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DESEMPENHO FÍSICO-FUNCIONAL

ANA PAULA DELGADO BOMTEMPO BATALHA

**EDUCAÇÃO NA AUTOGESTÃO DO DIABETES MELLITUS TIPO 2 EM
ADULTOS: REVISÃO SISTEMÁTICA DOS EFEITOS NA AUTOGESTÃO E
CONTROLE GLICÊMICO**

Juiz de Fora

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Dissertação apresentada ao Programa de Pós-Graduação em Ciências da Reabilitação e Desempenho Físico-Funcional da Universidade Federal de Juiz de Fora como requisito à obtenção do grau de Mestre em Ciências da Reabilitação e Desempenho Físico-Funcional. Área de concentração: Desempenho e reabilitação em diferentes condições de saúde.

Orientador(a): Raquel Rodrigues Britto - UFJF

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“Consagre ao Senhor tudo o que você faz,
e os seus planos serão bem-sucedidos”

(Provérbios 16.3)

Agradecimentos

Agradeço primeiramente a Deus como autor da minha vida, que me deu forças para continuar durante todas as vezes em que eu achei que não teria.

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Resumo

Introdução: Pacientes com Diabetes Melitus (DM) demandam altos custos relacionados aos seus cuidados, por isso, programas focados na mudança de comportamento de auto gestão então sendo implementados, pois estão relacionados com desfechos de doenças crônicas. Nesse sentido, os programas de educação dos pacientes com diabetes devem ser baseados no auto gerenciamento, autocuidado e auto eficácia do paciente a fim de melhorar a autogestão da doença. **Objetivo:** Identificar a evidência de intervenções para modificar o comportamento de pacientes com DM2 e o impacto na autogestão da doença e no controle glicêmico. **Métodos:** Trata-se de uma revisão sistemática, reportada conforme o *check list* PRISMA. O protocolo desta revisão foi registrada na base de dados *International Prospective Register of Systematic Reviews* (PROSPERO), CRD42020161162, e no banco de dados público online *Open Science Framework*, registro DOI 10.17605/OSF.IO/Z73U2. As bases de dados selecionadas foram: MEDLINE, EMBASE, CINAHL, Cochrane Library e LILACS, sem restrição de idioma. Foram incluídos ensaios clínicos randomizados (ECR), que incluíssem pacientes com DM apenas do tipo 2 maiores de 18 anos, de ambos os sexos, independente de nível de HbA1c (hemoglobina glicada) e duração do diabetes. Foram considerados estudos com diferentes tipos de intervenção comportamental de auto gestão ministrada de forma ambulatorial, podendo incluir dieta, exercício, medicação ou controle da insulina, monitoramento da glicemia e participação em consultas clínicas. Quanto ao comparador apenas estudos que apresentassem grupo controle que não recebeu intervenções comportamentais. Os desfechos considerados por essa revisão foram: Auto gestão e suas competências (auto gerenciamento, auto cuidado e auto eficácia) e HbA1c. A avaliação de risco de vieses foi feita utilizando a ferramenta de avaliação de ECR da Cochrane e a avaliação da qualidade da evidencia foi baseada no sistema *Grading of Recommendation, Assessment, Development, and Evaluation* (GRADE). **Resultados:** Foram analisados 2615 artigos, por fim foram incluídos na análise 27 estudos. Dentre todos os estudos avaliados 12 deles apresentaram diferença significativa inter grupos para o desfecho auto gestão, enquanto que para o desfecho hemoglobina glicada apenas 5 estudos apresentaram uma diferença significativa inter grupos. O risco de viés foi considerado como alto na maior parte dos estudos e a qualidade da evidencia foi categorizada como muito baixa. Devido às diferentes

abordagens metodológicas apresentadas nos estudos a meta-análise não pôde ser realizada. **Conclusão:** Algumas intervenções focadas na educação em auto gestão melhoraram a auto gestão e o controle glicêmico. Entretanto, o baixo número e a variedade de intervenções, o alto risco de viés e a baixa qualidade da evidência limitam a conclusão. Assim, novos estudos são necessários para verificar a evidência de intervenções na auto gestão da DM e controle glicêmico.

Palavras chave: Revisão sistemática, Diabetes Melitus tipo 2, Educação em autogerenciamento, Auto gestão e HbA1c.

Abstract

Background: Patients with diabetes mellitus (DM) demand high costs related to their care, therefore, programs focused on self-management behavior change then being implemented, because it is related to chronic disease outcomes. In this way, education programs to diabetes patients must be based on patient self-management, self-care, and self-efficacy that improve self-management disease. **Purpose:** identify the scientific evidence of intervention to modify patient's behavior with DM type 2 and the impact in self-management disease and glycemic control. **Methods:** This is a systematic review, reported according to the PRISMA checklist. This review's protocol was registered in the database International Prospective Register of Systematic Reviews (PROSPERO), CRD42020161162 and in a public open data bank Open Science Framework, DOI 10.17605/OSF.IO/Z73U2. The bases selected were: MEDLINE, EMBASE, CINAHL, Cochrane Library, and LILACS, without language restrict. Were included randomized clinical trials, with just patients diabetes type 2 with more than 18 years old, both gender, independent of glycated hemoglobin level and time with diabetes. The interventions considered were: behavioral self-management interventions which may include diet, exercise, medication or insulin control, blood glucose monitoring and participation in clinic consultations. About the comparator, just studies with a control group that does not receive a behavioral intervention. The risk of bias was assessed using an evaluating tool of Cochrane, the assess the quality of evidence was based on Grading of Recommendation, Assessment, Development, and Evaluation (GRADE). **Outcomes:** Were analyzed 2615 studies, in the end 27 studies were included in the analyses. Among all studies assessed, 12 there is a significant difference between groups to self- management outcome, while for the glycated hemoglobin outcome just 5 studies there is a significant difference between groups. The risk of bias was considered high in most of the studies and the quality of evidence was assessed as very low. Due to the different evaluating methods used in the studies, a meta-analysis could not be performed. **Conclusion:** Some interventions based on self-management education improved self-management and glycemic control. However, the few and with low variety of interventions, the high risk of bias and low quality of evidence limit the conclusion. Therefore, new studies are necessary to assess the intervention's evidence in self-management and glycemic control.

Key words: Systematic review, diabetes self-management education, self management and A1c.

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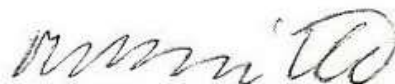
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Aprovada em 30 de Setembro de 2020

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LISTA DE ABREVIações E SIGLAS

OMS – Organização mundial de saúde
DCV – Doenças Cardiovasculares
DM - Diabetes Mellitus
DM2 – Diabetes Mellitus tipo 2
HbA1c – Hemoglobina glicada
PROSPERO - *International Prospective Register of Systematic Reviews*
PRISMA - *Preferred Reporting Items for Systematic Reviews and Meta-Analyses*
ECR – Ensaio clínico randomizado
MEDLINE - *Medical Literature Analysis and Retrieval System Online*
EMBASE - *Excerpta Medica*
CINAHL - *Cumulative Index to Nursing and Allied Health Literature*
LILACS - *Latin American and Caribbean Literature in Health Sciences*
GRADE - *Grading of Recommendation, Assessment, Development, and Evaluation*
GI – Grupo intervenção
GC – Grupo controle
ADA - *American Diabetes Association*
SDSCA - *Summary of Diabetes Self-care Activities*
PCS - *Perceived Competence Scale*
PDSMS - *Perceived Diabetes Self-Management Scale*
SDSMP - *Spanish Diabetes Self-Efficacy Scale*
DMSES - *Diabetes Management Self-Efficacy Scale*
PAM - *Patient activation*
DES-SF - *Diabetes Empowerment Scale–Short*
CAPES - Coordenação de Aperfeiçoamento de Pessoal de Nível Superior
CNPQ - Conselho Nacional de Desenvolvimento Científico e tecnológico
PROPP - UFJF - Pró-Reitoria de Pós Graduação da Universidade Federal de Juiz de Fora

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1. INTRODUÇÃO

Dados da Organização Mundial da Saúde (OMS) (WORLD HEALTH ORGANIZATION, 2017), mostram as Doenças Cardiovasculares (DCV) como a principal causa das mortes no mundo todo, totalizando 31% de todas as mortes em nível global e 17,5 milhões pessoas em 2015. No Brasil os dados do Ministério da Saúde mostram que, por ano, mais de 300 mil pessoas morrem por DCV, o que corresponde a uma morte a cada dois minutos (GOVERNO DO BRASIL, 2017). As estimativas são que essas doenças geraram um custo de R\$ 56,2 bilhões (17,3 bilhões de dólares) em 2015 no Brasil, desses, cerca de 62,9% foram custeados pelo Sistema Único de Saúde (STEVENS et al., 2018).

Grande parte das DCV pode ser prevenida por meio da redução dos fatores de risco comportamentais, como dieta, cessação do uso de tabaco, atividade física e reversão do uso de álcool. Também é importante a detecção precoce da doença e o controle dos riscos cardiovasculares, especialmente quando o paciente possui um ou mais fatores de risco como hipertensão, diabetes *mellitus* (DM) e hiperlipidemia (WORLD HEALTH ORGANIZATION, 2017).

Dentre os fatores de risco cardiovasculares o DM leva frequentemente ao desenvolvimento de DCV em adultos. Segundo os dados da *International Diabetes Federation*, o DM já é considerado uma epidemia global e conseqüentemente constitui um problema de saúde pública que deve ser administrado em todos os níveis de atenção à saúde (INTERNATIONAL DIABETES FEDERATION, 2017). Assim, incentivar as estratégias de prevenção, estabelecer o controle precoce e sustentado do DM é essencial (AGUIREE et al., 2013).

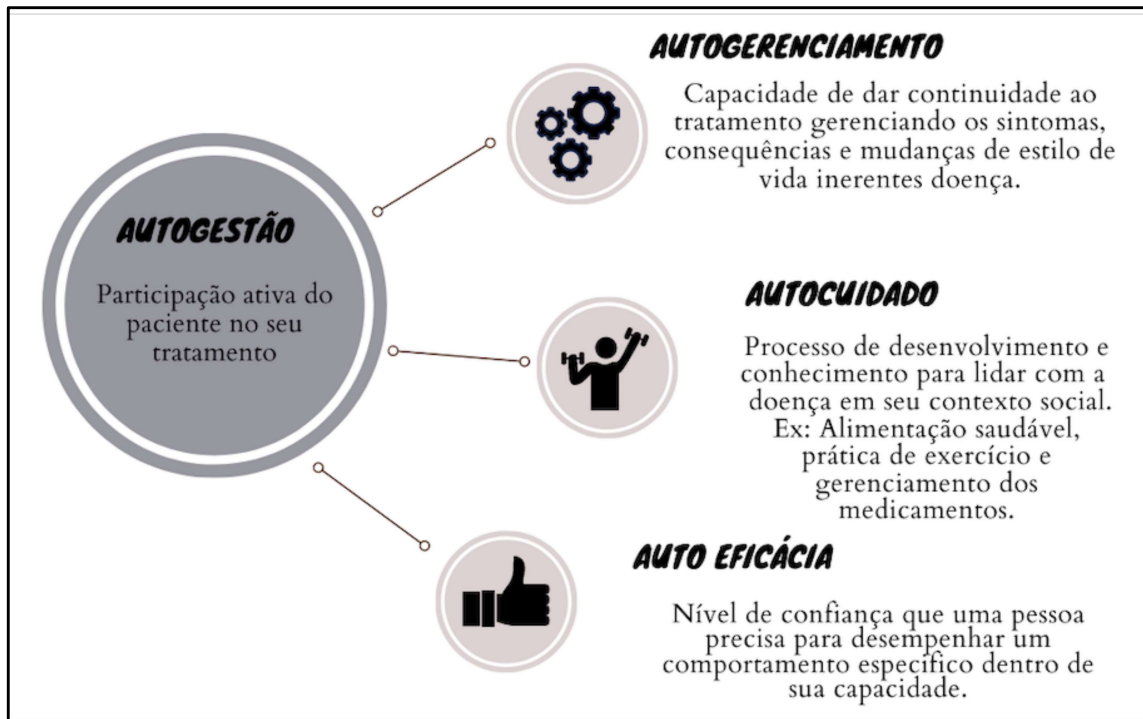
Baseado em dados compilados da edição mais recente do Atlas da *International Diabetes Federation*, existem 425 milhões de pacientes com DM no mundo. Aproximadamente 4 milhões de pessoas entre 20 e 79 anos morreram de DM em 2017 no mundo todo, o equivalente a uma morte a cada seis segundos e responsável por 14,5% da mortalidade global por todas as causas entre pessoas nessa faixa etária. Os gastos globais relacionados ao diabetes em 2017 foram de US \$1.736 por pessoa com DM (INTERNATIONAL DIABETES FEDERATION, 2017).

Ainda segundo o Atlas, no Brasil, os dados mostram que no ano de 2017 o país possuía quase 13 milhões de pessoas com DM o que, considerando a taxa de

crescimento ao longo dos anos, leva a crer que atingirá a marca de 23 milhões de pessoas no ano de 2045. Já o número de mortes por DM chegou a 108 mil pessoas no mesmo ano. Quanto aos custos para a rede pública, no Brasil U\$1.405 são gastos por pessoa com essa doença (INTERNATIONAL DIABETES FEDERATION, 2017). Diante dessa realidade é importante garantir que a comunidade tenha conhecimento e consciência suficiente sobre essa doença para possibilitar maior promoção de intervenções de saúde pública para controlar sua prevalência.

Definição e características dos termos relacionados com autogestão

O termo autogestão é descrito com o intuito de evidenciar a participação ativa do paciente no seu tratamento, com a finalidade de minimizar o impacto da doença crônica no funcionamento de sua saúde física (EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND; POLICIES SERIES, 2008). Na tentativa consciente de alcançarem o controle da sua doença, em vez de serem controlados por ela. A autogestão e suas competências estão intimamente relacionadas com desfechos de doenças crônicas (GALLAGHER et al., 2008). O termo autogestão é amplo e engloba aspectos relacionados ao autogerenciamento, auto cuidado e auto eficácia para os quais os programas que incluem aspectos de comportamento em relação à doença frequentemente aplicam atividades de promoção a saúde bem como atividades relacionadas a doença crônica (Figura 1) (WILDE; GARVIN, 2006).



Fonte: Criada pelo autor

Figura 1 - Relação da autogestão com os termos: autogerenciamento, autocuidado e auto eficácia.

A educação do autogerenciamento em diabetes pode desempenhar um papel significativo em reduzir os riscos de complicações relacionadas ao DM e também mortes prematuras, uma vez que é capaz de facilitar o conhecimento, a habilidade e a capacidade necessária para o autogerenciamento da doença (POWERS et al., 2017). A educação para o autogerenciamento é importante independentemente do nível de desenvolvimentos dos países, mas certamente tem um aspecto ainda mais relevante naqueles em desenvolvimento ou subdesenvolvidos, em especial com grandes dimensões geográficas e populacionais, que dificultam o acesso integrado aos serviços de saúde por todos os que demandam. Nestes cenários, o autogerenciamento da saúde assume um papel crucial no controle das doenças crônicas.

Autogerenciamento é definido como a capacidade do indivíduo de gerenciar os sintomas, tratamento, aspectos físicos e psicossociais, consequências e mudanças de estilo de vida inerentes à vida com DM (BARLOW, 2001). Embora o termo autogerenciamento seja usado de forma intercambiável com outros como autocuidado, educação do paciente, auto regulação e aconselhamento ao paciente, o autogerenciamento evoluiu além da prática de apenas fornecer informações e

aumentar o conhecimento do paciente (CLARK et al., 1991). Se trata de capacitar o mesmo para dar continuidade ao próprio tratamento.

O apoio da equipe de saúde ao autogerenciamento auxilia o paciente a implementar e manter os comportamentos necessários para gerenciar sua condição de saúde de maneira contínua. A educação e o desenvolvimento de habilidades para o autogerenciamento são pontos-chaves a serem trabalhados ao longo de todo o tratamento de pacientes com DM (BECK et al., 2017). Sendo assim entende-se que podemos melhorar o autogerenciamento a medida que melhoramos o autocuidado (SARKAR; FISHER; SCHILLINGER, 2006).

O autocuidado é um processo de desenvolvimento evolutivo e de conhecimento onde o paciente aprende a sobreviver com a complexa natureza da sua doença aplicando esse conhecimento ao seu contexto social (PATERSON, 2000). Este modelo de comportamento compreende conhecimentos, atitudes, comunicação, financiamento, apoio familiar, motivação e auto-eficácia (AMELIA, 2018). Os principais comportamentos de autocuidado que auxiliam na prevenção de complicações a curto e a longo prazo relacionadas ao DM são: alimentação saudável, exercícios regulares, cuidado com os pés, adaptação aos desafios psicossociais e gerenciamento de medicamentos (MULCAHY et al., 2003). O processo de autocuidado está intimamente relacionado com a crença sobre sua capacidade de fazê-lo, sendo esta denominada auto-eficácia.

Uma definição teórica de auto-eficácia, um dos cinco construtos da teoria cognitiva social de Bandura, é o nível de confiança que uma pessoa precisa para desempenhar um comportamento específico dentro de sua capacidade (BANDURA, 2004). Por exemplo, a auto-eficácia para o exercício é a confiança que o paciente precisa ter para realizar o exercício.

A auto-eficácia do paciente pode ser trabalhada no sentido de aumentar o autocuidado e conseqüentemente melhorar o autogerenciamento da doença, uma vez que o autogerenciamento do DM incorpora fatores comportamentais como dieta saudável e prática de exercícios, fatores pessoais e ambientais no desempenho das atividades diárias recomendadas (SARKAR; FISHER; SCHILLINGER, 2006).

Nesse sentido a educação para o autogerenciamento do Diabetes deve ser baseada além do auto-gerenciamento, com o autocuidado e auto-eficácia do paciente a fim de melhorar a autogestão da doença a longo prazo.

Impacto da autogestão no controle do Diabetes

A autogestão e suas competências (auto gerenciamento, auto cuidado e auto eficácia) estão intimamente relacionadas com desfechos de doenças crônicas, como visto, estas geram elevados níveis de morbidade e de custos relacionados aos cuidados destes pacientes, variáveis que podem ser minimizadas mediante a implementação de programas focados na mudança de comportamento de autogerenciamento, auto cuidado e auto eficácia relacionados com a doença (WILDE; GARVIN, 2006).

Na literatura estão disponíveis diversos instrumentos para avaliar as mudanças de comportamento e estilo de vida em pacientes com DM. A *American Diabetes Association* (ADA) (BECK et al., 2017) sugere instrumentos específicos para avaliar o comportamento de pacientes com DM, que podem se enquadrar em cada uma de suas competências, como: Auto gerenciamento (Patient Activation – PAM), auto cuidado (*Summary of Diabetes Self-care Activities* – SDSCA, e Self-Care Inventory – SCI) e auto eficácia (Diabetes self- efficacy scale - DSES).

A ferramenta SDSCA é um breve questionário de auto relato que aborda o auto cuidado por meio de aspectos relacionados ao diabetes como: dieta geral, dieta específica, exercícios, monitoramento de glicose no sangue, cuidados com os pés e hábito de fumar. (TOOBERT; HAMPSON; GLASGOW, 2000). A PAM é uma escala construída para avaliar o desenvolvimento da ativação do paciente, que esta fortemente relacionado com o processo de auto gerenciamento da doença (HIBBARD et al., 2004). O SCI é um breve questionário que avalia as percepções de adesão aos comportamentos de autocuidado com a doença recomendados de adultos com diabetes tipo 1 ou tipo 2 (WEINGER et al., 2005) . Por fim a DSES é uma escala curta par avaliar a auto eficácia em pacientes com DM, possui perguntas a serem respondidas de forma *Liket* (de 0 a 10) (RITTER; LORIG; LAURENT, 2016).

Em geral, diferentes revisões sistemáticas e metanálises disponíveis identificaram o benefício das intervenções comportamentais, para melhorar o comportamento e estilo de vida de pacientes com DM tipo 2 e também no controle de comorbidades (AZAMI et al., 2018; CHRVALA; SHERR; LIPMAN, 2016; HILDEBRAND et al., 2020; MIKHAEL; HASSALI; HUSSAIN, 2020; MOHAMED et al., 2019; ODGERS-JEWELL et al., 2017). No entanto, estas revisões apresentam questões muito especificas como: foco na região do oriente médio (AZAMI et al., 2018; MIKHAEL; HASSALI; HUSSAIN, 2020; MOHAMED et al., 2019), inclusão

apenas de estudos com intervenções em grupo (ODGERS-JEWELL et al., 2017) e a auto gestão não foi considerada como desfecho principal (CHRVALLA; SHERR; LIPMAN, 2016; HILDEBRAND et al., 2020; MOHAMED et al., 2019). Assim, não fica claro pelas revisões disponíveis qual é o papel de intervenções educativas com foco no autogerenciamento do DM na mudança da autogestão da doença e destas no controle clínico da DM. Além disso, o desfecho de controle clínico mais utilizado é a medida da hemoglobina glicada, um método quantitativo e universalmente aceito para avaliar resposta ao tratamento em pacientes com DM (HANAS; JOHN, 2010). Por outro lado, diversos métodos, essencialmente qualitativos, são utilizados para medir o desfecho de autogerenciamento da doença e assim, é importante que as revisões sejam desenvolvidas selecionando estudos que utilizaram métodos validados na literatura (LU et al., 2016).

As principais perguntas que pretendemos investigar no presente trabalho de dissertação são:

1: Quais são as características da educação de autogerenciamento do diabetes usadas com maior frequência no tratamento de pacientes com DM2?

2: Qual é a efetividade da intervenção em educação de autogerenciamento do diabetes no comportamento de autogestão e controle glicêmico de pacientes com DM2?

Assim, o objetivo deste estudo é, por meio de uma revisão sistemática identificar as características das evidências científicas de intervenções para modificar o comportamento de pacientes com DM2 e o impacto na autogestão da doença e no controle glicêmico, medidos por métodos validados.

2. MATERIAIS E MÉTODOS

Trata-se de uma revisão sistemática da literatura, cujo protocolo foi registrado na base de dados *International Prospective Register of Systematic Reviews* (PROSPERO) para registro de protocolos de revisões sistemáticas, CRD42020161162 (Anexo 1). Porém, devido a pandemia de COVID-19, a base de dados PROSPERO ampliou o prazo para avaliação dos protocolos submetidos, e assim, além de não dar o feedback sobre o protocolo, também fechou o sistema para atualizações do protocolo. Para garantir o compartilhamento de informações mais

atualizadas com a comunidade acadêmica optamos por publicar o protocolo no banco de dados público *Open Science Framework*, registro DOI [10.17605/OSF.IO/Z73U2](https://doi.org/10.17605/OSF.IO/Z73U2) (Anexo 2)

A revisão foi realizada segundo as diretrizes do grupo *Cochrane Collaboration* (HIGGINS JPT, THOMAS J, CHANDLER J, CUMPSTON M, LI T, PAGE MJ, 2019) e reportada segundo o *checklist* PRISMA (*Preferred Reporting Items for Systematic Reviews and Meta-Analyses*) (MOHER et al., 2009).

2.1. Estratégia de busca e seleção dos artigos

A população estudada inclui pacientes com DM apenas do tipo 2 maiores de 18 anos, de ambos os sexos, independente de nível de HbA1c e duração do diabetes. Além disso, considerando que os pacientes com DM2 comumente manejam outras doenças, a presença de outras condições de saúde associadas não foi considerada como critério de exclusão.

As intervenções consideradas foram: qualquer intervenção comportamental de autocuidado ministrada de forma ambulatorial, podendo incluir dieta, exercício, medicação ou controle da insulina, monitoramento da glicemia e participação em consultas clínicas, podendo ou não estar baseada no *National Standards for Diabetes Self-Management Education and Support 2017* (BECK et al., 2017).

Quanto ao comparador selecionamos apenas estudos que apresentassem grupo controle que recebeu intervenções não comportamentais, ou os pacientes poderiam receber cuidados usuais ou participar de uma lista de espera para a intervenção futura.

Para os desfechos consideramos estudos que apresentassem simultaneamente, o nível de autogerenciamento do paciente medido por instrumento validado e o nível de controle clínico da doença, expresso de forma objetiva pela medida considerada como padrão ouro para controle glicêmico, ou seja, os níveis de HbA1c. Estudos que apresentaram somente o valor de HbA1c e não apresentaram nenhum instrumento para mensurar o autogerenciamento, ou vice versa, foram excluídos.

Em relação aos tipos de estudos considerados, optamos por incluir apenas ensaios clínicos randomizados (ECR). Foram excluídos estudos desenvolvidos

para avaliar a eficácia de medicamentos, ou com pacientes com diabetes gestacional, DM tipo 1 ou ainda desenvolvidos em ambiente hospitalar.

Foram realizadas buscas eletrônicas de Janeiro de 2020 até Março de 2020. Foram utilizadas as seguintes bases de dados: *Medical Literature Analysis and Retrieval System Online* (MEDLINE), *Excerpta Medica* (EMBASE), CINAHL (Cumulative Index to Nursing and Allied Health Literature), Cochrane Library, *Latin American and Caribbean Literature in Health Sciences* (LILACS), sem restrição de idioma e data de publicação.

A estratégia de busca foi desenvolvida no *MedLine* (Apêndice 1) e adaptada para as demais bases de dados de acordo com os descritores e os manuais de busca. Os artigos encontrados a partir da estratégia de busca foram extraídos e armazenados no gerenciador de referências *Mendeley Desktop*.

2.2. Extração de dados

A extração dos dados dos estudos selecionados foi realizada de forma independente por dois revisores (APB e ICP) e, no caso de discordâncias, estas foram resolvidas por um terceiro revisor (RRB). Depois de avaliados os títulos e resumos pelos dois revisores independentes foi feita a leitura e avaliação do artigo na íntegra.

Os dados para esta revisão foram extraídos manualmente e armazenados em uma planilha do Microsoft Excel. A extração de dados relevantes ao tema em questão foi realizada por dois revisores independentes (APB e ICP). Para isso foi utilizado um formulário de extração de dados pré-definido e as discordâncias foram resolvidas por um terceiro revisor (RRB). Este formulário foi previamente testado, pelos dois revisores, em dez artigos selecionados, a fim de se verificar os ajustes necessários antes de sua aplicação no restante dos estudos. Quaisquer discrepâncias no resumo das evidências foram resolvidas por consenso entre os três autores.

Os dados deste formulário incluíram informações sobre a publicação (autores, ano, título), características dos participantes (número de participantes, idade, sexo e tempo de diagnóstico), detalhes sobre a coleta de dados, detalhes específicos sobre as intervenções, população estudada e os resultados do

tratamento, métodos de estudo e resultados significativos para a pergunta da revisão e objetivos específicos.

Autores de estudos, que não incluíram alguma informação relevante para esta revisão, foram contatados pelos e-mails disponibilizado nas publicações para obter informações consideradas importantes para a compreensão dos estudos.

2.2.1. Avaliação do risco de viés

A avaliação do risco de viés foi feita por dois pesquisadores independentes, utilizando a ferramenta de avaliação de ensaios clínicos randomizados da Cochrane (HIGGINS JPT, THOMAS J, CHANDLER J, CUMPSTON M, LI T, PAGE MJ, 2019) . A ferramenta contém cinco domínios denominados: viés decorrentes do processo de randomização, viés de desvios da intervenção pretendida, viés devido a falta de dados dos resultados, viés de julgamento e medição do resultado e viés na seleção do resultado relatado. Para cada domínio é feita uma avaliação que pode ser: "baixo risco" (se era improvável que um viés alterasse seriamente os resultados) ou "pouco claro" (se era provável que um viés levantasse alguma dúvida sobre os resultados) ou "Alto risco" (se fosse provável que um viés alterasse seriamente os resultados).

A qualidade geral da evidencia foi avaliada baseada no sistema *Grading of Recommendation, Assessment, Development, and Evaluation* (GRADE) (HOLGER SCHÜNEMANN et al., 2013). A avaliação se baseia em quatro categorias em que a evidência pode ser classificada: alta (o efeito verdadeiro está próximo ao da estimativa do efeito), moderada (é provável que o efeito verdadeiro esteja próximo da estimativa do efeito, mas há um possibilidade de que seja substancialmente diferente), baixa(o efeito real pode ser substancialmente diferente da estimativa do efeito) e muito baixa(é provável que o efeito verdadeiro seja substancialmente diferente da estimativa do efeito). A avaliação é baseada em cinco fatores, limitações dos estudos, consistência dos resultados, evidencia indireta, precisão e viés de publicação, que podem reduzir a qualidade da evidencia (HOLGER SCHÜNEMANN et al., 2013).

2.2.2. Análise e síntese dos dados

Devido a variedade das intervenções e dos métodos de avaliação a meta-análise não pôde ser realizada, assim os dados foram expressos em forma de textos e tabelas mantendo a maior fidedignidade possível dos resultados identificados.

3. RESULTADOS

Os resultados e a discussão serão apresentados no formato de artigo submetido a revista *Patient Education and Counseling*.

Title: Diabetes mellitus type 2 behavior changes interventions and effect on self-management and on glycemic control: a systematic review.

Running head: Self-management and glycemic control in diabetes

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ABSTRACT

Purpose: To identify the characteristics of the interventions used to change diabetes mellitus type 2 (T2DM) patient's behavior and the impact of these interventions on patient self-management and on glycemic control, using only validated methods to measure outcomes. **Methods:** This review's protocol was registered in the database international PROSPERO, CRD42020161162. Randomized clinical trials were searched in: MEDLINE, EMBASE, CINAHL, Cochrane Library, and LILACS. Were included randomized clinical trials, with T2DM with more than 18 years old, who received behavior self-management interventions which may include diet, exercise, medication or insulin control, blood glucose monitoring and participation in clinic consultations. About the comparator, just studies with a control group that does not receive a behavioral intervention. The outcomes considered were self-management and Glycated hemoglobin (A1c). The risk of bias and quality of evidence was assessed using an evaluating tool of Cochrane and GRADE, respectively. **Outcomes:** Were included 27 in the analyses, twelve studies show a significant difference between groups to self- management outcome, while for the A1c outcome just 5 studies there were a significant difference between groups. The risk of bias was considered high in most of the studies and the quality of evidence was assessed as very low. Due to the different evaluating methods used in the studies, a meta-analysis could not be performed. **Conclusion:** Several types of interventions may improve the self-management behavior reflecting on glucose level control in patients with T2DM. However, the wide variation in the interventions as well as in the measurement tools limit the overall conclusions. **Implications:** Interventions focusing on the self-management behavior are important to improve DM patients' participation on their own care and could contribute to improve the glucose level control.

Key-words: Self-Management behaviors, self-management and Glycated Hemoglobin A, diabetes mellitus type 2

Introduction

Diabetes Mellitus type 2 (T2DM)' complications eventually may be disable, compromise the quality of life and increase healthcare cost. Considering that, the less the control of glycated hemoglobin (A1c) the more the presence of complications in patients with T2DM, it is extremely important to improve the overall care as well as support patients to maintain A1c under control, a success predictor of the treatment [1]. Improvements in self-management are correlated with the control of chronic disease, including Diabetes Mellitus (DM), and it has been contributed to reduce costs and mortality [2,3].

Managing diabetes is more than controlling blood glucose levels. Reducing the risk of complications requires, besides medicines control [4], a multidimensional treatment, associating medicines, diet and physical exercise. Interventions to change health behavior allows patients to continue their own treatment, managing symptoms, consequences, and lifestyle changes inherent of the disease, which is the principle of self-management [5]. The behavior change is essential to assure the glycemic control benefit, in this way, education programs for diabetes patients, such as diabetes self-management education (DSME), for example, is a kind of intervention proposed to improve to improve self-management and self-efficacy [6].

Several systematic reviews and metaanalysis demonstrated the efficacy of educational behavior intervention to change the behavior and the lifestyle of T2DM patients as well as to improve glycemic control [7–12]. However, in the majority of these reviews, self-management was not considered as a primary outcome [10–12]. Moreover, it is not clear from the available reviews the role of education interventions focusing on diabetes self-management and the contribution of the improvement on self-management in the clinical control of diabetes. Furthermore, although there is a consensus on the use of A1c as a standard quantitative method universally accepted to assess response to treatment in patients with DM [13], many methods have been used to evaluate self-management outcomes, some of them not validated. So, reviews must be developed by selecting studies that used validated methods [14].

Therefore, the objectives of this study were to identify the characteristics of interventions used to change T2DM patient's behavior and the impact of these interventions on patient self-management and on glycemic control, using only validated methods to measure outcomes.

Methods

This systematic review was registered with the International Prospective Register of Systematic Reviews (PROSPERO), registration number CRD42020161162. However, because of the COVID-19 pandemic, the database PROSPERO was unable to give feedback and publish the protocol. Thus, to ensure the sharing of updated information with the academic community we chose to publish the protocol also in Open Science Framework, DOI 10.17605/OSF.IO/Z73U2.

Data sources and searches

The search for the literature was conducted from January 2020 to March 2020 in Medical Literature Analysis and Retrieval System Online (MEDLINE), Excerpta Medica (EMBASE), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Library, Latin American and Caribbean Literature in Health Sciences (LILACS), without language and publication date restrictions. The full- search strategy was developed on MedLine and was modified to match the differences across the other databases (see Appendix I).

The eligibility criteria were pre-determined as any randomized clinical trial (RTC) which included T2DM patients more than 18 years old, both gender, independent of A1c level and time of diagnostic. The interventions considered were: any behavior change intervention (including diet, exercise, medication or insulin control, blood glucose monitoring) focusing on self-management of the disease delivered on outpatient. As a comparator, we considered only studies with control group that did not receive a new behavior change intervention (could be patients in usual care or waitlist). We only considered studies that assessed, concurrently as outcome the level of self-management measured by any validated tool and the disease's level of clinical control, assessed by the objective measurement considered as a gold standard, the level of A1c.

To identify relevant studies, two independent reviewers evaluate the title and abstract, which were retrieved from the electronic search. The entire selected articles were read by both reviewers and included or not in the review, applying the inclusion criteria. In case of discrepancy it was solved by a third reviewer. Two independent reviewers read the entire article to assess and extract data using the same standardized data-extraction data. Authors that did not include important information for this review on their manuscripts were contacted by e-mail.

Risk of bias and quality of evidence assessment

The presence of any risk of bias was assessed by two independent reviewers, based on the Cochrane Risk of Bias tool [15]. This tool evaluates five domains: bias arising from the randomization process, due to deviations from intended interventions, due to missing outcome data, the bias in the measurement of the outcome, and bias in the selection of the reported result. For each domain, the risk-of-bias judgment is done, and assign one of three levels that can be: "low risk" (if present, is unlikely to alter the results seriously) or "Unclear" (the bias raises some doubts about the results) or "High risk" (if bias may alter the results seriously)

The overall quality of evidence was evaluated based upon the system of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) [16]. The evaluation is based on four factors (study limitations, the inconsistency of results, indirectness of evidence, imprecision, and publication bias) that can reduce the quality of the evidence [16].

Data synthesis and analysis

The meta-analysis could not be performed due to the high variability of self-management intervention methodologies used by studies included, as well as due to the different types of outcome measures related to self-management. Therefore, the details of the results are provided in the table-and-text formats keeping the highest possible reliability of the results.

Results

Flow and overall characteristics of trials included

In total, 2615 studies were analyzed by title and abstract and after screening 307 were selected as potentially relevant. In the end, after applying inclusion criteria, 27 studies were included in these analyses [4,17,26–35,18,36–42,19–25]. Figure 1 shows the flow of trials through the review, including the reasons for exclusion. Table 1 presents the overall characteristics of trials included based on the PICOT (population, intervention, comparison, outcomes and time) methodology [44]. Different

methodological approaches were used by the included studies in terms of participants enrolled, characteristics of behavior intervention, behavior assessment methods and time of follow-up (Table 1).

[Insert Figure 1 here]

[Insert Table 1 here]

Characteristics of included trials

Quality

Based on the Cochrane risk of bias tool [15], 26 of 27 studies were considered as a high risk of bias, just Seligman, 2018 et al. was judged as unclear [35]. Few studies [30,31] implemented the participants blinded intervention and the other studies did not report any information about the blinded. The selective reporting bias was high in 14 studies [4,20,38–40,42,24,26,27,29–32,37] because they did not report the number of protocol registration on Clinical Trials or another database to register RTC.

About the quality of evidence based on GRADE [16], 27 studies were assessed on domains that interfere in the quality of evidence: Study limitations (serious limitations reduce one point), Consistency (serious inconsistency reduces one point), Imprecision (absence of imprecision does not reduce the quality of the evidence), Indirect evidence (serious indirect evidence reduces one point) and Publication bias (serious risk of bias reduces one point). In general, the quality of evidence was considered as very low (that means it is probably the real effect that differs substantially from the estimate of the effect).

Participants

The total sample size on trials ranged from 30 to 285 (mean 98) participants. A total of 2307 participants was enrolled in the intervention group (IG), with a mean age of 59.4 years (standard deviation [SD] 6.4) and 2157 in the control group (CG) with a mean age of 59.2 (SD 5.6). Both groups had the same proportion of female: 54%. Details of the overall characteristics of participants enrolled in the included studies are provided in Table 1.

[Insert Table 2 here]

Interventions

Table 2 presents the characteristics of the education interventions on experimental and control groups in terms of way to delivery (individual or group), frequency and duration of interventions as well as a summary of the methodology and content.

All professionals delivering the education intervention were healthcare professionals, in exception of one trial where the responsible for intervention was a non-healthcare profession, a community leader trained to deliver the intervention [25]. In some studies, the intervention was provided by one specific healthcare profession as nurses [4,30,38,41,42], pharmacists [20,24,27,33], psychologist or a social service professional [40]. Six studies included in this review [17,19,29,31,36,37] delivered interventions by a multi-professional team including doctors, physiotherapists, nurses, pharmacists, and other professions. Three studies did not mention the profession of the responsible for the intervention, but mentioned that there was training on how to ministry the intervention [21,28,39]. Authors who did not report the professions or personal training to deliver intervention correspond to 22% of the sample [18,22,23,26,32,35].

The interventions could be categorized into 3 distinct mode of delivering: face-to-face, remote contact or mix. Face-to-face (70%) [4,17,28,30,35–39,41,42,18–21,23–25,27] was delivered individually [4,20,24,27,28,35,36,39,41] or in group [17–19,21,23,25,30,37,38,42]. Interventions in remote contact were delivered using text messaging [22,31] or phone calls [32–34,40]. Just one trial mixed the way of offering intervention: part face-to-face and other part by remote contact [26]. Total of sessions ranged from 1 to 19 sessions and the majority of trials had 3 sessions.

Effects on diabetes self-management

The assessment tools adopted in each trial to evaluate self-management presented large variety of terms (self-care, self-efficacy, self-management) and used different types of measurements properties (Table 3). Due to the differences on authors concepts between constructs like self-care, self-efficacy, and self-management, some authors [18,22,26,31,34,39] applied more than one tool to assess each construct.

The Summary of Diabetes Self-care Activities (SDSCA) is a tool proposed to assess the construct of self-care and was used by thirteen (48%) trials (14,17,35,37,39,18,20,23,24,28,30,32,33). The purpose of this tool is to measure levels of self-management across different components specifically on DM patients [43]. This assessment tool has a Cronbach's alpha = 0,47 [43], considered as a moderate internal consistency [44].

In twelve studies (44%) [4,19,39,41,20,24,28,30,31,33,34,36] the experimental group showed significant improvement in the self-management outcome comparing with control group. Improvements were observed in self-care [20,24,28,30,31,33,34,39,41] construct and self-efficacy [4,19,28,31,34,36,39,41] or in both. The way of assessments on these twelve studies was most face-to-face [4,24,28,36,39,41] and individual [4,20,24,28,36,39,41] with few exceptions using remote contact [31,33,34] or in group of patients [19,30].

Some studies showed the level of significance of the comparison between groups even when it was not significant [18,22,29,30,37,38,42] and other authors did not report any result about the comparison [17,25–27,32,35,40,45].

Even though without significant difference on self-management between groups, several studies showed significant improvement within the intervention group [4,20,23,28,29,32] , but some studies reported improvement in both groups (intervention and control) [17,23,25].

Effects on glycemic control

Between the 12 studies that showed significant improvement on self-management [4,19,39,41,20,24,28,30,31,33,34,36], just four (33,3% of 12 studies) [19,24,28,39] also reported significant difference in the intervention group comparing with control group on A1c outcome. Beyond these 4 studies, a fifth author [42] also observed a glycemic control improvement in the intervention group, even without improvement on self-management. In these interventions, three were individual [24,28,39] and two in groups [19,42]. In the others studies no significant improvement on A1c between groups was observed [4,17,36–38,41,18,20,22,23,30,33–35] and five studies did not report about comparison [25–27,32,40].

Six studies observed significant improvement only within the intervention group [17,23,27,30,37,40] (Table 2). The intervention delivered in these studies was: in-group [17,23,30,37] or individual [27] and all studies that reported a significant

reduction on A1c had face-to-face intervention, exception the Wolever, 2010, that had an intervention by automatic remote messages [40].

Follow-up

The follow-up after interventions varied from 1 to 24 months, mean 7.74 ± 2.12 months. The follow-up period was considered short (≤ 3 months) in 2 studies (7%) [28,37], intermediate ($>3 \leq 6$ months) in 6 studies (22%) [17,22,27,30,40] and long (>6 months) in 11 studies (40%) [20,24,26,29,33,34,39]. Some authors [21,25,36,38,42] realized more than one follow-up measurement (18%), but in this review, we considered the last follow-up that reported the outcomes of interest. Almost 30% of the trials did not realize or report the follow-up.

[Insert Table 3 here]

Discussion

The purpose of this systematic review was to identify the characteristics of the behavior interventions used to change T2DM patient's behavior and the impact of these interventions on patient self-management and on glycemic control, using only validated methods to measure outcomes. The aim was to identify studies with changes in the self-management behavior of the disease with impact on the clinic control. For this, one of the principles previously defined as inclusion criteria was the existence of at least two validate outcomes measured simultaneously: 1) the self-management behavior and 2) the glucose control expressed by the level of A1c. As we considered only studies using validate measurements, although we identified more studies than previous reviews on self-management of diabetes that focused only on A1c [11,12], from 2615 studies only 27 were included in the review after carefully reading. From these, only 4 studies (15%) identified simultaneously statistical improvement of the self-management behavior of the DM and of the A1c [19,24,28,39].

Several studies included in previous reviews [56–60] used intervention programs aiming to improve the self-management behavior, however they did not evaluate the efficacy of the intervention on this construct. It could be acceptable if no tools to access the self-management behavior was available and validate to be used in DM patients. However, it is not the case, as considering the importance of this theme, the American

Diabetes Association (ADA) [6] indicates several tools to evaluate self-management, and self-efficacy. Moreover, a systematic review [14] summarized and reported characteristics and measure proprieties of some tools, which is an important contribution for future trials.

In the present review, we selected only studies who evaluated this construct with validated tools, even though some of them [19,25,29–31,38,40] did not used tools specific for DM patients. Among the studies included in the present review using specific tools for DM [4,17,27,28,32–37,39,41,18,42,20–26], the SDSCA was employed by 13 (48%) studies. SDSCA is a self-administered questionnaire to evaluate self-care in the following domains: general diet, specific diet, exercise, blood sugar testing, foot care and smoking behavior [43]. This questionnaire was validated for many languages, in general with good measures proprieties [43,46–48].

The wide variety of self-management intervention (type of delivery; total number, time and duration of sessions and education tools) as well as the different types of tools to evaluate the outcome self-management behavior make it impossible to run a metaanalysis. Another challenge along the process of doing this review was the lack of consensus on the use of the term self-management, one aspect that probably also contributed to the wide variety of interventions and outcomes measurements. Recently, a concept analysis was conducted with the aim of clarifying this concept, and emphasized the need of consensus to make it more measurable and viable to compare research results [49] as well as to enhance understanding between researchers, health workers and patients.

Despite of the concept or the term reported by the majority of the authors, the selected studies delivered intervention with the objective of inform and training patients to be the more autonomous than possible to live with the consequences of DM in regard to medication, diet, exercise and/or monitoring of symptoms and glucose level. The interventions were delivery majority by health professionals or trained personal and face-to-face, reinforcing that there is a need of focusing on telehealth and remote technologies as a complimentary or alternative way to support DM patients and improve the participation on self-management programs.

The number of studies who had statistical significant improvement on the outcome self-management behavior [4,19,39,41,20,24,28,30,31,33,34,36] was 2.5 bigger than the ones on the outcome A1c [19,24,28,39,42]. The studies with significant improvement on both outcomes [19,24,28,39] had 5 to 12 sessions with intervals,

which may have contributed to the patients better assimilating the informed contents and having the questions answered in the subsequent sessions.

This systematic review has strengths and limitations. The main strength is the selection of studies with validate tools to evaluate the two outcomes: self-management behavior and A1c. The most complete databases for report clinical trials were screened. The main limitations it that a meta-analysis could not be performed and the overall quality of the evidence of the studies based upon the GRADE scale was found to be very low. The complexity and the different interventions protocols [6,50] as well as the multidimensional aspect [14] and different ambiguity of the concept [49] of self-management could be contributed for these limitations. The risk of bias was classified in general as high in 26 studies, in part because of the limitation do blind patients to the intervention. However, this kind of bias is frequently observed in systematic reviews analyzing interventions [45,50–54]. Despite the publication between 2009 and 2019 it was not possible evaluate the selective reporting bias in 14 studies [4,20,38–40,42,24,26,27,29–32,37] as trial registration was not available as demanded since 2005 [55].

Thus, it may be early to draw definitive conclusions regarding the effects of interventions focusing on the self-management of DM on the self-management behavior and on glucose control.

Conclusion

In conclusion, this present review evaluated twenty-seven randomized controlled trials and provides evidence that, several types of interventions may improve the self-management behavior reflecting on glucose level control in patients with T2DM. However, the variations in the interventions as well as in the measurement tools limit the overall conclusions. Therefore, more randomized controlled trials are necessary to verify and draw definitive conclusions regarding the effects of these kind of interventions in individuals with T2DM.

Practical implication

Interventions focusing on the self-management behavior are important to improve DM patients' participation on their own care and could contribute to improve the glucose level control. However, it is important to recognize the complexity of the concept self-management, which imply in wide variety of intervention and outcomes

measurement, and use criteria to plan programs as well to evaluate the effectiveness with appropriated and validated methods.

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APPENDIX 1

Search strategy - MEDLINE

1. exp diabetes mellitus/

2. exp diabetes mellitus type 2/
3. non insulin dependent diabetes mellitus.kw,tw.
4. (behaviour therapy or health behavior or healthy lifestyle or behavior modification or healthy diet or diet program or physical activity program or counseling or Cognitive Behavioral therapy or digital intervention or text messaging or telemedicine or self-management intervention or distance education or Mobile Applications).kw,tw.
5. 1 or 2 or 3
6. (self-efficacy or self-care or self-management intervention or self help or self monitor* or self directedness or personal autonomy or glycated hemoglobin a or blood glucose or Treatment Adherence or Compliance or Patient Compliance or Patient Education as Topic).ab.
7. Randomized Controlled Trial.pt.
8. 4 and 5 and 6 and 7

Figure 1. The flow of studies through the review: ^a Trial may have been excluded, for failing to meet more than one inclusion criterion.

ication

Records identified through
database searching

Records after duplicates removed
(n = 2615)

Records screened
(n = 2615)

Records excluded
(n = 2308)

Full-text articles assessed
for eligibility
(n = 307)

Studies included in
qualitative synthesis
(n = 27)



Table 1 - Characteristics of the Included Randomized Control Trial Studies based on the PICOT

Author/ Year	Enrolled Patients	Model of intervention	behavior Group	Clinical outcomes	Behavioral outcomes	Followup period (months)
Doucette, 2009 [20]	T2DM, A1C of 7.0% or greater as determined by the most recent laboratory test results.	Motivational interview	Usual care	A1C, LDL-C, BMI and blood pressure	SDSCA	12
Lorig [25]	T2MD, 18 years or older, not pregnant or in care for cancer.	Education on diabetes care + written diabetes education materials	Usual care	A1C	Bandura self-efficacy scale PAM-13	6, 12
Sacco, 2009 [32]	T2DM between the age of 18 and 65, able to read and speak English, reachable by telephone, hemoglobin A1c level greater than 6.5%, and at least one of the following cardiovascular risk factors	Phone calls (setting and goal attainment + Education on diabetes care)	Usual care	A1C	The multidimensional diabetes questionnaire self-efficacy subscale	-
Shillinger, 2009 [34]	Adults with T2DM who spoke English, Spanish, or Cantonese, made ≥ 1 primary care visit in the prior year, and had a most recent A1C $\geq 8.0\%$.	ARSM Group: prerecorded calls + automated health education messages GMV Group: presentational education on diabetes care	Usual care	A1C, LDL-C, BMI, blood pressure	SDSCA, PACIC, IPC, Functional status (diabetes interference on daily lives)	12
Wolever, 2010 [40]	T2DM for at least 1 year. English speaking, at least 18 years of age, be taking oral diabetes medication for at least 1 year, and have medical and pharmacy benefit available to the study team	Motivational and education interview + written diabetes education materials	Usual care	A1C	PAM-13 ASK-20, ADS, ISEL-12, PSS-4, SF-12 The Benefit finding scale Exercise frequency	6
Cohen, 2011 [17]	T2DM: A1C > 7.0%, LDL > 100 mg/dL (2.59 mmol/L) or LDL > 70 mg/dL (1.81 mmol/L) for those with coronary artery disease and blood pressure > 130/80 mmHg	Education on diabetes care + behavioral change discussion + Exercise prescriptions	Usual care	A1C blood pressure weight	SDSCA VR-36, PCS,	6
Albert Lee, 2011 [23]	T2DM patients with unstable control, A1c > 7.0%, capable of filling in study diary, capable of giving informed written consent.	Education on diabetes care + training skills + problem-solving activities	Usual care	A1C BMI, waist	DMSES	-
Rv9g, 2011 [29]	T2DM, 18 years or older, and who had been to a general practitioner	Education on diabetes care + training skills + group discussion	Waitlist	A1C BMI, LDL, HDL, creatinine, triglycerides	PAM-13 SF36, PSC and MSC PAID, DTSQ, Diabetes knowledge	12
Sperit-Hillen, 2011 [36]	T2DM, HbA1c test result in the last 6 months of 7% concentration or higher, and no codes for Education Group in the last 2 years or Individual Education n in the last year,	Education on diabetes care	Usual care	A1C	DES-SF	1,4,7,10
Trouilloud, 2012 [37]	T2DM, aged between 20 and 80 years, able to speak and read French.	Education on diabetes care + problem-solving activities	Waitlist	A1C	SDSCA PCS,	3
Crowley, 2013 [19]	T2DM patientes enrolled in primary care at either center, had poorly of the (HbA1c $\geq 7.5\%$) and hypertension (systolic blood pressure [BP] ≥ 140 mmHg or diastolic BP ≥ 90 mmHg), and used medication for diabetes and hypertension.	Education on diabetes care	Usual care	A1C	PCS	-
Sinclair, 2013 [28]	T2DM, 18 years of age or older, self-reported Native Hawaiian, Filipino, or other Pacific Islander ethnic background, English-speaking, and baseline A1c > 7 %.	Education on diabetes care	Waitlist	A1C BMI, LDL, HDL, triglycerides, body pressure	SDSCA Diabetes Care Profile PAID	3

Author/ Year	Enrolled Patients	Model of intervention	behavior	Control Group	Clinical outcomes	Behavioral outcomes	Followup period (months)
Arora, 2014 [22]	T2DM participants who speak and read English or Spanish, use text messages on their mobile telephones, have type 2 diabetes, and have Hb A1C level greater than or equal to 8%.	Phone message with education on diabetes care	with education on	Usual care	A1C	SDSCA DES-SF, MMAS-8, PAID Michigan Diabetes Knowledge test,	6
Peimani, 2015 [31]	T2DM patients owning a mobile phone, consenting to receive text messages, and ability to read text messages.	Phone message with problem-solving techniques	with problem-solving	Usual care	A1C fasting blood sugar test Lipid profile	SCI DMSES, DSCB-OA	-
Van Dijk-de Vries, 2015 [38]	T2DM having a mild to moderate depression towards suffering from both emotional distress and interference in their daily functioning due to the burden of diabetes.	Motivational interview		Usual care	A1C	GSES-12 DFT,4DSQ IPA,PAID,PIH-NL, SF-12	4, 12
Nascimento 2016 [27]	T2DM having a mild to moderate depression suffering from both emotional distress and interference in their daily functioning due to the burden of diabetes.	Education on diabetes care		Usual care	A1C fasting blood glucose	SDSCA	6
Yuan, 2016 [39]	Diagnosed T2DM for ≥ 3 months, aged 19–80 years and with ability to care for themselves.	Motivational interview + education on diabetes care	+ education on	Usual care	A1C	SDSCA DES-SF	12
Wichit, 2016 [41]	T2DM, aged 35 years or older and living in the Thachang District, Thailand; having a fasting plasma glucose level of more than 140 mg% recorded during two follow-up visits at least a month apart; an ability to communicate, read and write the Thai language; willingness to receive home visits; access to a telephone; and having a family member living with them	Written diabetes education materials + education on diabetes care		Usual care	A1C	DMSES SDSCA, PTES, SF- 12, DKQ	-
Cortez, 2017 [18]	T2DM, being literate, aged between 30 and 80 years, having no serious complications, being open to communication and cooperation, agreeing to attend group meetings at the health units and to receive visits at home, providing information for telephone contact, and being sufficiently independent to perform self-care activities.	Education on diabetes care		Usual care	A1C blood pressure BMI, Waist circumference triglycerides cholesterol LDL, HDL	Self-care questionnaire for DM2 ATT, KNW, EPW	-
Korcoez, 2017 [24]	T2DM for at least 6 months, with A1c levels $> 7\%$, and were prescribed at least 1 antidiabetic medication	Education on diabetes care		Usual care	A1C fasting glucose, blood pressure, lipid profile, BMI, waist circumference	SDSCA Morisky-Green	12
McEwen, 2017 [26]	T2DM for at least 1 year, between 35 and 74 years, of Mexican origin, spoke and read Spanish or English, A1C of 8.0% (84 mmol/mol) or greater, had not participated in a diabetes education program in the prior year, able to walk at least 1 mile (determined by self-report), access to and ability to talk on telephone, and had 1 adult family member willing to participate.	Education group classes + home visits + phone calls	+ home visits	Waitlist	A1C Height and weight	Self-Efficacy for Diabetes Scale ARMSA-I, DKQ Diabetes health literacy	9
Surucu, 2017 [30]	Diagnosed with T2DM at least six months before, literate, over 18 years of age, residing in the city center of Izmir, taking insulin or oral anti-diabetic medicines, without a severe vision, hearing, or perception problem, with no physical disability, having received basic diabetes education, and volunteering.	Motivational interview		Usual care	A1C	Self-Care SDSCA	6

Author/ Year	Enrolled Patients	Model of intervention	behavior Group	Clinical outcomes	Behavioral outcomes	Followup period (months)
Whitehead, 2017 [42]	T2DM for 12 months or more, age 18 years and over, and HbA1c >7%, in the past 12-18 months, with at least 2 records of HbA1c >7%, during this period and HbA1c >7%, on recruitment.	Education group: Education plus acceptance and commitment therapy; Education on diabetes care + mindfulness and acceptance training	Education on care	A1C	SDSCA AADQ, HADS Diabetes Care Profile, DTSQ	3,6
Gamboa Moreno, 2018 [21]	T2DM with >18 years old.	Workshop education + written diabetes education materials	Usual care	A1C BMI, LDL, HDL Body pressure	SDSMP ADDQoL-19;PAR	6,12,24
Sarayani, 2018 [33]	T2DM patients using oral hypoglycemic medications, and a HbA1c greater than 7% within the preceding month	Phone calls	Usual care	A1C cholesterol, triglyceride, LDL and HDL	SDSCA Morisky Medication Adherence Scale - 8	9
Seligman, 2018 [35]	T2DM that had an on-site HbA1c of greater than or equal to 7.5%, identified as an existing or new pantry client, were aged 18 years or older, spoke English or Spanish, had a phone or mailing address, and intended to remain in the area for 12months.	Education on diabetes care + written diabetes education materials + food packages with diabetes-appropriate foods	Waitlist	A1C	Multidimensional Questionnaire Patient Health Questionnaire-8 Medication adherence Self-care Food security and food stability, Fruit, vegetable, and sugar intake Costrelated medication nonadherence; Diabetes distress	-
Ayse Dogru, 2019 [4]	T2DM patients aged 18-79 years, diagnosed with T2DM within the preceding six months in accordance with criteria of American Diabetes Association, 3 who had no communication problem, mental confusion and no psychiatric	Motivational interview	Usual care	A1C BMI,FBG,PBG, cholesterol, triglyceride, LDL and HDL	PDSMS	-

Abbreviations: T2DM, type 2 diabetes mellitus; A1c, glycosylated hemoglobin; RCT, randomized controlled clinical trial; BMI: Body Mass Index; FBG: Fasting Blood Glucose; PBG: Postprandial Blood Glucose; LDL: Low Density Lipoprotein; HDL: High Density Lipoprotein

SDSCA, Summary of diabetes self-care questionnaire; PDSMS, Perceived Diabetes Self-Management Scale; SDSMP, Spanish Diabetes Self-Efficacy Scale; DMSES, Diabetes Management Self-Efficacy Scale; DES-SF, Diabetes Empowerment Scale-Short Form; GSES-12, The General Self-Efficacy Scale; DSCB-OA, Diabetes Self-Care Barriers assessment scale for Older Adults; SCI, Self-Care Inventory; PCS, Perceived Competence Scale; SF36, Medical Outcomes Study Short Form-36;; PSC and MSC, Physical and Mental Component Summary; PAID, Problem areas in diabetes; DTSQ, Diabetes treatment satisfaction questionnaire; VR-36, Quality-of-life questionnaire; ISEL-12, Interpersonal Support Evaluation List; PSS-4, Perceived Stress Scale, SF-12, Short-Form Health Survey; PACIC, Patient Assessment of Chronic Illness Care; IPC, Interpersonal Processes of Care for Diverse Populations; (SF)-12, quality of life Short Form; PAR, ADDQoL-19, Physical Activity Recall; The Audit of Diabetes-Dependent Quality of Life; AADQ, Acceptance and Action Diabetes Questionnaire; HADS, Hospital Anxiety and Depression Scale; DTSQ, Diabetes Treatment Satisfaction Questionnaire; ARMSA-I ,Acculturation Rating Scale for Mexican Americans; DKQ, Diabetes knowledge questionnaire; KNW, Knowledge for diabetes type 2; ATT, Attitude for DM2; EPW, Empowerment for DM2; PTES, Perceived Therapeutic Efficacy Scale; DFT, Daily Functioning Thermometer; 4DSQ, Four-Dimensional Symptom Questionnaire; IPA, Impact on Participation and Autonomy; PIH-NL, Partners in Health scale;; MMAS-8, Morisky Medication Adherence Scale; ADS, Appraisal of Diabetes Scale

Table 2. Characteristics of the groups

Author/ Year	Experimental group characteristics	Control group characteristics
Doucette, 2009 [20]	<p>Individual intervention, in person. Total of 4 sessions. In the first visit, pharmacists take a patient history, create a medication list, assess clinical markers, review medications and self-care behaviors, and identify drug therapy problems. Subsequent visits were intended to allow pharmacists to follow-up on previous problems, identify new problems, reassess clinical parameters such as blood glucose and blood pressure, and discuss self-care activities.</p>	<p>The control group received usual diabetes care from their primary care provider. Study participants did not receive additional diabetes education sessions from the participating diabetes education center during the study period.</p>
Lorig 2009 [25]	<p>Group intervention, in person, for 150 minutes per session, 1 time a week. Total of 19 sessions. Class sizes = 10 to 15 including participants' family and friends. Peer leaders came from the same communities as the participants. Most had type 2 diabetes and were not health professionals. Program content included all areas of the American Association of Diabetes Education Standards (AADES7), with 2 exceptions: the process of glucose monitoring and there is no discussion of specific medications. All participants also received a copy of the book <i>Living a Healthy Life With Chronic Conditions</i>.</p>	<p>Usual care ranged from community clinics to specialist care and was representative of care received in urban areas.</p>
Sacco, 2009 [32]	<p>Individual intervention, by phone call, during 15 to 20 minutes per session, weekly in the first 3 months, in the last 3 months every 15 days. Total of 16 sessions. Sessions began with a review of weekly blood glucose readings to identify causes and consequences of "out of range" readings. The remainder of the session focused on weekly goal setting and goal attainment. When goals were not met, the coach attempted to engage the participant in collaborative problem solving to overcome obstacles. Telephone sessions were guided by areas of diabetes self-care: blood sugar testing, medication management, diet/nutrition, exercise/physical activity, foot care, stress management, and when relevant, eye examinations, dental care, and influenza and pneumonia vaccinations.</p>	<p>The control group received treatment as usual from aboard certified endocrinologist</p>
Shilling, 2009 [34]	<p>ARSM Group: prerecorded weekly calls, for 6 to 10 minutes each call, over 9 months. Content of weekly self-management support with nurse follow-up calls symptoms, medication adherence, diet, physical activity, self-monitoring of blood glucose, smoking; psychosocial issues (coping, depressive symptoms, etc.). Depending on the response to an individual item, patients also receive automated health education messages in the form of narratives. GMV Group: Monthly sessions for 90 minutes, over 9 months, with 6 to 10 participants co-facilitated by a primary care physician and health educator. The basic structure: 1) participants report any problems or progress with action plans and the group facilitates problem-solving, 2) discussion of common concerns, or modeling of self-management practices, 3) social break with healthy snacks, 4) short planning session to select subsequent topics, and 5) brief, individualized care to patients with unmet medical needs.</p>	<p>Patients randomized to usual care continue to receive standard diabetes care.</p>

**Author/
Year****Control group characteristics**

Wolever, 2010 [40]
Individual intervention, by phone calls, during 30 minutes each call, 8 weekly calls, 4 biweekly calls, and one call at the end of the program. Total of 14 sessions. At the baseline visit, participants were asked to rate how successful or satisfied they felt (0%-100%) in each of the self-awareness domains (personal development, nutrition, communications and relationships, exercise and physical activity, stress reduction and self-care as taking medications as prescribed). Participants then chose areas on which to focus on coaching. They also received educational material.

Those randomized to the control group received no materials or correspondence during the 6-month period

Cohen, 2011 [17]
Group intervention, in person, during 120 minutes per session, 4 times per week. Total of 9 sessions. Family members, friends, and other sources of social support were encouraged to participate in the sessions with the participants. The educational component followed the curriculum of the American Diabetes Association (ADA), the second part of the intervention was more informal for open discussions about to achieve behavioral change through enhancement of self-efficacy, peer support through the group, and monitoring and reinforcement to target each participant's risk factor control. Participants set dietary goals, keeping a food log, and set goals to increase daily exercise with the use of a pedometer and the step function. Exercise prescriptions were given to each patient, following the recommendations of the American Heart Association.

The standard of care for patients with type 2 diabetes is provided through individual clinic visits with primary care providers once every 4 months. Patient visits with their primary care providers varied from 20- to 60-minute. The primary care providers have access to the same electronic medical record, which contains clinical reminders, computer-based references, drug formulary information, and referral services to diabetes self-management education, nutrition, physical therapy, and the VA's weight loss program MOVE!

Albert Lee, 2011 [23]
Group intervention, in person, for 150 minutes per session, once a week. The intervention was based on the Association of Diabetes Education (AADE) seven self-care behaviors: healthy eating, being active, monitoring, medication taking, problem-solving, reducing risk, and healthy coping. It stimulated learning motives by promoting their problem-solving skills related to their lifestyles and tackling the common problems by discussing every day caring difficulties encountered and hence constructing a healthy behavioral model. Activities included learning and practicing how to use a blood glucose meter; treating low and high values of blood glucose; prevention complications; taking drugs, and keeping medical appointments properly. Self-efficacy enhanced their confidence and ability on self-management so they did not get feelings of helplessness with regard to complications

Both groups (intervention and control) received their usual medical follow-ups in their general outpatient clinics (GOPCs)

Rygg, 2011 [29]
Group intervention, in person, during 300 minutes per session, once a week or once every fifteen days. Total of 3 sessions. The content focuses on information about diabetes type 2 and its complications, diet, physical activity, and improving metabolic control. The teaching methods are (1) lectures with introductory information and questions; (2) interactive learning/skills training (physical activities, measuring blood glucose and problem-solving exercises); (3) group discussion around the patients' experience and questions arising in the group.

Those randomized to the control group were placed on a waiting list and told that they would be offered the program after one year. All participants were informed that they should continue their health care and treatment regardless of the study.

Author/ Year

Control group characteristics

Experimental group characteristics

Spert-Hillen, 2011 [36]	There were two groups: Individual intervention; in person, during 60 minutes per session, once a month. Total of 3 sessions. Group intervention; in person, for 120 minutes per session, once a week, a total of 4 sessions. The intervention was based on the Association of Diabetes Education (AADE) seven self-care behaviors: healthy eating, being active, monitoring, medication taking, problem-solving, reducing risk, and healthy coping	Usual care. The engagement in concurrent education outside of the scheduled research sessions was not prohibited in any treatment group.
Trouilloud, 2012 [37]	Group intervention, in person, for 120 to 180 minutes per session. Total of 8 sessions. Sessions were interactive and patient-centered and consisted of both educational and problem-solving activities on the three main components of diabetes management: diet, physical activity, and medication.	In the control condition, patients were placed on a waiting list for three months.
Crowley, 2013 [19]	Group intervention, in person, during 120 minutes per session, one session every 2 months. Total of 6 sessions. The curriculum if the intervention was: foot care, medications, and how they work, signs and symptoms of hyper and hypoglycemia, diet, managing illness days, blood glucose monitoring, and exercise. patients selected both the topics and the sequence of presentation; the intent was to empower groups to identify their own educational needs.	Patients in the UC group received their usual primary care but no active intervention.
Sinclair, 2013 [28]	Individual intervention, in person, for 60 minutes each session. Total of 12 sessions. The educational component followed the curriculum of the American Diabetes Association (ADA), the program sought to help participants gain knowledge and skills related to blood glucose monitoring, adherence to medication therapy, healthy eating, physical activity, stress reduction, skill-building activities to improve communication with health care providers and help participants become better consumers of diabetes-related healthcare	The waitlist control participants were informed that they should continue to manage their diabetes as usual. They did not receive further contact, information, or educational materials from study staff until it was time to schedule the 3-month assessment. All waitlist control participants were invited to crossover to the intervention after completion of the 3-month assessment.
Arora, 2014 [22]	Individual intervention, by text messaging, two times a day over 6 months. Specific content for each message was: (1) Educational/motivational, these messages were based on the National Diabetes Education Program (NDEP) content. (2) Medication reminders messages provided a trigger to increase adherence with prescribed medications. (3) Healthy living challenges were based on healthy living principles championed by the ADA and the NDEP. (4) Trivia, these messages were derived from NDEP materials and designed to educate and engage patients and were presented in question form.	Usual care
Peimani, 2015 [31]	Text messaging intervention, one per day for 3 months. The curriculum if the intervention was based on areas of diabetes self-care tasks (diet, exercise, blood glucose monitoring, taking medications). The message' content also provided some practical solutions to specific problems of each patient.	None description of the control group.
Van Dijk-de Vries, 2015 [38]	Group intervention, in person, for 20 minutes per session. The intervention delivered was to support patients in the processes of defining problems and finding solutions themselves, by applying problem-solving and reattribution techniques. Both problems solving and reattribution techniques were intended to result in action plans indicating how patients would achieve their personal goals.	Participants in the control arm provided usual diabetes care, conforming to the Dutch guidelines.

Author/ Year Experimental group characteristics

Control group characteristics

Nascimento 2016 [27] Individual Therapeutic education on diabetes care and especially on the patient's pharmacotherapy was provided.

The control group received standard medical care consultation.

Yuan, 2016 [39] Individual intervention, in person, once a month. Total of 12 sessions. Goals were set for dietary changes, physical exercise, and self-monitoring. Participants' diabetes self-care regimens were evaluated with a standard set of questions: (1) How often did you go to the hospital to see the doctor? (2) What kind of medication do you use now? (3) Have you checked your blood glucose. BP, weight, HbA1c, and lipid levels? (4) How often did you exercise? (5) Have you suffered from hypoglycemia this month? How did you deal with it? She gave sufficient information, suggested strategies for change, and answered questions to help participants (a) make decisions related to self-care or managing diabetes-related problems and (b) apply strategies to self-care at home.

In the control group, the diabetes educator met with the participants monthly to go through the same standard set of questions that were used with the CM group. The control group received no CM intervention. If a participant asked questions about how to deal with diabetes, she did not give this information and asked the participant to talk with his/her doctor about these questions.

Wichit, 2016 [41] Individual intervention, in person, for 120 minutes, once a month. Total of 3 sessions. The intervention group received a diabetes information book developed for the authors. The teaching program contained a range of relevant topics including blood sugar monitoring, diet, foot hygiene, physical activity, and coping with diabetes-related complications. Goal setting was demonstrated and then participants established their own goals and designed their action plans.

The controls received standard routine care from clinical staff which included blood sugar testing, medical and nursing physical examinations, and medication follow-up.

Cortez, 2017 [18] Group intervention, in person, during 120 minutes each session. Total of 10 sessions. The content of the curriculum was based on the main topics listed by the users: physical activity, nutritional reeducation, quality of life, complications of DM, self-care, and empowerment. At the end of each meeting, each user set a goal to be achieved as a way to respond to the problem that was addressed.

The control group maintained the traditional care through individual consultations and information about the disease

Korcegez, 2017 [24] Individual intervention, in person, one time every 3 months. Total of 5 sessions. The intervention was the pharmacist explained the importance of self-monitoring blood glucose (SMBG), a healthy diet, physical exercise, and smoking cessation and also provided a different pamphlet (contained information about type 2 diabetes, complications, medications, treatment goals, and self-care)during each visit.

Patients in the usual care group received standard care provided by the outpatient diabetes clinic. Usual care consisted of appointments with physicians every 4-8 weeks to renew prescriptions for their medicines during the study period.

Author/ Year

Experimental group characteristics

McEwen, 2017 [26]
Individual and group intervention, in person and by phone calls, during 120 minutes each session, 20 minutes by phone calls, once a week. Total of 6 group sessions, 3 home visits, and 3 phone call sessions. The intervention sessions included information about managing diabetes to improve glycemic control and prevent complications through food consumed, physical activity, and stress management. The home visits built on and tailor knowledge and skills acquired in the group sessions tailored to the family context. Goals established in the group sessions goal approach were evaluated and redefined if needed in each home visit. The promotor made telephone calls to follow up on the participants' progress and/or barriers in meeting their SMART goals for healthy eating, physical activity, and managing diabetes-related distress.

Surucu, 2017 [30]
Group intervention, in person, during 180 minutes each session, once a week. Total of 3 sessions. At each session, a knowledge deficit of the patients was completed, their treatment and the results were discussed, goals were set and what they will be able to do for achieving the goals were determined. Goals that couldn't be achieved were addressed at each session, the cause of failure was discussed, and a new decision was made.

Whitehead, 2017 [42]
Group intervention, in person, during 390 minutes in a single session.
Education group: The education intervention covered the topics of the basic pathophysiology of diabetes, understanding diabetes, and glucose, understanding the risk factors and complications associated with diabetes, food groups, portion sizes, self-management of diabetes through diet, exercise, medication, and stress management, monitoring diabetes, including awareness of hypo and hyperglycemia, and when to seek help.
Education plus acceptance and commitment therapy (ACT): This group received the same content in education but did not have the opportunity to discuss the material. The ACT component addressed mindfulness and acceptance training about difficult thoughts and feelings about diabetes, exploration of personal values related to diabetes, and a focus on the ability to act in a valued direction while contacting difficult experiences.

Gamboa Moreno, 2018 [21]
Group intervention, in person, during 150 minutes each session, once a week. Total of 6 sessions. The session content includes techniques for dealing with problems in general, promotion of exercise, nutrition concepts, proper use of medication, effective communication, and basic knowledge about diabetes and its complications. The sessions are supported by educational material.

Sarayani, 2018 [33]
Individual intervention, by phone calls. In the first month 2 times a week, the second and third months once a week. Total of 3 sessions. Total of 16 sessions. The intervention included elements of diabetes management, self-care (diet, exercise, blood sugar monitoring, foot examination, smoking), drug therapy (particularly oral medications and their possible side effects), and hands-on training for blood glucose self-monitoring devices. The pharmacist reinforced the training provided in the live session, discussed the trend of blood glucose levels, and solved drug therapy problems, or referred the patients to their physician when appropriate.

Control group characteristics

After the final data collection, a nurse educator conducted the waitlist control group program. Two-hour educational sessions were provided weekly for 3 weeks.

The control group was received routine clinical care and had not been implemented any intervention by researchers during the study.

Participants in the control group continued to receive routine diabetes care. Routine care generally comprised visits to the practice nurse as initiated by the patient with an annual invitation by the practice to attend for a health check. The control groups were not offered the opportunity to participate in an intervention posttrial.

Usual care for T2DM is mainly provided by the primary care professionals and education on diabetes is usually offered by the nurse on an individual basis.

Patients attend the diabetes education workshop (4 hours). SMBG and logbook are provided for all the patients in this group. Test strips are also provided for the study period. The patients receive usual care for the following 3 months.

**Author/
Year****Control group characteristics**

Seligman, 2018 [35]
The intervention included 2 sessions for 2 hours in the first two months, after these sessions were optional, for one hour per month. The intervention included formal diabetes self-management classes and individual check-ins with educators, and twice-monthly food packages containing diabetes-appropriate foods. Participants also received written diabetes education materials at each food distribution, including simple, diabetes-appropriate recipes using foods included in the food packages.

Ayşe Dogru, 2019 [4]
Individual intervention, in person, for 15 to 20 minutes per session, once a month. Total of 4 sessions. Sessions of the motivational interview had 5 steps: self-introduction, data collection, intervention strategies for type 2 diabetes, evaluating the readiness of the patient for change, and strategies used in the motivational interview.

Control participants continued to receive regular food pantry services for 6 months. After their wait period, they received a modified intervention.

The control group received their standard treatments.

Table 3: Description of results (n=27)

Author/ Year	Mensurements	Results [Mean (SD)]
Doucette, 2009 [20]	A1C, SDSCA (cronbach's alpha = 0,47)	<p>A1C: IG : Baseline =7,9 (1,4); Post intervention = 7,72. CG : Baseline = 7,91 (1,91); Post intervention = 8,13 (1,33); Pós - intervenção = 5,43. CG : Baseline = 5,06 (1,33); Pós - intervenção = 5,12.</p> <p>There were no significant differences between groups (p= 0,27) on A1c. Was observed a significant difference (p = 0,027) in self-management of patients on IG compared with the control group.</p>
Lorig 2009 [25]	A1C Bandura self efficacy scale (cronbach's alpha = 0,85) PAM-13 (Infit and Outfit Range = 0,5 to 1,5)	<p>A1C: IG : Baseline = 6,7 (1,48); Post intervention = 6,6. CG : Baseline = 6,74 (1,38); Post intervention = 6,57 (1,7).</p> <p>Bandura self efficacy scale: IG - Baseline = 6,78 (1,86); Post intervention = 7,27 (1,52).CG - Baseline = 6,93 (1,17); Post intervention = 6,78 (1,5,3).</p> <p>PAM : IG - Baseline = 62,9 (16,8); Post intervention = 67,42 (15,8).CG - Baseline = 60,4 (14,9); Post intervention = 62,1 (15,3).</p> <p>There was no significant improvement in A1c in both groups. Was observed a significant self-management improvement in the IG (p = 0,001) and CG. (p = 0,017). Comparations between groups were not significant in any outcome.</p>
Sacco, 2009 [32]	A1C The Multidimensional Diabetes Questionnaire Self-Efficacy subscale (cronbach's alpha = 0,70 to 0,91)	<p>A1C: IG : Baseline = 8,4 (1,37); Post intervention = 7,4 (1,12). CG : Baseline = 8,5 (2,01); Post intervention = 7,8 (1,3).</p> <p>The Multidimensional Diabetes Questionnaire Self-Efficacy subscale: IG - Baseline = 331,6 (180,3); Post intervention = 422,9 (176,4). CG - Baseline = 330,9 (167,6); Post intervention = 352,4 (163,4).</p> <p>There was no significant improvement in A1c in both groups. The intervention had a significant improvement in IG (p<0,01) to activities related to self-care (diet, exercise, food care, blood sugar testing, and medication). Comparations between groups were not significant in any outcome.</p>
Shillinger, 2009 [34]	A1C SDSCA (cronbach's alpha = 0,47)	<p>A1C:Group telephone self-management support : Baseline = 9,3 (1,7); Post intervention = 8,7 (1,9)</p> <p>Group medical visits with physician and health educator facilitation – Baseline = 9,3 (1,9); Post-intervention = 9 (2)GC : Baseline = 9,8 (2); Post intervention = 9 (2,2)</p> <p>SDSCA: Group telephone self-management support - Baseline = 3,7 (1,1); Pos intervention = 4,4 (1,1). Group medical visits with physician and health educator facilitation– Baseline = 3,9 (1,2); Post intervention = 4,1 (1,1) GC - Baseline = 3,9 (1,2); Post intervention = 3,8 (1,1). There was no significant improvement in A1c in both groups. The participant of both groups (Group telephone self-management support and group medical visits with physician and health educator facilitation) had a significant self-management improvement (p=0,02) between groups.</p>
Wolever, Wolever, 2010 [40]	A1C PAM-13(Infit and Outfit Range = 0,5 to 1,5)	<p>A1C: IG : Baseline = 7,9 (1,98) ; Post intervention = 7,5 (1,76). CG : Baseline = 8,11 (1,92) ; Post intervention = 8,2 (1,92)</p> <p>PAM-13 : IG - Baseline = 64,6 (19,54); Post intervention = 79,3 (18,62)</p> <p>CG - Baseline = 64,5 (16,09); Post intervention = 67,4 (14,41).</p> <p>There was a significant improvement on A1c (p=0,03) in the IG after 6 months of follow-up and, in the CG was not observed significant improvement. The self-management had a significant improvement in the intervention (p<0,01) group after 6 months of follow-up and, in the CG was not observed significant improvement. Comparations between groups were not significant in any outcome.</p>
Cohen, 2011 [17]	A1C SDSCA (cronbach's alpha = 0,47)	<p>A1C: IG : Baseline = 7,8 (1); Post Intervention = 7,39. CG : Baseline = 8,1 (1,4); Post Intervention = 7,9.</p> <p>SDSCA : IG - Baseline General diet :4,49 (1,93), specific diet: 3,98 (1,50), exercise: 2,98 (2,01), blood sugar monitoring: 3,81 (2,78), foot care: 4,04 (2,37), smoking (31,25(20,16). Post Intervention: = General diet: 4,81, exercise: 3,81, blood sugar monitoring: 6,11, foot care: 5,5), smoking: 22,5 CG – Baseline = General diet:3,91 (1,79), specific diet: 3,41 (1,69) exercise: 2,34 (2,30), blood sugar monitoring: 4,08 (2,86), foot care: 3,84 (2,47) smoking 15 (5). Post Intervention: = General diet : 4,62, specific diet: 4,23, exercise: 2,78, blood sugar testing: 4,75, foot care: 4,31and smoking: 12,67. There was a significant improvement on A1c in the intervention group (p<0,05). Was observed a significant improvement to activities related to self-care (general diet, specific diet, blood sugar testing; p<0,05) in both groups, but just the IG had a significant improvement (p<0,05) on activities like exercise and foot care.</p>

Tabela 3: Continuation

Author/ Year	Mensurements	Results [Mean (SD)]
Albert Lee, 2011 [2]	A1C DMSES (cronbach's alpha = 0,95)	A1C: IG : Baseline =8,12; Post intervention = 7,2. CG : Baseline = 8,4; Post intervention = 7,47 DMSES: GI - Baseline = 76 Post intervention = 82. GC - Baseline = 75 Post intervention = 76. In the IG was observed a significant improvement (p<0,05) on A1c. Both groups had a significant improvement in self-efficacy. Comparisons between groups were not significant in any outcome.
Rygg, 2011 [29]	A1C PAM-13(Infit and Outfit range = 0,5 to 1,5)	A1C: IG : Baseline = 7,1 (1,4); Post intervention = 7,2 (1,2). CG : Baseline = 6,9 (1,3); Post intervention = 7,2 (1,4) PAM: IG - Baseline = 71 (14,4); Post intervention = 73 (12,5). CG - Baseline = 72,4 (15); Post intervention = 73 (15,3). Comparisons between groups were not significant on A1c. In the IG was observed a significant self-management improvement (p=0,05) after 12 months, there was no significant difference in the control group, although comparisons between groups were not significant.
Sperl-Hillen, [36]	201 HbA1C DES-SF (cronbach's alpha = 0,90)	A1C: Group individual education : Baseline = 8,14 ; Post intervention = 7,63. Group education in groups – Baseline = 8,07; Post intervention = 7,8. GC : Baseline = 8; DES-SF: Group individual education - Baseline = 3,82; Post intervention = 3,98(14,6). Group education in groups – Baseline =3,8; Post intervention = 3,85 GC - Baseline = 3,76; Post intervention = 3,82. There was a significant improvement on A1c (p = 0,01) in the group individual education (-0,51%), with patients from group education in groups (-0,27%) and, with patients of CG (-0,24%). Comparisons between groups were not significant on A1c. Comparing group individual education with group education in groups were found a significant difference between groups (p=0,04), favoring the group individual education.
Trouilloud, 2012[37]	A1C SDSCA (cronbach's alpha = 0,47)	A1C: IG : Baseline = 7,61 (1,45); Post intervention = 6,68 (1,17). CG : Baseline = 7,46 (1,16); Post intervention = 7,29 (1,04) SDSCA: IG - Baseline General diet :3,22 (2,74), exercise: 1,17 (1,71), medication = 6,4 (0,97). Pós-intervenção: = General diet: 5,54 (2,51), exercise: 2,99 (2,04), medication = 6,39 (0,8). CG – Baseline = General diet:3,33 (2,77), exercise: 2,28 (2,17), medication = 6,53 (1,27). Post intervention: = General diet :3,86 (1,59), exercise: 2,7 (1,99), medication = 6,69 (1,47). IG showed a significant improvement in A1c (p < 0.001). The self-management activities (exercise and diet) increased in the IG (p < 0.001). Comparisons between groups were not significant in any outcome.
Crowley, 2013 [19]	A1C PCS (cronbach's alpha > 0,80)	A1C: IG : Baseline; No insulin = 8,8; Basal only: 8,6; Complex: 8,4 ; No insulin = 8,8; Basal only: 8,6; Complex: 8,4. Post intervention; No insulin = 8,3; basal only: 8,6; Complex: 8,0. GC : Baseline; no insulin = 8,8; Basal only: 8,2 ; Complex: 9,4. Post intervention ; No insulin = 8,2; PCM: Baseline; IG: No insulin = 15,8; Basal only: 15,8; Complex: 15,5. Post intervention: No insulin = 16,6; Basal only: 15,8; Complex: 15,7. GC : No insulin = 14,5; Basal only: 15,8; Complex: 14,7. Post intervention: No insulin = 14,5; Basal only: 15,4; Complex: 13,8. The complex group showed a significant reduction in A1c (p= 0,01) between groups with complex patients. There was a significant self-efficacy improvement between groups with no insulin (p=0,0004) patients and complex (p=0,004).
Sindlair, 2013 [28]	A1C SDSCA (cronbach's alpha = 0,47)	A1C: IG : Baseline = 9,9 (2); Post intervention = 8,9 (1,7). CG : Baseline = 9,8 (2,2); Post intervention = 9,4 (2,2) SDSCA IG : Baseline = 19(5); Post intervention = 24 (4). CG : Baseline = 20 (5); Post intervention = 21 (5). There was a significant reduction in A1c (p = 0,001) between IG and CG. Was observed a significant self-management improvement (p < 0,0001) between groups.
Arora, 2014 [22]	A1C SDSCA (cronbach's alpha = 0,47) Diabetes Empowerment Scale Short Form (cronbach's alpha = 0,85)	A1C: IG : Baseline = 10,1; Post intervention = 9,05. CG : Baseline = 9,85; Post intervention = 9,25. SDSCA : IG - Baseline General diet :3,1 (2,4), specific diet: 4 (1,6), exercise: 2,4 (2,4), blood sugar testing: 2,7 (2,8), foot care: 3,9 (2,6). Post intervention: = general diet: 4,7 (2,2), specific diet: 4,8 (1,6), exercise: 3,5 (2,4), blood sugar testing: 4,1 (2,7), foot care: 5,4 (2,7). CG – Baseline = General diet :3 (2,2), Specific diet: 4,2 (1,5) exercise: 2,9 (2,6), blood sugar testing: 3,2 (2,9) foot care: 4,1 (2,5). Postt intervention: = General diet : 4,5(2,3), Specific diet: 4,5 (1,2), Exercise: 3,4(2,7), blood sugar testing: 4 (2,7), foot care: 5,5 (2,5). Empowerment Scale : IG - Baseline = 3,6 (0,9); Post intervention = 4 (0,8). CG - Baseline = 3,6 (0,8); Post intervention = 3,9 (0,9).

IG showed more A1c reduction (1,05%) comparing with CG (0,60%). Was not observed a significant self-management improvement in any group. Comparisons between groups were not significant in any outcome.

Tabela 3: Continuation

Author/ Year	Measurements	Results [Mean (SD)]
Peimani, 2015 [31]	A1C SCI (cronbach's alpha = 0,88) DMSES(cronbach's alpha = 0,95)	A1C: Individually tailored SMS group : Baseline = 7,29 (1,33); Post intervention = 7,06 (1,31). Non-tailored SMS group – Baseline = 7,53 (1,47); Post intervention = 7,26 (1,32). CG: Baseline = 7,52 (1,49); Post intervention = 7,55 (1,44). SCI: Individually tailored SMS group - Baseline = 55,4 (10,5); Post intervention = 49,9 (11,2). Non-tailored SMS group – Baseline = 55,4 (10,6); Post intervention = 65,7 (9,9) CG - Baseline = 54,5 (9,13); Post intervention = 49,9 (11,5). DMSES: Individually tailored SMS group - Baseline = 57,4 (12,9); Post intervention = 43,7 (11,5). Non-tailored SMS group – Baseline = 53,6 (12,3); Post intervention = 39,7 (8,6). CG - Baseline = 58,9 (11,8); Post intervention = 66,9 (11,3). There was no significant improvement between groups in A1c. IG had a significant self-efficacy and self-care improvement between groups (p<0,001).
Van Dijk-de Vrie 2015 [38]	Vrie A1C GSES-12 (cronbach's alpha > 0,60)	A1C: IG : Baseline = 7 (3,2); Post intervention = 6,9 (3,1). CG : Baseline = 6,9 (3,1); Post intervention = 6,8 (3) GSES-12 : IG - Baseline = 38,6 (7,5); Post intervention = 38,6 (7,6). CG - Baseline = 39,2 (7); Pos intervention = 40,4 (6,9). Comparisons between groups were not significant in any outcome.
Nascimento, 201 A1C [27]	A1C SDSCA (cronbach's alpha = 0,47)	A1C: GI : Baseline = 8,6 (1,2); Post intervention = 7,7 (0,8). GC : Baseline = 8,2 (0,7); Post intervention = 7,99 (0,67). SDSCA: GI - Baseline General diet :4,7 (1,2), Specific diet: 2,8 (0,6), exercise: 2,4 (2,3), blood sugar testinf: 6,5 (0,5), foot care: 6,9 (0,5). Post intervention: = General diet : 5,5 (1,2), Specific diet: 2,5 (0,6), Exercise: 3,6 (1,7), Blood sugar testing: 6,9 (0,5), foot care: 7 (0). GC – Baseline = General diet :5,2 (1,3), Specific diet: 2,5 (0,7), Exercise: 1,9 (1,8), blood sugar testing: 6,8 (0,6), foot care: 6,7 (0,9). Post intervention: = General diet : 5,5 (1,3), specific diet: 2,5 (0,7), exercise: 2,4 (0,7), blood sugar testing: 6,8 (0,4), foot care: 6,8 (0,7). IG and CG had a significant reduction in A1C (p <0,05). There were not significant self-care improvement in the IG and CG.
Yuan, 2016 [39]	A1C SDSCA (cronbach's alpha = 0,47) DES-SF (cronbach's alpha = 0,85)	A1C: IG : Baseline = 7,75 ; Post intervention = 7,05. CG : Baseline = 7,44 ; Post intervention = 7,24 SDSCA: IG - Baseline = 48,89 (16,55); Post intervention = 58,58 (6,62) CG - Baseline = 44,69 (14,68); Post intervention = 45,98 (18,22) DES-SF: IG Baseline = 34,72 (4,1); Post intervention = 38,85 (2,94) CG - Baseline = 33,96 (4,18); Post intervention = 35,33 (3,07). There was a significant improvement between groups in A1c (p = 0,034) after 6 months. After 12 months the self-management behavior had a significant improvement (p<0,001) between groups.
Wichit, 2016 [41]	A1C DMSES(cronbach's alpha = 0,95) SDSCA (cronbach's alpha = 0,47)	A1C: IG : Baseline = 7 (2) ; Post intervention = 7 (1,2). CG : Baseline = 6,3 (1,5) ; Post intervention = 7,3 (1,4) DMSES: IG - Baseline = 55,6 (12); Post intervention = 76 (9,4). CG - Baseline = 58,7 (11,4); Post intervention = 60,7 (13,1) SDSCA: IG - Baseline = 80,9 (15,9); Post intervention = 102,8 (12,1). CG - Baseline = 80,5 (13,4); Post intervention = 80,4 (18,1) No significant differences in A1C were found between baseline, post-intervention, and follow-ups for any of the groups, neither comparisons between groups. IG had a significant self-efficacy and self-care improvement between groups (p < 0,001).
Cortez, 2017 [18]	A1C ESM (Cohen's kappa coefficient = 0,56 to 0,69)	A1C: IG : Baseline = 8,1 (2,0); Post intervention = 7,5(1,7). CG : Baseline = 7,9 (19); Post intervention = 8,1 (2,2) Self-care questionnaire: IG : Baseline = 3,4 (1,1); Post intervention = 4,2 (1,2) CG : Baseline = 3,9 (1,2); Post intervention = 3,3 (1,1). Significant differences in A1C (p = 0,029) were found between baseline, post-intervention. IG had a significant self-care improvement (p<0,001). Comparisons between groups were not significant in any outcome.

Table 3: Continuation

Author/ Year	Measurements	Results [Mean (SD)]
Korcegez, 2017 [24]	A1C SDSCA (cronbach's alpha = 0,47)	A1C: IG : Baseline = 8,29 (0,98); Post intervention = 7,55 (0,57). CG : Baseline = 8,31 (0,84); Post intervention = 8,26 (0,74). SDSCA : IG - Baseline General diet : 2,93 (1,1), exercise: 1,56 (2,49), blood sugar testing: 3,11 (2,85), Foot care: 0,22 (0,83, smoking: 12 (16). Post intervention: = General diet: 3,33 (0,85), exercise: 2,34(2,33), blood sugar testing: 3,93 (2,53), foot care: 1,82 (1,05), smoking: 8 (10,7), CG – Baseline = General diet:2,94 (1,13), exercise: 1,66 (2,3), blood sugar testing: 2,31 (2,5), Foot care: 0,3 (0,8), smoking: 14 (18,2). Post intervention: = General diet : 2,84 (0,72), exercise: 1,57 (1,79), blood sugar testing : 2,22 (2,23), Foot care: 0,33 (0,76), smoking: 13 (16,9). IG had a significant reduction (p<0.001) in A1C between groups. Comparing groups, the IG had a significant self-care improvement in some activities (General diet, blood sugar testing, foot care; p<0,001)
McEwen, 2017 [26]	A1C Self-Efficacy for Diabetes Scale (cronbach's alpha = 0,81)	A1C: IG : Baseline = 9,9 (1,6); Post intervention = 9,19 (2,1). CG : Baseline = 9,87 (1,6); Post intervention = 9,2 (2) Self-Efficacy for Diabetes Scale : IG - Baseline = 3,66 (0,9); Post intervention = 4,18 (0,7). CG - Baseline = 3,76 (1,1); Post intervention = 3,98 (0,9). There was no significant improvement in A1c with any group. IG had a significant self-efficacy improvement (p=0,01).
Surucu, 2017 [30]	A1C Self-Care Agency Scale (test retest reliability = 0,79 to 0,84) SDSCA (cronbach's alpha = 0,47)	A1C: IG : Baseline = 7,85 (1,73); Post intervention = 7,47 (1,51). CG : Baseline = 7,68 (1,6); Post intervention = 7,48 (1,42). Self-Care Agency Scale: IG - Baseline = 106,9 (13,9); Post intervention = 113,6 (12,1).CG - Baseline = 108,2 (14,4); Post intervention = 108,1 (13,1). SDSCA: IG - Baseline = 4,07 (1,85); Post intervention = 4,57 (1,6).CG - Baseline = 5,64 (1,95); Post intervention = 5,06 (1,89). There was no significant improvement in A1c between groups (p=0,97). The Self-care agency Scale showed a significant self-care improvement after the intervention. (p=0,018)
Whitehead, [42]	201 A1C SDSCA (cronbach's alpha = 0,47)	A1C: Education group : Baseline = 8,13 ; Post intervention = 7,92. Education and acceptance and commitment therapy group : Baseline = 7,78 ; Post intervention = 7,74. GC : Baseline = 8,08 ; Post intervention = 8,40. SDSCA: Education group : Baseline = 10,3 (4,25) ; Post intervention = 9,5 (5,16). Education and acceptance and commitment therapy group: Baseline = 10,8 (4,78) ; Post intervention = 12,17 (4,05). GC : Baseline = 9,77 (4,62) ; Post intervention = 9,73 (4,78). There was a significant difference between groups in A1c (p = 0.01) with CG and education group after 6 months of intervention, but there was not a significant difference between CG and education and acceptance and commitment therapy group (p = 0.07). Was observed a self-care improvement on education and acceptance and commitment therapy group but it was not significant (p=0,07)
Gamboa 2018 [21]	Moren ⁿ A1C SDSMP(cronbach's alpha = 0,82 to 0,88)	A1C: IG : Baseline =7,2 (1,3); Post intervention = 7,2(1,4). CG : Baseline = 7,1 (1,2); Post intervention = 7 (1,1) SDSMP: IG - Baseline = 6,8 (1,6); Post intervention = 7,5 (1,3).CG - Baseline = 6,7 (1,7); Post intervention = 7,2(1,5). There was no significant improvement between groups and between baseline and post-intervention in A1c. IG had a significant self-efficacy improvement (p = 0.041) between groups.

Table 3: Continuation	Author/ Year	Measurements	Results [Mean (SD)]
	Sarayani, 2018 [33]	A1C SDSCA (cronbach's alpha = 0,47)	IG : Baseline = 7,84 (1,17); CG : Baseline = 8,16 (1,66); SDSCA: IG - Baseline General diet = 0,0 (0), Specific diet: 2,5 (1,7), exercise = 1 (3,5), blood sugar testing = 1 (2,7), Foot care = 3,5 (7) and smoking = 10. Post intervention: = General diet = 6 (4), Specific diet = 3,7 (2,5), exercise = 3,5 (3), blood sugar testing = 3 (2), Foot care = 7 (0) and smoking = 8. CG – Baseline: General diet = 0,0 (0), Specific diet = 2,7 (1,5), exercise = 1,5 (3), blood sugar testing = 1 (3,2), Foot care = 3,5 (5,5) and smoking = 6. Post intervention; General diet = 3 (6) , Specific diet = 2,7 (1,5), exercise = 2 (3), blood sugar testing = 3 (2), Foot care = 7 (2,5) and smoking= 5. There was no significant improvement between groups (p= 0,78) but between baseline and post-intervention in A1c both groups had an improvement. Self-care activities as a general diet, specific diet, and exercise had a significant improvement between groups after 9 months of intervention (p<0,05).
	Seligman, 2018 [35]	A1C Multidimensional Diabetes Questionnaire (cronbach's alpha = 0,70 to 0,91)	IG : Baseline = 9,75 (1,79); CG : Baseline = 9,74 (1,76); Multidimensional Diabetes Questionnaire: IG - Baseline = 6,7 (1,8); Post intervention = 7,4. CG - Baseline = 6,8 (2); Post intervention = 7,2. Comparations between groups were not significant in any outcome.
	Ayşe Dogru, 2014 [4]	A1C PDSMS(cronbach's alpha = 0,82 to 0,90)	IG : Baseline = 10,1 (2,9); Post intervention = 9,1(2,5). CG : Baseline = 8,4 (2,2); Post intervention = 8,9 (2,4) PDSMS: IG - Baseline = 17,1(5,6) Post intervention = 35 (4,1). CG : Baseline = 21,7 (3,3); Post intervention = 16,5 (2,6). There was a significant improvement (p<0,05) between baseline and post-intervention in A1c but, there was not significant improvement between groups. IG had a significant self-management improvement (p<0,001) between groups.

SD: standard deviation IG: Intervention group,CG: control group A1c: glycated hemoglobin SDSCA: Summary of Diabetes Self Care Activities; PCS: Perceived Competence Scale; PDSM: Perceived Diabetes Self-Management Scale; SDSMP: Spanish Diabetes Self-Efficacy Scale; ESM: Self-care questionnaire for T2DM; DMSES: Diabetes Management Self-Efficacy Scale; PAM: Patient activation; DES-SF: Diabetes Empowerment Scale–Short Form; SMS: Mobile Short Message Service

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APÊNDICE 1

Estratégia de busca MEDLINE

1. exp diabetes mellitus/
2. exp diabetes mellitus type 2/
3. non insulin dependent diabetes mellitus.kw,tw.
4. (behaviour therapy or health behavior or healthy lifestyle or behavior modification or healthy diet or diet program or physical activity program or counseling or Cognitive Behavioral therapy or digital intervention or text messaging or telemedicine or self-management intervention or distance education or Mobile Applications).kw,tw.
5. 1 or 2 or 3
6. (self-efficacy or self-care or self-management intervention or self help or self monitor* or self directedness or personal autonomy or glycated hemoglobin a or blood glucose or Treatment Adherence or Compliance or Patient Compliance or Patient Education as Topic).ab.
7. Randomized Controlled Trial.pt.
8. 4 and 5 and 6 and 7

Estratégia de busca EMBASE

('diabetes mellitus':ti,ab,kw OR 'non insulin dependent diabetes mellitus':ti,ab,kw) AND ('behavior therapy':ti,ab,kw OR 'health behavior':ti,ab,kw OR 'healthy lifestyle':ti,ab,kw OR 'healthy diet':ti,ab,kw OR 'cognitive behavioral therapy':ti,ab,kw OR 'text messaging':ti,ab,kw OR telemedicine:ti,ab,kw OR 'mobile application':ti,ab,kw OR 'education, distance':ti,ab,kw OR 'diet program':ti,ab,kw OR 'physical activity program':ti,ab,kw OR counseling:ti,ab,kw OR 'digital intervention':ti,ab,kw) AND ('self care':ti,ab,kw OR 'self-management':ti,ab,kw OR 'personal autonomy':ti,ab,kw OR 'patient compliance':ti,ab,kw OR 'patient education':ti,ab,kw OR 'self help':ti,ab,kw OR 'self directedness':ti,ab,kw OR 'self monitor*':ti,ab,kw OR 'glycosylated hemoglobin':ti,ab,kw OR 'glucose blood level':ti,ab,kw)

Estratégia de busca Cochrane Library

1. diabetes mellitus OR diabetes type 2 OR non insulin dependent diabetes mellitus in Title Abstract Keyword AND
2. behaviour therapy or health behavior or healthy lifestyle or behavior modification or healthy diet or diet program or physical activity program or counseling or Cognitive Behavioral therapy or digital intervention or text messaging or telemedicine or self-management intervention or distance education or Mobile Applications in Title Abstract Keyword AND
3. self-efficacy or self-care or self-management intervention or self help or self monitor* or self directedness or personal autonomy or glyated hemoglobin a or blood glucose or Treatment Adherence or Compliance or Patient Compliance or Patient Education as Topic in Title Abstract Keyword AND
4. randomized controlled trials OR randomized control trial OR rtc in Publication Type

Estratégia de busca Cinahal

1. AB (TX diabetes mellitus OR TX diabetes type 2 OR non insulin dependent diabetes mellitus) AND
2. TX (behaviour therapy or health behavior or healthy lifestyle or behavior modification or healthy diet or diet program or physical activity program or counseling or Cognitive Behavioral therapy or digital intervention or text messaging or telemedicine or self-management intervention or distance education or Mobile Applications) AND
3. AB (self-efficacy or self-care or self-management intervention or self help or self monitor* or self directedness or personal autonomy or glyated hemoglobin a or blood glucose or Treatment Adherence or Compliance or Patient Compliance or Patient Education as Topic) AND
4. PT (randomized controlled trials or randomized controlled trial or rct)

Estratégia de busca BVS

("Diabetes Mellitus" OR "Diabetes Mellitus" OR "Diabetes Mellitus" OR diabete OR "Diabete Melito" OR diabetes OR "Diabetes Melito" OR "Diabetes Mellitus, Type 2" OR "Diabetes Mellitus Tipo 2" OR "Diabetes Mellitus Tipo 2" OR "Diabetes Mellitus não Dependente de Insulina" OR "Diabetes Mellitus não Insulino-Dependente" OR "Diabetes Mellitus não Insulinodependente" OR "Diabetes Tipo 2" OR "Diabetes do Tipo 2") AND ("Behavior Therapy" OR "Terapia Conductista" OR "Terapia Comportamental" OR "Modificação de Comportamento" OR "Terapia de Condicionamento" OR "Health Behavior" OR "Conductas Relacionadas con la Salud" OR "Comportamentos Relacionados com a Saúde" OR "Healthy Lifestyle" OR "Estilo de Vida Saludable" OR "Estilo de Vida Saudável" OR "Healthy Diet" OR "Dieta Saludable" OR "Dieta Saudável" OR "Alimentação Saudável" OR "Índice de Alimentação Saudável" OR "Cognitive Behavioral Therapy" OR "Terapia Cognitivo-Conductual" OR "Terapia Cognitivo-Comportamental" OR "Text Messaging" OR "Mensaje de Texto" OR "Mensagem de Texto" OR "SMS" OR telemedicine OR telemedicina OR telemedicina OR "Education, Distance" OR "Educación a Distancia" OR "Educação a Distância" OR "Mobile Applications" OR "Aplicaciones Móviles" OR "Aplicativos Móveis" OR "Diet program" OR "Physical activity program" OR counseling OR "Digital intervention") AND ("Self Care" OR autocuidado OR autocuidado OR autoajuda OR "Self-Management" OR automanejo OR autogestão OR "Personal Autonomy" OR "Autonomía Personal" OR "Autonomia Pessoal" OR "Treatment Adherence and Compliance" OR "Cumplimiento y Adherencia al Tratamiento" OR "Cooperação e Adesão ao Tratamento" OR "Patient Compliance" OR "Cooperación del Paciente" OR "Cooperação do Paciente" OR "Patient Education as Topic" OR "Educación del Paciente como Asunto" OR "Educação de Pacientes como Assunto" OR "self management" OR "self help" OR self monitor* OR "self directedness" OR "Hemoglobin A" OR "blood glucose") AND (db:("campusvirtualsp_brasil" OR "LILACS" OR "IB ECS" OR "BDENF" OR "MedCarib" OR "SMS-SP" OR "PAHOIRIS" OR "BBO" OR "BRISA" OR "INDEXPSI" OR "coleccionaSUS"))

Systematic review

1. * Review title.

Give the title of the review in English

Effectiveness interventions used to change Diabetes Mellitus type 2 patient's behavior: a systematic review of the effects on self-management and glycemetic control

2. Original language title.

For reviews in languages other than English, give the title in the original language. This will be displayed with the English language title.

Eficácia de intervenções para mudar o comportamento de pacientes com diabetes melitus tipo 2: uma revisão sistemática dos efeitos na autogestão e controle glicêmico.

3. * Anticipated or actual start date.

Give the date the systematic review started or is expected to start.

06/01/2020

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

08/08/2020

5. * Stage of review at time of this submission.

Tick the boxes to show which review tasks have been started and which have been completed. Update this field each time any amendments are made to a published record.

Reviews that have started data extraction (at the time of initial submission) are not eligible for inclusion in PROSPERO. If there is later evidence that incorrect status and/or completion date has been supplied, the published PROSPERO record will be marked as retracted.

This field uses answers to initial screening questions. It cannot be edited until after registration.

The review has not yet started: No

Review stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	Yes
Risk of bias (quality) assessment	Yes	Yes
Data analysis	Yes	Yes

Provide any other relevant information about the stage of the review here.

6. * Named contact.

The named contact is the guarantor for the accuracy of the information in the register record. This may be any member of the review team.

Ana Paula Delgado Bomtempo Batalha

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

Sra. Batalha

7. * Named contact email.

Give the electronic email address of the named contact.

ana.dbomtempo@gmail.com

8. Named contact address

Give the full institutional/organisational postal address for the named contact.

Rua Professor JosĂ© Spinelı 115V202, Bairro, Juiz de Fora, Minas Gerais, Brasil. CEP: 36050120

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

+5532991458596

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

Universidade Federal de Juiz de Fora

Organisation web address:

Av. Eugenio do Nascimento s/n Bairro Dom Bosco, Juiz de Fora – MG – CEP: 36038-330

11. * Review team members and their organisational affiliations.

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. **NOTE: email and country now MUST be entered for each person, unless you are amending a published record.**

Ms Ana Paula Delgado Bomtempo Batalha. Universidade Federal de Juiz de Fora
Dr Raquel Rodrigues Britto. Universidade Federal de Juiz de Fora
Miss Isabela Poncciano. Universidade Federal de Juiz de Fora
Dr Gabriela Chaves. York University, Toronto
Dr Diogo de Carvalho Felicio. Universidade Federal de Juiz de Fora

12. * Funding sources/sponsors.

Details of the individuals, organizations, groups, companies or other legal entities who have funded or sponsored the review.

Coordination for the Improvement of Higher Education Personnel and the National Council for Scientific and Technological Development

Grant number(s)

State the funder, grant or award number and the date of award

13. * Conflicts of interest.

List actual or perceived conflicts of interest (financial or academic).

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country must be completed for each person, unless you are amending a published record.**

15. * Review question.

State the review question(s) clearly and precisely. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS or similar where relevant.

Question 1: What are the characteristics of interventions to change the behavior used most often in the treatment of patients with diabetes type 2?

Question 2: What are the types of interventions to change the behavior more used in the treatment of diabetes type 2 patients?

16. * Searches.

State the sources that will be searched (e.g. Medline). Give the search dates, and any restrictions (e.g. language or publication date). Do NOT enter the full search strategy (it may be provided as a link or attachment below.)

A literature search will be performed using four electronic databases including MEDLINE, EMBASE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Cochrane Library, LILACS from the date of database inception (06 January 2020) to current. The search strategy was developed in MEDLINE, peer-

~~The review and trials are identified in all languages and search terminologies of the other databases.~~

17. URL to search strategy.

Upload a file with your search strategy, or an example of a search strategy for a specific database, (including the keywords) in pdf or word format. In doing so you are consenting to the file being made publicly accessible. Or provide a URL or link to the strategy. Do NOT provide links to your search results.

https://www.crd.york.ac.uk/PROSPEROFILES/161162_STRATEGY_20200122.pdf

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Do not make this file publicly available until the review is complete

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied in your systematic review.

Diabetes is a public health issue worldwide. It has a global pandemic status with over 400 million people suffering from the disease worldwide, and its prevalence continues to increase every year. This systematic review will assess the effectiveness of diabetes self-management educations associated with improvement of self-management and glycemic control of adults with Type 2 diabetes.

19. * Participants/population.

Specify the participants or populations being studied in the review. The preferred format includes details of both inclusion and exclusion criteria.

~~Inclusion criteria:~~
Inclusion criteria:

- diagnosed with type 2 diabetes.

Exclusion criteria:

- Type 1 diabetes
- Gestational diabetes
- Patients in hospital inpatient settings,

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the interventions or the exposures to be reviewed. The preferred format includes details of both inclusion and exclusion criteria.

We will include trials that evaluated the effectiveness of a self-management intervention in adults with Type 2 DM. Nature of interventions: self-management intervention. Self-management interventions include diet, exercise, medication or insulin management, blood glucose monitoring and attending clinical consultations.

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the intervention/exposure will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

~~Will be patients with type 2 diabetes who receive a behavioral intervention~~

22. * Types of study to be included.

Give details of the study designs (e.g. RCT) that are eligible for inclusion in the review. The preferred format includes both inclusion and exclusion criteria. If there are no restrictions on the types of study, this should be stated.

We will include only randomized controlled trials.

23. Context.

Give summary details of the setting or other relevant characteristics, which help define the inclusion or exclusion criteria.

24. * Main outcome(s).

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

The primary outcomes are changes in objective clinical parameters from baseline to the last available follow-up. Self-management behaviour measured by any validated instrument;

2. Glycated hemoglobin (HbA1C) level;

*** Measures of effect**

Please specify the effect measure(s) for you main outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

We will measure the effect of the intervention at any time.

25. * Additional outcome(s).

List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state 'None' or 'Not applicable' as appropriate to the review

None

*** Measures of effect**

Please specify the effect measure(s) for you additional outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

Not applicable

26. * Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

Data will be extracted from papers included in the review by two independent reviewers. The results of these processes will then be discussed between reviewers, and any disagreements regarding study selection will be raised with a third independent reviewer, who will be blinded to the judgements of the first and second

The selected studies will be recorded by a reporting and coding

Desktop software.

Data regarding study design and methodology, and data regarding participant demographics and treatment

outcomes (including effect sizes) will then be extracted from the relevant studies by the reviewer, and exported into a table in a Microsoft Word document.

The method of combining individual study data will involve manually tabulating the relevant extracted data using Microsoft Word software.

The data extracted will include specific details about the interventions, populations, data regarding participant demographics and treatment outcomes (including effect sizes), study methods and outcomes of significance to the review question and specific objectives.

27. * Risk of bias (quality) assessment.

State which characteristics of the studies will be assessed and/or any formal risk of bias/quality assessment tools that will be used.

Two authors will independently review risk of bias for the randomized controlled trials using the Cochrane Risk of Bias Tool, which includes seven domains of potential bias (bias arising from the randomization process, bias due to deviation from intended intervention, bias due to missing outcomes data, bias in measurement of the outcome and bias in selection of the reported result) and overall risk of bias categorization.

Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with the involvement of a third review author where necessary.

28. * Strategy for data synthesis.

Describe the methods you plan to use to synthesise data. This must not be generic text but should be specific to your review and describe how the proposed approach will be applied to your data. If meta-analysis is planned, describe the models to be used, methods to explore statistical heterogeneity, and software package to be used.

This systematic review will include a qualitative synthesis, which will provide information, both in the text and in the tables, to summarize included studies results.

Data extracted from included studies will be synthesized statistically using meta-analytic techniques if studies are sufficiently homogeneous in relation to interventions and outcomes. Data synthesis will be performed according to the statistical guidelines provided in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green 2011). Will be conducted analyses to explore associations between self-management intervention content and changes in HbA1c.

29. * Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.

If the required data are available and homogeneous, subgroup analyses will be carried out for the following

Subgroup diagnostic: more than 10 years and less than 10 years.

2. Age: (65 years versus older)

3. Baseline glycaemic control: HbA1C of less than 7% and 7% or higher.

4. Type of intervention.

30. * Type and method of review.

Select the type of review, review method and health area from the lists below.

Type of review

Cost effectiveness

No

Diagnostic

No

Epidemiologic

No

Individual patient data (IPD) meta-analysis

No

Intervention

Yes

Meta-analysis

Yes

Methodology

No

Narrative synthesis

No

Network meta-analysis

No

Pre-clinical

No

Prevention

No

Prognostic

No

Prospective meta-analysis (PMA)

No

Review of reviews

No

Service delivery

No

Synthesis of qualitative studies

No

Systematic review

Yes

Other
No

Health area of the review

Alcohol/substance misuse/abuse
No

Blood and immune system
No

Cancer
No

Cardiovascular
Yes

Care of the elderly
No

Child health
No

Complementary therapies
No

COVID-19
No

Crime and justice
No

Dental
No

Digestive system
No

Ear, nose and throat
No

Education
No

Endocrine and metabolic disorders
No

Eye disorders
No

General interest
No

Genetics
No

Health inequalities/health equity
No

Infections and infestations
No

International development

No

Mental health and behavioural conditions

No

Musculoskeletal

No

Neurological

No

Nursing

No

Obstetrics and gynaecology

No

Oral health

No

Palliative care

No

Perioperative care

No

Physiotherapy

No

Pregnancy and childbirth

No

Public health (including social determinants of health)

No

Rehabilitation

Yes

Respiratory disorders

No

Service delivery

No

Skin disorders

No

Social care

No

Surgery

No

Tropical Medicine

No

Urological

No

Wounds, injuries and accidents

No

Violence and abuse

No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.

English
Portuguese-Brazil

There is not an English language summary

32. * Country.

Select the country in which the review is being carried out. For multi-national collaborations select all the countries involved.

Brazil

33. Other registration details.

Name any other organisation where the systematic review title or protocol is registered (e.g. Campbell, or The Joanna Briggs Institute) together with any unique identification number assigned by them. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

34. Reference and/or URL for published protocol.

If the protocol for this review is published provide details (authors, title and journal details, preferably in Vancouver format)

Add web link to the published protocol.

Or, upload your published protocol here in pdf format. Note that the upload will be publicly accessible.

No I do not make this file publicly available until the review is complete

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans.

Do you intend to publish the review on completion?

Yes

Give brief details of plans for communicating review findings.?

A paper will be submitted to a journal in this field.

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords help PROSPERO users find your review (keywords do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

Systematic review; Diabetes mellitus type 2; self-management education

37. Details of any existing review of the same topic by the same authors.

If you are registering an update of an existing review give details of the earlier versions and include a full

bibliographic reference, if available.

38. * Current review status.

Update review status when the review is completed and when it is published. New registrations must be ongoing so this field is not editable for initial submission.

Please provide anticipated publication date

Review_Completed_not_published

39. Any additional information.

Provide any other information relevant to the registration of this review.

40. Details of final report/publication(s) or preprints if available.

Leave empty until publication details are available OR you have a link to a preprint (NOTE: this field is not editable for initial submission). List authors, title and journal details preferably in Vancouver format.

Give the link to the published review or preprint.

Effectiveness interventions used to change Diabetes Mellitus type 2 patient's behavior: a systematic review protocol of the effects on self-management and glycemic control

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Public

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Date created: 2020-04-07 02:35 PM | Last Updated: 2020-11-26 11:06 AM

Identifier: DOI 10.17605/OSF.IO/Z73U2

Category: Project

Description: Summary Diabetes is a public health issue worldwide. It has a global pandemic status with over 400 million people suffering from the disease worldwide, and its prevalence continues to increase every year. This systematic review will assess the effectiveness of diabetes self-management educations associated with improvement of self-management and glycemic control of adults with Type 2 diabetes.

Our key research questions are: Question 1: What are the characteristics of interventions to change the behavior used most often in the treatment of patients with diabetes type 2?

Question 2: What are the types of interventions to change the behavior more used in the treatment of diabetes type 2 patients?

Literature search will be performed using four electronic databases including MEDLINE, EMBASE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Cochrane Library, LILACS from the date of database inception (06 January 2020) to current.

The search strategy was developed in MEDLINE, peer-reviewed and translated to accommodate the search terminologies of the other databases. The search will not be limited to language and date.

Inclusion criteria: - 18 years old or over - diagnosed with type 2 diabetes.

Exclusion criteria: - Type 1 diabetes - Gestational diabetes - Patients in hospital inpatient settings,

We will include trials that evaluated the effectiveness of a self-management intervention in adults with Type 2 DM. Nature of interventions: self-management intervention. Self-management interventions include diet, exercise, medication or insulin management, blood glucose monitoring and attending clinical consultations.

Usual care will be any kind of diabetes treatment without behavioral intervention or waitlist.

The primary outcomes are changes in objective clinical parameters from baseline to the last available follow-up from baseline, which include:

1. Self-management behavior measured by any validated instrument;
2. Glycated hemoglobin (HbA1C) level; Data will be extracted from papers included in the review by two independent reviewers.

The results of these processes will then be discussed between reviewers, and any disagreements regarding study selection will be raised with a third independent reviewer, who will be blinded to the judgements of the first and second reviewers, and who will hold the right to make the final decision. The selected studies will be recorded by exporting and storing the relevant references using Mendeley Desktop software. Data regarding study design and methodology, and data regarding participant demographics and treatment outcomes (including effect sizes) will then be extracted from the relevant studies by the reviewer, and exported into a table in a Microsoft Word document.

The method of combining individual study data will involve manually tabulating the relevant extracted data using Microsoft Word software. The data extracted will include specific details about the interventions,

OSF | Effectiveness interventions used to change Diabetes Mellitus type 2 patient's behavior: a systematic review protocol of the effects on self-management and glycemic control populations, data regarding participant demographics and treatment outcomes (including effect sizes), study methods and outcomes of significance to the review question and specific objectives. Two authors will independently review risk of bias for the randomized controlled trials using the Cochrane Risk of Bias Tool, which includes seven domains of potential bias (bias arising from the randomization process, bias due to deviation from intended intervention, bias due to missing outcomes data, bias in measurement of the outcome and bias in selection of the reported result) and overall risk of bias categorization. Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with the involvement of a third review author where necessary. This systematic review will include a qualitative synthesis, which will provide information, both in the text and in the tables, to summarize included studies results. Data extracted from included studies will be synthesized statistically using meta-analytic techniques if studies are sufficiently homogeneous in relation to interventions and outcomes. Data synthesis will be performed according to the statistical guidelines provided in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green 2011). Will be conducted analyses to explore associations between self-management intervention content and changes in HbA1c. If the required data are available, subgroup analyses will be carried out for the following subgroups: 1. Time of diagnostic: more than 10 years and less than 10 years. 2. Age: (<65 years versus older) 3. Baseline glycemic control: HbA1C of less than 7% and 7% or higher. 4. Type of intervention.

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Ana Paula Delgado Delgado Bomtempo Batalha (/duqzs/) added Diogo Carvalho Felício as contributor(s) to Effectiveness interventions used to change Diabetes Mellitus type 2 patient's behavior: a systematic review


2020-11-26 11:06 AM

 Ana Paula Delgado Delgado Bomtempo Batalha (/duqzs/) edited description of Effectiveness interventions used to change Diabetes Mellitus type 2 patient's behavior: a systematic review protocol of the effects on self-management and glycemic control (/z73u2/)


2020-11-24 11:16 AM

 Ana Paula Delgado Delgado Bomtempo Batalha (/duqzs/) changed the title from Effective of different types of self care behavior intervention and clinic control in diabetes type 2 patients: a systematic review protocol to Effectiveness interventions used to change Diabetes Mellitus type 2 patient's behavior: a systematic review protocol of the effects on self-management and glycemic control (/z73u2/)


2020-11-24 11:12 AM

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2020-07-07 03:34 PM

 Ana Paula Delgado Delgado Bomtempo Batalha (/duqzs/) added Gabriela Chaves (/jm386/), Isabela Coelho Ponciano, and Raquel Rodrigues Britto (/jwx5v/) as contributor(s) to Effectiveness interventions used to change Diabetes Mellitus type 2 patient's behavior: a systematic review protocol of the effects on self-management and glycemic control (/z73u2/)

2020-04-08 04:40 PM

 Ana Paula Delgado Delgado Bomtempo Batalha (/duqzs/) created external identifier(s) doi:10.17605/OSF.IO/Z73U2 on Effectiveness interventions used to change Diabetes Mellitus type 2 patient's behavior: a systematic review protocol of the effects on self-management and glycemic control (/z73u2/)

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