women to promote self-care and these gender differences for HL need to be better evaluated considering health care characteristics.

In conclusion, the developed scale to measure HL related to diabetes showed an optimal fit considering as factors the access, understand/appraise and apply by factor analysis. As novelty the access factor was developed considering the different sources of information, topics

discussed and professionals/people who provided the information. Moreover, high access to information showed a trend for a better profile of understand/appraise and apply. Interestingly, high HL literacy profile considering each factor (access, understand/appraise and apply) was associated with socioeconomic, biochemical and cognitive conditions. Some gender differences were found with a higher access to information among men.

REFERENCES

1. Wang, H. Naghavi, M. Allen, C. Global, regional, and national life expectancy, all-cause mortality, and cause-specific mortality for 249 causes of death, 1980–2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet* 2016; 388:1459–1544.

2. American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of Medical Care in Diabetes. *Diabetes Care* 2018;41:S13–S27.

3. International Diabetes Federation. IDF Diabetes Atlas, 9th edn. Brussels: International Diabetes Federation, 2019.

4. Nathan DM. Diabetes: Advances in Diagnosis and treatment. *JAMA* 2015;314:1052-1062.

5. Jing X, Chen J, Dong Y, et al. Related factors of quality of life of type 2 diabetes patients: a systematic review and meta-analysis. *Health Qual Life Outcomes* 2018;16:189.

6. Jiang HJ, Stryer D, Friedman B, Andrews R. Multiple Hospitalizations for Patients With Diabetes. *Diabetes Care* 2003; 26:1421-1426.

7. Matheus AS, Tannus LR, Cobas RA, Palma CC, Negrato CA, Gomes MB. Impact of diabetes on cardiovascular disease: an update. *Int J Hypertens* 2013; 2013:653789

8. Chatterjee S, Davies MJ, Heller S, Speight J, Snoek FJ, Khunti K. Diabetes structured self-management education programmes: a narrative review and current innovations. *Lancet Diabetes Endocrinol* 2018;6:130-142.

9. Sykes S, Wills J, Rowlands G, Popple K. Understanding critical health literacy: a concept analysis. *BMC Public Health* 2013;13:150.

10. Schonlau M, Martin L, Haas A, Derose KP, Rudd R. Patients' Literacy Skills: More than just reading ability. *J Health Commun* 2011;16:1046–1054.

11. Sørensen K, Van den Broucke S, Fullam J, et al. Health literacy and public health: a systematic review and integration of definitions and models. *BMC Public Health* 2012;12:80.

12. Baker DW, Wolf MS, Feinglass J, Thompson JA, Gazmararian JA, Huang J. Health literacy and mortality among elderly persons. *Arch Intern Med* 2007;167:1503e9.

13. Lee YJ, Shin SJ, Wang RH, Lin KD, Lee YL, Wang YH. Pathways of empowerment perceptions, health literacy, self-efficacy, and self-care behaviors to glycemic control in patients with type 2 diabetes mellitus. *Patient Educ Couns* 2016;99:287-94.

14. Ueno H, Ishikawa H, Suzuki R, et al. The association between health literacy levels and patient-reported outcomes in Japanese type 2 diabetic patients. *SAGE Open Med* 2019;7:2050312119865647.

15. Pashaki MS, Eghbali T, Niksima SH, Albatineh AN, Gheshlagh RG. Health literacy among Iranian patients with type 2 diabetes: A systematic review and meta-analysis. Diabetes *Metab Syndr* 2019;13:1341-1345.

16. Abdullah A, Liew SM, Salim H, Ng CJ, Chinna K. Prevalence of limited health literacy among patients with type 2 diabetes mellitus: A systematic review. *PLoS One* 2019;14:e0216402.

17. Sayah AL, Majumdar SR, Williams B, Robertson S, Johnson JA. Health literacy and health outcomes in diabetes: a systematic review. *J Gen Intern Med* 2013;28:444-52.

18. Ishikawa H, Takeuchi T, Yano E. Measuring functional, communicative, and critical health literacy among diabetic patients. *Diabetes Care* 2008;31:874-9.

19. Lee EH, Lee YW, Lee KW, Nam M, Kim SH. A new comprehensive diabetes health literacy scale: Development and psychometric evaluation. *Int J Nurs Stud* 2018;88:1-8.

20. Kang SJ, Sim KH, Song BR, et al. Validation of the health literacy scale for diabetes as a criterion-referenced test with standard setting procedures. *Patient Educ Couns* 2018;101:1468-1476.

21. El-Den S, Schneider C, Mirzaei A, Carter S. How to measure a latent construct: Psychometric principles for the development and validation of measurement instruments. *Int J Pharm Pract* 2020. doi: 10.1111/ijpp.12600.

22. Xu XY, Leung AYM, Chau PH. Health Literacy, Self-Efficacy, and Associated Factors Among Patients with Diabetes. *Health Lit Res Pract* 2018;2:e67-e77.

23. Caruso R, Magon A, Baroni I, et al. Health literacy in type 2 diabetes patients: a systematic review of systematic reviews. *Acta Diabetol* 2018;55:1-12.

24. Martins, AMEBL, Neto EN, et al. Creation and verification of content validity and psychometric properties of an instrument for the evaluation of literacy in health among diabetic. *REAS* 2018;10 (3):1693-1703.

25. American Diabetes Association. Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care* 2010; 33:S62–S69.

26. Hair JF, Black WC, Babin B, Anderson RE, Tatham RL (2005). Multivariate data analysis, 6th ed. New York City, NY: Prentice Hall.

27. Maroco J. Análise de Equações Estruturais: Fundamentos teóricos, software &aplicações. Pêro Pinheiro: Edição em Português. 2010.

28. Queiroz FA, Pace AE, Santos CB. Cross-cultural adaptation and validation of the instrument Diabetes - 39 (D-39): brazilian version for type 2 diabetes mellitus patients - stage 1. *Rev Lat Am Enfermagem* 2009;17:708-15.

29. Almeida OP. The Mini-Mental State Examination and the Diagnosis of Dementia in Brazil. *Arq Neuro-Psiquiatr* 1998; 56:3.

30. Eleutério, T. P., Pereira, É. J., Farias, P. K. S., Hott, K. P. S., Paula, F. M. T. d. and Martins, A. M. E. d. B. L., 2018. "Elaboração e verificação da validade e confiabilidade de um instrumento de letramento em nutrição entre pessoas com diabetes." Cadernos Saúde Coletiva. 26, 298-307.

31. Martins, M., Oliveira, I., Alcântara, V., Silva, L., Campos, L., Silva, M. and Cardoso, M., 2018. "Elaboração de um instrumento de alfabetização em saúde quanto à prática de atividade física entre diabéticos." Revista Eletrônica Acervo Saúde. Esp., S1202-S1213. 10.25248/REAS269_2018: 10.25248/REAS269_2018.

32. Cardoso, M., Santos, A. S. F., Fonseca, A. D. G., Silva-Junior, R. F. D., Carvalho, P. D. and Martins, A., 2019. "Validity and reliability of the Health Literacy Assessment Scale for adherence to drug treatment among diabetics." Einstein (Sao Paulo). 17,2, eAO4405. 10.31744/einstein_journal/2019AO4405:

33. Crespo TS, Andrade JMO, Lelis DF, et al. Adherence to medication, physical activity and diet among older people living with diabetes mellitus: Correlation between cognitive function and health literacy. *IBRO reports* 2020; 9:132-137.

34. Rodacki Melanie, Zajdenverg Lenita, Milech Adolpho, Oliveira José Egídio Paulo de. Dosagem do peptídeo C sérico ao acaso em adultos com diagnóstico clínico de diabetes mellitus tipo 1. Rev. Assoc. Med. Bras. 2008 June; 54(3): 238-241.

35. American Geriatrics Society Expert Panel on Care of Older Adults with Diabetes M, Moreno G, Mangione CM, Kimbro L, Vaisberg E. Guidelines abstracted from the American Geriatrics Society Guidelines for Improving the Care of Older Adults with Diabetes Mellitus: 2013 update. J Am Geriatr Soc. 2013;61(11):2020-6.idf

36. American Diabetes A. Standards of Medical Care in Diabetes-2017 Abridged for Primary Care Providers. Clin Diabetes. 2017;35(1):5-26.

37. Thoolen B, De Ridder D, Bensing J, et al. Effectiveness of a self-management intervention in patients with screen-detected type 2 diabetes. *Diabetes Care* 2007;30:2832-7.

38. Van Puffelen AL, Rijken M, Heijmans MJWM, Nijpels G, Schellevis FG, Diacourse study group. Effectiveness of a self-management support program for type 2 diabetes patients in the first years of illness: Results from a randomized controlled trial. *PLoS One* 2019;14:e0218242.

39. Ghoreishi MS, Vahedian-Shahroodi M, Jafari A, Tehranid H. Self-care behaviors in patients with type 2 diabetes: Education intervention base on social cognitive theory. *Diabetes Metab Syndr* 2019;13:2049-2056.

40. Diabetes Prevention Program (DPP) Research Group. The Diabetes Prevention Program (DPP): description of lifestyle intervention. *Diabetes Care* 2002;25:2165-71.

41. De Man J, Aweko J, Daivadanam M, et al. Diabetes self-management in three different income settings: Cross-learning of barriers and opportunities. *PLoS One* 2019;14:e0213530.

42. Funnell MM, Anderson RM. Empowerment and Self-Management of Diabetes. *Clinical Diabetes* 2004; 22:123-127.

43. Peek ME, Cargill A, Huang ES. Diabetes Health Disparities: A Systematic Review of Health Care Interventions. *Med Care Res Rev* 2007; 64:101S–156S.

44. Storms H, Claes N, Aertgeerts B, Van den Broucke S. Measuring health literacy among low literate people: an exploratory feasibility study with the HLS-EU questionnaire. *BMC Public Health* 2017;17:475.

45. Federman AD, Sano M, Wolf MS, Siu AL, Halm EA. Health literacy and cognitive performance in older adults. *J Am Geriatr Soc* 2009;57:1475-80.

46. Regitz-Zagrosek V. Sex and gender differences in health: Science & Society Series on Sex and Science. *EMBO Rep* 2012; 13: 596–603.

47. Kautzky-Willer A, Harreiter J, Pacini G. Sex and Gender Differences in Risk, Pathophysiology and Complications of Type 2 Diabetes Mellitus. *Endocr Rev* 2016; 37:278–316.

48. Merzel C. Gender differences in health care access indicators in an urban, low-income community. *Am J Public Health* 2000; 90: 909–916.

3.2 ARTIGO 2

Research Paper

Adherence to medication, physical activity and diet among older people living with diabetes mellitus: Correlation between cognitive function and health literacy

Thaísa Soares Crespo[a,b], João Marcus Oliveira Andrade[a,c], Deborah de Farias Lelis[a],
Alice Crespo Ferreira[a], João Gabriel Silva Souza[d],
Andréa Maria Eleutério de Barros Lima Martins[a,e,1], Sérgio Henrique Sousa Santos[a,e,f,1,*]

[a] Laboratory of Health Sciences, Montes Claros State University, Montes Claros, Minas Gerais, Brazil
[b] Department of Physiopathology, Center of Health and Biological Sciences, Montes Claros State University, Montes Claros, Minas Gerais, Brazil
[c] Department of Nursing, Center of Health and Biological Sciences, Montes Claros State University, Montes Claros, Minas Gerais, Brazil
[d] Piracicaba Dental School, University of Campinas, Piracicaba, Brazil
[e] Department of Dentistry, Center of Health and Biological Sciences, Montes Claros State University, Montes Claros, Minas Gerais, Brazil
[f] Institute of Agricultural Sciences. Food Engineering College, Federal University of Minas Gerais (UFMG), Montes Claros, Minas Gerais, Brazil

ARTICLE INFO

ABSTRACT

Background: Diabetes mellitus (DM) is a public health problem, which requires enhanced self-care in order to avoid complications. However, cognitive impairment can reduce these abilities and may affect health literacy (HL) of patients in terms to understand and apply information. Therefore, this study evaluated the correlation between cognitive condition and HL related to medication adherence, physical activity and nutritional status among people living with DM.

Methods: A cross-sectional study was carried out among elderly people ($\geq$ 60 years old) with DM. The cognitive condition was evaluated using the Mini-Mental State Examination (MMSE) and the HL using the following questionnaires: Literacy Assessment for Diabetes (LAD-60), Nutritional Literacy among People with Diabetes (NLD), Health Literacy on the Practice of Physical Activities among Diabetics (HLPPA - D), and Health Literacy regarding Drug Adherence among Diabetics (HLDA-D). Sociodemographic and biochemical profile was also evaluated. Spearman correlation was used ($p < 0.05$).

Results: 187 individuals with DM were included. Regarding laboratory analyses, insulin dosage had a mean value of 12.3 microUI/mL (SD: $\pm$ 15.7), mean blood glucose was 148.1 mg/dl (SD: $\pm$ 59.7) and mean HbA1c was 7.54 % (SD: $\pm$ 1.8). In the correlation analysis, higher age and lower income were weakly correlated with lower cognitive level. No correlation was identified for biochemical variables and cognitive condition. A positive and weak correlation between cognition and HL was observed in the studied population.

Conclusions: In older people living with DM the cognitive condition is correlated to specific topics of HL (nutritional status, physical activity and medication adherence).

1. Introduction

Diabetes Mellitus (DM) is an important public health concern worldwide, which has been associated with environmental and genetic factors (Mambiya et al., 2019). In 2019, the International Diabetes Federation estimated that 463.0 million adults (20–79 years) were living with DM in the world (Mambiya et al., 2019). Although the burden of disease is already high, the projection for 2030 is that 578.4 million adults and, in 2045 that 700.2 million adults in the same age group will be affected by DM. However, this projection may be much higher considering the significant increase in the risk factors (Mambiya et al., 2019).

DM is characterized by a metabolic disorder resulting from the breakdown of glycemic homeostasis with persistent hyperglycemia.

This occurs due to insulin production deficiency, and/or reduced insulin sensitivity associated to impaired insulin receptor signaling, which produce acute and chronic complications (Stumvoll et al., 2005; American Diabetes Association, 2010). Interestingly, type 2 diabetes, which represents ≈ 90 % of cases, is preventable since its main risk factors are related to body conditions, such as physical inactivity, diet and overweight/obesity (Jorge et al., 2017; Chatterjee et al., 2018; International Diabetes Federation, 2019; Batista-Jorge et al., 2020). Even among diagnosed patients, these conditions need to be controlled as part of treatment and to avoid complications related to diabetes (International Diabetes Federation, 2019). Therefore, an essential part of the DM management should include health literacy (HL) of patients, since this concept consider the importance of the patient to understand and apply information regarding the disease and its complications (Bailey et al., 2014). These abilities could improve patients' behaviors to reduce the risk of complications, such as medication adherence and healthy lifestyle, and improve DM treatment (Bailey et al., 2014).

Previous studies have shown the association between DM literacy and healthy behaviors, such as medication adherence, better nutritional status, regular use of insulin or other drugs, and physical activity (Lee et al., 2016; Yeh et al., 2018). Importantly, these results suggest an improvement in the patient's health self-care, which is essential to reduce morbi-mortality burdens in the DM treatment (Lee et al., 2016; Yeh et al., 2018). In contrast, scientific evidence suggests that people living with DM and poor HL have a higher risk to develop cognitive impairments, such as Alzheimer's disease and cognitive disorders (Bruce et al., 2003). As well DM, cognitive impairments have a high prevalence in the world and may affect 42 million people in 2020 and 81 million in 2040, and this increasing has been associated with the prevalence of DM (Ferri et al., 2005).

In the evaluation of cognitive impairments, the Mini-Mental State Examination (MMSE) is the most used tool for the initial assessment of cognition level. This questionnaire evaluates the orientation, memory, attention, language and visual-spatial skills related to cognitive condition (Folstein et al., 1975; Almeida, 1998; Scazufca et al., 2009). Therefore, it is expected that people living with DM have a properly cognitive condition to achieve a better level of HL and, consequently, improve self-care. In fact, previous study identified the association between HL and cognitive condition among older adults living with DM (Nguyen et al., 2013). However, since the management of diabetes should include healthy behaviors related to medication adherence, physical activity and nutritional status, the association between cognitive condition and HL related to these aspects among people living with DM has not been widely evaluated. Moreover, the early screening of cognitive condition and HL levels could enhance the DM management by health professionals (Mendes et al., 2019). Thus, this study evaluated the correlation between cognitive condition and socio-demographic, clinical conditions, and HL among people living with DM. It is expected that better cognitive condition be positively correlated with high HL levels.

2. Material and methods

2.1. Ethical considerations

This study is part of a research project - Impact of educational actions on HL levels among elderly people registered in the Family Health Strategy: a randomized trial - which presents as one of the goals to create HL instruments for people with DM. It was carried out in accordance with the ethical principles of the Declaration of Helsinki and approved by the Ethics Committee of the State University of Montes Claros. CAAE: 34687414.0.0000.5146. Opinion Number: 764,743. Reporting Date: 9/19/2014.

2.2. Sample

A cross-sectional study was carried out (2017–2018) among elderly people with a diagnosis of DM attended by the public health service of a medium-sized city (estimated population: 400,000 inhabitants) in the southeastern region of Brazil (Paim et al., 2011). All individuals that attended inclusion and exclusion criteria, accepted to participate in the study and were present in two services randomly selected from public health system (primary care) in the city, were included.

The following inclusion criteria were considered: 1) registered in the service; 2) ≥ 60 years old; 3) diagnosed with DM according to the American Diabetes Association (fasting plasma glucose ≥ 126 mg / dL (7.0 mmol / L), 2 h of plasma glucose ≥ 200 mg / dL (11.1 mmol / L) during an oral glucose tolerance test performed according to the description of the World Health Organization, glycated hemoglobin (HbA1c) ≥ 6.5 % (48 mmol / mol), or in patients with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥ 200 mg / dL (11.1 mmol / L) (American Diabetes Association, 2010, 2018).

The exclusion criteria were: 1) Not having Portuguese as native language; 2) special needs that do not allow properly communication such as decreased or lost visual/auditory acuity (reported or perceived); 3) use of any drug or alcohol at the time of the interview; 4) neurological diseases with cognitive impairment and dementia of non-vascular etiologies (dementia by Lewy bodies, dementia associated with Parkinson's disease, frontotemporal dementia, Alzheimer's dementia and Creutzfeldt-Jakob dementia). Respecting these criteria, participants were evaluated until reaching the "n" of the sample calculation necessary for the study.

2.2.1. Sample size

Since no previous study estimated the number of elderly people with DM in the city evaluated, the sample size was calculated by using a sampling procedure for infinite population that considered the following parameters: p = 0.5; q = 0.5; E = 0.075 and Z = 1.96, (q = 1 - p value; E = sampling error; Z = constant of 1.96) using the formula $n = \frac{Z^2 \propto /2 \cdot P \cdot q}{E^2}$ (Triola, 1999). The non-response rate was considered to be 10 %, totaling a population sample of 186 elderly people with DM.

2.3. Procedures

After signing the informed consent, the individuals were evaluated and interviewed by a researcher at the health care service unit, called Family Health Strategy (FHS), on days and times previously scheduled or, through active search, at their own home when they did not come to the service. The following variables were considered: sociodemographic characteristics (age, gender, skin color or self-report race, marital status, education and per capita income), blood samples for biochemical tests (glycated hemoglobin, insulin and plasma glucose), the Mini-Mental State Examination (MMSE) and questionnaires to assess health literacy (HL) with a focus on literacy in medication adherence, diet and physical activity. The assessment of individuals was standardized to reduce the effect on our results. All individuals were submitted to blood draw that was conducted in the morning after 8 h on fasting. Moreover, previous instructions were provided for all individuals to avoid physical activity before blood draw and the use of any medication that could affect biochemical analysis.

2.4. Measures

2.4.1. Analysis of sociodemographic profile

The sociodemographic aspects evaluated were the age (≤ 63, 64 − 67, 68 − 72 and ≥ 73), the gender (male and female), skin color or self-report race (white and non-white), the marital status (single or with partner), the education (0, 1 − 4, 5 − 8 and ≥ 9 years) and the per

capita income (> 291, 202 − 291, 134 − 201 and < 134 dollars) by the description of the absolute and relative frequencies for the categorical variable and of the mean, standard deviation and maximum and minimum values for continuous variables.

2.4.2. Biochemical analysis

Serum measurements of glucose, glycated hemoglobin (HbA1c) and insulin were performed using a blood sample. All analyses were performed at the same laboratory. Glucose measurement was performed using the enzymatic colorimetric method, with values between 70 and 99 mg/dl being considered as reference. The measurement of glycated hemoglobin was performed by high-performance liquid chromatography (HPLC) and the results were dichotomized into good controls (HbA1c < 7%) and poor controls (≥ 7%). The insulin dosage was done by chemiluminescence and the reference value was 1.90–23.00 microUI/mL. Data were expressed as mean and standard deviation. The HOMA (Homeostatic Model Assessment for Insulin) index was also evaluated considering glucose x insulin / 22.5.

2.4.3. Cognition assessment: mini-mental state examination (MMSE)

MMSE is a screening tool for cognitive assessment developed by Folstein in 1975. The tool evaluates five areas of cognitive function including orientation, immediate memory, attention and calculation, language and verbal construction (evocation memory) (Folstein et al., 1975). The total score ranges from 0 (impaired) to 30 (normal) and several cutoff points have been used for the application of MMSE depending on the number of years of education (Brucki et al., 2003). In the present study, in accordance with the suggestions for the use of the questionnaire in Brazil, it was adopted the cutoff point of "20″ for individuals with no education and "24″ for individuals with some education (Almeida, 1998; Brucki et al., 2003).

2.4.4. Health literacy in diabetes

Some questionnaires were used to measure overall HL and others focusing on the HL related to nutrition, physical activity and medication adherence, using previous developed questionnaires (Souza et al., 2006; Eleutério et al., 2018; Martins et al., 2018; Cardoso et al., 2019).

2.4.4.1. Literacy assessment for diabetes (LAD-60). LAD-60 was developed and validated in the English language and consists of 60 words to be read by people with DM in order to assess HL (Nath et al., 2001). The questionnaire showed a properly cross-cultural adaptation for the Brazilian Portuguese version and was used as a screening tool to identify HL levels among people with DM. The 60 words are distributed in three lists of 20 words that must be read by the researcher in front of the interviewer that evaluates if the pronunciation is accurate and, therefore, the score can vary from 0 to 60 (Nath et al., 2001; Neto et al., 2018). The cutoff point adopted was the low-limit of the confidence interval.

2.4.4.2. Nutritional literacy among people with diabetes (NLD). The evaluation of HL related to nutritional habits was assessed by the Nutritional Literacy among People with Diabetes (NLD) questionnaire whose interpretability is made by identifying and counting the correctness of the associations between 24 trios of words (correct/incorrect/I don't know), with scores from 0 to 24 (cut ≤ 18). Therefore, scores > 18 indicate adequate literacy (75 % of associations are correct) and scores between 0 and 18 indicate inadequate NLD (Eleutério et al., 2018).

2.4.4.3. Health literacy on the practice of physical activities among diabetics (HLPPA-D). For the evaluation of HL regarding the physical activity practice among people living with DM, a questionnaire was used based on the interpretability of the identification and counting of the correctness of the associations between 18 trios of words (correct/incorrect/I don't know), with scores from 0 to 18 (cut ≤ 14). Thus,

scores > 14 indicate literacy regarding the practice of physical exercise and scores between 0 and 14 indicate illiteracy (Martins AMEBL, 2018).

2.4.4.4. Health literacy regarding drug adherence among diabetics (HLDA-D). To assess HL related to drug adherence among people living with DM, a questionnaire called HLDA was used to assess the skills of association and understanding of the most common medical terminology used for DM (Cardoso et al., 2019). It includes 18 words related to DM and its treatment, with scores from 0 to 18 (cut ≤ 14). Thus, scores > 14 indicate literacy regarding adherence to drug treatment and scores between 0 and 14 indicate illiteracy (Cardoso et al., 2019).

2.5. Statistical analysis

The sample was described as absolute and relative frequencies for the categorical variables, and mean/standard deviation for the quantitative variables. The normality of data was checked by Kolmogorov-Smirnov test. Correlation among socio-demographic/clinical conditions and cognitive impairment, and among health literacy and cognitive impairment was conducted by Spearman test. The significance level was set as p < 0.05. The effect size of correlation was interpreted according to Cohen, 1988 (Cohen, 1988), as: a weak/small effect of 0.2, a medium effect of 0.5 and a large effect of 0.8 (Lakens, 2013). Statistical analyzes were performed using the Statistical Package for the Social Sciences version 25 for Windows (SPSS).

3. Results

3.1. Sociodemographic and clinical characteristics of the sample

The final sample included 187 older people living with DM, with a mean age of 68.97 years (SD: ± 7.17; minimum: 60, maximum: 92). Most of sample had 73 years or more (29.4 %), were women (68.4 %), non-white people (66.8 %) and with an average education time of 6.59 years (SD: ± 4.75; minimum: 0, maximum: 28). Regarding the biochemical parameters, insulin dosage had a mean value of 12.3 microUI/mL (SD: ± 15.7) and HbA1c was 7.54 % (SD: ± 1.8) (Table 1). The average of HOMA index was 80.5 (SD: ± 122.4).

3.2. Correlation between sociodemographic/clinical characteristics and cognitive condition

The variables age, education, and income showed significant correlation with cognition condition. Higher age, lower per capita income and the number of years of schooling, were correlated with lower MMSE scores. However, the effect size (r) shows a small/weak correlation among these variables. Regarding the serum levels of glucose, insulin and glycated hemoglobin, there was no significant correlation with the MMSE scores (Table 2). No correlation was identified between HOMA index and MMSE scores (p = 0.263).

3.3. Correlation between health literacy on medication adherence, nutrition, physical activity, and cognitive condition

For the HL evaluation considering specific aspects, medication adherence, nutrition, physical activity, and cognitive condition, a positive and significant correlation was found among these questionnaires with higher MMSE scores. It suggests that better cognitive condition is correlated with higher HL in terms of medication adherence, nutrition, physical activity, and cognitive condition among elderly people living with DM (Table 3). However, the effect size shows a weak correlation among them.

Table 1

Socio-demographic and clinical conditions of elderly people with DM from a medium-sized municipality in the southeastern region of Brazil.

Variables	mean (SD)
Age (years)	68.97 (± 7.17)
Education (years)	6.59 (± 4.75)
Insulin (microUI/mL)	12.3 (± 15.7)
Glucose (mg/dL)	148.1 (± 59.7)
HbA1c (%)	7.54 (± 1.8)
	n (%)
Age	
≤ 63	51 (27.3)
64 − 67	44 (23.5)
68 − 72	37 (19.8)
≥ 73	55 (29.4)
Gender, n (%)	
Male	59 (31.6)
Female	128 (68.4)
Education	
0	22 (30.5)
1 − 4	61 (25.1)
5 − 8	47 (32.6)
≥ 9	57 (11.8)
Marital status, n (%) *	
Single	95 (51.1)
With partner	91 (48.9)
Race/Skin color	
White	62 (33.2)
Non-white	125 (66.8)
Per capita income (US$) **	
> 291	43 (23.0)
202 − 291	44 (23.5)
134 − 201	42 (22.5)
< 134	43 (23.0)
Cognitive impairment	
Present	35 (18.7)
Absent	152 (81.3)

* Variation in the number of individuals.

** R$ 1.00 was equivalent to US$ 3.23 at the time of this study.

Table 2

Correlation among sociodemographic/clinical conditions and cognitive impairment among elderly people living with DM.

Variables	Cognitive Function	
	r	p
Age	− .174	0.017*
Education	.477	0.000*
Per capita income	.186	0.014*
Insulin	− .105	0.197
Glucose	.059	0.451
HbA1c	− .032	0.679

* p < 0.05.

Table 3

Correlation among health literacy and cognitive condition among elderly people living with DM.

Variables	Cognitive Function	
	r	p
LAD-60	.328	0.000*
NLD	.309	0.001*
HLDA - D	.358	0.000*
HLPPA - D	.297	0.000*

* p < 0.05.

4. Discussion

HL considers the development of personal, cognitive and social skills necessary to access, understand, evaluate and apply information related to health. For people living with DM, low HL level has been associated with low adherence to treatment and the development of complications (Sorensen et al., 2012). Previous studies suggest that several risk factors are associated with poor/non-adherence to DM treatment, including sociodemographic factors, clinical conditions, such as cognitive impairment, and factors related to the health system, which determine self-care practices among people with DM (Al-Hayek et al., 2012; Mendes et al., 2019). Interestingly, the results found here showed a correlation between better cognitive condition with higher level of HL considering important aspects of DM management, such as nutrition, physical activity and medication adherence. Although the correlations were weak, these results suggest the existence of relationship between cognitive condition and HL among people living with DM.

Cognitive impairment is common among elderly people with DM, but it is unclear to what extent cognitive function is associated with HL (Nguyen et al., 2013). Our hypothesis was that cognitive function is associated with HL and it was accepted. This suggests that poor cognitive function may reduce HL level. In fact, previous study evidenced that cognitive function indicators were significantly associated with HL, showing that and increase in unity in the MMSE score was associated with a 20 % increase in the chances of improve HL level (Nguyen et al., 2013). Thus, the relationship between cognition and HL deserves more attention from clinicians and public health, since both aspects can contribute to undesirable health outcomes (Federman et al., 2009).

The association between cognitive function and HL has not been widely evaluated, mainly in Brazil. Since people with low HL show a worse ability for verbal communication, mental processing and efficiency to understand text and numerical information, as well critical thinking, a relationship with low cognitive condition is expected (Federman et al., 2009). An improvement in the cognitive ability and, consequently, in the HL level may promote the self-care among people living with DM, especially elderly people which is naturally affected by cognitive impairment.

In the scientific literature, studies evaluating the correlation among HL, DM, cognitive condition and physical activity practice are scarce (Iwata and Munshi, 2009; Nguyen et al., 2013; Friis et al., 2016; Ueno et al., 2019). A previous study showed that HL had a direct positive effect on medication adherence and possibly an indirect and positive effect on physical activity practice and diet (Ueno et al., 2019). Furthermore, it has been shown that regular physical activity among adults and elderly optimizes cognitive condition (especially in those already with mild cognitive impairment) (Sanders et al., 2019). Interventions focusing to improve HL and physical activity practice have been able to enhance glycemic control among people living with DM (Liu et al., 2018). The practice of physical activity among people with DM is essential to achieve clinical goals and to prevent complications associated with the disease. However, some studies have shown that people with DM exercise less regularly compared to non-diabetics (Hamasaki, 2016; Joseph et al., 2016). A previous study evidenced that people who did not adhere to the practice of physical activity showed more cognitive impairment than the adherents; this impairment was attributed to less autonomy (Rothman et al., 2004). A previous meta-analysis described that HL interventions to improve physical activity among adults and the elderly with DM increase the frequency and duration of physical activity among people with high levels of HL enhancing glycated hemoglobin levels control (Lam and Leung, 2016). It is important to highlight that the aging process is directly related to changes in cognitive function, such as reduced memory and motor capacity, and older people are more likely to not understand health-related information (Gazmararian et al., 1999; Moura et al., 2019).

Education level is also an important factor that affects the HL level and cognitive function (Roundtable on Health Literacy et al., 2013).

This fact can compromise the acquisition of knowledge, especially the level of health education (Estrada et al., 2004). Considering that elderly people can show lower education levels, compared to younger people, a poor HL level in this age group is expected. Therefore, this harmful combination of education level, HL and cognitive condition among elderly people suggests a profile of people more susceptible to morbidity and mortality related to the disease (Gazmararian et al., 1999; Apolinario et al., 2012), such as DM.

Another condition that may affect HL is income. The results are in accordance with the literature since families with lower income can have less access to the health services and information related to health and disease (Friis et al., 2016). Thus, in a low-income population living with DM, it is expected a lower glycemic control and, consequently, a higher probability of complications from the disease (Bains and Egede, 2011).

Despite the important results, the sample size included must be considered a limitation, since it was properly to identify the outcome and correlation analysis, but not for robust statistical analysis, such as logistic regression. Further studies should consider the correlation with cognitive condition according with the type of diabetes, as well to expand this area of research, including other potential risk factors for DM, such as specific diet (sugar intake) and alcohol use. Moreover, although HL questionnaires have properly psychometric properties and are easily and quickly applied, due the age of individuals some answers may be sub or overestimated.

5. Conclusions

The present study showed a correlation between cognitive condition with socio-demographic, and health literacy among elderly people living with DM. Cognitive function is an important factor associated with HL in elderly people with DM, for all elements associated with treatment (physical activity, diet and medication use). In the context of Brazilian public health, the use of instruments/tools to evaluate the HL and cognitive function among people living with DM could improve the effectiveness in the management of the disease. Therefore, interventions aiming to improve the treatment of DM for those with poor HL should also consider the improvement of cognitive condition that is commonly affected by age.

Informed consent

All volunteers signed an informed consent, according to Brazilian ethical regulations (National Health Council, resolution 466/12) and Declaration of Helsinki. For individuals unable to sign it (for example, individual with dementia), the document was obtained from a guardian. The informed consent was signed in duplicate (copy for researchers and participants).

Compliance with ethical standards

All experiments were performed according to procedures approved by Ethics Committee of Universidade Estadual de Montes Claros Plataforma Brasil (protocol number 764.743).

Funding sources

This work was supported by grants from *Coordenadoria de Aperfeiçoamento do Pessoal de Nível Superior* (CAPES), *Conselho Nacional de Desenvolvimento Científico e Tecnológico* (CNPq) and *Fundação de Amparo à Pesquisa de Minas Gerais* (FAPEMIG).

Conflicts of Interest

The authors declare no conflict of interest.

References

Al-Hayek, A.A., Robert, A.A., Alzaid, A.A., Nusair, H.M., Zbaidi, N.S., Al-Eithan, M.H., Sam, A.E., 2012. Association between diabetes self-care, medication adherence, anxiety, depression, and glycemic control in type 2 diabetes. Saudi Med. J. 33 (6), 681–683.

Almeida, O.P., 1998. Mini mental state examination and the diagnosis of dementia in Brazil. Arq. Neuropsiquiatr. 56 (3b), 605–612. https://doi.org/10.1590/s0004-282x1998000400014.

American Diabetes Association, 2010. Diagnosis and classification of diabetes mellitus. Diabetes Care 33 (Suppl 1), S62–69. https://doi.org/10.2337/dc10-S062.

American Diabetes Association, 2018. 2. Classification and diagnosis of diabetes: standards of medical care in diabetes-2018. Diabetes Care 41 (Suppl 1), S13–s27. https://doi.org/10.2337/dc18-S002.

Apolinario, D., Braga Rde, C., Magaldi, R.M., Busse, A.L., Campora, F., Brucki, S., Lee, S.Y., 2012. Short assessment of health literacy for portuguese-speaking adults. Rev. Saude Publica 46 (4), 702–711. https://doi.org/10.1590/s0034-89102012005000047.

Bailey, S.C., Brega, A.G., Crutchfield, T.M., Elasy, T., Herr, H., Kaphingst, K., Karter, A.J., Moreland-Russell, S., Osborn, C.Y., Pignone, M., Rothman, R., Schillinger, D., 2014. Update on health literacy and diabetes. Diabetes Educ. 40 (5), 581–604. https://doi.org/10.1177/0145721714540220.

Bains, S.S., Egede, L.E., 2011. Associations between health literacy, diabetes knowledge, self-care behaviors, and glycemic control in a low income population with type 2 diabetes. Diabetes Technol. Ther. 13 (3), 335–341. https://doi.org/10.1089/dia.2010.0160.

Batista-Jorge, G.C., Barcala-Jorge, A.S., Silveira, M.F., Lelis, D.F., Andrade, J.M.O., de Paula, A.M.B., Guimarães, A.L.S., Santos, S.H.S., 2020. Oral resveratrol supplementation improves Metabolic Syndrome features in obese patients submitted to a lifestyle-changing program. Life Sci. 10, 117962. https://doi.org/10.1016/j.lfs.2020.117962.

Bruce, D.G., Casey, G.P., Grange, V., Clarnette, R.C., Almeida, O.P., Foster, J.K., Ives, F.J., Davis, T.M., Fremantle Cognition in Diabetes, S., 2003. Cognitive impairment, physical disability and depressive symptoms in older diabetic patients: the Fremantle Cognition in Diabetes Study. Diabetes Res. Clin. Pract. 61 (1), 59–67. https://doi.org/10.1016/s0168-8227(03)00084-00086.

Brucki, S.M., Nitrini, R., Caramelli, P., Bertolucci, P.H., Okamoto, I.H., 2003. Suggestions for utilization of the mini-mental state examination in Brazil. Arq. Neuropsiquiatr. 61 (3b), 777–781. https://doi.org/10.1590/s0004-282x2003000500014.

Cardoso, M., Santos, A.S.F., Fonseca, A.D.G., Silva-Junior, R.F.D., Carvalho, P.D., Martins, A., 2019. Validity and reliability of the Health Literacy Assessment Scale for adherence to drug treatment among diabetics. Einstein (Sao Paulo) 17 (2), eAO4405. https://doi.org/10.31744/einstein_journal/2019AO4405.

Chatterjee, S., Davies, M.J., Heller, S., Speight, J., Snoek, F.J., Khunti, K., 2018. Diabetes structured self-management education programmes: a narrative review and current innovations. Lancet Diab. Endocrinol. 6 (2), 130–142. https://doi.org/10.1016/S2213-8587(17)30239-5.

Cohen, J., 1988. Statistical Power Analysis for the Behavioral Sciences. L. Erlbaum Associates, Hillsdale, N.J.

Eleutério, T.P., Pereira, É.J., Farias, P.K.S., Hott, K.P.S., Paula, F.M.Td., Martins, A.M.E.B.L., 2018. Elaboração e verificação da validade e confiabilidade de um instrumento de letramento em nutrição entre pessoas com diabetes. Cadernos Saúde Coletiva 26, 298–307.

Estrada, C.A., Martin-Hryniewicz, M., Peek, B.T., Collins, C., Byrd, J.C., 2004. Literacy and numeracy skills and anticoagulation control. Am. J. Med. Sci. 328 (2), 88–93. https://doi.org/10.1097/00000441-200408000-00004.

Federman, A.D., Sano, M., Wolf, M.S., Siu, A.L., Halm, E.A., 2009. Health literacy and cognitive performance in older adults. J. Am. Geriatr. Soc. 57 (8), 1475–1480. https://doi.org/10.1111/j.1532-5415.2009.02347.x.

Ferri, C.P., Prince, M., Brayne, C., Brodaty, H., Fratiglioni, L., Ganguli, M., Hall, K., Hasegawa, K., Hendrie, H., Huang, Y., Jorm, A., Mathers, C., Menezes, P.R., Rimmer, E., Scazufca, M., Alzheimer's Disease, I., 2005. Global prevalence of dementia: a Delphi consensus study. Lancet 366 (9503), 2112–2117. https://doi.org/10.1016/S0140-6736(05)67889-0.

Folstein, M.F., Folstein, S.E., McHugh, P.R., 1975. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. J. Psychiatr. Res. 12 (3), 189–198. https://doi.org/10.1016/0022-3956(75)90026-6.

Friis, K., Vind, B.D., Simmons, R.K., Maindal, H.T., 2016. The Relationship between health literacy and health behaviour in people with diabetes: a danish population-based study. J. Diabetes Res. 2016, 7823130. https://doi.org/10.1155/2016/7823130.

Gazmararian, J.A., Baker, D.W., Williams, M.V., Parker, R.M., Scott, T.L., Green, D.C., Fehrenbach, S.N., Ren, J., Koplan, J.P., 1999. Health literacy among Medicare

enrollees in a managed care organization. JAMA 281 (6), 545–551. https://doi.org/10.1001/jama.281.6.545.

Hamasaki, H., 2016. Daily physical activity and type 2 diabetes: a review. World J. Diabetes 7 (12), 243–251. https://doi.org/10.4239/wjd.v7.i12.243.

International Diabetes Federation, 2019. Diabetes Atlas. International Diabetes Federation, Brussels.

Iwata, I., Munshi, M.N., 2009. Cognitive and psychosocial aspects of caring for elderly patients with diabetes. Curr. Diab. Rep. 9 (2), 140–146. https://doi.org/10.1007/s11892-009-0024-0027.

Jorge, A.S., Jorge, G.C., Paraiso, A.F., Franco, R.M., Vieira, L.J., Hilzenderger, A.M., Guimaraes, A.L., Andrade, J.M., De-Paula, A.M., Santos, S.H., 2017. Brown and white adipose tissue expression of IL6, UCP1 and SIRT1 are associated with alterations in clinical, metabolic and anthropometric parameters in obese humans. Exp. Clin. Endocrinol. Diabetes 125 (3), 163–170. https://doi.org/10.1055/s-0042-119525: 10.1055/s-0042-119525.

Joseph, J.J., Echouffo-Tcheugui, J.B., Golden, S.H., Chen, H., Jenny, N.S., Carnethon, M.R., Jacobs Jr., D., Burke, G.L., Vaidya, D., Ouyang, P., Bertoni, A.G., 2016. Physical activity, sedentary behaviors and the incidence of type 2 diabetes mellitus: the Multi-Ethnic Study of Atherosclerosis (MESA). BMJ Open Diabetes Res. Care 4 (1), e000185. https://doi.org/10.1136/bmjdrc-2015-000185.

Lakens, D., 2013. Calculating and reporting effect sizes to facilitate cumulative science: a practical primer for t-tests and ANOVAs. Front. Psychol. 4, 863. https://doi.org/10.3389/fpsyg.2013.00863.

Lam, M.H., Leung, A.Y., 2016. The effectiveness of health literacy oriented programs on physical activity behaviour in middle aged and older adults with type 2 diabetes: a systematic review. Health Psychol. Res. 4 (1), 5595. https://doi.org/10.4081/hpr.2016.5595.

Lee, Y.J., Shin, S.J., Wang, R.H., Lin, K.D., Lee, Y.L., Wang, Y.H., 2016. Pathways of empowerment perceptions, health literacy, self-efficacy, and self-care behaviors to glycemic control in patients with type 2 diabetes mellitus. Patient Educ. Couns. 99,2, 287–294. https://doi.org/10.1016/j.pec.2015.08.021.

Liu, X.N., Xia, Q.H., Fang, H., Li, R., Chen, Y.Y., Yan, Y.J., Zhou, P., Yao, B.D., Jiang, Y., Rothman, W.G., Xu, W., 2018. Effect of health literacy and exercise-focused interventions on glycemic control in patients with type 2 diabetes in China. Zhonghua Liu Xing Bing Xue Za Zhi 39 (3), 357–362. https://doi.org/10.3760/cma.j.issn.0254-6450.2018.03.021.

Mambiya, M., Shang, M., Wang, Y., Li, Q., Liu, S., Yang, L., Zhang, Q., Zhang, K., Liu, M., Nie, F., Zeng, F., Liu, W., 2019. The Play of Genes and Non-genetic Factors on Type 2 Diabetes. Front. Public Health 7, 349. https://doi.org/10.3389/fpubh.2019.00349.

Martins, A., Bauman, C., Ávila, W., Farias, P., Pereira, É., Ferreira, F., Santos, A., Martins, M., Oliveira, I., Alcântara, V., Silva, L., Campos, L., Silva, M., Cardoso, M., 2018. Elaboração de um instrumento de alfabetização em saúde quanto à prática de atividade física entre diabéticos. Revista Eletrônica Acervo Saúde. Esp. S1202–S1213. https://doi.org/10.25248/REAS269_2018.

Mendes, R., Martins, S., Fernandes, L., 2019. Adherence to medication, physical activity and diet in older adults with diabetes: its association with cognition, anxiety and depression. J. Clin. Med. Res. 11 (8), 583–592. https://doi.org/10.14740/jocmr3894.

Moura, N.D.S., Lopes, B.B., Teixeira, J.J.D., Oria, M.O.B., Vieira, N.F.C., Guedes, M.V.C., 2019. Literacy in health and self-care in people with type 2 diabetes mellitus. Rev. Bras. Enferm. 72 (3), 700–706. https://doi.org/10.1590/0034-7167-2018-0291.

Nath, C.R., Sylvester, S.T., Yasek, V., Gunel, E., 2001. Development and validation of a literacy assessment tool for persons with diabetes. Diabetes Educ. 27 (6), 857–864. https://doi.org/10.1177/014572170102700611.

Neto, E.Z., O. C, Oliveira, I.A., Pereira, V.B.V., Nogueira, J.F.M., Procópio, J.P.M., Alcântara, V.R.A., Cardoso, M.L.F., Silva, L.T.S., Farias, P.K.S., Martins, A.M.E.B.L., 2018. Cross-cultural adaptation and evaluation of psychometric properties of the Literacy Assessment for Diabetes - LAD-60. REAS, Revista Eletrônica Acervo Saúde 10 (2), 1683–1692. https://doi.org/10.25248/REAS266_2018.

Nguyen, H.T., Kirk, J.K., Arcury, T.A., Ip, E.H., Grzywacz, J.G., Saldana, S.J., Bell, R.A., Quandt, S.A., 2013. Cognitive function is a risk for health literacy in older adults with diabetes. Diabetes Res. Clin. Pract. 101 (2), 141–147. https://doi.org/10.1016/j.diabres.2013.05.012.

Paim, J., Travassos, C., Almeida, C., Bahia, L., Macinko, J., 2011. The Brazilian health system: history, advances, and challenges. Lancet 377 (9779), 1778–1797. https://doi.org/10.1016/S0140-6736(11)60054-60058.

Rothman, R.L., DeWalt, D.A., Malone, R., Bryant, B., Shintani, A., Crigler, B., Weinberger, M., Pignone, M., 2004. Influence of patient literacy on the effectiveness of a primary care-based diabetes disease management program. JAMA 292 (14), 1711–1716. https://doi.org/10.1001/jama.292.14.1711.

Roundtable on Health Literacy, Board on Population Health and Public Health Practice, Institute of Medicine, 2013. Health Literacy: Improving Health, Health Systems, and Health Policy Around the World: Workshop Summary. National Academies Press (US), Washington (DC).

Sanders, L.M.J., Hortobagyi, T., la Bastide-van Gemert, S., van der Zee, E.A., van Heuvelen, M.J.G., 2019. Dose-response relationship between exercise and cognitive function in older adults with and without cognitive impairment: a systematic review and meta-analysis. PLoS One 14 (1), e0210036. https://doi.org/10.1371/journal.pone.0210036.

Scazufca, M., Almeida, O.P., Vallada, H.P., Tasse, W.A., Menezes, P.R., 2009. Limitations of the mini-mental state examination for screening dementia in a community with low socioeconomic status: results from the Sao Paulo Ageing & Health Study. Eur. Arch. Psychiatry Clin. Neurosci. 259 (1), 8–15. https://doi.org/10.1007/s00406-008-0827-6.

Sorensen, K., Van den Broucke, S., Fullam, J., Doyle, G., Pelikan, J., Slonska, Z., Brand, H., Consortium Health Literacy Project, E., 2012. Health literacy and public health: a systematic review and integration of definitions and models. BMC Public Health 12, 80. https://doi.org/10.1186/1471-2458-12-80.

Souza, A.C., Magalhães, I.d.C., Teixeira-Salmela, L.F., 2006. Adaptação transcultural e análise das propriedades psicométricas da versão brasileira do Perfil de Atividade Humana. Cadernos de Saúde Pública 22, 2623–2636.

Stumvoll, M., Goldstein, B.J., van Haeften, T.W., 2005. Type 2 diabetes: principles of pathogenesis and therapy. Lancet 365 (9467), 1333–1346. https://doi.org/10.1016/S0140-6736(05)61032-X.

Triola, M., 1999. Introdução à Estatística. Rio De Janeiro.

Ueno, H., Ishikawa, H., Suzuki, R., Izumida, Y., Ohashi, Y., Yamauchi, T., Kadowaki, T., Kiuchi, T., 2019. The association between health literacy levels and patient-reported outcomes in Japanese type 2 diabetic patients. SAGE Open Med. 7, 2050312119865647. https://doi.org/10.1177/2050312119865647.

Yeh, J.Z., Wei, C.J., Weng, S.F., Tsai, C.Y., Shih, J.H., Shih, C.L., Chiu, C.H., 2018. Disease-specific health literacy, disease knowledge, and adherence behavior among patients with type 2 diabetes in Taiwan. BMC Public Health 18 (1), 1062. https://doi.org/10.1186/s12889-018-5972-x.

4 CONSIDERAÇÕES FINAIS

Em consequência às maiores taxas de obesidade e sobrepeso no mundo, o diabetes cursa com aumento progressivo da prevalência, uma vez que estes são os principais fatores de risco modificáveis para o desenvolvimento dessa patologia. Atualmente, o diabetes figura dentre as principais causas diretas e indiretas de óbitos no mundo, consistindo em um desafio para os sistemas de saúde. Por ser essencial o desenvolvimento de habilidades de autocuidado, a literacia em saúde (LS) emerge como uma ferramenta no nível individual para atender necessidades específicas, sendo extensiva também ao âmbito comunitário. Apesar de despontar como medida essencial à identificação de fatores de risco modificáveis para o desenvolvimento e agravamento da doença e do potencial desenvolvimento de políticas que visem a equidade em saúde, há escassez de evidências na literatura concernente à abrangência da LS. Nesse sentido, ter a oportunidade de fazer parte do "Projeto Health Literacy" permitiu compreender melhor a realidade dos pacientes que vivem com diabetes, atendidos pelos profissionais da Estratégia de Saúde da Família e que têm a Atenção Primária em Saúde como o principal acesso ao sistema de saúde para obter informações, orientações e cuidados relativos ao manejo da doença. No recorte do projeto, avaliar especificamente a LS em uma população de idosos com diabetes permitiu inferências da importância do declínio cognitivo nesse subgrupo e o quanto a LS pode ser afetada por essa vulnerabilidade, com consequente dificuldade de controle metabólico e, de modo bidirecional, o decréscimo nos níveis de literacia agravando os déficits cognitivos. A LS, com relação à adesão medicamentosa, atividade física e status nutricional nessa população de idosos que vivem com diabetes, foi correlacionada à cognição e condições sociodemográficas. Além disso, trabalho metodológico permitiu avaliar as propriedades psicométricas e a interpretabilidade de um instrumento de LS diabetes-específico ("Alfabetização em Saúde para Diabéticos") desenvolvido recentemente por membros da equipe do "Projeto Health Literacy" e permitiu, estatisticamente, validar seu constructo e demonstrar sua confiabilidade. Nesse trabalho, a ausência de significância estatística da LS com parâmetros bioquímicos amplia o entendimento da complexidade da doença e as dimensões da LS que precisam ser aventadas no contexto dos desfechos clínicos. O instrumento contemplou a conceituação inclusiva e integrativa da LS e abrangeu os âmbitos do acesso, da avaliação, da compreensão e da aplicação das informações obtidas e, nessa perspectiva, pode se tornar útil para estudos posteriores que busquem otimizar a avaliação da LS como ferramenta para a elaboração de estratégias de prevenção de doenças, minimização de complicações e promoção da saúde. A expectativa é dar

seguimento ao "Projeto Health Literacy" com propostas de realização de intervenções nessa população e avaliar a relação da LS com autoeficácia, desfechos clínicos e custo-efetividade das ações.

REFERÊNCIAS

1.   World Health Organization (WHO) [internet]. Geneva, Switzerland; 2020 [accessed on January 5, 2021]. [Available from: http://www.who.int/health-topics/diabetes].
2.   World Health Organization (WHO) [internet]. Classification of Diabetes Mellitus 2019. NDC Management-Screening, Diagnosis and Treatment. Geneva, Switzerland; 2019 [accessed on January 5, 2021] [Available from: http://www.who.int].
3.   Cho NH, Shaw JE, Karuranga S, Huang Y, da Rocha Fernandes JD, Ohlrogge AW, et al. IDF Diabetes Atlas: Global estimates of diabetes prevalence for 2017 and projections for 2045. Diabetes Res Clin Pract. 2018;138:271-81.
4.   International Diabetes Federation (IDF). Bruxelas. IDF Diabetes Atlas Ninth Edition 2019 Available at: http://wwwdiabetesatlasorg Acessed January 2021.
5.   Instituto Brasileiro de Geografia e Estatística. Pesquisa Nacional de Saúde 2013: percepção do estado de saúde, estilos de vida e doenças crônicas. Brasil, grandes regiões e unidades da federação. 2014:180p.
6.   Dias OV, Chagas RB, Gusmão BM, Pereira FS, Costa SM, Costa FM, et al. Diabetes mellitus em Montes Claros: inquérito de prevalência autorreferida. Revista Brasileira em Promoção da Saúde. 2016;29(3):406-13.
7.   Fernandes TF, Pereira MI, Fernandes VBL, Grilo LEM, Rocha SR, Maciel AG. Morbimortalidade por diabetes no município de Montes Claros–MG. Revista de Administração em Saúde. 2018;18(71).
8.   Paim J, Travassos C, Almeida C, Bahia L, Macinko J. The Brazilian health system: history, advances, and challenges. Lancet. 2011;377(9779):1778-97.
9.   Chan M. Obesity and Diabetes: The Slow-Motion Disaster. Milbank Q. 2017;95(1):11-4.
10.   Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Diabetes care. 1997;20(7):1183-97.
11.   Awad N, Gagnon M, Messier C. The relationship between impaired glucose tolerance, type 2 diabetes, and cognitive function. Journal of clinical and experimental neuropsychology. 2004;26(8):1044-80.
12.   Biessels GJ, Staekenborg S, Brunner E, Brayne C, Scheltens P. Risk of dementia in diabetes mellitus: a systematic review. The Lancet Neurology. 2006;5(1):64-74.
13.   Ott A, Stolk RP, van Harskamp F, Pols HA, Hofman A, Breteler MM. Diabetes mellitus and the risk of dementia: The Rotterdam Study. Neurology. 1999;53(9):1937-42.
14.   Kopf D, Frölich L. Risk of incident Alzheimer's disease in diabetic patients: a systematic review of prospective trials. J Alzheimers Dis. 2009;16(4):677-85.
15.   Ferri CP, Prince M, Brayne C, Brodaty H, Fratiglioni L, Ganguli M, et al. Global prevalence of dementia: a Delphi consensus study. Lancet. 2005;366(9503):2112-7.
16.   de Wet H, Levitt N, Tipping B. Executive cognitive impairment detected by simple bedside testing is associated with poor glycaemic control in type 2 diabetes. South African medical journal = Suid-Afrikaanse tydskrif vir geneeskunde. 2007;97(11):1074-6.
17.   Cukierman-Yaffe T, Gerstein HC, Williamson JD, Lazar RM, Lovato L, Miller ME, et al. Relationship between baseline glycemic control and cognitive function in individuals with type 2 diabetes and other cardiovascular risk factors: the action to control cardiovascular risk in diabetes-memory in diabetes (ACCORD-MIND) trial. Diabetes care. 2009;32(2):221-6.
18.   Nguyen HT, Kirk JK, Arcury TA, Ip EH, Grzywacz JG, Saldana SJ, et al. Cognitive function is a risk for health literacy in older adults with diabetes. Diabetes Res Clin Pract. 2013;101(2):141-7.

19.   American Diabetes Association. Diabetes Care 2018 Jan; 41(Supplement 1): S13-S27. [accessed on January 6, 2021] [Available from: https://doi.org/10.2337/dc18-S002].

20.   Moreno G, Mangione CM, Kimbro L, Vaisberg E. Guidelines abstracted from the American Geriatrics Society Guidelines for Improving the Care of Older Adults with Diabetes Mellitus: 2013 update. J Am Geriatr Soc. 2013;61(11):2020-6.

21.   Munshi M, Grande L, Hayes M, Ayres D, Suhl E, Capelson R, et al. Cognitive dysfunction is associated with poor diabetes control in older adults. Diabetes care. 2006;29(8):1794-9.

22.   Lalla E, Papapanou PN. Diabetes mellitus and periodontitis: a tale of two common interrelated diseases. Nat Rev Endocrinol. 2011;7(12):738-48.

23.   Taylor GW, Burt BA, Becker MP, Genco RJ, Shlossman M, Knowler WC, et al. Severe Periodontitis and Risk for Poor Glycemic Control in Patients with Non-Insulin-Dependent Diabetes Mellitus. J Periodontol. 1996;67 Suppl 10S:1085-93.

24.   Chapple IL, Genco R, working group 2 of the joint EFPAAPw. Diabetes and periodontal diseases: consensus report of the Joint EFP/AAP Workshop on Periodontitis and Systemic Diseases. J Periodontol. 2013;84(4 Suppl):S106-12.

25.   Shrivastava SR, Shrivastava PS, Ramasamy J. Role of self-care in management of diabetes mellitus. Journal of diabetes and metabolic disorders. 2013;12(1):14.

26.   Brown AF, Mangione CM, Saliba D, Sarkisian CA. Guidelines for improving the care of the older person with diabetes mellitus. J Am Geriatr Soc. 2003;51(5 Suppl Guidelines):S265-80.

27.   Mendes R, Martins S, Fernandes L. Adherence to Medication, Physical Activity and Diet in Older Adults With Diabetes: Its Association With Cognition, Anxiety and Depression. Journal of clinical medicine research. 2019;11(8):583-92.

28.   Boustani M, Peterson B, Hanson L, Harris R, Lohr KN, Force USPST. Screening for dementia in primary care: a summary of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med. 2003;138(11):927-37.

29.   Prince M, Dementia Research G. Care arrangements for people with dementia in developing countries. Int J Geriatr Psychiatry. 2004;19(2):170-7.

30.   Almeida OP. [Mini mental state examination and the diagnosis of dementia in Brazil]. Arquivos de neuro-psiquiatria. 1998;56(3b):605-12.

31.   Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. Journal of psychiatric research. 1975;12(3):189-98.

32.   Scazufca M, Almeida OP, Vallada HP, Tasse WA, Menezes PR. Limitations of the Mini-Mental State Examination for screening dementia in a community with low socioeconomic status: results from the Sao Paulo Ageing & Health Study. European archives of psychiatry and clinical neuroscience. 2009;259(1):8-15.

33.   Triebel KL, Martin R, Griffith HR, Marceaux J, Okonkwo OC, Harrell L, et al. Declining financial capacity in mild cognitive impairment: A 1-year longitudinal study. Neurology. 2009;73(12):928-34.

34.   Magaldi RM, Busse AL, Coelho VA, Apolinario D, Lopes LDC, Satomi E, et al. Clinical conditions and memory complaints in outpatient elderly. Dementia & neuropsychologia. 2008;2(4):315-20.

35.   Muangpaisan W, Petcharat C, Srinonprasert V. Prevalence of potentially reversible conditions in dementia and mild cognitive impairment in a geriatric clinic. Geriatr Gerontol Int. 2012;12(1):59-64.

36.   Andersen F, Viitanen M, Halvorsen DS, Straume B, Engstad TA. Co-morbidity and drug treatment in Alzheimer's disease. A cross sectional study of participants in the dementia study in northern Norway. BMC Geriatr. 2011;11:58.

37.   Connell CM, Gallant MP. Spouse caregivers' attitudes toward obtaining a diagnosis of a dementing illness. J Am Geriatr Soc. 1996;44(8):1003-9.

38.   Carpenter BD, Xiong C, Porensky EK, Lee MM, Brown PJ, Coats M, et al. Reaction to a dementia diagnosis in individuals with Alzheimer's disease and mild cognitive impairment. J Am Geriatr Soc. 2008;56(3):405-12.

39.   Teixeira CV, Gobbi LT, Corazza DI, Stella F, Costa JL, Gobbi S. Non-pharmacological interventions on cognitive functions in older people with mild cognitive impairment (MCI). Arch Gerontol Geriatr. 2012;54(1):175-80.

40.   Unverzagt FW, Smith DM, Rebok GW, Marsiske M, Morris JN, Jones R, et al. The Indiana Alzheimer Disease Center's Symposium on Mild Cognitive Impairment. Cognitive training in older adults: lessons from the ACTIVE Study. Curr Alzheimer Res. 2009;6(4):375-83.

41.   Sorensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, et al. Health literacy and public health: a systematic review and integration of definitions and models. BMC Public Health. 2012;12:80.

42.   In Health and Modernity. The Role of Theory in Health Promotion. Edited by: McQueen, DV; Kickbusch, I; Potvin, L; Pelikan, JM; Balbo, L; Abel, Th. Springer; 2007.

43.   Sørensen K, Pelikan JM, Röthlin F, Ganahl K, Slonska Z, Doyle G, et al. Health literacy in Europe: comparative results of the European health literacy survey (HLS-EU). European journal of public health. 2015;25(6):1053-8.

44.   Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. Health Promotion International. 2000;15(3):259-67.

45.   Nutbeam D. The evolving concept of health literacy. . Soc Sci Med. 2008;67:2072-8.

46.   Nutbeam D. Health outcomes and health promotion: defining sucess in health promotion. Health Promotion Journal of Australia. 1996;;6:58-60.

47.   Gonzalez JS, Tanenbaum ML, Commissariat PV. Psychosocial factors in medication adherence and diabetes self-management: Implications for research and practice. Am Psychol. 2016;71(7):539-51.

48.   Schillinger D, Grumbach K, Piette J, Wang F, Osmond D, Daher C, et al. Association of health literacy with diabetes outcomes. JAMA. 2002;288(4):475-82.

49.   Cramer JA. A systematic review of adherence with medications for diabetes. Diabetes care. 2004;27(5):1218-24.

50.   Ishikawa H, Takeuchi T, Yano E. Measuring functional, communicative, and critical health literacy among diabetic patients. Diabetes care. 2008;31(5):874-9.

51.   Sarkar U, Fisher L, Schillinger D. Is self-efficacy associated with diabetes self-management across race/ethnicity and health literacy? Diabetes care. 2006;29(4):823-9.

52.   Leung AY, Lou VW, Cheung MK, Chan SS, Chi I. Development and validation of Chinese Health Literacy Scale for Diabetes. J Clin Nurs. 2013;22(15-16):2090-9.

53.   Caruso R, Magon A, Baroni I, Dellafiore F, Arrigoni C, Pittella F, et al. Health literacy in type 2 diabetes patients: a systematic review of systematic reviews. Acta Diabetol. 2018;55(1):1-12.

54.   Bains SS, Egede LE. Associations between health literacy, diabetes knowledge, self-care behaviors, and glycemic control in a low income population with type 2 diabetes. Diabetes Technol Ther. 2011;13(3):335-41.

55.   Morris NS, MacLean CD, Chew LD, Littenberg B. The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability. BMC Fam Pract. 2006;7:21.

56.   White RO, 3rd, Osborn CY, Gebretsadik T, Kripalani S, Rothman RL. Development and validation of a Spanish diabetes-specific numeracy measure: DNT-15 Latino. Diabetes Technol Ther. 2011;13(9):893-8.

57.   Souza JG, Apolinario D, Magaldi RM, Busse AL, Campora F, Jacob-Filho W. Functional health literacy and glycaemic control in older adults with type 2 diabetes: a cross-sectional study. BMJ Open. 2014;4(2):e004180.

58.   Tang YH, Pang SM, Chan MF, Yeung GS, Yeung VT. Health literacy, complication awareness, and diabetic control in patients with type 2 diabetes mellitus. J Adv Nurs. 2008;62(1):74-83.

59.   Brega AG, Ang A, Vega W, Jiang L, Beals J, Mitchell CM, et al. Mechanisms underlying the relationship between health literacy and glycemic control in American Indians and Alaska Natives. Patient Educ Couns. 2012;88(1):61-8.

60.   Osborn CY, Bains SS, Egede LE. Health literacy, diabetes self-care, and glycemic control in adults with type 2 diabetes. Diabetes Technol Ther. 2010;12(11):913-9.

61.   Al Sayah F, Majumdar SR, Williams B, Robertson S, Johnson JA. Health literacy and health outcomes in diabetes: a systematic review. J Gen Intern Med. 2013;28(3):444-52.

62.   Macek MD, Haynes D, Wells W, Bauer-Leffler S, Cotten PA, Parker RM. Measuring conceptual health knowledge in the context of oral health literacy: preliminary results. J Public Health Dent. 2010;70(3):197-204.

63.   Horowitz AM, Kleinman DV. Oral health literacy: a pathway to reducing oral health disparities in Maryland. J Public Health Dent. 2012;72 Suppl 1:S26-30.

64.   Bailey SC, Brega AG, Crutchfield TM, Elasy T, Herr H, Kaphingst K, et al. Update on health literacy and diabetes. Diabetes Educ. 2014;40(5):581-604.

65.   Pleasant A. Advancing health literacy measurement: a pathway to better health and health system performance. J Health Commun. 2014;19(12):1481-96.

66.   Souza ACd, Alexandre NMC, Guirardello EdB. Propriedades psicométricas na avaliação de instrumentos: avaliação da confiabilidade e da validade. Epidemiologia e Serviços de Saúde. 2017;26:649-59.

67.   Al Sayah F, Johnson ST, Vallance J. Health literacy, pedometer, and self-reported walking among older adults. American Journal of Public Health. 2016;106(2):327-33.

68.   Davis TC, Crouch MA, Long SW, Jackson RH, Bates P, George RB, et al. Rapid assessment of literacy levels of adult primary care patients. Fam Med. 1991;23(6):433-5.

69.   Davis TC, Long SW, Jackson RH, Mayeaux EJ, George RB, Murphy PW, et al. Rapid estimate of adult literacy in medicine: a shortened screening instrument. Fam Med. 1993;25(6):391-5.

70.   Nurss JR, Baker DW, Davis TC, Parker RM, Williams MV. Difficulties in functional health literacy screening in Spanish-speaking adults. Journal of Reading. 1995;38(8):632-7.

71.   Parker RM, Baker DW, Williams MV, Nurss JR. The test of functional health literacy in adults: a new instrument for measuring patients' literacy skills. J Gen Intern Med. 1995;10(10):537-41.

72.   Baker DW, Williams MV, Parker RM, Gazmararian JA, Nurss J. Development of a brief test to measure functional health literacy. Patient Educ Couns. 1999;38(1):33-42.

73.   Aguirre AC, Ebrahim N, Shea JA. Performance of the English and Spanish S-TOFHLA among publicly insured Medicaid and Medicare patients. Patient Educ Couns. 2005;56(3):332-9.

74.   Baron-Epel O, Balin L, Daniely Z, Eidelman S. Validation of a Hebrew health literacy test. Patient Educ Couns. 2007;67(1-2):235-9.

75.   Connor M, Mantwill S, Schulz PJ. Functional health literacy in Switzerland--validation of a German, Italian, and French health literacy test. Patient Educ Couns. 2013;90(1):12-7.

76.   Mantwill S, Schulz PJ. Health literacy in Mainland China: Validation of a functional health literacy test in simplified Chinese. Health Promot Int. 2016;31(4):742-8.

77.	Carthery-Goulart MT, Anghinah R, Areza-Fegyveres R, Bahia VS, Brucki SM, Damin A, et al. Performance of a Brazilian population on the test of functional health literacy in adults. Rev Saude Publica. 2009;43(4):631-8.

78.	Apolinario D, Braga Rde C, Magaldi RM, Busse AL, Campora F, Brucki S, et al. Short Assessment of Health Literacy for Portuguese-speaking Adults. Rev Saude Publica. 2012;46(4):702-11.

79.	Lee SY, Bender DE, Ruiz RE, Cho YI. Development of an easy-to-use Spanish Health Literacy test. Health Serv Res. 2006;41(4 Pt 1):1392-412.

80.	Lee SY, Stucky BD, Lee JY, Rozier RG, Bender DE. Short Assessment of Health Literacy-Spanish and English: a comparable test of health literacy for Spanish and English speakers. Health Serv Res. 2010;45(4):1105-20.

81.	Mokkink LB, Terwee CB, Knol DL, Stratford PW, Alonso J, Patrick DL, et al. The COSMIN checklist for evaluating the methodological quality of studies on measurement properties: a clarification of its content. BMC Med Res Methodol. 2010;10:22.

82.	Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res. 2010;19(4):539-49.

83.	Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol. 2010;63(7):737-45.

84.	Martins AMEdBL, Neto EN, Ferreira CMM, Farias PKS, Freitas CVd, Maia EL, et al. Criação e verificação da validade de conteúdo e das propriedades psicométricas de um instrumento para avaliação da Alfabetização em Saúde entre Diabéticos. Revista Eletrônica Acervo Saúde. 2018;10(3):1693-703.

85.	Weiss BD, Mays MZ, Martz W, Castro KM, DeWalt DA, Pignone MP, et al. Quick assessment of literacy in primary care: the newest vital sign. Ann Fam Med. 2005;3(6):514-22.

86.	Rawson KA, Gunstad J, Hughes J, Spitznagel MB, Potter V, Waechter D, et al. The METER: a brief, self-administered measure of health literacy. J Gen Intern Med. 2010;25(1):67-71.

87.	Paiva D, Silva S, Severo M, Ferreira P, Santos O, Lunet N, et al. Cross-cultural adaptation and validation of the health literacy assessment tool METER in the Portuguese adult population. Patient Educ Couns. 2014;97(2):269-75.

88.	Nath CR, Sylvester ST, Yasek V, Gunel E. Development and validation of a literacy assessment tool for persons with diabetes. Diabetes Educ. 2001;27(6):857-64.

89.	Neto EZ OC, Oliveira IA, Pereira VBV, Nogueira JFM, Procópio JPM, Alcântara VRA, Cardoso MLF, Silva LTS, Farias PKS, Martins AMEBL. Cross-cultural adaptation and evaluation of psychometric properties of the Literacy Assessment for Diabetes - LAD-60. REAS, Revista Eletrônica Acervo Saúde. 2018;10 (2):1683-92.

90.	Fitzgerald JT, Funnell MM, Hess GE, Barr PA, Anderson RM, Hiss RG, et al. The reliability and validity of a brief diabetes knowledge test. Diabetes care. 1998;21(5):706-10.

91.	Huizinga MM, Elasy TA, Wallston KA, Cavanaugh K, Davis D, Gregory RP, et al. Development and validation of the Diabetes Numeracy Test (DNT). BMC Health Serv Res. 2008;8:96.

92.	Dunn SM, Bryson JM, Hoskins PL, Alford JB, Handelsman DJ, Turtle JR. Development of the diabetes knowledge (DKN) scales: forms DKNA, DKNB, and DKNC. Diabetes care. 1984;7(1):36-41.

93.	Speight J, Bradley C. The ADKnowl: identifying knowledge deficits in diabetes care. Diabet Med. 2001;18(8):626-33.

94.   Rothman RL, Malone R, Bryant B, Wolfe C, Padgett P, DeWalt DA, et al. The Spoken Knowledge in Low Literacy in Diabetes scale: a diabetes knowledge scale for vulnerable patients. Diabetes Educ. 2005;31(2):215-24.

95.   Souza JG, Apolinario D, Farfel JM, Jaluul O, Magaldi RM, Busse AL, et al. Applicability of the Spoken Knowledge in Low Literacy Patients with Diabetes in Brazilian elderly. Einstein (Sao Paulo). 2016;14(4):513-9.

96.   Lee EH, Lee YW, Lee KW, Nam M, Kim SH. A new comprehensive diabetes health literacy scale: Development and psychometric evaluation. Int J Nurs Stud. 2018;88:1-8.

97.   Eleutério TP, Pereira ÉJ, Farias PKS, Hott KPS, Paula FMTd, Martins AMEdBL. Elaboração e verificação da validade e confiabilidade de um instrumento de letramento em nutrição entre pessoas com diabetes. Cadernos Saúde Coletiva. 2018;26:298-307.

98.   Martins AMEdBL, Bauman CD, Ávila WRdMe, Farias PKS, Pereira ÉJ, Ferreira FdN, et al. Elaboração de um instrumento de alfabetização em saúde quanto à prática de atividade física entre diabéticos. Revista Eletrônica Acervo Saúde. 2018;Esp.(12):S1202-S13.

99.   Cardoso M, Santos ASF, Fonseca ADG, Silva-Junior RFD, Carvalho PD, Martins A. Validity and reliability of the Health Literacy Assessment Scale for adherence to drug treatment among diabetics. Einstein (Sao Paulo). 2019;17(2):eAO4405.

100.   Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. Fam Med. 2004;36(8):588-94.

101.   Apolinario D, Mansur LL, Carthery-Goulart MT, Brucki SM, Nitrini R. Detecting limited health literacy in Brazil: development of a multidimensional screening tool. Health Promot Int. 2014;29(1):5-14.

102.   Aaronson N, Alonso J, Burnam A, Lohr KN, Patrick DL, Perrin E, et al. Assessing health status and quality-of-life instruments: attributes and review criteria. Qual Life Res. 2002;11(3):193-205.

103.   Mokkink LB, Terwee CB, Knol DL, Stratford PW, Alonso J, Patrick DL, et al. Protocol of the COSMIN study: COnsensus-based Standards for the selection of health Measurement INstruments. BMC Med Res Methodol. 2006;6:2.

104.   Mokkink LB, Prinsen CA, Bouter LM, Vet HC, Terwee CB. The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) and how to select an outcome measurement instrument. Braz J Phys Ther. 2016;20(2):105-13.

105.   Cook DA, Beckman TJ. Current concepts in validity and reliability for psychometric instruments: theory and application. The American journal of medicine. 2006;119(2):166. e7-.e16.

106.   Pittman J, Bakas T. Measurement and instrument design. J Wound Ostomy Continence Nurs. 2010;37(6):603-7.

APÊNDICE

Apêndice – Artigo: Psychometric properties of an oral health literacy scale for people living with diabetes

Andrea Maria Eleutério de Barros Lima Martins

Teacher of Department of Dentistry, Graduate Program in Health Sciences, Center of Health and Biological Sciences, Universidade Estadual de Montes Claros, Montes Claros, Minas Gerais, Brazil.

Email: martins.andrea.mebl@gmail.com / andrea.eleuterio@unimontes.br

Gizelton Pereira Alencar

Teacher of Faculdade de Saúde Pública, Universidade de São Paulo. São Paulo, SP, Brasil.

Email: gizelton@usp.br

João Gabriel Silva Souza

Teacher of Dentistry and the Post-Graduation Program in Dentistry and Orthodontics at Universidade de Guarulhos (UNG).

Email: jgabriel.ssouza@yahoo.com.br

Melissa Barral Maia

Teacher of Department of Dentistry Center of Health and Biological Sciences, Universidade Estadual de Montes Claros, Montes Claros, Minas Gerais, Brazil

Email: melissa.barral@yahoo.com.br / melissa.maia@unimontes.br

Marise Fagundes Silveira

Teacher of Department of Exact Sciences, Graduate Program in Health Sciences, Center of Health and Biological Sciences, Montes Universidade Estadual de Montes Claros, Montes Claros, Minas Gerais, Brazil

Email: marise.silveira@unimontes.br / ciaestatistica@yahoo.com.br

Maria Barros Lima Martins

Dentistry course student at the Universidade Federal de Minas Gerais (UFMG). Belo Horizonte, MG, Brasil.

Email: maria.b.l.m@hotmail.com

Paula Karoline Soares Farias

PhD student in Health Sciences, Graduate Program in Health Sciences, Universidade Estadual de Montes Claros, Montes Claros, MG, Brasil.

Email: paulak.soares@hotmail.com

Raquel Conceição Ferreira

Teacher of Dentistry at Universidade Federal de Minas Gerais (UFMG). Belo Horizonte, MG, Brasil.

Email: raquelconceicaoferreira@gmail.com

Thaísa Soares Crespo

PhD student in Health Sciences, Graduate Program in Health Sciences, Universidade Estadual de Montes Claros, Montes Claros, MG, Brasil.

Teacher of Department of Physiopathology, Center of Health and Biological Sciences, Universidade Estadual de Montes Claros, Montes Claros, Minas Gerais, Brazil.

Email: thaisacrespo@gmail.com>

Author for correspondence

Andrea Maria Eleutério de Barros Lima Martins

Avenida Dr. Ruy Braga, S/N - Vila Mauriceia, Montes Claros - MG, 39401-089 Telephone: +55 (38) 3224- 8372. E-mail: martins.andrea.mebl@gmail.com / andrea.eleuterio@unimontes.br

CONFLICT OF INTEREST: there is no conflict of interest between the authors.

CONTRIBUTION OF THE AUTHORS

Andrea Maria Eleutério de Barros Lima Martins, idealization and design of all phases of the manuscript, writing and critical review of the content of the manuscript and final approval of the version to be published.

Gizelton Pereira Alencar, statistical analysis and manuscript writing.

João Gabriel Silva Souza, statistical analysis and manuscript writing.

Melissa Barral Maia, idealization, data collection, statistical analysis and manuscript writing.

Marise Fagundes Silveira, analysis and interpretation of data.

Maria Barros Lima Martins, writing and reviewing the manuscript.

Paula Karoline Soares Farias, data collection, statistical analysis and manuscript review.

Raquel Conceição Ferreira, statistical analysis and manuscript writing.

Thaísa Soares Crespo, statistical analysis and manuscript writing.

LOGISTICAL AND FINANCIAL SUPPORT

Abstract

Objective: since health literacy concept should consider the access to information, understand/appraise and apply, this study evaluated the construct validity of the instrument Oral Health Literacy among people living with diabetes based on these domains. Methods: a probabilistic random sample of 239 people diagnosed with diabetes from an infinite population answered the 10 items of the questionnaire in an interview setup. The structural and convergent validity was assessed by confirmatory factor analysis and goodness of fit, chi-square per degrees of freedom ratio (X^2/df), Comparative Fit Index (CFI), Goodness-of-Fit Index (GFI), and Root-Mean-Square Error of Approximation (RMSEA). Convergent validity was estimated by the Average Variance Extracted (AVE) and Composite Reliability (CR). The scores were dichotomized with the upper limit of the 95% confidence interval as the cutoff point. Results: all first and second order unidimensional, bidimensional, and three-dimensional models presented good quality parameters: X^2/df = 3.219 / 3.286 / 2.875 / 2.459; CFI = 0.979 / 0.979 / 0.984 / 0.988; GFI = 0.924 / 0.925 / 0.937 / 0.947 and poor value for RMSEA = 0.097 / 0.098 / 0.089 / 0.078, respectively. Convergent validity was adequate; the AVE ranged from 0.5317-0.6675 and the CR from 0.677-0.965. Low literacy prevalence ranged from 43.1 to 48.1%. Conclusions: three dimensions (access, understand/appraise and apply) were identified and the instrument showed structural and convergent validity, in addition to good understandability.

Most of the evaluated models presented adequate goodness-of-fit parameters and the three-dimensional model presented higher quality.

Key Words: Psychometrics. Reliability and Validity. Oral Health. Health Education, Dental. Diabetes Mellitus. Health Literacy.

Introduction

Health Literacy involves personal, cognitive, and social skills to access, understand, evaluate, and apply information for health promotion, disease prevention, and maintenance of good health conditions, according to the theoretical model presented by Sørensen and collaborators in 2012[1]. Despite a focus on individual skills for making appropriate health decisions, a shift from the individual to a social focus is needed for better results, considering the interaction between individual skills and the demands of the health system. Health Literacy allows people to have greater control over their health with their individual and social aspects and the environmental determinants of health. The purpose of health literacy is to form and orient peoples' values, transforming knowledge and understanding about healthcare. Therefore, expanding access to information and improving the understanding of health-related issues is crucial for improving personal and community health outcomes[1,2].

The World Health Organization (WHO) has proposed an evidence-based global strategy for diet, physical activity, and health information[3]. The approval and implementation of this strategy creates opportunities for health promotion and prevention of chronic non-communicable diseases[4], resulting in lower costs for society[5]. Low levels of Health Literacy are associated with complications of many diseases, including to diabetes. Health policies should address the social determinants of health[6] and promote interventions that aim the causes

of diseases and the mechanisms by which social contexts affect health. These mechanisms can be modified by specific actions aimed at minimizing health inequities. Among the modifiable social determinants, access to preventive health measures[7] stands out, especially those aimed at preventing complications of chronic diseases, which include increasing health literacy.

Diabetes is a complex and multifactorial chronic disease, currently considered a global epidemic. It is estimated that Brazil in the year 2025 will rank 6th among countries with the highest number of diabetes cases, with 10.7 affected people per million[8]. As a disease that develops throughout people's lives, diabetes and related complications have some preventable factors. The factors associated with type 2 diabetes (the most prevalent type) are potentially modifiable, including financial and non-financial factors at the individual level (access to care and information) and at the healthcare system level (patient tracking and treatment guideline adherence). A healthy lifestyle and access to information based on scientific evidence are important to reduce the preventable burden of diabetes and minimize complications[9]. As the level of Health Literacy is correlated with diabetes knowledge and its prevention and treatment measures, it is important to effectively assess the level of Health Literacy of the community, and explore which interventions can promote health[10].

People living with diabetes are more susceptible to oral diseases, including periodontal disease that has a bi-directional relationship with diabetes[11]. Efforts to increase primary prevention, improve the quality of care, reduce costs, and reduce inequalities in oral health could benefit from improvements in Oral Health Literacy. Actions for oral health literacy must be offered in several contexts, especially in health services by health professionals and public policy makers [12]. Low levels of Oral Health Literacy are linked to worse general and oral health outcomes[13], and educational actions and the consequent empowerment of patients with diabetes may contribute to the prevention of oral diseases.

To evaluate the Oral Health Literacy among people living with Diabetes (OHLD) a questionnaire/scale was developed[14] (ref). The tool is applied in an interview, and it has 10 questions, with responses on a Likert-type scale. The quality of this instrument was previously assessed using content validity and reliability (internal consistency and reproducibility) parameters[14]. However, the dimensional structure of the instrument must be assessed to verify its construct validity and to improve its understanding in different settings and populations. Several studies and systematic reviews have evaluated health literacy or related interventions among people with diabetes [15-16]. However, investigations that address Oral Health Literacy are scarce[17,18] and no study was found on the quality and psychometric properties of an oral health literacy instrument for people with diabetes[19] considering its dimensional structure.

According to the theoretical model proposed by Sørensen and collaborators, evaluations on Health Literacy must consider four conceptual dimensions: access, understanding, evaluation and application of health-related information[1]. Thus, the purpose of this study was to evaluate the quality of the OHLD and investigate its dimensional structure, convergent validity, and understandability, based on the Sørensen model.

Materials and Methods

Ethical aspects

The study was carried according to the ethical principles of Resolution 196/96 of the National Health Council, and the Declaration of Helsinki. The protocol was approved and registered by the National Research Ethics Commission (CONEP) (protocol: 34687414.0.0000.5146).

Sampling procedure

A cross-sectional study was carried out among people diagnosed with diabetes under treatment by the public health service in a medium-size municipality (400,000 inhabitants) in northern Minas Gerais, Brazil. A probabilistic random sample was estimated for an infinite population considering a prevalence of 50% (p = 0.50), q = 1-p, (q = 0.50), an error (E) of 0.07; Z-value = 1.96, to achieve a 95% confidence. By adding a 10% to account for missing data, a sample of 250 was calculated (n = 227 + 23 = 250). Participants were randomly selected from two primary health care units among the 73 units in the region. The selected units provide care to users from seven Family Health Strategy groups, the primary healthcare provider system adopted by the Brazilian Unified Health System[20]. The following inclusion criteria were considered: having a diagnosis of diabetes, being 18 years old or older, and being registered in the Family Health Strategy system. All users of the two randomly selected health units were invited to participate, and those who accepted were interviewed by trained researchers.

Diabetes diagnosis

The diagnosis of diabetes was confirmed by the medications used or by laboratory tests as proposed by the American Diabetes Association: fasting plasma glucose ≥126 mg/dL; 2-h plasma glucose ≥ 200 mg/dL; glycated hemoglobin ≥ 6.5%; and in patients with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥ 200 mg/dL[21].

Oral Health Literacy among people living with Diabetes (OHLD) scale

Three items of the questionnaire explore the access to information including: the information provider (doctor, dentist, nurse, community health agent, family or others), the issues of the information (dental caries, root canal treatment, gingival problems / gingival bleeding, bone loss / tooth mobility, plaque index, dental trauma, bruxism / clenching, oral cancer, dental prosthesis, implant dental, orthodontic treatment, and others), and the source of

the information (telephone, television, internet, radio, billboard, heard or viewed from others, newspaper, magazine, pamphlet / booklet, medication leaflet, medical prescription, mouthwash, toothpaste label and other text read). The first three questions regarding access were estimated considering five questions about the health professionals or people who passed on information about oral health, twelve questions about issues addressed, and seventeen questions about the sources of information, all with dichotomous (yes/no) answers. The responses of each category are summed and scores are given considering quintile approximate values in the case of merge values. The other seven items evaluate the understanding, appraisal, and application of the information and include questions about the level of importance of the information, if the quality and accuracy of the information is verifiable, if the advantages and disadvantages of different oral health treatments could be identified, and if the respondent incorporated the information on daily life, making appropriate choices based on the information received.

Statistical analysis

A descriptive analysis of the 10 items of the OHLD was performed to estimate the absolute and relative frequency (n, %), and the mean and standard deviation of the quantitative variables. Confirmatory Factor Analysis (AFC) analyzed the factorial structure of the OHLD. Factor loading ($\lambda \geq 0.50$) was used to assess factor variability and the chi-square to degrees of freedom ratio (X^2/df) was used to assess the goodness-of-fit of the model, with values less than 5 indicating an adequate model. The quality of the factorial model was assessed using the following parameters: Goodness-of-Fit Index (GFI), considered adequate if > 0.90, the Bentler's Comparative Fit Index (CFI), considered adequate if> 0.90, and Root-Mean-Square Error of Approximation (RMSEA), considered adequate if <0.05. One-dimensional, two-dimensional, and polydimensional models (according to statistical indication) of first and second order were estimated. Since the dimensions of the factorial model can generate a single construct, a

reflective model of analysis was proposed. The Software Statistical Package for Social Sciences (SPSS) version 24.0 (IBM) was used in the descriptive analyzes and the SPSS Analysis of Moment Structures (AMOS) module was used for CFA. Convergent validity was estimated by Average Variance Extracted (AVE) and Composite Reliability (CR). AVE values ≥ 0.5 and CR ≥ 0.7 were considered adequate[22,23]. Internal consistency was estimated using Cronbach's Alpha.

The OHLD overall and subscale scores, considering the different models, were estimated using the weighted sum method, based on the estimates of the scores generated in the CFA. Next, exploratory analyses of the scores were conducted, estimating the minimum and maximum values, the average distribution, standard deviation and 95% confidence intervals (95% CI) of the generated scores. The scores can be interpreted in a quantitative or categorical way by dichotomization taking the upper limit of the 95% CI as the cutoff point, creating the categories "adequate" and "inadequate". Then, the absolute values and percentages of the categories were estimated.

Results

A total of 239 people participated in the study (response rate = 95.6%). The mean age was 61.42 (SD 12.85), ranging from 22 to 92 years, and 95%CI of 59.86 to 62.98. Mean formal education was 7.98 years (SD = 4.6, 95%CI = 7.39-8.57), ranging from 0 to 28 years. The majority (72%) received information related to oral health. The descriptive analysis of the OHLD scale are shown in Table 1.

The unidimensional model, bi-dimensional model, and first and second order three-dimensional models from the hierarchical CFA of the OHLD are shown in Figures 1A and B and 2A and B. The figures describe the values of the standardized factor loading of the items in the model adjusted according to the latent dimensions and their correlations.

The unidimensional, bidimensional, and three-dimensional models of first and second order presented X^2/df values that varied from 2.5 to 3.3, CFI that ranged from 0.979 to 0.988, and GFI from 0.924 to 0.946. The RMSEA values ranged from 0.078 to 0.098. The unidimensional, bidimensional, and three-dimensional models presented AVE values that varied from 0.66 to 0.94 and CR that varied from 0.85 to 0.98 (Table 2). A 0.967 Cronbach's Alpha was obtained. Three dimensions (access, understand/appraise and apply) were identified and the instrument showed proper structural and convergent validity, and good understandability. Three-dimensional model presented higher quality based on X^2/df, CFI and GFI values and was considered the best model.

The OHLD overall and subscales scores (access, appraisal, understanding and application) with their minimum and maximum values, means, standard deviation, and 95%CI are shown in Table 3. The data were dichotomized considering the upper limit of the 95% CI as the cutoff point. In addition, the absolute and relative frequencies of inadequate literacy are presented.

Figure 1. One-dimensional model (Figure 1A) and two-dimensional model (Figure 1B) of the

Oral Health Literacy among people with Diabetes questionnaire.
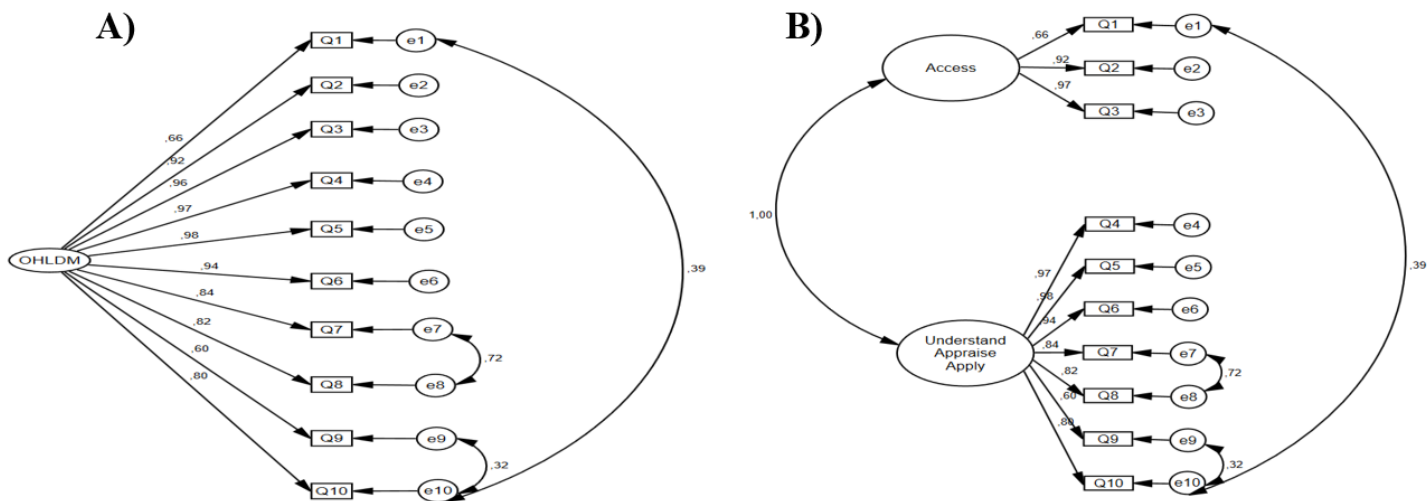
Figure 2. First-order three-dimensional model (Figure 2A) and second-order three-dimensional

model (Figure 2B) of Oral Health Literacy among people with Diabetes questionnaire.
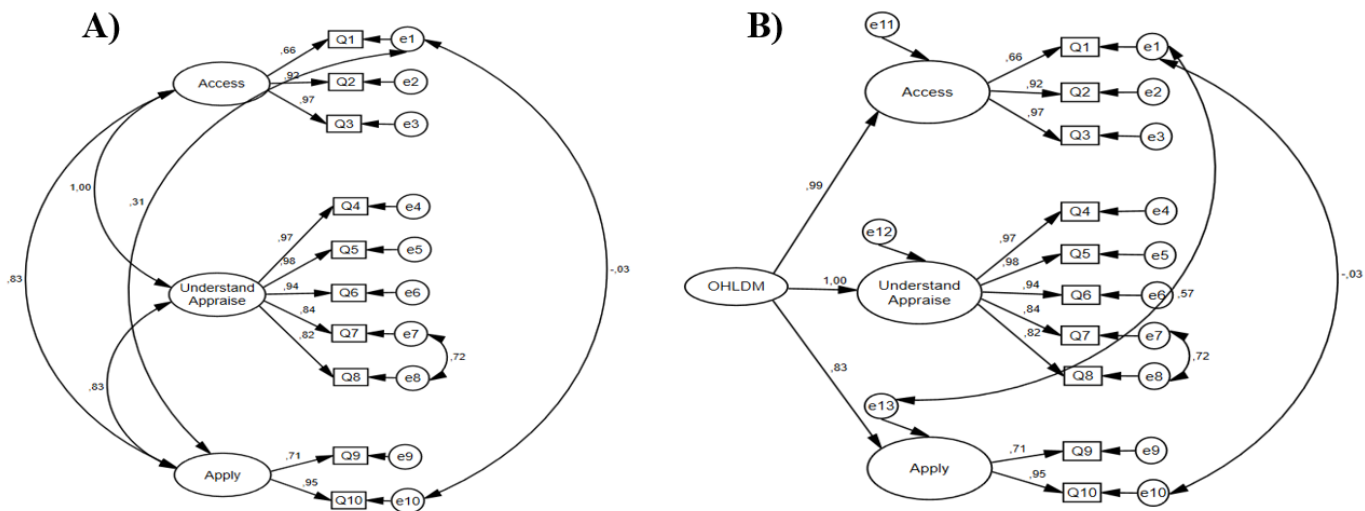
Table 1. Description of the responses to each item of the instrument among individuals with diabetes.

Variable	n	%
OHLD		
Q1 Number of professionals/people who provided information on Oral Health		
0 Never received information of professionals/people	81	33,9
1	107	44,8
2	34	14,2
3	6	2,5
4	11	4,6
Q2 Number of issues covered in the information on Oral Health		
Never received information of issues	70	29,3
1 to 2	25	10,5
3 to 5	49	20,5
6 to 9	59	24,7
10 to 12	36	15,1
Q3 Number of media from which information on oral health was obtained		
Never received information of source	91	38,1
1	37	15,5
2	25	10,5
3 to 6	47	19,7

7 to 16	39	16,3

Q4 Did you understand the oral health information that was presented

Never received information of professionals/people, issues or source	67	28,0
Did not understand / Understood very little	13	5,4
Understood partially	28	11,7
Understood almost everything	37	15,5
Understood everything	94	39,3

Q5 Can you classify the information you have received about oral health into more or less important?

Never received information of professionals/people, issues or source	67	28,0
Cannot / Yes, but is very difficult	20	8,4
Yes, with difficulty	19	7,9
Yes, with little difficulty	22	9,2
Yes, easily	111	46,4

Q6 Can you identify whether the information you have received about oral health is of good quality?

Never received information of professionals/people, issues or source	67	28,0
Cannot / Yes, but is very difficult	21	8,8
Yes, with difficulty	19	7,9
Yes, with little difficulty	13	5,4
Yes, easily	119	49,8

Q7 Can you assess whether the information you have received about oral health is true or false?

Never received information of professionals/people, issues or source	67	28,0
Cannot / Yes, but is very difficult	20	8,4
Yes, with difficulty	15	6,3
Yes, with little difficulty	16	6,7
Yes, easily	121	50,6

Q8 Can you evaluate the advantages and disadvantages of different oral treatments, considering the information you have received?

Never received information of professionals/people, issues or source	67	28,0
Cannot / Yes, but is very difficult	24	10,0
Yes, with difficulty	20	8,4
Yes, with little difficulty	26	10,9
Yes, easily	102	42,7

Q9 Do you put into practice the information you received about oral health in your daily life?

Never received information of professionals/people, issues or source	67	28,0
Never / Rarely	12	5,0
Sometimes	43	18,0
Often	30	12,6
Always	87	36,4

Q10 Do you maintain a healthy behavior, considering the information you received about Oral Health?

Never received information of professionals/people, issues or source	67	28,0
Never / Rarely	10	4,2

Sometimes	40	16,7
Often	33	13,8
Always	89	37,2

Table 2 Analysis of goodness-of-fit of the dimensional structures of Oral Health Literacy among people with Diabetes questionnaire.

Model	X2/df	CFI	GFI	RMSEA	AVE	CR
One-dimensional	3.219	0.979	0.924	0.097	0.5658	0.965
Two-dimensional	3.286	0.979	0.925	0.098		
Factor 1 - Access					0.5327	0.893
Factor 2 - Understand/ appraise / apply					0.5843	0.951
Tri-dimensional – 1st Order	2.875	0.984	0.937	0.089		
Factor 1 - Access					0.5317	0.893
Factor 2 - Understand/ appraise					0.6442	0.962
Factor 3 - Apply					0.6675	0.804
Tri-dimensional – 2nd Order	2.459	0.988	0.946	0.078		
Factor 1 - Access					0.5317	0.802
Factor 2 - Understand/ appraise					0.6442	0.924
Factor 3 - Apply					0.6675	0.677

X^2/df: chi-square for degree of freedom ratio; CFI: *Comparative Fit Index;* GFI: *Goodness-of-Fit Index*; RMSEA: *Root-Mean-Square Error of Approximation;* AVE: *Average Variance Extracted;* CR: *Composite Reliability*

Table 3. Overall scores of the Oral Health Literacy among people with Diabetes questionnaire for the 2nd order three-dimensional model and dimension (access, appraise / understand, and apply) scores in the 1st order three-dimensional model, with minimum and maximum values, means, standard deviation, 95%CI, and understandability.

Score	Minimum	Maximum	Mean	SD	95% CI	Interpretation 95%CI cut-off	Poor literacy	
							n	%
OHLD	0.00	2.43	1.4377	1.0120	1.3088-1.5667	1.5667	103	43.1
Access	0.00	2.45	1.4415	1.0137	1.3123-1.5707	1.5707	103	43.1
Understand/appraise	0.00	4.10	2.4185	1.7026	2.2015-2.6355	2.6355	103	43.1
Apply	0.00	2.08	0.9269	0.6848	0.8397-1.0142	1.0142	115	48.1

Discussion

The evaluation of the psychometric properties and the quality of instruments for the assessment of health-related outcomes, such as the OHLD, is important to ensure the adequate measure of the construct[19]. Validation studies are often incomplete, lacking for example, CFA, which is necessary to establish construct validity. This study evaluated different dimensional structures of the OHLD and verified the quality of the different models that best represent the construct through the factorial and convergent validity. In addition, the different possibilities for score interpretation for the construct and its dimensions were presented.

The values of the standardized factor loadings of the items in the one-, two-, and three-dimensional models were adequate, indicating that different dimensional structures could be used for the OHLD, as previously proposed[14]. The models showed high goodness of fit, except for the RMSEA values. However, in this research, the second-order three-dimensional model presented the best fit, and it should be the model applied for measuring the construct "Oral Health Literacy among people living with Diabetes". Acceptable values for convergent validity were identified in all tested models, and we found that the hierarchical models were more parsimonious, thus this methodological proposal[22] is indicated for measuring the theoretical concept with the best quality.

The "apply" dimension of the scale had a low influence of item 1 (number of professionals / people who provided information on oral health). It is may explained by the prevalence of people who never received oral health information or received it from a single person or from a maximum of four people, which may limit the quality and amount of information received and, consequently, adequate health behaviours. Previous research has shown that communication between dentists and patients plays an important role in the self-perception of treatment need, in the use of dental services[24,25], and consequently increase the chance of adopting healthy behaviors and having better health conditions.

Low levels of oral health literacy among people living with diabetes can contribute to the worsening of the disease. Diabetes can affect oral health, and it is up to the dentist to observe and alert diabetic patients about this association[26]. Poorly controlled diabetes can affect oral tissues in a similar way to what happens in other systems of the body[27]. Additionally, it is biologically plausible that chronic unresolved inflammation in the oral cavity has an impact on diabetes control. Significant independent associations between periodontal inflammation, glycemic condition, and complications of diabetes were found[28].

An instrument that assesses oral health literacy in people with diabetes was not found in the literature. The OHLD, using hierarchical measures, can be used in this specific population where the improvement of oral health can reflect in an improvement in the systemic condition[28]. The evaluation of the OHLD psychometric properties, quality, and understandability allows the future use of this instrument and guarantees reliable and valid conclusions, including the high internal consistency of the scale evaluated by Cronbach's alpha[19].

The overall OHLD scores and the scores of the access, appraisal, understanding, and application dimensions can be interpreted using statistical parameters (minimum and maximum values, means, standard deviation and 95% CI). However, the dichotomized score is also adequate and may be used to identify the profile of people living with diabetes whose levels of oral health literacy need to be assessed.

With an inclusive and integrative proposal, health literacy is one of the most promising approaches for improving public health outcomes, and essential to meet the challenging health demands of modern society[29]. Health literacy involves the knowledge, motivation, and competence of people to access, understand, evaluate, and apply health information in order to make informed judgments and allow good decision-making in self-care and in the community, social, cultural, economic and political spheres. Possible factors dynamically

associated with health literacy were presented in the model proposed by Sørensen and collaborators in 2012. Some of the factors are unchallengeable but others can be modified by health policies such as promotion of health service use, managing health costs, promotion of health-related behaviors, improving health outcomes, people's participation and empowerment in health care, equity and maintenance of health education actions in health services, disease prevention, and health promotion[1]. Within this context, the validation of the OHLD allows its use in the clinical and research scenarios aimed at improving health conditions. As education and communication are fundamental to health literacy, the use of the OHLD contributes to the identification of modifiable variables with bidirectional effects on health literacy. These effects can be complex and should be the target of future research on disease prevention and health promotion strategies[1].

As a limitation, our results could not be compared with the literature, since our methodological approach and statistical analysis have been rarely used in the field of dentistry[30]. The use of the maximum likelihood method, implemented by the AMOS software, can be considered another limitation, since it requires univariate and multivariate data normality and continuous variables. However, even in severe cases of data normality violation, the maximum likelihood method produces centered estimates, that is, estimates that tend towards the true population value, although their statistical significance tends to be inflated[24]. On the other hand, for this analysis approach, when data violate the assumption of multivariate normality, a generally accepted rule is having 10 to 20 respondents per item [23], which was considered in the OHLD analysis.

The OHLD can be used considering the four dimensional structures, which demonstrated factorial and convergent validity, reliability, and understandability. The first and second order three-dimensional models showed the best parameters. The overall scores and dimension scores, considering the weights for each item, can be used as needed. It is hoped

that the instrument can serve as a basis for future studies that aim to investigate this construct in different populations.

References

1.   Sørensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, et al. Health literacy and public health: a systematic review and integration of definitions and models. BMC Public Health. 2012;12:80.

2.   Nutbeam D. The evolving concept of health literacy. Soc Sci Med. 2008;67:2072-78.

3.   World Health Organization (WHO). Global strategy on diet, physical activity and health. Fifty-seventh world health assembly [WHA57.17] [Internet]. 2004 [cited 2021 Jan 06]; [about 38-55 p.]. Available from: https://apps.who.int/gb/ebwha/pdf_files/WHA57/A57_R17-en.pdf

4.   Barreto SM, Pinheiro ARO, Sichieri R, Monteiro CA, Batista Filho M, Schimidt MI, et al. Análise da estratégia global para alimentação, atividade física e saúde, da Organização Mundial da Saúde. Epidemiol Serv Saúde. 2005; 14(1):41-68.

5.   Selby JV, Ray GT, Zhang D, Colby CJ. Excess costs of medical care for patients with diabetes in a managed care population. Diabetes Care. 1997;20(9):1396-402.

6.   World Health Organization (WHO). A conceptual framework for action on the social determinants of health. Geneve: Commission on Social Determinants of Health. [Internet]. 2007 [cited 2021 Jan 06]; [about 1-77 p.]. Available from: https://www.who.int/social_determinants/resources/csdh_framework_action_05_07.pdf

7.   Geib LTC. Determinantes sociais da saúde do idoso. Ciênc. Saúde Colet. 2012; 17(1):123-33.

8.   International Diabetes Federation (IDF). Diabetes Atlas, 7th edn. Brussels, Belgium. [Internet]. 2015 [cited 2021 Jan 06]; [about 1-140 p.]. Available from: https://www.diabetesatlas.org/upload/resources/previous/files/7/IDF%20Diabetes%20Atlas %207th.pdf

9.   Narayan KM, Gregg EW, Fagot-Campagna A, Engelgau MM, Vinicor F. Diabetes - a common, growing, serious, costly, and potentially preventable public health problem. Diabetes Res Clin Pract. 2000; 50(2):S77-S84.

10.   Bailey SC, Brega AG, Crutchfield TM, Elasy T, Herr H, Kaphingst K, et al. Update on health literacy and diabetes. Diabetes Educ. 2014;40(5):581-604.

11.   Lalla E, Papapanou PN. Diabetes mellitus and periodontitis: a tale of two common interrelated diseases. Nat Rev Endocrinol. 2011;7(12):738-48.

12.   Horowitz AM, Kleinman DV. Oral health literacy: a pathway to reducing oral health disparities in Maryland. J Public Health Dent. 2012;72(1):S26-S30.

13.   Macek MD, Haynes D, Wells W, Bauer-Leffler S, Cotten PA, Parker RM. Measuring conceptual health knowledge in the context of oral health literacy: preliminary results. J Public Health Dent. 2010;70(3):197-204.

14.   Martins AMEBL, Amorim MMTA, Carvalho BO, Pinto RA, Fróes DTC, Santos ASF. Development, judgment of the validity and reliability of an instrument of assessment of Oral Health Literacy among diabetics. RGO, Rev. Gaúch. Odontol. 2020;68:e20200039.

15. Jacobs RJ, Lou JQ, Ownby RL, Caballero J. A systematic review of eHealth interventions to improve health literacy. Health Informatics J. 2016;22(2):81-98.

16. Caruso R, MAgon A, Baroni I, Dellafiore F, Arrigoni C, Pitella F, Ausll D. Health literacy in type 2 diabetes patients: a systematic review of systematic reviews. Acta Diabetol. 2017; 55(1), 1-12.

17. Junkes MC, Fraiz FC, Sardenberg F, Lee JY, Paiva SM, Ferreira FM. Validity and reliability of the Brazilian version of the Rapid Estimate of Adult Literacy in Dentistry: BREALD-30. PLoS ONE, 2015;10(7):e0131600.

18. Bado FMR, Rebustini F, Jamieson L, Cortellazzi KL, Mialhe FL. Evaluation of the psychometric properties of the Brazilian version of the Oral Health Literacy Assessment in Spanish and development of a shortened form of the instrument. PloS one. 2018;13(11): e0207989.

19. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res. 2010;19(4):539-49.

20. Paim J, Travassos C, Almeida C, Bahia L, Macinko J. The Brazilian health system: history, advances, and challenges. Lancet. 2011;377(9779):1778-97.

21. American Diabetes Association (ADA). 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes-2021. Diabetes Care. 2021;44(1): S15-S33.

22. Hair JF, Black WC, Babin B, Anderson RE, Tatham RL (2005). Multivariate data analysis, 6th ed. New York City, NY: Prentice Hall.

23. Maroco J. Análise de Equações Estruturais: Fundamentos teóricos, software & aplicações. Pêro Pinheiro: Edição em Português. 2010.

24. Martins AMEBL, Barreto SM, Pordeus IA. Fatores relacionados à autopercepção da necessidade de tratamento odontológico entre idosos. Rev Saúde Pública 2008;42:487-96.

25. Schönwetter DJ, Wener ME, Mazurat N. Determining the validity and reliability of clinical communication assessment tools for dental patients and students. J Dent Educ. 2012;76(10):1276-90.

26. Nelson RG. Periodontal disease and diabetes. Oral Dis. 2008;14(3):204-5.

27. Taylor GW, Burt BA, Becker MP, Genco RJ, Shlossman M, Knowler WC, et al. Severe periodontitis and risk for poor glycemic control in patients with non-insulin-dependent diabetes mellitus. J Periodontol. 1996;67(10):1085-93.

28. Chapple ILC, Genco R, working group 2 of the joint EFP/AAP workshop. Diabetes and periodontal diseases: consensus report of the Joint EFP/AAP Workshop on Periodontitis and Systemic Diseases. J Periodontol. 2013;84(4):S106-12.

29. Pleasant A. Advancing health literacy measurement: a pathway to better health and health system performance. J Health Commun. 2014;19(12):1481-96).

30. Zucoloto ML, Maroco J, Campos JA. Psychometric Properties of the Oral Health Impact Profile and New Methodological Approach. J Dent Res. 2014;93(7):645-50.

ANEXOS

ANEXO A - Parecer consubstanciado do Comitê de Ética e Pesquisa

UNIVERSIDADE ESTADUAL DE
MONTES CLAROS -
UNIMONTES

Plataforma Brasil

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação do impacto de ações educativas nos níveis de alfabetização em saúde entre idosos cadastrados na Estratégia Saúde da Família: um ensaio randomizado

Pesquisador: Andréa Maria Eleutério de Barros Lima Martins
Área Temática:
Versão: 1
CAAE: 54417616.1.0000.5146
Instituição Proponente: Universidade Estadual de Montes Claros - UNIMONTES
Patrocinador Principal: CNPQ

DADOS DO PARECER

Número do Parecer: 1.461.818

Apresentação do Projeto:
O envelhecimento populacional e a consequente transição epidemiológica demandam uma reorganização da sociedade e dos serviços de saúde.Nesse sentido, propõe-se avaliar o impacto de atividades educativas multiestratégicas e interprofissionais nos níveis de "alfabetização em saúde" dos idosos cadastrados na Estratégia de Saúde da Família. Será conduzido um ensaio randomizado em uma amostra probabilística a ser estimada após condução do estudo piloto. Serão coletados dados entre idosos alocados de forma randômica em dois grupos: grupo intervenção e grupo controle.

Objetivo da Pesquisa:
Avaliar, através de ensaio randomizado, o impacto de atividades educativas multiestratégicas e interprofissionais nos níveis de "alfabetização em saúde" entre idosos cadastrados na Estratégia de Saúde da Família-ESF.

Avaliação dos Riscos e Benefícios:
Os principais riscos previsíveis são: perda de privacidade das informações obtidas nas entrevistas ou eventuais acidentes de punção durante a coleta do sangue (material biológico). Para minimizar estes riscos a coleta de sangue será conduzida por profissionais habilitados e experientes e as

Endereço: Av.Dr Rui Braga s/n-Camp Univers Profº Darcy Rib
Bairro: Vila Mauricéia   **CEP:** 39.401-089
UF: MG   **Município:** MONTES CLAROS
Telefone: (38)3229-8180   **Fax:**   (38)3229-8103   **E-mail:** smelocosta@gmail.com

UNIVERSIDADE ESTADUAL DE MONTES CLAROS - UNIMONTES

Continuação do Parecer: 1.461.818

informações serão manuseadas apenas pela equipe de pesquisadores. Durante a implementação das intervenções devem ser considerados os riscos relacionados à atividade física, que seriam, principalmente, a possibilidade de

quedas ou fenômenos isquêmicos. Os participantes serão submetidos às atividades somente após consentimento médico, sendo monitorados a todo o tempo por um profissional.

São esperados os seguintes benefícios: os resultados poderão subsidiar políticas de saúde apropriadas às reais condições de saúde dos diabéticos e hipertensos cadastrados na ESF do município com o intuito de melhorar a qualidade de vida dos mesmos, acredita-se que a participação nas atividades educativas e físicas, dentre outras poderão melhorar a qualidade de vida e condição de saúde.

Comentários e Considerações sobre a Pesquisa:

Pesquisa relevante na área da saúde, com ênfase na avaliação de impacto de atividades educativas para idosos. O estudo tem como hipótese que as intervenções educativas multiestratégicas e interprofissionais apresentarão impactos nos indicadores e índices avaliados junto aos idosos. E conta com financiamento do CNPq.

Considerações sobre os Termos de apresentação obrigatória:

Todos os termos foram apresentados e estão em consonância com os preceitos éticos da pesquisa envolvendo seres humanos.

Recomendações:

Apresentação de relatório final por meio da plataforma Brasil, em "enviar notificação".

Conclusões ou Pendências e Lista de Inadequações:

Projeto aprovado.

Considerações Finais a critério do CEP:

O projeto respeita os preceitos éticos da pesquisa envolvendo seres humanos, sendo assim somos favoráveis à aprovação do mesmo.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações	PB_INFORMAÇÕES_BÁSICAS_DO_P	19/03/2016		Aceito

Endereço: Av.Dr Rui Braga s/n-Camp Univers Profº Darcy Rib
Bairro: Vila Mauricéia   **CEP:** 39.401-089
UF: MG   **Município:** MONTES CLAROS
Telefone: (38)3229-8180   **Fax:** (38)3229-8103   **E-mail:** smelocosta@gmail.com

UNIVERSIDADE ESTADUAL DE MONTES CLAROS - UNIMONTES

Continuação do Parecer: 1.461.818

Básicas do Projeto	ETO_659735.pdf	18:36:17		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Biobanco.pdf	19/03/2016 18:34:46	Andréa Maria Eleutério de Barros Lima Martins	Aceito
Outros	TermosDeConcessao.pdf	15/03/2016 00:45:11	Árlen Almeida Duarte de Sousa	Aceito
Declaração de Instituição e Infraestrutura	TCI.jpg	15/03/2016 00:44:32	Árlen Almeida Duarte de Sousa	Aceito
Folha de Rosto	Folha_de_Rosto.pdf	15/03/2016 00:43:33	Árlen Almeida Duarte de Sousa	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Detalhado.docx	10/03/2016 10:15:35	Árlen Almeida Duarte de Sousa	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

MONTES CLAROS, 22 de Março de 2016

_____

Assinado por:
SIMONE DE MELO COSTA
(Coordenador)

ANEXO B - Termo de Consentimento Livre e Esclarecido

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO PARA PARTICIPAÇÃO EM PESQUISA

Título da pesquisa: Avaliação do impacto de ações educativas nos níveis de alfabetização em saúde entre adultos e idosos cadastrados na Estratégia Saúde da Família: um ensaio randomizado

Instituição responsável: Universidade Estadual de Montes Claros – UNIMONTES.

Instituição onde será realizada a pesquisa: Unidades de saúde da ESF / Secretaria Municipal de Saúde de Montes Claros – MG.

Pesquisadora responsável: Andrea Maria Eleutério de Barros Lima Martins

Endereço Avenida Rui Braga SN Vila Mauricéia Montes Claros Minas Gerais / Departamento de Odontologia / 3229 8284

E-mail: martins.andreamebl@gmail.com – **Telefone:** (38) 3 229 8284

Este é um convite para o(a) Sr(a). participar da pesquisa "Avaliação do impacto de ações educativas nos níveis de alfabetização em saúde entre adultos e idosos cadastrados na Estratégia Saúde da Família: um ensaio randomizado", coordenado por Andrea Maria Eleutério de Barros Lima Martins e que segue as recomendações da resolução 466/12 do Conselho Nacional de Saúde e suas complementares. O estudo será realizado nas Estratégias de Saúde da Família (ESF) da cidade de Montes Claros-Minas Gerais. Sua participação é voluntária, o que significa que o(a) Sr(a). poderá desistir a qualquer momento, retirando seu consentimento, sem que isso lhe traga qualquer prejuízo ou penalidade.

O objetivo deste estudo é avaliar o impacto de atividades educativas multiestratégicas e interprofissionais nos níveis de "alfabetização em saúde" entre adultos e idosos cadastrados na ESF. Caso decida aceitar o convite, o(a) Sr(a). será submetido(a) ao(s) seguinte(s) procedimentos: responder as entrevistas, contendo perguntas relacionadas ao seu estado de saúde; permitir que os pesquisadores realizem a avaliação de suas medidas pregas cutâneas, quadril, cintura, peso, altura e pressão arterial. Deverá ainda comparecer a um laboratório de análises clinicas e/ ou a unidade de saúde da Estratégia de Saúde da Família, em data e horário marcado para que seja realizado exame de sangue. Após o processo de coleta de dados e do sangue, você será motivado a participar das atividades educativas em saúde, assim como de atividades físicas dentre outras atividades que serão desenvolvidas em um período temporal a ser definido. Em seguida, todos os dados coletados no primeiro momento, serão novamente coletados pelos pesquisadores. Destaca-se que o material biológico será armazenado no

Biobanco da Universidade Estadual de Montes Claros - Unimontes para fins de pesquisa, conforme normas técnicas, éticas e operacionais pré-definidas, sob responsabilidade e gerenciamento institucional, sem fins comerciais.

Como toda pesquisa oferece algum tipo de risco, nesta pesquisa os principais riscos previsíveis são: perda de privacidade das informações obtidas nas entrevistas ou eventuais acidentes de punção durante a coleta do sangue (material biológico). Para minimizar estes riscos a coleta de sangue será conduzida por profissionais habilitados e experientes e as informações serão manuseadas apenas pela equipe de pesquisadores. Durante a implementação das intervenções devem ser considerados os riscos relacionados à atividade física, que seriam, principalmente, a possibilidade de quedas ou fenômenos isquêmicos. Os participantes serão submetidos às atividades somente após consentimento médico, sendo monitorados a todo o tempo por um profissional.

São esperados os seguintes benefícios: os resultados poderão subsidiar políticas de saúde apropriadas às reais condições de saúde dos diabéticos e hipertensos cadastrados na ESF do município com o intuito de melhorar a qualidade de vida dos mesmos, acredita-se que a participação do(a) Sr(a). nas atividades educativas e físicas, dentre outras poderão melhorar a sua qualidade de vida e condição de saúde.

Todas as informações obtidas serão sigilosas e seu nome não será identificado em nenhum momento. Os dados serão guardados em local seguro e a divulgação dos resultados será feita de forma a não identificar os voluntários. Caso decida aceitar ceder o excedente de material biológico proveniente da coleta de sangue, gostaríamos de esclarecer você mais alguns pontos importantes:

- A coleta do sangue não envolverá riscos, além dos riscos esclarecidos pela equipe de saúde, para a realização do procedimento necessário ao seu tratamento, já definido pela equipe que está cuidando da sua saúde. - O material coletado (sangue) armazenado no biobanco será o excedente do procedimento realizado pela equipe de saúde.

- Através da doação, você estará contribuindo cedendo o material biológico necessário para a realização de pesquisas para melhor entender as causas e mecanismos das doenças.

- Quanto aos benefícios, a doação do material poderá favorecer a realização de pesquisas que buscam um melhor tratamento das doenças.

- Você terá direito ao acesso, a qualquer momento, aos resultados obtidos a partir do seu material biológico armazenado e às orientações quanto às suas implicações, incluindo o aconselhamento genético, quando aplicável. Para isso, você deverá entrar em contato com a equipe do biobanco através do endereço ou telefone de contato abaixo, informando o código de cadastro que você recebeu no ato da doação e, também, está escrito no seu cartão de cadastro, que ficou guardado com você:

Biobanco de Materiais Biológicos do norte de Minas Gerais / Laboratório de Pesquisa em Saúde - Hospital Universitário Clemente Faria – UNIMONTES / Av Cula Mangabeira, 562 - Bairro Santo Expedito, Montes Claros, MG - cep: 39401-001 / Telefone: (38) 3224-8327

Em qualquer momento, se você sofrer algum dano comprovadamente decorrente desta pesquisa, você terá direito a indenização.

Você ficará com uma via original deste Termo e toda a dúvida que você tiver a respeito desta pesquisa, poderá perguntar diretamente para Andrea Maria Eleutério de Barros Lima Martins, no endereço Avenida Rui Braga SN Vila Mauricéia Montes Claros Minas Gerais / Departamento de Odontologia / 3229 8284.

Se houver dúvidas sobre a ética da pesquisa entre em contato com o Comitê de Ética em Pesquisa da UNIMONTES: Campus Universitário Professor Darcy Ribeiro; Vila Mauricéia - Montes Claros – MG, Caixa Postal 126 - CEP 39401-089 Fone: (38) 3229-8000.

Consentimento Livre e Esclarecido

Estou de acordo com a participação e concordo em ceder o material biológico excedente, proveniente da coleta de sangue que será realizada devido à necessidade já definida pelo médico para o diagnóstico de alguma doença ou tratamento.

Estou de acordo com a participação no estudo descrito acima.

Fui devidamente esclarecido(a) quanto aos objetivos da pesquisa, aos procedimentos aos quais serei submetido e dos possíveis riscos que possam advir de tal participação.

Foram garantidos esclarecimentos caso eu venha a solicita-los durante o curso da pesquisa e o direito de desistir da participação em qualquer momento, sem que minha desistência implique em qualquer prejuízo a minha pessoa ou de minha família.

A minha participação na pesquisa não implicará em custos ou prejuízos adicionais, sejam esses custos ou prejuízos de caráter econômico, social, psicológico ou moral. Autorizo assim a publicação dos dados da pesquisa a qual me garante o anonimato e o sigilo dos dados referentes à minha identificação.

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO PARA PARTICIPAÇÃO EM PESQUISA

Título da pesquisa: Avaliação do impacto de ações educativas nos níveis de alfabetização em saúde entre adultos e idosos cadastrados na Estratégia Saúde da Família: um ensaio randomizado

Instituição responsável: Universidade Estadual de Montes Claros – UNIMONTES.

Instituição onde será realizada a pesquisa: Unidades de saúde da ESF / Secretaria Municipal de Saúde de Montes Claros – MG.

Pesquisadora responsável: Andrea Maria Eleutério de Barros Lima Martins

Endereço Avenida Rui Braga SN Vila Mauricéia Montes Claros Minas Gerais / Departamento de Odontologia / 3229 8284

E-mail: martins.andreamebl@gmail.com – **Telefone:** (38) 3 229 8284

Reutilização dos dados ou material biológico:

O material biológico coletado (amostra sanguínea) para este estudo ficará armazenado no Biobanco da UNIMONTES. Em relação à utilização deste material para outros estudos:

(   ) NÃO autorizo a utilização de dados ou material biológico (amostra sanguínea) em outra pesquisa. Então este material será descartado seguindo os protocolos de segurança determinados pelo próprio Biobanco.
(   ) SIM autorizo a utilização de dados ou material biológico (amostra sanguínea) em outra pesquisa.

Para utilização dos meus dados e material coletado (amostra sanguínea) em outra pesquisa:

(   ) NÃO preciso ser consultado da utilização dos meus dados ou material biológico em outra pesquisa, desde que a nova pesquisa seja aprovado pelo Comitê de Ética em Pesquisa,

(   ) SIM quero ser consultado da utilização dos meus dados ou material biológico em outra pesquisa.

Em caso de óbito ou alguma outra condição em que eu não possa dar o consentimento para

utilização   dos   meus   dados   em   outro   estudo,   autorizo

_____   a

consentir a utilização ou descarte de meu material biológico armazenado.

Descarte do Material Biológico: o material armazenado poderá ser descartado, seguindo-se normas específicas, somente após aprovação pelo COMITÊ DE ÉTICA E COMISSÃO NACIONAL DE ÉTICA EM PESQUISA. Poderá ainda ser descartado de acordo com manifestação da minha vontade.

Participante da pesquisa ou responsável legal:

Pesquisador responsável

Andréa Maria Eleutério de Barros Lima Martins

Andrea Maria Eleutério de Barros Lima Martins

Departamento de Odontologia / 3229 8284. / Avenida Rui Braga SN Vila Mauricéia Montes Claros Minas Gerais

Coordenador Geral do Biobanco

Dr. André Luiz Sena Guimarães

Laboratório de Pesquisa em Saúde - Hospital Universitário Clemente Faria - UNIMONTES

Av Cula Mangabeira, 562 - Bairro Santo Expedito, Montes Claros, MG - cep: 39401-001 / Telefone: (38) 3224-8327

Responsável técnico pela coleta e transporte do material coletado ao biobanco

ANEXO C - Termo de concordância da instituição para participação em pesquisa

Título da pesquisa: Avaliação do impacto de ações educativas nos níveis de alfabetização em saúde entre adultos e idosos cadastrados na Estratégia Saúde da Família: um ensaio randomizado

Instituição responsável: Universidade Estadual de Montes Claros – UNIMONTES.

Instituição onde será realizada a pesquisa: Unidades de saúde da ESF / Secretaria Municipal de Saúde de Montes Claros – MG.

Pesquisadora responsável: Andrea Maria Eleutério de Barros Lima Martins. E-mail: martins.andreamebl@gmail.com Fone: (38) 9 8828-8191

Endereço: Avenida Rui Braga SN Vila Mauricéia Montes Claros Minas Gerais / Departamento de Odontologia / 3229 8284

E-mail: martins.andreamebl@gmail.com – Telefone: (38) 8828-8191

Atenção: antes de aceitar participar desta pesquisa, é importante que o Sr(a) leia com bastante

atenção este termo para que compreenda a seguinte explicação sobre os procedimentos propostos. Esta declaração descreve o objetivo; metodologia; justificativa; desconfortos e riscos; danos, confidencialidade, compensação, e outras informações do estudo. Também descreve os procedimentos alternativos que estão disponíveis e o seu direito de interromper o estudo a qualquer momento. Nenhuma garantia ou promessa pode ser feita sobre os resultados do estudo.

1) OBJETIVO: Avaliar, através de ensaio randomizado, o impacto de atividades educativas multiestratégicas e interprofissionais nos níveis de "alfabetização em saúde" entre adultos e idosos cadastrados na ESF.

2) METODOLOGIA/PROCEDIMENTOS: Será conduzido um ensaio randomizado em uma amostra probabilística a ser estimada após condução do estudo piloto. Serão coletados dados entre adultos e idosos alocados de forma randômica em dois grupos: grupo intervenção e grupo controle. Será considerado critério de exclusão dos voluntários o comprometimento da condição cognitiva, tal condição será avaliada através do Mini-exame do Estado Mental. Serão realizadas entrevistas e exames por pesquisadores treinados e calibrados que desconhecem em qual grupo o participante foi alocado. Serão considerados os seguintes potenciais fatores de confusão: determinantes sociais e ambientais (pessoais e sociais: sexo, raça, idade, renda, escolaridade, ocupação, estrutura familiar, saneamento, exposições a doenças, acesso a bens materiais e serviços, redes de apoio social, discriminação social, dentre outros determinantes); uso dos serviços de saúde; custos com a saúde; comportamentos relacionados à saúde (nível de atividade física, hábitos etilistas e tabagistas, adesão ao uso de medicamentos, autocuidados em Diabetes e/ou Hipertensão dentre outras condições);

desfechos de saúde (condições de saúde e qualidade de vida, dentre outras condições); participarão adultos e idosos no controle da sua saúde; empoderamento dos idosos; questões referentes a equidade; assim como, questões referentes à manutenção dos comportamentos relacionados à saúde e ou aos desfechos de saúde. Idosos do "grupo intervenção" serão motivados a participar das atividades educativas em saúde, atividades estas que serão desenvolvidas em um determinado period temporal, considerando as contribuições desses idosos no planejamento e execução das mesmas. Os idosos do "grupo controle" receberão os cuidados ofertados habitualmente pela ESF. Em um segundo momento, todos os idosos serão reavaliados e as mesmas estratégias de intervenção serão conduzidas entre aqueles do "grupo controle". Os dados serão analisados utilizando o programa estatístico SPSS, a fim de se verificar se houve impacto nos níveis de "alfabetização em saúde" dos idosos após as intervenções, bem como se houveram diferenças nos impactos registrados nos grupos "controle" e "intervenção".

3) JUSTIFICATIVA: A análise e avaliação de ações educacionais no SUS, devem ser articuladas e permear políticas públicas, buscando a interação entre as pessoas e seu meio, produzindo uma rede de corresponsabilidade pelo seu bem-estar geral.

4) BENEFÍCIOS: São esperados os seguintes benefícios: os resultados poderão subsidiar políticas de saúde apropriadas às reais condições de saúde dos diabéticos e hipertensos cadastrados na ESF do município com o intuito de melhorar a qualidade de vida dos mesmos, acredita-se que a participação do(a) Sr(a). nas atividades educativas e físicas, dentre outras poderão melhora a sua qualidade de vida e condição de saúde.

5) DESCONFORTOS E RISCOS: Como toda pesquisa oferece algum tipo de risco, nesta pesquisa os principais riscos previsíveis são: perda de privacidade das informações obtidas nas entrevistas ou eventuais acidentes de punção durante a coleta do sangue (material biológico). Para minimizar estes riscos a coleta de sangue será conduzida por profissionais habilitados e experientes e as informações serão manuseadas apenas pela equipe de pesquisadores. Durante a implementação das intervenções devem ser considerados os riscos relacionados à atividade física, que seriam, principalmente, a possibilidade de quedas ou fenômenos isquêmicos. Os participantes serão submetidos às atividades somente após consentimento médico, sendo monitorados a todo o tempo por um profissional.

6) DANOS: será garantida a manutenção da integridade física, psíquica e social dos participantes, se houver danos ou agravos conseqüentes da pesquisa os participantes serão devidamente assistidos e ou indenizados.

7) PROCEDIMENTOS ALTERNATIVOS DISPONÍVEIS: não existem.

8) CONFIDENCIALIDADE DAS INFORMAÇÕES: é garantida à instituição e aos sujeitos envolvidos na amostra a confidencialidade pela participação no estudo; a manutenção do sigilo das informações relativas à identidade civil; o anonimato e a preservação dos dados. As informações obtidas serão utilizadas apenas para fins de pesquisa e apresentados coletivamente.

9) COMPENSAÇÃO/INDENIZAÇÃO: Nos casos pertinentes os participantes serão devidamente indenizados.

10) OUTRAS INFORMAÇÕES PERTINENTES: o Sr(a) não será prejudicado de qualquer forma caso sua vontade seja de não colaborar. Se quiser mais informações sobre o presente estudo, por favor, ligue para o telefone que consta no cabeçalho deste termo.

11) CONSENTIMENTO: Li e entendi as informações precedentes. Tive oportunidade de fazer perguntas e todas as minhas dúvidas foram respondidas a contento. Este formulário está sendo assinado voluntariamente por mim, indicando meu consentimento para a participação desta instituição/ empresa, até que eu decida o contrário. Receberei uma cópia assinada deste consentimento. E que o mesmo só poderá ser aprovado nesta instituição após aprovação no Comitê de Ética da Instituição formentadora da pesquisa. Declaro conhecer e cumprir as Resoluções Éticas Brasileiras, em especial a Resolução CNS 466/12. Esta instituição está ciente de suas co-responsabilidades como instituição co-participante do presente projeto de pesquisa, e de seu compromisso no resguardo da segurança e bem-estar dos sujeitos de pesquisa nela recrutados, dispondo de infra-estrutura necessária para a garantia de tal segurança e bem-estar.

NOME DO RESPONSÁVEL PELA INSTIUIÇÃO	ASSINATURA	DATA
Danilo Fernando Macedo Narciso Secretário Adjunto de Atenção Primária a Saúde	_____	____/____/____

COORDENADOR DA PESQUISA	ASSINATURA	DATA
Andréa Maria Eleutério de Barros Lima Martins	_____	____/____/____

ANEXO D – Normas da revista *The Science of Diabetes Self-Management and Care - Formerly known as The Diabetes Educator Journal*

https://journals.sagepub.com/author-instructions/TDE

Please read the guidelines below then visit the Journal's submission site to upload your manuscript. Please note that manuscripts not conforming to these guidelines may be returned.

Only manuscripts of sufficient quality that meet the aims and scope of *The Diabetes Educator* will be reviewed.

There are no fees payable to submit or publish in this journal.

To download a PDF version of the submission guidelines, click here.

This Journal is a member of the Committee on Publication Ethics (COPE)

This Journal recommends that authors follow the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals formulated by the International Committee of Medical Journal Editors (ICMJE).

Please submit manuscripts electronically in the SAGE Track system at http://mc.manuscriptcentral.com/tde. Authors will be required to set up an online account.

Aims and Scope

The Diabetes Educator is the official journal of the Association of Diabetes Care & Education Specialists (ADCES). It is a peer-reviewed journal intended to serve as a reference source for the science and art of diabetes management.

The Diabetes Educator publishes original articles that relate to (1) aspects of patient care and education, (2) clinical practice and/or research, and (3) the multidisciplinary profession of diabetes education as represented by nurses, dietitians, physicians, pharmacists, mental health professionals, podiatrists, and exercise physiologists.

**Article
Categories**

Features

All feature articles must include a structured abstract of 150-200 words. Feature articles include: Original Research; Meta-analysis, Systematic Reviews, Integrative Reviews; and Perspectives in Practice.

There is no limit on the number of references allowed for Original Features.

Original Research

This type of feature reports original investigations that are relevant to the education and care of people with diabetes. Research papers should be 12-14 double-spaced pages, excluding tables, figures, and references. The following elements should be included in reports of original research: (1) structured abstract; (2) introduction with statement of the purpose of the study; (3) complete description of the methods (eg, design, sample, evaluation instruments, procedures, statistical analyses); (4) clear report of the results; (5) conclusions/discussion of the findings; and (6) implications and/or recommendations that summarize how the findings can be applied to the practice of diabetes education.

All randomized controlled trials submitted for publication should include a completed CONSORT flow chart as a cited figure and the completed CONSORT checklist should be uploaded with your submission as a supplementary file.

Meta-analysis, Systematic Reviews, and Integrative Reviews

Meta-analysis manuscripts are systematic, critical assessments of literature and data sources.

Integrative and Systematic reviews address a specific question or issue that is relevant for clinical practice and provide an evidence-based, balanced, patient-oriented review on a focused topic. Authors are responsible to check if a paper used in a systematic review or meta-analysis has been retracted.

Reviews should include the clinical question or issue and its importance for diabetes care and education, description of how the relevant evidence was identified, assessed for quality, and selected for inclusion; synthesis of the available evidence such that the best-quality evidence (eg, well-conducted clinical trials, meta-analyses, and prospective cohort studies) should receive the greatest emphasis; and discussion of controversial aspects and unresolved issues. The specific type of study or analysis, population, intervention and outcomes should be described for each article or data source. Grading of scientific evidence of studies along with a description of the grading system used should be included in the table. Authors should submit the PRISMA flow diagram and checklist. A structured abstract is required.

The Diabetes Educator journal publishes reviews using a scientific method and does not publish comprehensive literature reviews, nor scoping reviews.

Perspectives in Practice

Perspectives in Practice addresses the science behind the evolving role of the diabetes care and education specialist. Papers in this category should be 8-10 double-spaced pages, excluding tables, figures, and references

Letters to the Editor

These letters provide a forum for commenting on articles published in *The Diabetes Educator* and topics of general interest in diabetes care and education. The length should not exceed 800 words of text with a minimal number of references. One table or figure may be included, if necessary. Any comments regarding a specific article must include the title, author(s), and date of publication. Letters that contain questions or criticisms in response to a previously published paper will be forwarded to the author(s) of that article for a reply. The sharing of ideas, experiences, opinions, and alternative views is encouraged. The editor-in-chief reserves the right to accept, reject, or excerpt letters for clarity and appropriateness of content, and to accommodate space requirements.

Writing Your Paper

The SAGE Author Gateway has some general advice and on how to get published, plus links to further resources.

Make Your Article Discoverable

When writing up your paper, think about how you can make it discoverable. The title, keywords and abstract are key to ensuring readers find your article through search engines such as Google. For information and guidance on how best to title your article, write your abstract and select your keywords, have a look at this page on the Gateway: How to Help Readers Find Your Article Online.

Editorial policies

Peer Review Policy

The Diabetes Educator is a peer-reviewed journal. The Editors review manuscripts that have been submitted and assign them to selected peers for additional review. The review decision is sent to the corresponding author; additional information and/or clarification may be required before a manuscript is accepted for publication.

Periodically, authors may be asked to provide the names of peers who specialize in a narrow field and could be called upon to review the manuscript. Recommended reviewers should be experts in their fields and should be able to provide an objective assessment of the manuscript. Please be aware of any conflicts of interest when recommending reviewers. Examples of conflicts of interest include (but are not limited to) the below:

- The reviewer should have no prior knowledge of your submission
- The reviewer should not have recently collaborated with any of the authors
- Reviewer nominees from the same institution as any of the authors are not permitted

You may also be asked to nominate peers who you do not wish to review your manuscript (opposed reviewers).

Please note that the Editors are not obliged to invite/reject any recommended/opposed reviewers to assess your manuscript.

The Editor or members of the Editorial Board may occasionally submit their own manuscripts for possible publication in the journal. In these cases, the peer review process will be managed by alternative members of the Board and the submitting Editor/Board member will have no involvement in the decision-making process.

Authorship

Papers should only be submitted for consideration once consent is given by all contributing authors. Those submitting papers should carefully check that all those whose work contributed to the paper are acknowledged as contributing authors.

The list of authors should include all those who can legitimately claim authorship. This is all those who:

1. Made a substantial contribution to the concept or design of the work; or acquisition, analysis or interpretation of data,
2. Drafted the article or revised it critically for important intellectual content,
3. Approved the version to be published

Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Authors should meet the conditions of all of the points above. When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship.

Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship, although all contributors who do not meet the criteria for authorship should be listed in the Acknowledgments section. Please refer to the International Committee of Medical Journal Editors (ICMJE) authorship guidelines for more information on authorship.

When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship/contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Other members of the group are listed in the Acknowledgments.

Authors should determine the order of authorship among themselves and should settle any disagreements before submitting their manuscript. Please refer to the Committee on Publication Ethics (COPE) flow charts regarding addition and removal of authors before and after publication. https://publicationethics.org/resources/flowcharts/request-addition-extra-author- after-publication

Contributors Listed in Acknowledgments

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chairperson who provided general support. Financial and material support should also be acknowledged.

Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under such headings as "clinical investigators" or "participating investigators," and their function or contribution should be described—for example, "served as scientific advisors," "critically reviewed the study proposal," "collected data," or "provided and cared for study patients." Because readers may infer their endorsement of the data and conclusions, these persons must give written permission to be acknowledged.

Acknowledgment of a Medical Writer

The Diabetes Educator editorial board and Association of Diabetes Care & Education Specialists recognize the valuable contributions of medical writers to the publication team. Individuals who provided writing or editing assistance, eg, from a specialist communications company, do not qualify as authors and so should be included in the Acknowledgments section. Authors must disclose any writing assistance—including the individual's name, company, and level of input— and identify the entity that paid for this assistance.

Personal Acknowledgments

Please supply any personal acknowledgments on the Title Page (not in the main document) to facilitate anonymous peer review.

It is not necessary to disclose use of language polishing services.

Funding

The Diabetes Educator requires all authors to acknowledge their funding in a consistent fashion under a separate heading on the Title Page. Please visit the Funding Acknowledgments page on the SAGE Journal Author Gateway to confirm the format of the acknowledgment text in the event of funding, or state that: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Declaration of Conflicting Interests

It is the policy of *The Diabetes Educator* journal to require a declaration of conflicting interests from all authors enabling a statement to be carried within the paginated pages of all published articles.

Please ensure that a "Declaration of Conflicting Interests" statement is included on your Title Page. If no conflict exists, please state that "The Author(s) declare(s) that there is no conflict of interest. "For guidance on conflict of interest statements, please see the ICMJE recommendations here

Research Ethics and Patient Consent

Medical research involving human subjects must be conducted according to the World Medical Association Declaration of Helsinki.

Submitted manuscripts should conform to the ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, and all papers reporting animal and/or human studies must state in the methods section that the relevant Ethics Committee or Institutional Review Board provided (or waived) approval. Please ensure that you have provided the full name and institution of the review committee, in addition to the approval number.

For research articles, authors are also required to state in the methods section whether participants provided informed consent and whether the consent was written or verbal.

Information on informed consent to report individual cases or case series should be included in the manuscript text. A statement is required regarding whether written informed consent for patient information and images to be published was provided by the patient(s) or a legally authorized representative. Please do not submit the patient's actual written informed consent with your article, as this in itself breaches the patient's confidentiality. The Journal requests that you confirm to us, in writing, that you have obtained written informed consent but the written consent itself should be held by the authors/investigators themselves, for example in a patient's hospital record. The confirmatory letter may be uploaded with your submission as a separate file.

Please also refer to the ICMJE Recommendations for the Protection of Research Participants

Clinical Trials

The Diabetes Educator journal endorses the ICMJE requirement that clinical trials are registered in a WHO-approved public trials registry at or before the time of first patient enrolment.

However, consistent with the AllTrials campaign, retrospectively registered trials will be considered if the justification for late registration is acceptable. The trial registry name and URL, and registration number must be included at the end of the abstract.

Reporting guidelines

The relevant EQUATOR Network reporting guidelines should be followed depending on the type of study. For example, all randomized controlled trials submitted for publication should include a completed CONSORT flow chart as a cited figure and the completed CONSORT checklist should be uploaded with your submission as a supplementary file. Systematic reviews and meta-analyses should include the completed PRISMA flow chart as a cited figure and the completed PRISMA checklist should be uploaded with your submission as a supplementary file. The EQUATOR wizard can help you identify the appropriate guideline.

Other resources can be found at NLM's Research Reporting Guidelines and Initiatives

Research Data

At SAGE we are committed to facilitating openness, transparency and reproducibility of research. Where relevant, The Journal encourages authors to share their research data in a suitable public repository subject to ethical considerations and where data is included, to add a data accessibility statement in their manuscript file. Authors should also follow data citation principles. For more information please visit the SAGE Author Gateway, which includes

information about SAGE's partnership with the data repository Figshare.

Publishing Policies

Publication Ethics

The Diabetes Educator (*TDE*) journal is a member of the Committee on Publication Ethics.

TDE recommends that authors follow the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals formulated by the International Committee of Medical Journal Editors (ICMJE) and view the Publication Ethics page on the SAGE Author Gateway.

As part of the submission process you will be required to warrant that you are submitting your original work, that you have the rights in the work, that you are submitting the work for first publication in the Journal and that it is not being considered for publication elsewhere and has not already been published elsewhere, and that you have obtained and can supply all necessary permissions for the reproduction of any copyright works not owned by you.

Plagiarism

The Diabetes Educator and SAGE take issues of copyright infringement, plagiarism or other breaches of best practice in publication very seriously. We seek to protect the rights of our authors and we always investigate claims of plagiarism or misuse of published articles. Equally, we seek to protect the reputation of the journal against malpractice. Submitted articles may be checked with duplication-checking software. Where an article, for example, is found to have plagiarized other work or included third-party copyright material without permission or with insufficient acknowledgment, or where the authorship of the article is contested, we reserve the right to take action including, but not limited to: publishing an erratum or corrigendum (correction); retracting the article; taking up the matter with the head of department or dean of the author's institution and/or relevant academic bodies or societies; or taking appropriate legal action.

Multiple Publications From One Study

Authors usually publish one comprehensive article from a large data set. However, there may be reasons why authors publish several articles from the same data set or study. These include the following: (a) each submitted manuscript has a very distinct and clear purpose that addresses a different research question or hypothesis from the originally published study, and (b) an additional manuscript makes an independent and significant discovery of new information or insights into knowledge and practice. *The Diabetes Educator* requires that authors submitting manuscripts from one data set or study include the following information within the body of the manuscript: (a) information about the originally published study, including an appropriate reference to the originally published paper; (b) extent of overlap in method, variables, and data analyses from the originally published paper; (c) description of participants; and (d) clear indication about the discovery of new information and how the current study differs from other publications. A clear and comprehensive disclosure about the originally published study will facilitate the editorial decision-making process and avoid duplicate or salami publishing

Prior Publication

If material has been previously published it is not generally acceptable for publication in a SAGE journal. However, there are certain circumstances where previously published material can be considered for publication. Please refer to the guidance on the <u>SAGE Author Gateway</u> or if in doubt, contact the Editor at the address below.

Manuscripts based on papers that have been presented at conferences may be considered for publication as long as they have not been published and provided that the author(s) still retain the rights to the manuscript. The Editor-in-Chief may review whether the version of your article considered for publication is materially different from the work you presented at a conference and/or whether publication in the journal will enable you to reach an audience that the conference paper did not previously reach.

Prior publication of an abstract or poster presented at a conference will generally not impact the manuscript's eligibility for publication.

If material in a manuscript has been presented at a conference or professional meeting, this needs to be noted in the Acknowledgments section. For example, "This study was presented in part at the Association of Diabetes Care & Education Specialists (ADCES 2020) Annual Conference; August 14, 2020; Atlanta, Georgia."

Contributor's Publishing Agreement

Before publication, SAGE requires the author as the rights holder to sign a Journal Contributor's Publishing Agreement. SAGE's Journal Contributor's Publishing Agreement is an exclusive license agreement which means that the author retains copyright in the work but grants SAGE the sole and exclusive right and license to publish for the full legal term of copyright. Exceptions may exist where an assignment of copyright is required or preferred by a proprietor other than SAGE. In this case copyright in the work will be assigned from the author to the society. For more information please visit the SAGE Author Gateway

Preparing Your Manuscript for Submission

Formatting

The preferred format for your manuscript is Word. Word templates are available on the Manuscript Submission Guidelines page of our Author Gateway.

Manuscripts should be prepared in Word format and in accordance with the *AMA Manual of Style: A Guide for Authors and Editors. 11th ed.* Oxford University Press; 2019. All accepted manuscripts will be edited according to the *AMA Manual of Style.* 11th ed.In consultation with the author(s), the journal reserves the right to edit manuscripts for clarity, length, readability, and consistency with the style of the journal.

Manuscripts must be typed double-spaced throughout including references. Use margins of at least 1 inch on the top, bottom, and sides of each page. Nothing should be typed in all upper case letters. Number pages consecutively in the upper right-hand corner, beginning with the title page, and provide a running head (not exceeding 50 characters) at the top of each page.

The manuscript should be organized in the following manner:

1. Title Page (including Acknowledgments)
2. Structured Abstract
3. Introduction (no heading)
4. Research Design, Methodology, Results, Conclusions (for features)
5. Text Divided into Logical Headings and Subheadings as Appropriate
6. Implications/Relevance for Diabetes Care and Education Specialists
7. References
8. Tables, Figures, Legends, and Illustrations/photos on Separate Pages

Upload each of the following **separately**: Title page, Main document (abstract, body of manuscript and references), each table, each figure.

Title Page

The title page should include (1) title of the manuscript; (2) suggested running head; (3) full name and academic degree(s) for each author. Do not include fellowships such as FADCES or FAND; (4) institutional affiliation, including department name and city/state; (5) complete mailing address, with daytime telephone and fax numbers, and email address for corresponding author; (6) acknowledgment of financial and/or other support; and (7) any acknowledgments.

The title page is the only place in the manuscript where the author(s) should be identified by name. The title should be written in a brief, concise manner that accurately reflects the main idea of the paper. The running head is a shortened version of the title that should not contain the names or initials of any authors.

Structured Abstract

All original feature articles must include a structured abstract of no more than 250 words using the following headings:

a. Purpose (Begin this section with the sentence: The purpose of this study is to. ......Include the

rationale for the study, hypotheses, objectives)

b. Methods (study design, setting, characteristics of the sample, intervention, data collection procedures, evaluation measures)
c. Results (key findings only, no details or statistics)
d. Conclusions (information supported by the data, implications)
In general, the abstract should be written in a brief, concise style that provides an overview of the information in the article and allows the reader to survey the contents. Use simple, concrete words and short sentences that provide factual information rather than describing what information will appear in the article.

All non-original feature articles must include a structured abstract of no more than 250 works using the following headings:

a. Purpose
b. Conclusions

Author Guidelines

- Throughout the manuscript, avoid using the personal pronouns I or we.
- Employ nonsexist language.
- Spell out abbreviations and acronyms on first mention followed by the abbreviation in parentheses. Limit the overall use of abbreviations in the text.
- Avoid jargon. For example, instead of *the patient was on insulin* use the patient was taking insulin or injecting insulin.
- In general, authors should use the active voice. If the subject is mentioned in the sentence, the active voice is preferred over the passive voice. For example, *Passive voice*: The definition of target blood glucose range used in the survey was taken from previous studies. *Active voice*: The authors used previous definitions of the target blood glucose range in the survey.
- Throughout the text, use generic, nonproprietary names for medications and devices.

- Use brief headings and subheadings to divide the text into logical sections and enhance readability. Indicate placement of tables, figures, illustrations, and photos in the text by referring to the graphic with the appropriate designation in parentheses (eg, Table 1, Figure 1) following the referent sentence.

Terminology

The Diabetes Educator journal supports person-first language. Do not use the word diabetic, for a list of language to avoid and suggested substitutions, please refer to:
Dickinson JK, Guzman SJ, Marynuik MD, et al. The use of language in diabetes care and education. *Diabetes Educ*. 2017; 43(6):551-564. doi: 10.1177/0145721717735535

Use blood glucose monitoring (not blood sugar monitoring), blood glucose check not test, and blood glucose not blood sugar.
Use type 1 (Arabic numeral) diabetes and type 2 diabetes. Do not use Type I or II nor IDDM or NIDDM.
T1DM and T2DM are acceptable abbreviations for type 1 diabetes and type 2 diabetes.
A1C (not A1c or HbA1c) should be used.
Low income" and "no income" preferred over "the poor" or "the unemployed".
"First world/third world" and "developed/developing" not recommended for descriptors for countries/regions.
The term diabetes educator has been replaced by diabetes care and education specialist.

Laboratory Data

All clinical laboratory data including A1C should be given in traditional units followed in parentheses by units in the metric system according to the Systéme International d'Unités (SI units). Use the NGSP's A1C converter at http://www.ngsp.org/convert1.asp to calculate A1C values as both percent and mmol/mol. For example, a blood glucose level should be stated in the following manner: 80 mg/dL (4.44 mmol/L). Abbreviate units of measure in the text only when accompanied by numbers; units of measure should be abbreviated in tables.

Artwork, Figures and Other Graphics

Figures should be presented as simply and clearly as possible. It is the author's responsibility to provide original, high-resolution images (a minimum of 300 dpi [dots per inch]) for all figures, photos and illustrations. Low resolution is 72 dpi, and this is too low for good print quality.

Images should be about 1200 x 1800 (4 x 6 prints) pixels or 2400 x 3000 pixels (8 x 10 prints).

- Save images that do not include text or graphs as TIF or JPG files.
- Save charts, graphs and line art as EPS files. In addition, they can be submitted as Microsoft PowerPoint (PPTX), Word (DOC) or Excel (XLSX) files.

Each figure file name should include the lead author's last name and the figure number (e.g. Smith Fig 1, Smith Fig 2, Smith Fig 3, etc.).

There is no charge for images that appear in black and white. Authors who wish to publish color images may do so for a fee to subsidize additional printing expenses. Color charges are $800 for the first color page and $200 for each color page thereafter. **Otherwise, figures will print in black and white free of charge and they will appear in color online only.** If authors choose the color option for print, an invoice will be sent later in the production process.

Supplemental material

This journal is able to host additional materials online (e.g. datasets, podcasts, videos, images etc) alongside the full-text of the article. For more information please refer to our guidelines on submitting supplemental files

Reference Style

Authors are responsible for the accuracy and completeness of all reference citations. Format the reference list according to the style shown in the *AMA Manual of Style*.11th ed. Reference numbers should be typed in Arabic superscript numerals in the text, outside periods and commas and inside colons and semicolons. A hyphen should be used to join a series of references. For example, As supported by previous research,[1,5-8,23]

The reference list should be typed double-spaced and start on a separate sheet immediately following the end of the text. Number references consecutively in the order they appear in the text, including references cited in tables, figures, and other graphics. All references included on the reference list must be cited at least once in the text. **Abbreviate journal names** and italicize. Search www.ncbi.nlm.nih.gov/nlmcatalog/journals for journal title abbreviations.

Inclusive page numbers must be provided (eg, 88-104) for all print references.

References to personal communication (including email) may be cited parenthetically in the text but not in the reference list; include the name of the person, the email address, and the date of the communication. Material that has been accepted for publication but not yet published may be cited in the reference list with the journal name followed by "Forthcoming." Un-published material may not be cited. Electronic forms of documents may be included in the reference list and should be cited according to the style for each type of electronic source. Following are some examples of correct forms of references:

Journal Article

List all authors if six or less; for more than six, list only first three authors followed by "et al."

Beck J, Greenwood DA, Blanton L, et al. 2017 National standards for diabetes self-management education and support. *Diabetes Educ*. 2017; 2017; 43(5):449-464. doi:10.1177/0145721717722968

Book With Editor(s)

Cornell S, Halstenston C, Miller DK, eds. *The Art and Science of Diabetes Self-Management Education Desk Reference*. 4th ed. American Association of Diabetes Educators; 2017.

Electronic Citations

Centers for Disease Control and Prevention. National diabetes statistics report, 2020: estimates of diabetes and its burden in the United States. Accessed month, date year. https://www.cdc.gov/diabetes/data/statistics/national-diabetes-statistics

English Language Editing Services

Authors seeking assistance with English language editing, translation, or figure and manuscript formatting to fit the journal's specifications should consider using SAGE Language Services. Visit SAGE Language Services on our Journal Author Gateway for further information.

Manuscript Submission Checklist
- Review and follow *TDE* author guidelines.
- Review manuscript submission guidelines on our web-based submission and review system (http://mc.manuscriptcentral.com/tde).
- Designate a corresponding author. Please note *TDE* contributorship policy.
- Provide an abstract for all manuscripts.
- Double-space manuscript and references.
- Check all references for accuracy and completeness. Follow the reference style of the *AMA Manual of Style*.11th ed. Italicize and abbreviate journal names according to National Library of Medicine's abbreviations.
- Include a title for each table and figure and explanatory legend including abbreviations used as needed.
- Upload the title page, main document including references, and each table and figure separately.
- Include research or project support/funding on the title page in the Acknowledgment.
- Include permission agreements for use of third party material requiring permission.
- If appropriate, include information on institutional review board/ethics committee approval or waiver and informed consent.
- For clinical trials, add the clinical trial identification number and the URL of the registration site.

Submitting Your Manuscript
The Diabetes Educator is hosted on SAGE Track, a web based online submission and peer review system powered by ScholarOne™ Manuscripts. Visit http://mc.manuscript central.com/tde to log in and submit your article online.

IMPORTANT: Please check whether you already have an account in the system before trying to create a new one. If you have reviewed or authored for the journal in the past year

it is likely that you will have had an account created. For further guidance on submitting your manuscript online please visit ScholarOne.

ORCID

As part of our commitment to ensuring an ethical, transparent and fair peer review process SAGE is a supporting member of ORCID, the Open Researcher and Contributor ID. ORCID provides a persistent digital identifier that distinguishes researchers from every other researcher and, through integration in key research workflows such as manuscript and grant submission, supports automated linkages between researchers and their professional activities ensuring that their work is recognized.

The collection of ORCID IDs from corresponding authors is now part of the submission process of this journal. If you already have an ORCID ID you will be asked to associate that to your submission during the online submission process. We also strongly encourage all co-authors to link their ORCID ID to their accounts in our online peer review platforms. It takes seconds to do: click the link when prompted, sign into your ORCID account and our systems are automatically updated. Your ORCID ID will become part of your accepted publication's metadata, making your work attributable to you and only you. Your ORCID ID is published with your article so that fellow researchers reading your work can link to your ORCID profile and from there link to your other publications.

If you do not already have an ORCID ID please follow this link to create one or visit our ORCID homepage to learn more.

Information Required for Completing Your Submission

You will be asked to provide contact details and academic affiliations for all co-authors via the submission system and identify who is to be the corresponding author. These details must match what appears on your manuscript. At this stage please ensure you have included all the required statements and declarations and uploaded any additional supplementary files (including reporting guidelines where relevant).

Permissions

Please also ensure that you have obtained any necessary permission from copyright holders for reproducing any illustrations, tables, figures or lengthy quotations previously published elsewhere. For further information including guidance on fair dealing for criticism and review, please see the Copyright and Permissions page on the SAGE Author Gateway

On Acceptance and Publication
SAGE Production

Your SAGE Production Editor will keep you informed as to your article's progress throughout the production process. A preliminary version of your manuscript is called a proof and a PDF will be sent to the corresponding author for review before publication. The production editor may include specific questions for the author to address. Substantial changes are not accepted at the proof stage of production. Authors are reminded to check their proofs carefully to confirm that all author information, including names, affiliations, sequence, and contact details are correct, and that Funding and Conflict of Interest statements, if any, are accurate.

Online First Publication

OnlineFirst allows final articles (completed and approved articles awaiting assignment to a future issue) to be published online prior to their inclusion in a journal issue, which significantly reduces the lead time between submission and publication. Visit the SAGE Journals help page for more details, including how to cite OnlineFirst articles.

SAGE Policy Regarding NIH Compliance

SAGE Publications fully understands the shifting demands on authors whose work is funded by bodies such as the NIH and Wellcome Trust among others. SAGE allows authors the right to post the final accepted, prepublished version of their manuscript (not the final PDF) on an institutional repository or national database, such as PubMedCentral, with the understanding that the article will not be made available until 12 months after the official date of publication.

If an author is funded by NIH and chooses to pay the SAGE Choice fee for open access, SAGE will deposit the manuscript on the author's behalf and make the article freely available immediately on publication. Please see more information about this option at https://us.sagepub.com/en-us/nam/sage-choice-faqs.

Further Information

Any correspondence, queries or additional requests for information on the manuscript submission process should be sent to the editorial office as follows:

James A. Fain, PhD, RN, BC-ADM, FADCES, FAAN

University of Massachusetts Medical School
Graduate School of Nursing

James.fain@umassmed.edu

Appealing the publication decision

Editors have very broad discretion in determining whether an article is an appropriate fit for their journal. Many manuscripts are declined with a very general statement of the rejection decision. These decisions are not eligible for formal appeal unless the author believes the decision to reject the manuscript was based on an error in the review of the article, in which case the author may appeal the decision by providing the Editor with a detailed written description of the error they believe occurred.