

UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL
PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS MÉDICAS:
ENDOCRINOLOGIA

O EFEITO DE UM CURSO EDUCATIVO PARA AGENTES COMUNITÁRIOS
DE SAÚDE E DA ENTREVISTA MOTIVACIONAL NA
HEMOGLOBINA GLICADA DE PACIENTES COM DIABETES: ENSAIO
CLÍNICO RANDOMIZADO E META-ANÁLISE

TESE DE DOUTORADO

CAMILA FURTADO DE SOUZA

Porto Alegre, agosto de 2015.

UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL
PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS MÉDICAS:
ENDOCRINOLOGIA

O EFEITO DE UM CURSO EDUCATIVO PARA AGENTES COMUNITÁRIOS
DE SAÚDE E DA ENTREVISTA MOTIVACIONAL NA
HEMOGLOBINA GLICADA DE PACIENTES COM DIABETES: ENSAIO
CLÍNICO RANDOMIZADO E META-ANÁLISE

CAMILA FURTADO DE SOUZA

Orientadora: Profa. Dra. Cristiane Bauermann Leitão

Tese de Doutorado a ser apresentada ao
Programa de Pós-Graduação em
Ciências Médicas: Endocrinologia da
Universidade Federal do Rio Grande
do Sul (UFRGS) como requisito para
obtenção do título de Doutor em
Endocrinologia.

Porto Alegre, agosto de 2015.

CIP - Catalogação na Publicação

FURTADO DE SOUZA, CAMILA
O EFEITO DE UM CURSO EDUCATIVO PARA AGENTES
COMUNITÁRIOS DE SAÚDE E DA ENTREVISTA MOTIVACIONAL NA
HEMOGLOBINA GLICADA DE PACIENTES COM DIABETES:
ENSAIO CLÍNICO RANDOMIZADO E META-ANÁLISE / CAMILA
FURTADO DE SOUZA. -- 2015.
66 f.

Orientador: Cristiane Bauermann Leitão .

Tese (Doutorado) -- Universidade Federal do Rio
Grande do Sul, Faculdade de Medicina, Programa de Pós-
Graduação em Ciências Médicas: Endocrinologia, Porto
Alegre, BR-RS, 2015.

1. Diabetes. 2. Hemoglobina glicada. 3.
Entrevista motivacional. 4. Agentes comunitários de
saúde. 5. Educação em saúde. I. Bauermann Leitão ,
Cristiane , orient. II. Título.

DEDICATÓRIA

Aos meus pais, com muito amor.

“Não se preocupe em entender, viver ultrapassa qualquer entendimento.”

Clarice Lispector

AGRADECIMENTOS

A minha querida orientadora e amiga Profa. Dra. Cristiane Bauermann Leitão, a motivação para seguir na Pós-Graduação, com a certeza da sua orientação presente, do seu apoio e compreensão; e por dividir comigo sua sabedoria e seus conhecimentos muita além das nossas pesquisas científicas.

À amiga Alessandra Teixeira Netto Zucatti, pela ajuda na coleta dos dados, pelo profissionalismo e companheirismo durante toda a Pós-Graduação, a minha e a dela.

Às alunas de iniciação científica Mériane Boeira Dalzochio, Marília Tavares de Almeida e Rosana De Nale, pela indispensável colaboração na coleta de dados e realização de todos os procedimentos do estudo com responsabilidade e dedicação.

À Gerência Distrital Partenon-Lomba do Pinheiro, que permitiu que abrissemos a UBS São Pedro nos sábados e domingos para realizar a pesquisa.

À equipe de ESF São Pedro, da qual eu sinto muita saudade, especialmente às agentes comunitárias de saúde, pela participação, apoio e dedicação na pesquisa que realizamos durante todo o ano de 2010 na comunidade desta unidade de saúde.

Ao Serviço de Atenção Primária do Hospital de Clínicas de Porto Alegre, pelo incentivo ao estudo, ao ensino e à pesquisa.

Ao meu namorado Micael, que me fez aproveitar mais o mundo durante esse período, que suaviza a minha caminhada, que me alegra tanto e faz o tempo passar mais devagar e mais leve.

Aos meus queridos irmãos, Gabriel, Fernanda, Thais e Augusto, com quem eu posso contar sempre, pelo carinho, companheirismo, incentivo e apoio.

Aos meus pais, maior razão e motivação para tudo isso.

Ao meu pai, que me faz a maior falta do mundo. A minha mãe, por ser quem ela é.

SUMÁRIO

Agradecimentos	iv
Lista de Abreviaturas	viii
Resumo	ix
<i>Introdução</i>	xii
<i>Artigo 1</i>	19
Effect of motivational interviewing on HbA1c of patients with diabetes: A systematic review and meta-analysis of randomized controlled trials	
Abstract	20
Introduction	21
Methods	22
Search strategy and eligibility criteria	22
Studies selection and Data Extraction	23
Quality Assessment	24
Statistical Analysis	24
Results	25
Literature search results and studies characteristics	25
Motivational Interviewing and HbA1	26
Effect at three months	26
Effect at six months	27
Effect at 12 months	27
Effect at 24 months	27
Publication bias	28
Discussion	28

Author Contributors	31
Conflict of interest statement.....	32
Acknowledgments.....	32
References.....	33
<i>Artigo 2.....</i>	44
Efficacy of an Education Course Delivered to Community Health Workers in Diabetes Control: a Randomized Clinical Trial	
Abstract	45
Introduction	47
Research Design and Methods	48
Trial design and study settings	48
Participants	48
Baseline assessments.....	48
Interventions	49
Laboratory analysis.....	50
Statistical analysis.....	51
Results.....	51
Baseline characteristics.....	51
Follow-up results	52
Discussion	53
Conflict of interest statement.....	56
Acknowledgments.....	56
References.....	58

LISTA DE TABELAS E FIGURAS

Artigo 1

Table 1.	Characteristics of the included studies	39
Table 2.	Studies risk of bias assessment.....	40
Figure 1.	Flow diagram of literature search to identify randomized clinical trials of Motivational Interviewing for Diabetes Management.....	41
Figure 2.	Effect of motivational interviewing on HbA1c at 3 (A), 6 (B), 12 (C) and 24 months (D).....	42
Figure 3.	Funnel plots for studies evaluating HbA1c at 3 (A), 6 (B), 12 (C) and 24 months (D).....	43

Artigo 2

Table 1.	Baseline clinical and laboratory characteristics according to group of randomization.....	62
Table 2.	Changes in clinical and laboratory variables before and after intervention	63
Figure 1.	HbA1c values in control and intervention groups.....	64

LISTA DE ABREVIATURAS

ADA	<i>American Diabetes Association</i>
ANOVA	<i>One- way analysis of variance</i>
APS	<i>Atenção Primária à Saúde</i>
BMI	<i>Body Mass Index</i>
BP	<i>Blood Pressure</i>
CHW	<i>Community Health Workers</i>
CI	<i>Confidence interval</i>
DAWN2	<i>Diabetes Attitudes, Wishes and Needs second study</i>
DBP	<i>Diastolic Blood Pressure</i>
DCNT	<i>Doenças Crônicas Não Transmissíveis</i>
DM	<i>Diabetes Mellitus ou Diabetes Melito</i>
DSME/S	<i>Diabetes Self-Management Education and Support</i>
GRADE	<i>The Grading Recommendations Assessment, Development and Evaluation</i>
HbA1c	<i>Hemoglobina glicada ou glycated hemoglobin</i>
MI	<i>Motivational Interviewing</i>
MS	<i>Ministério da Saúde</i>
ND	<i>No demonstrable</i>
PAID	<i>Problem Areas in Diabetes</i>
PRISMA	<i>Preferred Reporting Items for Systematic Reviews and Meta-Analyses</i>
RCT	<i>Randomized Clinical Trials</i>
SBP	<i>Systolic Blood Pressure</i>
SUS	<i>Sistema Único de Saúde</i>

Resumo

O Diabetes Melito (DM) é uma doença crônica que se tornou uma epidemia mundial. O tratamento do DM é complexo e requer mudanças comportamentais e adesão ao uso de medicamentos. Entretanto, a má adesão entre pacientes com DM é muito prevalente e está relacionada a múltiplos fatores biopsicossociais e a características dos serviços de saúde.

A Associação Americana de Diabetes preconiza padrões de educação e suporte para o autocuidado em DM que levam em consideração crenças individuais relacionadas à saúde, bem como questões relacionadas à cultura e ao meio em que esse indivíduo está inserido. No Brasil, o Ministério da Saúde estabeleceu ações programáticas para melhorar o acesso ao tratamento e acompanhamento do DM nos serviços de atenção primária. Entretanto, apesar dos recursos disponíveis, as metas de controle da doença são atingidas em menos de 50% dos pacientes e os déficits no conhecimento e habilidades no autocuidado do DM atingem 50 a 80% dos pacientes.

A entrevista motivacional (EM) é uma abordagem não-confrontativa que trabalha com a motivação do indivíduo, levando em consideração suas necessidades e experiências. Tem como objetivo principal promover a mudança comportamental em pessoas que resistem a mudar um comportamento de risco. Os agentes comunitários de saúde (ACS) são profissionais que atuam na integração dos serviços de saúde da Atenção Primária com a comunidade. Desenvolvem ações de promoção e vigilância em saúde na comunidade, contribuindo para melhoria da qualidade de vida das pessoas. O primeiro artigo desta tese demonstrou, através de uma revisão sistemática e meta-análise, que a entrevista motivacional está associada à melhora do controle glicêmico em pacientes com DM. O benefício foi detectado em três e 12 meses em pacientes com DM tipo 2, e em estudos com duração de 24 meses em pacientes com DM tipo 1. O segundo artigo demonstrou, através

de um ensaio clínico randomizado com pacientes com DM tipo 2, que um curso educativo administrado para agentes comunitários de saúde reduz significativamente a HbA1c e o estresse relacionado ao DM ao longo do tempo, porém de forma semelhante nos grupos intervenção e controle. Uma melhora significativa no perfil lipídico (colesterol total e triglicerídios) foi observada no grupo intervenção.

O maior desafio dos profissionais de saúde que tratam o DM é apoiar os pacientes na realização de mudanças comportamentais necessárias usando estratégias bem aceitas e que levem em consideração o seu contexto individualmente. Nesse sentido, a EM e o suporte social e educacional dos ACS são intervenções que podem ser utilizadas para alcançar metas e que podem ser úteis no complexo contexto do manejo de pacientes com DM.

Esta tese de doutorado será apresentada no formato exigido pelo Programa de Pós-Graduação em Ciências Médicas: Endocrinologia. Ela será constituída de uma introdução em português e de dois artigos em inglês: uma revisão sistemática com meta-análise e um ensaio clínico randomizado.

Introdução

Atualmente, as doenças e agravos não transmissíveis são responsáveis por 60% de todo o ônus decorrente de doenças no mundo. O crescimento é tão vertiginoso que em 2020, estima-se que 80% da carga de doença dos países em desenvolvimento devam advir destas doenças.¹ O Diabetes Mellitus (DM) é uma doença crônica que se configura hoje como uma epidemia mundial.^{2,3}

Estima-se que o Brasil passe da 8ª posição em frequência de pacientes com DM, com prevalência de 4,6% em 2000, para a 6ª posição, com 11,3% em 2030.^{1,3,4} Os fatores de risco relacionados aos hábitos alimentares e estilo de vida da população estão associados a este incremento na prevalência do DM globalmente. As complicações agudas e crônicas do DM causam alta morbimortalidade, acarretando elevados custos para os sistemas de saúde. Estudo realizado pela Organização Mundial da Saúde mostrou que os custos governamentais de atenção ao DM variam de 2,5% a 15% dos orçamentos anuais de saúde, e os custos de produção perdidos podem exceder, em até cinco vezes, os custos diretos de atenção à saúde.^{1,4,5}

O tratamento do DM requer mudanças comportamentais, especialmente na dieta e na atividade física diária, e adesão ao uso de medicamentos. Entretanto, a má adesão entre pacientes com DM é muito prevalente.⁶ Em pacientes com DM tipo 1, estudos prospectivos mostram que a taxa de pacientes que “nunca deixam de fazer uma injeção de insulina” pode variar de 92% em adultos jovens⁷ a 53% em crianças⁸. Em pacientes com DM tipo 2, somente 52% dos pacientes aderem ao plano alimentar recomendado⁹, 26% aderem ao plano de atividade física orientado⁹, 52% se exercitam pelo menos 3 vezes na semana¹⁰, e 70 a 80% aderem ao tratamento com anti-hiperglicemiante oral¹¹. Vários fatores influenciam a taxa de adesão ao tratamento do DM, dentre eles o subtipo de DM (ou seja, tipo 1, tipo 2 ou gestacional), idade, sexo e o nível de complexidade do regime de

tratamento. Além desses, também têm um papel importante na adesão a nacionalidade, a cultura e a subcultura do indivíduo, bem como a organização do sistema de saúde, a cobertura dos cuidados de saúde e fatores socioeconômicos.^{6, 12} Considerando que a adesão ao tratamento está associada a um melhor controle glicêmico e a uma menor utilização dos recursos de saúde¹³, é imprescindível que todos esses fatores sejam levados em consideração na abordagem e manejo de pacientes com DM.

A má adesão ao tratamento não parece estar associada a um perfil psicológico específico. Entretanto, transtornos depressivos e distúrbios alimentares são relativamente comuns em pacientes com DM e podem estar associados com hiperglicemia. Ansiedade e estresse não estão associados a um efeito hiperglicêmico consistente, mas podem piorar o controle glicêmico, causando episódios recorrentes de hipoglicemia grave e cetoacidose diabética.^{14, 15} O estudo DAWN2 demonstrou que o DM afeta negativamente a qualidade de vida dos pacientes e também de seus familiares. Pessoas com DM relatam um impacto negativo sobre a sua relação com a família, amigos e colegas (21%), nas atividades de lazer (38%), no trabalho/estudos (35%) e na sua situação financeira (44%); e 39% referem que tomar medicação interfere com a sua capacidade de levar uma vida normal.¹⁶ O entendimento do autocuidado em DM como um processo que envolve fatores cognitivos, emocionais, comportamentais e sociais é o primeiro passo para ajudar os pacientes a melhorar o controle da doença.¹⁴

O DM é uma doença difícil de ser manejada com sucesso. A análise epidemiológica, econômica e social do número crescente de pessoas que vivem com DM mostra a necessidade da implantação de políticas públicas de saúde que minimizem as dificuldades dessas pessoas e de suas famílias, e propiciem a manutenção da sua qualidade de vida.² Para tanto, a Associação Americana de Diabetes (ADA) estabelece padrões de educação e suporte para o autocuidado em DM, denominados *Diabetes Self-Management*

Education and Support (DSME/S). O DSME/S é um componente importante do cuidado integral do diabetes. Trata-se de uma intervenção em que os pacientes aprendem sobre o DM e como implementar o autocuidado que é imperativo no controle da doença, com o suporte contínuo necessário.^{17, 18}

Atualmente, as intervenções do DSME/S têm uma abordagem centrada no paciente e são projetadas para levar em consideração as crenças individuais relacionadas à saúde, as necessidades culturais, o conhecimento atual do paciente, as suas limitações físicas, suas preocupações emocionais, o apoio à família, a situação financeira, a história médica, a alfabetização, e outros fatores que possam influenciar a capacidade de cada pessoa para enfrentar os desafios do autocuidado. A ADA preconiza que todos os indivíduos com DM recebam DSME/S no momento do diagnóstico e, se necessário, posteriormente.^{17, 18}

No Brasil, o Plano de Reorganização da Atenção à Hipertensão Arterial e ao Diabetes Mellitus e a Política Nacional de Medicamentos, implementados pelo Ministério da Saúde (MS) em 2000, teve por objetivo estabelecer diretrizes e metas para essa reorganização no Sistema Único de Saúde (SUS), investindo na atualização dos profissionais da atenção primária à saúde (APS), oferecendo a garantia do diagnóstico e do acesso gratuito ao tratamento medicamentoso, e proporcionando a vinculação dos pacientes às unidades de saúde para tratamento e acompanhamento a partir de ações programáticas específicas nas equipes de Saúde da Família, ampliando o atendimento resolutivo e de qualidade para esses pacientes.¹⁹

Em 2011, foi criado o Plano de Ações Estratégicas para o Enfrentamento das Doenças Crônicas Não Transmissíveis (DCNT) no Brasil, 2011-2022 do MS, que visa preparar o Brasil para enfrentar e deter, nos próximos dez anos, as DCNT dentre as quais estão: acidente vascular cerebral, infarto, hipertensão arterial, câncer, diabetes e doenças respiratórias crônicas. No país, essas doenças constituem o problema de saúde de maior

magnitude e correspondem a cerca de 70% das causas de mortes, atingindo fortemente camadas pobres da população e grupos mais vulneráveis, como a população de baixa escolaridade e renda. Dentre as ações propostas pelo plano, estão a expansão da atenção farmacêutica e da distribuição gratuita de mais de 15 medicamentos para hipertensão e diabetes (anti-hipertensivos, insulinas, hipoglicemiante, ácido acetil salicílico, estatina, entre outros). Em março de 2011, o programa Farmácia Popular passou a ofertar medicamentos gratuitos para hipertensão e diabetes em mais de 17.500 farmácias privadas credenciadas. Essa medida ampliou ainda mais o acesso e aumentou em 70% a distribuição de medicamentos para hipertensos e diabéticos.²⁰

Esse plano também prevê a expansão da APS– nível de atenção que cobre cerca de 60% da população brasileira. As equipes de saúde de APS atuam em território definido, com população adstrita, realizando ações de promoção, vigilância em saúde, prevenção, assistência, além de acompanhamento longitudinal dos usuários, o que é fundamental na melhoria da resposta ao tratamento dos usuários com DCNT.²⁰ Entretanto, mesmo com todos os recursos disponíveis e abordagens oferecidas, ainda existem déficits significativos de conhecimentos e habilidades em 50 a 80% dos indivíduos com DM, e o controle glicêmico ideal (hemoglobina glicada - HbA1c <7,0%) é obtido em menos da metade das pessoas com DM tipo 2.^{21, 22} O alcance dessas metas está relacionado a uma menor chance de complicações micro e macrovasculares.^{23, 24} Nesse sentido, a principal tarefa dos profissionais que tratam o DM é apoiar os pacientes na realização das mudanças comportamentais necessárias usando estratégias bem aceitas e que os fortaleça no seu autocuidado. No controle do DM, as metas são otimizar o controle metabólico, prevenir complicações agudas e crônicas, e melhorar a qualidade de vida, mantendo os custos aceitáveis.

Inúmeras pesquisas identificaram intervenções para mudanças de comportamento eficazes e comumente utilizadas para melhorar desfechos em saúde. A entrevista motivacional (EM) é uma técnica de abordagem não-confrontativa e semi-estruturada, centrada na pessoa, que trabalha com a motivação do próprio indivíduo, levando em consideração suas necessidades e experiências.²⁵ Tem como objetivo principal promover a mudança comportamental em pessoas que resistem a mudar um comportamento de risco. Seu benefício já foi demonstrado no tratamento da dependência química e na redução do índice de massa corporal, da pressão arterial sistólica e do colesterol total.²⁶ Os agentes comunitários de saúde (ACS) são profissionais que atuam na integração dos serviços de saúde da Atenção Primária com a comunidade. Desenvolvem ações de promoção e vigilância em saúde na comunidade em que atuam— que é a mesma em que moram, contribuindo para melhoria da qualidade de vida das pessoas. A atuação desses profissionais valoriza e reafirma questões culturais e empodera a comunidade para o controle social dentro do SUS brasileiro.²⁷

A EM e o suporte social e educacional dos ACS são intervenções que podem ser utilizadas para alcançar as metas de controle do DM e suas comorbidades. Essas intervenções podem ser vinculadas às mudanças de comportamento propostas e contribuir no complexo contexto do manejo de pacientes com DM.²⁸

Os dois artigos que compõem essa tese de doutorado abordam: 1) o efeito da entrevista motivacional na HbA1c de pacientes com DM, avaliado através de uma revisão sistemática e meta-análise e 2) a eficácia de um curso educativo para agentes comunitários de saúde no controle metabólico do DM tipo 2, avaliada através de um ensaio clínico randomizado.

Referências

1. ORGANIZAÇÃO MUNDIAL DA SAÚDE. Cuidados inovadores para condições crônicas: componentes estruturais de ação. Brasília: Organização Mundial da Saúde, 2003.
2. Brasil. Ministério da Saúde. Estratégia nacional para para educação em saúde para o autocuidado em Diabetes Mellitus. Florianópolis: SEAD/UFSC, 2009.
3. Wild S, Roglic G, Green A, Sicree R, King R. Global Prevalence of Diabetes Estimates for the year 2000 and projections for 2030. Diabetes Care 2004; 27 (5): 1047–1053.

4. Diabetes Atlas. Disponible at: <http://www.idf.org/diabetesatlas>. Accessed in April 2015.
5. Brasil. Ministério da Saúde. Secretaria de Atenção à Saúde. Departamento de Atenção Básica. Estratégias para o cuidado da pessoa com doença crônica: diabetes mellitus / Ministério da Saúde, Secretaria de Atenção à Saúde, Departamento de Atenção Básica. – Brasília: Ministério da Saúde, 2013. 160 p.: il. (Cadernos de Atenção Básica, nº 36).
6. World Health Organization. Adherence to long-term therapies: evidence for action, 2003. Disponible at: <http://apps.who.int/medicinedocs/pdf/s4883e/s4883e.pdf>.
7. Glasgow RE, McCaul KD, Schafer LC. Self-care behaviors and glycemic control in Type 1 diabetes. *Journal of Chronic Diseases* 1987; 40: 399–412.
8. Przemysława Jarosz-Chobot, Diana W. Guthrie, Ewa Otto-Buczowska, Brygida Koehler. Self-care of young diabetics in practice. *Medical Science Monitor* 2000; 6: 129–132.
9. Schultz J, Sprague MA, Branen LJ, Lambeth S. A comparison of views of individuals with type 2 diabetes mellitus and diabetes educators about barriers to diet and exercise. *Journal of Health Communication* 2001; 6: 99–115.
10. Anderson JW, Gustafson NJ. Adherence to high-carbohydrate, high-fiber diets. *Diabetes Educator* 1998; 15: 429–434.
11. Boccuzzi SJ, Wogen J, Fox J, Sung JC, Shah AB, Kim J. Utilization of oral hypoglycemic agents in a drug-insured U.S. population. *Diabetes Care* 2001; 24: 1411–1415.
12. Wilson W, Ary DV, Biglan A, Glasgow RE, Toobert DJ, Campbell DR. Psychosocial predictors of self-care behaviours (compliance) and glycemic control in non-insulin dependent diabetes mellitus. *Diabetes Care* 1986; 9: 614–622.
13. Asche C, LaFleur J, Conner C. A review of diabetes treatment adherence and the association with clinical and economic outcomes. *Clin Ther* 2011; 33 (1): 74-109.

14. Snoek FJ. Psychological aspects of diabetes management. *Medicine* 2002; 30 (1): 14–15.
15. Lustman PJ, Anderson RJ, Freedland KE, de Groot M, Carney RM, Clouse RE. Depression and poor glycemic control: a meta-analytic review of the literature. *Diabetes Care* 2000; 23 (7): 934–42.
16. Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M. DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. *Diabet Med* 2013; 30 (7): 767–77.
17. Powers MA, Bardsley J, Cypress M, Duker P, Funnel MM, Fishl AH, Maryniuk MD, Siminerio L, Vivian E. Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. *Diabetes Care*, June 5, 2015.
18. Standards of Medical Care in Diabetes 2015. *Diabetes Care* 2015; 38 (1): S1–94.
19. Brasil. Ministério da Saúde. Informes Técnicos Institucionais. Plano de reorganização da atenção à hipertensão arterial e ao diabetes mellitus. *Rev Saúde Pública*, 2001; 35 (6): 585–8.
20. Brasil. Ministério da Saúde. Secretaria de Vigilância em Saúde. Departamento de Análise de Situação de Saúde. Plano de ações estratégicas para o enfrentamento das doenças crônicas não transmissíveis (DCNT) no Brasil 2011-2022 / Ministério da Saúde. Secretaria de Vigilância em Saúde. Departamento de Análise de Situação de Saúde. – Brasília : Ministério da Saúde, 2011. 148 p. : il. – (Série B. Textos Básicos de Saúde)

21. Viana LV, Leitão CB, Kramer CK, Zucatti AT, Jezini DL, Felício J, Valverde AB, Chacra AR, Azevedo MJ, Gross JL. Poor glycaemic control in Brazilian patients with type 2 diabetes attending the public healthcare system: a cross-sectional study. *BMJ Open* 2013; 3(9): e003336.
22. Norris SL, Engelgau MM, Narayan KMV. Effectiveness of Self-Management Training in Type 2 Diabetes: A systematic review of randomized controlled trials. *Diabetes Care* 2001; 24:561–587.
23. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. *Lancet* 1998; 352: 837–53.
24. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). UK Prospective Diabetes Study (UKPDS) Group. *Lancet* 1998; 352: 854–65.
25. Rubak S, Sandbæk A, Lauritzen T, Christensen B. Motivational interviewing: a systematic review and meta-analysis. *British Journal of General Practice* 2005; 55: 305–312.
26. Pereira, Alexandre de Araújo Diretrizes para saúde mental em atenção básica / Organizado por Alexandre de Araújo Pereira. -- Belo Horizonte: NESCON/UFMG, 2009. 44p. (Série Nescon de Informes Técnicos, nº. 3).
27. Brasil. Ministério da Saúde. Secretaria de Atenção à Saúde. Departamento de Atenção Básica. O trabalho do agente comunitário de saúde / Ministério da Saúde, Secretaria de Atenção à Saúde, Departamento de Atenção Básica. – Brasília : Ministério da Saúde, 2009. 84 p. : il. – (Série F. Comunicação e Educação em Saúde).
28. Peyrot M, Rubin RR. Behavioral and psychosocial interventions in diabetes: a conceptual review. *Diabetes Care* 2007; 30(10): 2433–40.

Artigo

Effect of motivational interviewing on HbA1c of patients with diabetes:

A systematic review and meta-analysis of randomized controlled trials

Short title: Motivational interviewing and diabetes

Camila Furtado de Souza, MD, MSc^{1,2}

Mérianne Boeira Dalzochio, MD²

Priscila dos Santos Ledur, RN²

Carolina Gross, PsyD, PhD³

Jorge Luiz Gross, MD, PhD²

Beatriz D'Agord Schaan, MD, PhD²

Cristiane Bauermann Leitão, MD, PhD²

¹Primary Care Division, Hospital de Clínicas de Porto Alegre, Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil; ²Division of Endocrinology, Hospital de Clínicas de Porto Alegre, Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil; ³Division of Endocrinology, Diabetes and Clinical Nutrition, University Hospital, Bern, Switzerland.

Corresponding author: Cristiane B. Leitão, Serviço de Endocrinologia do Hospital de Clínicas de Porto Alegre. Rua Ramiro Barcelos 2350, Prédio 12, 4º andar, 90035-003, Porto Alegre, RS, Brazil. E-mail: crisbleitao@yahoo.com.br. Phone: + 55 51 3359 8127. Fax: + 55 51 3359 8777.

Abstract

Background: Motivational Interviewing (MI) is a promising counseling strategy in the management of diseases requiring lifestyle changes. MI was developed as a brief intervention in the management of alcoholism. Thereafter, the method began to be tested on other health problems, particularly in chronic diseases, in which behavior change is a key point in treatment outcomes. In diabetes care MI effectiveness is still controversial.

Objective: To assess the efficacy of MI in diabetes glycemic control assessed by glycosylated hemoglobin (HbA1c) changes, through a systematic review and meta-analysis of randomized controlled trials.

Methods: To identify randomized controlled studies that report the effect of MI on glycemic control of patients with DM, we searched the electronic databases (beginning in 1950 up to May, 2014) PubMed, Medline, Embase and Cochrane as well as the Cochrane Central Register of Controlled Trials. Studies were grouped and a distinct meta-analysis was conducted based on the time-points that HbA1c was measured: 3, 6, 12 or 24 months. **Results:** A total of 13 studies fulfilled inclusion criteria and were included, providing data from 3511 individuals. At three months, a decrease of 0.77% in HbA1c was observed only in patients with type 2 DM. At 6 months, no benefit was found. At 12 months, a decrease in HbA1c of 0.17% was observed overall, mainly due to effects observed on type 2 DM studies. At 24 months a decrease in HbA1c of 0.31% was found only in patients with type 1 DM.

Conclusions: MI is associated with improved glycemic control in patients with DM. The benefit was detected at 3 and 12 months in patients with type 2 DM, and only in studies lasting 24 months in patients with type 1 DM. The inclusion of this counseling strategy to DM patients care may contribute to improve glycemic control.

Introduction

The burden of diabetes mellitus (DM) is increasing globally, particularly in developing countries. The causes are multifactorial, but are in large part due to rapid increases in overweight, obesity and physical inactivity.¹ DM management includes diet, exercise and medication.² Diabetes self-management Education and Support (DSME/S) is a critical part of DM care and has been used to stimulate lifestyle changes and to improve medication compliance, as it focus in improving knowledge, skills, and abilities necessary for diabetes self-care.^{2, 3, 4}

However, self-management of diabetes requires patients' ability to reconcile their resources and preferences with therapeutic regimens, which can be challenging for many patients.^{5, 6} DSME/S programs have traditionally approached DM as a physical rather than a biopsychosocial illness.³ In this model, the health care provider is the problem solver and identifies the patient's learning needs, while the patient remains passive and powerless.^{3, 7} Instead of trying to fit patients into predetermined self-management interventions, flexible self-management interventions that are responsive to the unique and individual lives of patients are needed.⁸ Recently, DSME/S programs have included a patient centered care in their delivery systems. Through this approach, patients are able to explore options, choose their own course of action, and feel empowered to make informed self-management decisions.^{8, 9} As people living with diabetes are responsible for a large number of behavioral choices and activities in daily basis, they must play a central role in their own treatment.¹⁰

Motivational Interviewing (MI) is a promising counseling strategy in the management of diseases requiring lifestyle changes. MI is defined as a client-centered,

directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence.¹¹ Health care providers involved with MI base their interaction on four guiding principles: (1) listen with empathy, (2) roll with resistance, (3) develop discrepancy, and (4) support self-efficacy.¹² In contrast to traditional, more paternalistic and medication centered counseling styles, MI gives the patients' knowledge and provides the individual the experience to play a central role in finding the best behavior change strategy.

MI has been originally developed in the drug addiction field, but this relatively new counseling style is increasingly being advocated in other health areas.^{13, 14, 15} A recent narrative review evaluating the effect of MI in health behavior changes in patients with diabetes suggested improvement in adherence to diet and exercise recommendations.¹⁶ Nevertheless, consistent evidence for the effectiveness of MI in these areas is still limited and there has not been yet consensus on the effect of MI on clinical^{4, 17, 18, 19} and psychosocial aspects of diabetes^{20, 21, 22}. Therefore, the aim of the present review was to assess the efficacy of MI in the diabetes glyceemic control, assessed by glycated hemoglobin (HbA1c) changes, through a systematic review and meta-analysis of randomized controlled trials.

Methods

Search strategy and eligibility criteria

To identify randomized controlled studies that report the effect of MI on glyceemic control of patients with DM, we searched the electronic databases (beginning in 1950 up to May, 2014) PubMed, Medline, Embase and Cochrane as well as the Cochrane Central Register of Controlled Trials for the following medical subject readings (Mesh): "Motivation"[Mesh] OR "Interview" [Publication Type] OR "Interviews as Topic"[Mesh]

OR "Interview, Psychological"[Mesh] OR "motivational interviewing" OR "motivational behaviour" OR "behaviour/motivational interviewing" OR "behaviour change" OR "motivational change" OR "behaviour change/motivational interviewing" OR "patient centered interviewing" AND "Diabetes Mellitus"[Mesh] OR "Diabetes Mellitus, Type 2"[Mesh] OR "Diabetes Mellitus, Type 1"[Mesh] AND "randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh] OR ("clinical trial"[tw]) OR ((singl*[tw] OR doubl*[tw] OR trebl*[tw] OR tripl*[tw]) AND (mask*[tw] OR blind*[tw])) OR ("latin square"[tw]) OR placebos[mh] OR placebo*[tw] OR random*[tw] OR research design[mh:noexp] OR follow-up studies[mh] OR prospective studies[mh] OR cross-over studies[mh] OR control*[tw] OR prospectiv*[tw] OR volunteer*[tw]) NOT (animal[mh] NOT human[mh]). All potentially eligible studies were considered for review, regardless of the primary outcome or language.

Studies were considered eligible for inclusion if they fulfilled the following inclusion criteria: presented original data of randomized controlled trial assessing the effect of MI on DM control by measurement of HbA1c; examined the effect of MI on DM control after a minimum of 12 weeks of intervention; report means (or differences between means) and standard deviations (SD) of HbA1c at baseline and after the intervention. The cutpoints periods for outcome evaluation were decided based on included studies duration.

Studies selection and Data Extraction

Titles and abstracts of retrieved articles were independently evaluated by two investigators (C.F.S and P.S.L). Reviewers were not blinded to authors, institutions, or manuscript journals. Abstracts that did not provide enough information regarding the

inclusion and exclusion criteria had the full-text evaluated. Reviewers independently assessed full-text articles and determined study eligibility. The same investigators (C.F.S and P.S.L.) independently conducted data extraction. Disagreements were resolved by consensus and if disagreement persisted, by a third reviewer (C.B.L.).

Extracted data included the first author's name, year of publication, number of participants, age, gender, trial duration, duration of DM, number of individuals with type 1 DM, the professional delivering the intervention, number of sessions, and assessment of HbA1c change as mean \pm SD.

Quality Assessment

Randomized controlled trials risk of bias was evaluated according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guideline²³ and quality of the meta-analysis was assessed based on GRADE (The Grading Recommendations Assessment, Development and Evaluation) recommendations²⁴, and the following characteristics were evaluated: limitations in the study design and implementation, indirectness of evidence, unexplained heterogeneity or inconsistency of results, imprecision of results, and probability of publication bias.

Statistical Analysis

Absolute changes in HbA1c in both MI and control groups were reported as differences between arithmetic means before and after interventions. Cochran's Q test was used to evaluate heterogeneity between studies, and a threshold p value <0.1 was considered statistically significant. The I^2 test was also conducted to evaluate the magnitude of the heterogeneity between studies, and values greater than 50% were considered indicative of heterogeneity. We used random effects model for all analysis.

Studies were grouped and a distinct meta-analysis was conducted based on the time-points that HbA1c was measured: 3, 6, 12 or 24 months. For each time point a subgroup analysis was undertaken based on the type of DM. Heterogeneity between studies was explored using three strategies. First, meta-regression analyses were carried out to recognize variables that influenced the association of MI and HbA1c changes. Intervention duration and HbA1c at baseline were the variables selected *a priori* to be include in the meta-regression models. A threshold p value of 0.05 was considered statistically significant in meta-regression analyses. Second, subgroup analyses were performed with the variables found to be associated with heterogeneity in the meta-regression analysis. Third, sensitivity analyses were applied and meta-analyses were rerun removing each study at a time to check if a particular study was explaining heterogeneity.

Publication bias was assessed using funnel plot analysis, with asymmetry evaluated by Begg and Egger tests. A significant publication bias was considered if the P value was less than 0.1. The trim-and-fill computation was used to estimate the effect of publication bias on the interpretation of results, if necessary. Meta-regression and funnel plot analyses were conducted using Stata software version 11.0 (Stata Inc, College Station, Texas).

Results

Literature search results and studies characteristics

We identified 2240 studies in the database searches. Of them, 2089 were excluded based on titles and abstracts, leaving 151 studies for further evaluation. A total of 13 studies fulfilled the inclusion criteria and were included, providing data from 3511 individuals (**Figure 1**).

Table 1 shows the characteristics of the included studies. The trials were published between 1997 and 2014, and varied in sample size. The length of the trials varied from 12 to 192 weeks, and the number of MI sessions varied from 3 to 15. Five studies evaluated only patients with type 1 DM, 6 studies only patients with type 2 DM and 1 study both type 1 and 2 DM. One study did not make clear the type of DM of the included patients.

Individual quality of studies was low, since details about randomization and researcher's or statisticians' blindness were not described or were unclear for most studies (**Table 2**). Only 7 studies described concealment of randomization, and 3 studies reported intention-to-treat analyses. Losses during follow up were described in all studies. GRADE quality rating was considered low for 6 months meta-analysis and moderate for 3, 12 and 24 months.

Motivational Interviewing and HbA1c

Effect at three months

There were three studies that evaluated the HbA1c at three months, with a total of 616 participants. The average reduction in HbA1c levels was not significant overall (-0.41; 95% CI -1.14 to 0.31) (**Figure 2A**), and high heterogeneity was found among studies (I^2 : 84.9%; p-value for heterogeneity = 0.001). Subgroup analysis according to type of DM showed a significant decrease in HbA1c (-0.77%; 95% CI -1.16 to -0.38; I^2 = 0%; p-value for heterogeneity = 0.806) for patients with type 2, and in this meta-analysis no heterogeneity was observed. On the other hand, the only study including patients with type 1⁴ showed no decrease in HbA1c associated with MI.

Effect at six months

Six studies with 1136 participants reported HbA1c values at six months. No significant reduction in Hba1c was observed with the intervention (-0.24; 95% CI -0.52 to 0.04) (**Figure 2B**). Heterogeneity was significant between studies (I^2 : 56.3%; p-value for heterogeneity = 0.043). These results were unchanged when the subgroup analysis according to type of DM was performed. In univariate meta-regression, intervention duration (adjusted R^2 = -87.21%; p = 0.71), and mean baseline HbA1c (adjusted R^2 = -113.48%; p = 0.917) did not explain heterogeneity. In the sensitivity analyses the exclusion of Hawkins et al. study²⁷ did reduce heterogeneity (I^2 : 31.1%; p for heterogeneity = 0.214), but no benefit of the intervention was observed (-0.011%; 95% CI -0.28 to 0.06). However, the exclusion of Ismail et al. study⁴ did not decrease heterogeneity, but a benefit of the intervention came out (HbA1c reduction of -0.20%; 95% CI -0.36 to -0.04); I^2 = 50.7%; p-value for heterogeneity = 0.087).

Effect at 12 months

Five studies with 1497 participants measured the HbA1c at 12 months. A benefit in HbA1c was observed (-0.17%; 95%CI -0.27 to -0.07; I^2 : 7%; p-value for heterogeneity = 0.367; **Figure 2C**) and no heterogeneity was found. The subgroup analysis showed that this benefit was attributed mainly to studies including type 2 DM patients (-0.20; 95% CI -0.32 to -0.08; I^2 : 0%; p-value for heterogeneity = 0.917).

Effect at 24 months

There were four studies with 1304 participants with a follow-up of 24 months. Patients in MI group had no reduction in Hba1c levels (-0.19; 95% CI -0.41 to 0.03; **Figure 2D**) in comparison with the control group, and heterogeneity was found (I^2 :

66.6%; p-value for heterogeneity = 0.030). Notably, patients with type 1 DM showed a reduction in HbA1c (-0.31 CI 95% -0.38 to -0.25; I²: 0%; p-value for heterogeneity = 0.331) while those with type 2 DM did not (-0.04 CI 95% -0.25 to 0.17 I²: 14%; p-value for heterogeneity = 0.281).

Publication bias

Contour-enhanced funnel plots (**Figure 3**) and the Egger regression test revealed no publication bias. P-value assessed at each time-point was: at three months p = 0.561, at six months p = 0.177, at 12 months p= 0.626 and at 24 months p= 0.534.

Discussion

The present systematic review and meta-analysis showed that MI is associated with a decrease in HbA1c. The presence and magnitude of the benefit differed depending of the type of DM and the time point evaluated. At three months, a decrease of 0.77% in HbA1c was observed, but only in patients with type 2 DM. A decrease in HbA1c at six months was only apparent in the sensitive analysis after the exclusion of one study⁴. However the small reduction in HbA1c (-0.20%) observed was associated with unexplained heterogeneity. At 12 months a decrease in HbA1c of 0.17% was observed overall, but it was mainly due to studies including type 2 DM. Finally, a reduction of 0.31% in HbA1c was found at 24 months after intervention, but only in patients with type 1 DM.

DM is a chronic health condition associated with a range of serious complications and requires a demanding treatment, which involves lifestyle modification and a lifelong use of medications.² Depression, anxiety, and eating disorder patterns are common among people living with DM and are associated with suboptimal glycemic control,

complications, and death.^{32, 33, 35, 36, 37} Moreover, patients may develop diabetes-related emotional distress, such as concerns related with treatment, such as insulin self-injections or glucose self-testing, and to adverse effects of treatment, such as hypoglycemia or the possibility of developing DM complications.^{38, 39} Although psychological approaches have been recognized as an important tool to better understand the needs of people living with DM, there is a lot of room for improvement.⁴⁰

The clinical potential of MI was originally developed in adults with drug addiction problems.⁴¹ Subsequent systematic reviews and meta-analysis have now shown that MI may be effective in promoting a range of psychological, physiological and lifestyle changes in different clinical scenarios (mostly in adults), including change in diet, physical activity, diabetes, hypertension, hyperlipidemia and cigarette smoking.^{42, 43} However, the clinical implications of the findings of most studies is still uncertain due to their small size, lack of power, use of different outcomes, and poorly defined interventions.

Our review did not show benefit of MI at all the time points evaluated. In three months, meta-analysis heterogeneity was attributed to the type of DM, and the analysis of studies including only patients with type 2 DM resulted in an HbA1c reduction of 0.77%. At six months, the heterogeneity was attributed to one study²⁷, but we were not able to find out any clinical particularity that could justify its exclusion from the analysis. Furthermore, the exclusion of this particular study was not associated with a demonstrable benefit in HbA1c. However, in the sensitivity analysis, the exclusion of another study⁴ did not decrease the heterogeneity, but a significant reduction in HbA1c (-0.20%) was revealed. At 12 months, MI was associated with a small decrease in HbA1c (-0.17%) when all studies were analyzed together, but the main benefit was attributed to

patients with type 2 DM. Interestingly, only studies with a longer duration (24 months) were able to detect a significant reduction of HbA1c in type 1 DM patients. When the studies included in the 24 months meta-analysis are carefully evaluated, the one with greater influence in the results was Ridge et al.³¹ This study, which is the long-term follow-up of the patients first reported by Ismail, et al.⁴, included only patients with type 1 DM, and was responsible for the lack of benefit of MI at three and six months. This observation suggests that patients with type 2 DM benefit earlier from MI (3 months and 12 months) and patients with type 1 DM probably requires a longer exposure to the intervention to be motivated for a behavior change (24 months).

Use of MI probably depends on other aspects such as duration and number of encounters. Features such as training and experience in MI methods and client–counselor relationships also influence its effectiveness.⁴³ This review puts together studies with different characteristics regarding to: type of DM, insulin use, health care providers conducting the intervention with different trainings, length of study and number of meetings and meeting’s duration. These factors may have introduced clinical heterogeneity and influenced the results.

The relevance of the clinical effect of this intervention should consider that MI aims to increase patient’s awareness of the potential of the behavior change to improve health parameters, considering that small changes may also mark the beginning of a changing process. The nature of transformation in the patient is almost always related to both adherence to prescribed medication and to the type of changes the patient makes in their lifestyle.^{41, 43}

This study has limitations. Data extraction was not blinded, which is a potential source of bias. Additionally, high heterogeneity was identified in the meta-analyses at

some time-points. To address this, we have performed analyses to identify clinical (baseline HbA1c, type of DM and intervention duration) differences between studies. Finally, the general quality of the studies was low, reflecting increased risk of bias in some studies. This may have contributed to the heterogeneity of our analyses. Even that publication bias was not detected, we cannot exclude this possibility because of the small number of studies included in each meta-analysis (<10 trials).⁴⁴

In conclusion, MI is associated with improved glyceemic control in patients with DM. The benefit was detected at 3 and 12 months in patients with type 2 DM, and only in studies lasting 24 months in patients with type 1 DM. The incorporation of this technique to DM patients care may contribute to improve glyceemic control.

Author Contributors

CBL had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: CFS, CBL, BDS.

Acquisition of data: CFS, MBD, PSL.

Analysis and interpretation of data: CFS, CBL.

Drafting of the manuscript: CFS.

Critical revision of the manuscript for important intellectual content: CG, JLG, BDS, CBL.

Statistical analysis: CBL.

Obtained funding: JLG.

Conflict of interest statement

All authors have no conflict of interest to declare.

Acknowledgments

The authors gratefully acknowledge the support of the collaborating organizations: CNPq and Fundo de Incentivo à Pesquisa (FIPE). CBL, BDS and JLG were recipients of a scholarship from CNPq. The Authors are also grateful to Hospital de Clínicas de Porto Alegre, Porto Alegre, Rio Grande do Sul, Brazil, for the support in the conduction of this research.

References

1. <http://www.who.int/diabetes/en/>
2. Standards of Medical Care 2015: Summary of revisions. *Diabetes Care* 2015; 38 (Suppl.1): S4.
3. Funnell MM, Brown TL, Childs BP, Haas LB, Hoseney GM, Jensen B, Maryniuk M, Peyrot M, Piette JD, Rieder D, Siminerio LM, Weinger K, Weiss MA. National standards for diabetes self-management education. *Diabetes Care* 2008; 31 Suppl 1: S97–104.
4. Ismail K, Thomas SM, Maissi E, Chalder T, Schmidt U, Bartlett J, Patel A, Dickens CM, Creed F, Treasure J. Motivational Enhancement Therapy with and without Cognitive Behavior Therapy to Treat Type 1 Diabetes: A Randomized Trial. *Ann Intern Med* 2008; 149: 708–719.
5. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes, estimates for the year 2000 and projections for 2030. *Diabetes Care* 2004; 27: 1047–53.
6. Deakin T, McShane CE, Cade JE, Williams RDRR. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev* 2005.
7. Osborn C, Fisher J. Diabetes education: Integrating theory, cultural considerations, and individually tailored content. *Clinical Diabetes* 2008; 26 (4): 148–150.
8. Funnell M, Tang T, Anderson R. From DSME to DSMS: Developing empowerment based diabetes self-management support. *Diabetes Spectrum* 2007; 20 (4): 221–226.
9. Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Fishl AH, Maryniuk MD, Siminerio L, Vivian E. Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. *Diabetes Care*, June 5, 2015.

10. Heinrich E, Candel MJJM, Schaper NC, Vries NK. Effect evaluation of a Motivational Interviewing based counselling strategy in diabetes care. *Diabetes Research and Clinical Practice* 2010; 90: 270–278.
11. Miller WR, Rollnick S. *Motivational interviewing: preparing people for change*. New York, NY: Guilford; 2002.
12. Welch G, Rose G, Ernst D. Motivational interviewing and diabetes: What is it, how is it used, and does it work? *Diabetes Spectrum* 2006; 19 (1): 5–11.
13. Hettema J, Steele J, Miller WR. Motivational interviewing. *Annu Rev Clin Psychol* 2005; 1: 91–111.
14. Miller WR, Rose GS. Toward a theory of motivational interviewing. *Am Psychol* 2009; 64: 527–37.
15. Resnicow K, DiIorio C, Soet JE, Ernst D, Borrelli B, Hecht J. Motivational interviewing in health promotion: it sounds like something is changing. *Health Psychol* 2002; 21: 444–51.
16. Martins RK, McNeil DW. Review of motivational interviewing in promoting health behaviors. *Clin Psychol Rev* 2009; 29: 283–293.
17. Brug J, Spikmans F, Aartsen C, Breedveld B, Bes R, Fereira I. Training dietitians in basic motivational interviewing skills results in changes in their counseling style and in lower saturated fat intakes in their patients. *J Nutr Educ Behav* 2007; 39: 8–12.
18. Channon SJ, Huws-Thomas MV, Rollnick S, Hood K, Cannings-John RL, Rogers C, Gregory JW. A multicenter randomized controlled trial of motivational interviewing in teenagers with diabetes. *Diabetes Care* 2007; 30: 1390–1395.
19. West DS, DiLillo V, Bursac Z, Gore SA, Greene PG. Motivational interviewing improves weight loss in women with type 2 diabetes. *Diabetes Care* 2007; 30: 1081–1087.

20. Clark M, Hampson SE. Implementing a psychological intervention to improve lifestyle self-management in patients with type 2 diabetes. *Patient Educ Couns* 2001; 42: 247–256.
21. Knight KM, Bundy C, Morris R, Higgs JF, Jameson RA, Unsworth P, Jayson D. The effect of group motivational interviewing and externalizing conversations for adolescents with type 1 diabetes. *Psychol Health Med* 2003; 8: 149–157.
22. Smith DE, Heckemeyer CM, Kratt PP, Mason DA. Motivational interviewing to improve adherence to a behavioral weight-control program for older obese women with NIDDM. A pilot study. *Diabetes Care* 1997; 20: 52–54.
23. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP, Clarke M, Devereaux PJ, Kleijnen J, Moher D. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *Ann Intern Med* 2009; 151: W65–94.
24. Balshem H, Helfand M, Schuenemann HJ, Oxman AD, Kunz R, Brozek J, Vist GE, Falck-Ytter Y, Meerpohl J, Norris S, Guyatt GH. GRADE guidelines: 3. Rating the quality of evidence. *Journal of Clinical Epidemiology* 2011; 64: 401–6.
25. Chen SM, Creedy D, Lin HS, Wollin J. Effects of motivational interviewing intervention on self-management, psychological and glycemetic outcomes in type 2 diabetes: A randomized controlled trial. *International Journal of Nursing Studies* 2012; 49: 637–644.
26. Gabbay RA, Añel-Tiango RM, Dellasega C, Mauger DT, Adelman A, Van Horn DHA. Diabetes Nurse case management and motivational interviewing for change (DYNAMIC): Results of a 2-year randomized controlled pragmatic trial. *Journal of Diabetes* 2013; 5: 349–357.

27. Hawkins SY. Improving Glycemic Control in Older Adults Using a Videophone Motivational Diabetes Self-Management Intervention. *Research and Theory for Nursing Practice: An International Journal* 2010; 24: 4.
28. Ismail K, Maissi E, Thomas SM, Chalder T, Schmidt U, Bartlett J, Patel A, Dickens CM, Creed F, Treasure J. A randomized controlled trial of cognitive behavior therapy and motivational interviewing for people with type 1 diabetes mellitus with persistent sub-optimal glycemic control: A Diabetes and Psychological Therapies (ADaPT) Study. *Health Technology Assessment* 2010; 14: 22.
29. Jansink R, Braspenning J, Keizer E, Weijden TVD, Elwyn G, Grol R. No identifiable HbA1c or lifestyle change after a comprehensive diabetes programme including motivational interviewing: a cluster randomized trial. *Scandinavian Journal of Primary Health Care*, 2013; 31: 119–127.
30. Minet LKR, Wagner L, Lønvig EM, Hjelmberg J, Henriksen JE. The effect of motivational interviewing on glycemic control and perceived competence of diabetes self-management in patients with type 1 and type 2 diabetes mellitus after attending a group education programme: a randomised controlled trial. *Diabetologia* 2011; 54: 1620–1629.
31. Ridge K, Bartlett J, Cheah Y, Thomas S, Lawrence-Smith G, Winkley K, Ismail K. Do the Effects of Psychological Treatments on Improving Glycemic Control in Type 1 Diabetes Persist Over Time? A Long-Term Follow-Up of a Randomized Controlled Trial. *Psychosomatic Medicine* 2012; 74: 319–323.
32. Grigsby AB, Anderson RJ, Freedland KE, Clouse RE, Lustman PJ. Prevalence of anxiety in adults with diabetes: a systematic review. *J Psychosom Res* 2002; 53: 1053–60.
33. Mannucci E, Rotella F, Ricca V, Moretti S, Placidi GF, Rotella CM. Eating disorders in patients with type 1 diabetes: a meta-analysis. *J Endocrinol Invest* 2005; 28: 417–9.

34. Ciechanowski PS, Katon WJ, Russo JE. Depression and diabetes: impact of depressive symptoms on adherence, function, and costs. *Arch Intern Med* 2000; 160: 3278–85.
35. Lustman PJ, Anderson RJ, Freedland KE, de Groot M, Carney RM, Clouse RE. Depression and poor glycemic control: a meta-analytic review of the literature. *Diabetes Care* 2000; 23: 934–42.
36. De Groot M, Anderson R, Freedland KE, Clouse RE, Lustman PJ. Association of depression and diabetes complications: a meta-analysis. *Psychosom Med* 2001; 63: 619–30.
37. Egede LE, Nietert PJ, Zheng D. Depression and all-cause and coronary heart disease mortality among adults with and without diabetes. *Diabetes Care* 2005; 28: 1339–45.
38. Polonsky WH, Anderson BJ, Lohrer PA, Welch G, Jacobson AM, Aponte JE, Schwartz CE. Assessment of diabetes-related distress. *Diabetes Care* 1995; 18: 754–60.
39. Mollema ED, Snoek FJ, Ade`r HJ, Heine RJ, Van Der Ploeg HM. Insulin treated diabetes patients with fear of self-injecting or fear of self-testing: psychological comorbidity and general well-being. *J Psychosom Res* 2001; 51: 665–72.
40. Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. *Diabet Med* 2013; 30 (7): 767–77.
41. Rollnick S, Miller WR, Butler CC. Entrevista Motivacional no cuidado à saúde: ajudando pacientes a mudar comportamento. Tradução Ronaldo Cataldo Costa. Porto Alegre: ArtMed, 2009.

42. Greaves CJ, Sheppard KE, Abraham C, Hardeman W, Roden M, Evans PH, Schwarz P, The IMAGE Study Group. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC Public Health* 2011, 11: 119.
43. Rubak S, Sandbæk A, Lauritzen T, Christensen B. Motivational interviewing: a systematic review and meta-analysis. *British Journal of General Practice* 2005; 55: 305–312.
44. Lau J, Ioannidis JPA, Terrin N, Schmid CH, Olkin I. The case of the misleading funnel plot. *BMJ* 2006; 333: 597–600.

Table 1 – Characteristics of the included studies

Author	Year	Professional	N	Trial Duration (months)	Intervention Duration (months)	Time of outcome Evaluation (months)	Men (%)	Age (mean±SD)	Type 1 DM (%)	Basal HbA1c (mean±SD)
BRUG ¹⁷	2007	dietitian	209	6	6	6	ND	59 ± 10	ND	8.0 ± 2
CHANNON ¹⁸	2007	psychologist	66	24	12	6, 12, 24	50	15.3 ± 0.97	100	9.3 ± 2.1
CHEN ²⁵	2012	nurse	250	3	3	3	49.8	58.92 ± 10.22	0	8.71 ± 2
GABBAY ²⁶	2013	nurse	545	24	24	12, 24	38	58 ± 11	0	8.82 ± 2.38
HAWKINS ²⁷	2010	nurse	66	6	6	6	14.7	64	0	9.0 ± 2.3
ISMAIL ⁴	2008	nurse	344	12	2	3, 6, 9, 12	35	35.7 (28.4–42.3)	100	9.4 (8.8 - 9.9)
ISMAIL ²⁸	2010	nurse	344	12	2	3, 6, 9, 12	35	35.6 ± 9.6	100	9.6 ± 1
JANSINK ²⁹	2013	nurse	521	14	14	14	55.9	64.1 ± 8.9	0	7.8 ± 0.9
MINET ³⁰	2011	diabetic nurse, physiotherapist, dietitian, psychologist	349	4	12	12, 24	52	56.4 ± 12.1	23	7.0 ± 1.2
RIDGE ³¹	2012	nurse	344	48	2	3, 6, 9, 12, 18, 24, 30, 36, 42	40.1	37 ± 10.2	100	9.59 ± 1.17
SMITH ²²	1997	psychologist	22	4	4	4	0	62.4 ± 7.0	0	10.25 ± 2.2
WELCH ¹²	2011	diabetic nurse	234	6	6	6	41	55.7 ± 10.2	0	8.9 ± 1.2
WEST ¹⁹	2007	psychologist	217	18	18	6, 12, 18	0	53 ± 10	0	7.58 ± 1.4

DM: diabetes mellitus, ND: non demonstrable, SD: standard deviation

Table 2 – Studies risk of bias assessment

	Clear inclusion/ exclusion criteria?	Confidential randomization?	Blinded reaserchers?	Blinded outcome evaluation?	Blinded statistics?	Intention to treat analysis?
BRUG 2007¹⁷	No	Unclear	No	Yes	Unclear	Unclear
CHANNON 2007¹⁸	Yes	Yes	Unclear	Unclear	Unclear	Yes
CHEN 2012²⁵	Yes	Yes	Yes	Yes	Unclear	Unclear
GABBAY 2013²⁶	Yes	Yes	Unclear	Unclear	Unclear	Unclear
HAWKINS 2010²⁷	Yes	Yes	No	Unclear	Unclear	Yes
ISMAIL 2008⁴/2010²⁸	Yes	Unclear	No	Unclear	Unclear	Unclear
JANSINK 2013²⁹	Yes	Yes	No	Unclear	Unclear	Unclear
MINET 2011³⁰	Yes	Yes	No	Unclear	Unclear	Yes
RIDGE 2012³¹	Yes	Yes	Unclear	Unclear	Unclear	Unclear
SMITH 1997²²	Yes	Unclear	No	Unclear	Unclear	Unclear
WELCH 2011¹⁹	Yes	Unclear	No	Unclear	Unclear	Unclear
WEST 2007¹²	Yes	Yes	No	Unclear	Unclear	Unclear

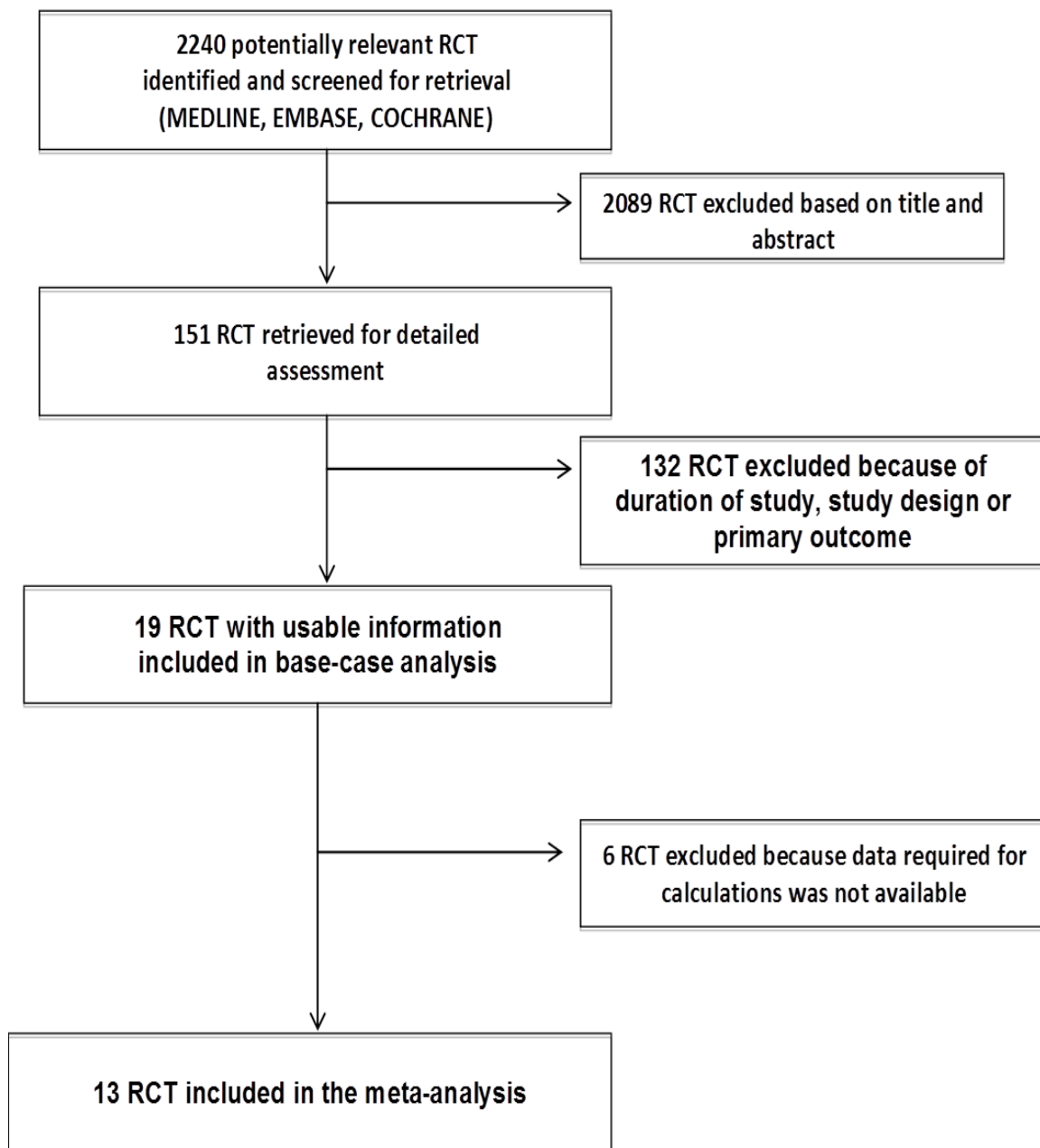


Figure 1. Flow diagram of literature search to identify randomized clinical trials of motivational interviewing for diabetes management

RCT: Randomized Clinical Trials

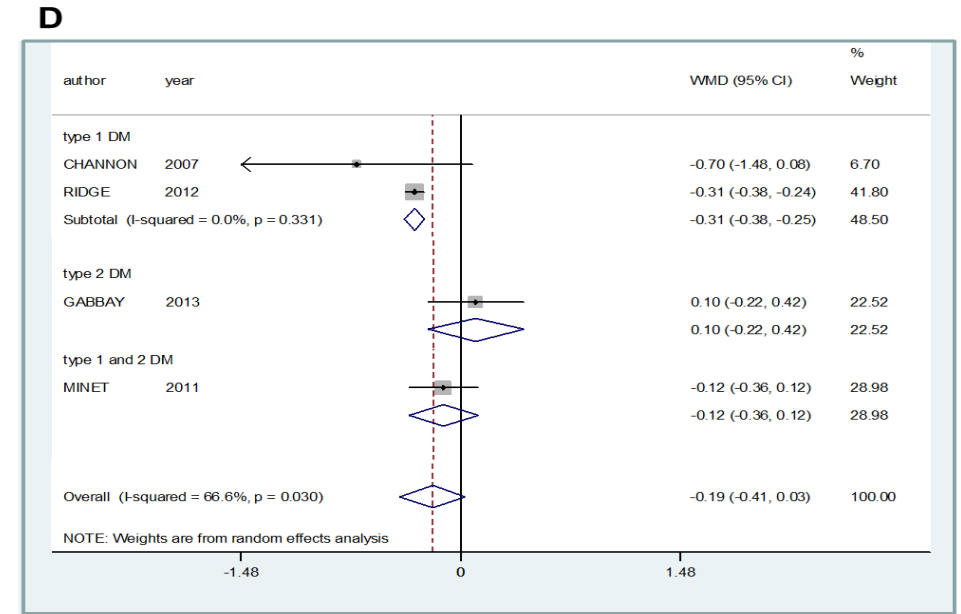
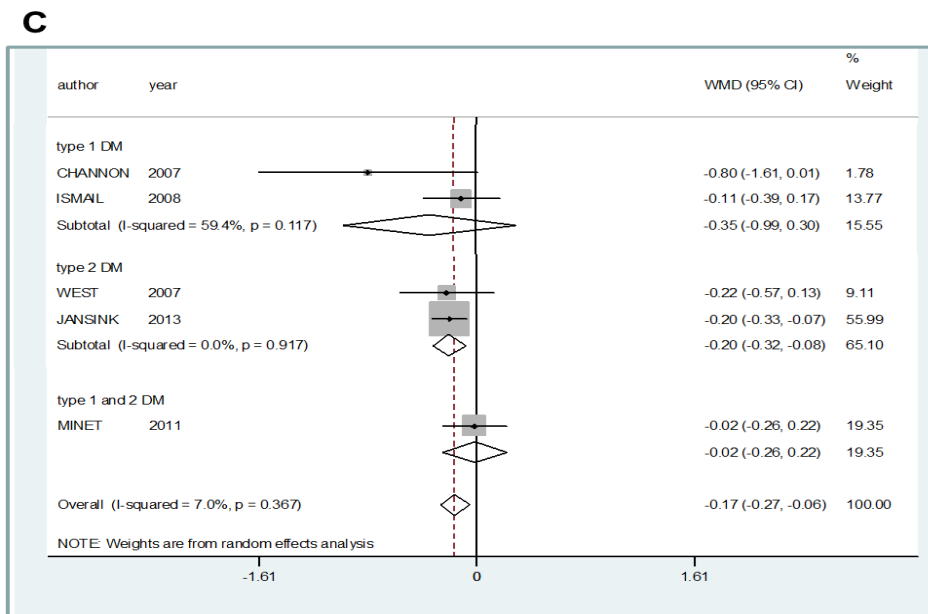
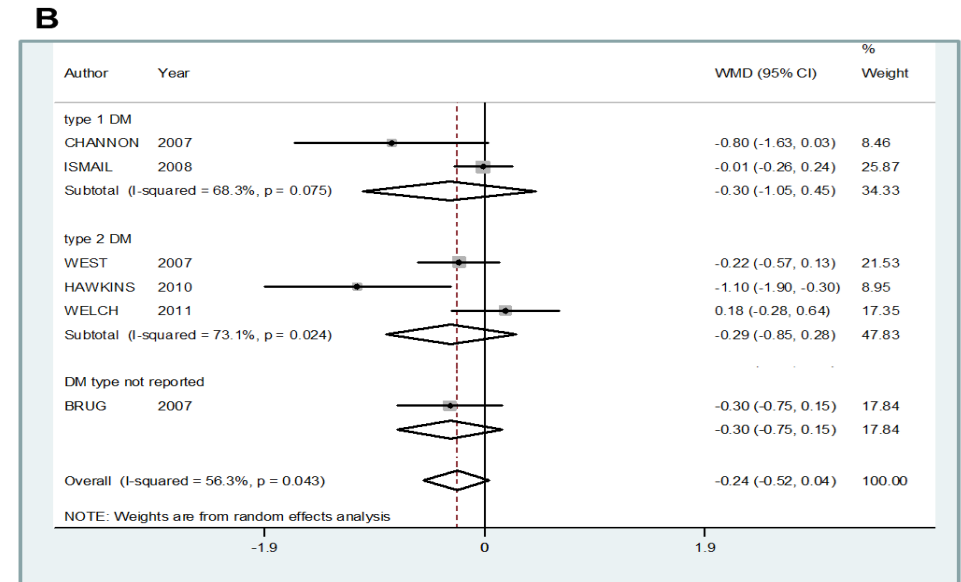
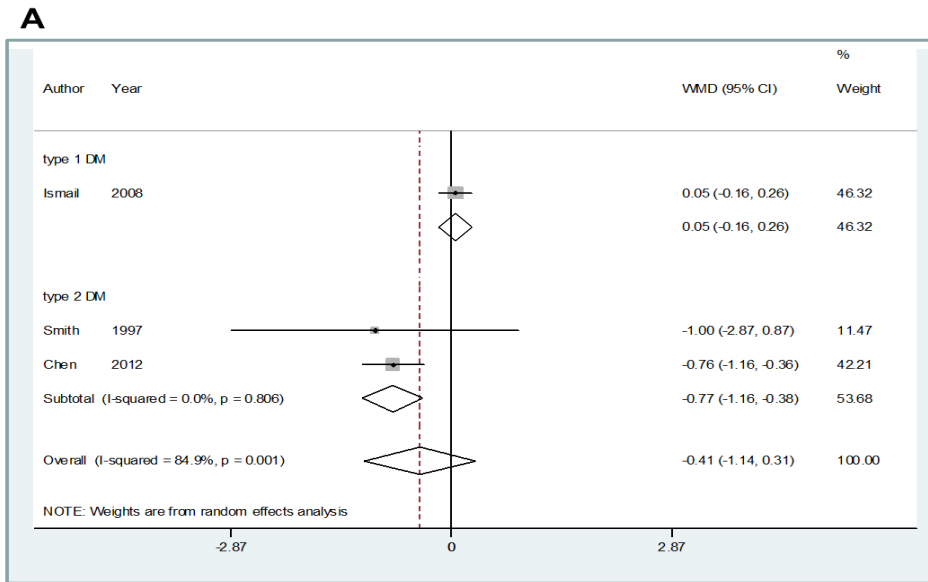


Figure 2. Effect of motivational interviewing on HbA1c at 3 (A), 6 (B), 12 (C) and 24 months (D).

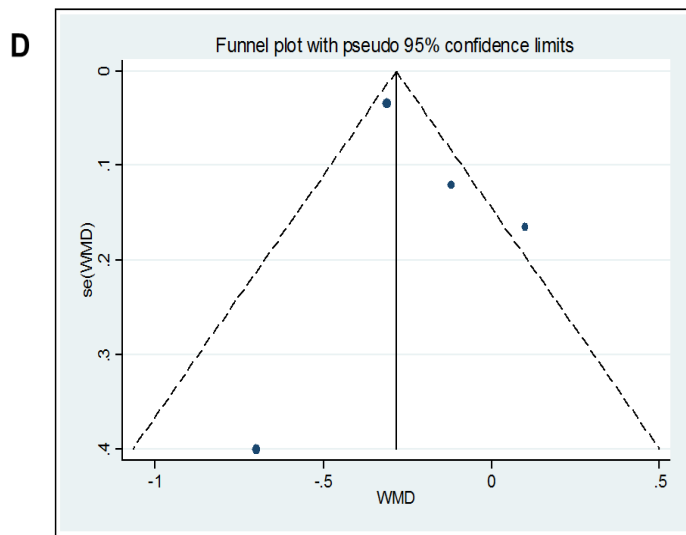
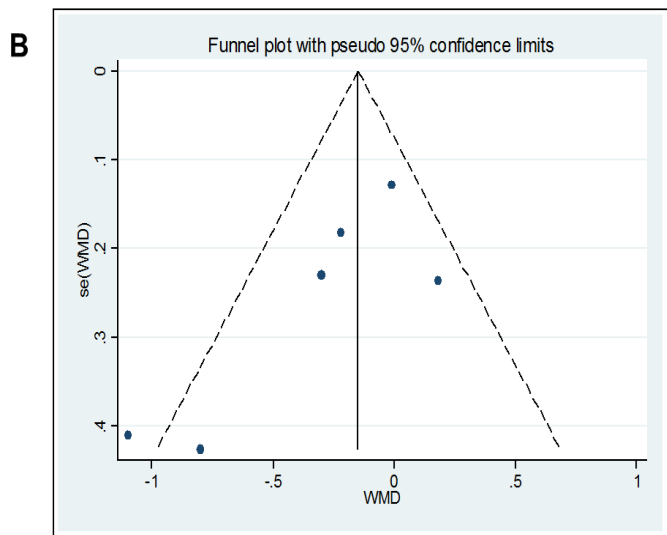
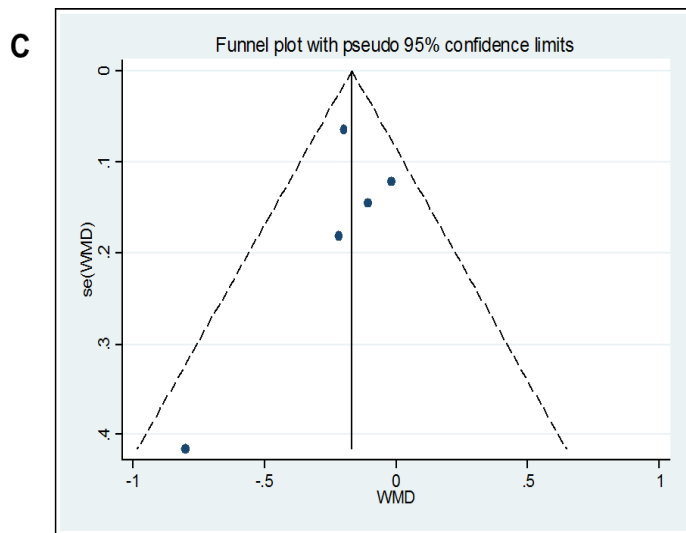
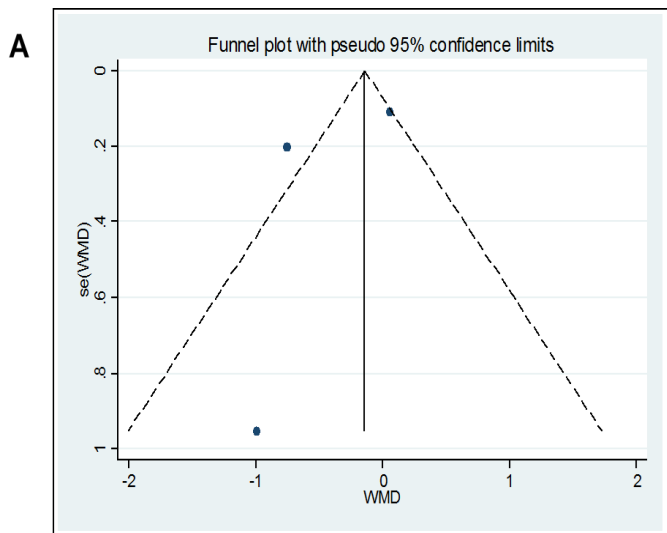


Figure 3. Funnel plots for studies evaluating HbA1c at 3 (A), 6 (B), 12 (C) and 24 months (D).

Artigo 2

**Efficacy of an Education Course Delivered to Community Health Workers in
Diabetes Control: a Randomized Clinical Trial**

Short running title: community health workers and diabetes education

Camila Furtado de Souza, MD, MSc^{1,2}

Mérianne Boeira Dalzochio, MD¹

Alessandra Teixeira Netto Zucatti, PED¹

Rosana De Nale, MD¹

Marília Tavares de Almeida, MD¹

Jorge Luiz Gross, MD, PhD²

Cristiane Bauermann Leitão, MD, PhD²

¹Primary Care Division, Hospital de Clínicas de Porto Alegre, Universidade Federal do Rio Grande do Sul; ²Division of Endocrinology, Hospital de Clínicas de Porto Alegre, Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil.

Corresponding author: Cristiane B. Leitão, Serviço de Endocrinologia do Hospital de Clínicas de Porto Alegre. Rua Ramiro Barcelos 2350, Prédio 12, 4º andar, 90035-003, Porto Alegre, RS, Brazil. E-mail: crisbleitao@yahoo.com.br. Phone: + 55 51 3359 8127. Fax: + 55 51 3359 8777.

Abstract

Background: In Brazil, community health workers (CHW) are members of the community hired by the government to provide education and care for patients for a broad range of health issues, including diabetes mellitus (DM). However, few CHW are trained for diabetes education and little is known about the effectiveness of their interventions. The aim of this study is to evaluate the effect of a diabetes education program delivered to CHW in improving the metabolic control of patients with type 2 DM.

Materials and methods: A randomized controlled trial was conducted in a primary care unit. Eight CHW, providing care for 118 patients, were randomized in two groups to receive a one-month diabetes education program (intervention group, patients n= 62) or an education course in other health issues (control group, patients n= 56). Each CHW was then responsible for transmitting the acquired knowledge to patients from their respective working areas. The primary outcome was change in HbA1C three months after intervention.

Results: Participants mean age was 61 ± 11 years, with median diabetes duration of 6 (3-5) years, 35% were men and 62% were whites. Mean BMI was 31 ± 6 kg/m² and mean HbA1c was $9.1 \pm 2.1\%$. HbA1c levels were reduced in both groups (intervention: 9.1 ± 2.2 vs. $7.9 \pm 1.9\%$; control: 9.1 ± 2.1 vs. $8.4 \pm 2.5\%$, $p < 0.001$), but no statistically significant differences were observed between groups (p between groups=0.13). Stress related to diabetes also reduced in both groups. Notably, total cholesterol (intervention: 192 ± 43 vs. 182 ± 39 mg/dl; control: 197 ± 44 vs. 191 ± 45 mg/dl, p between groups=0.035) and triglycerides (intervention: 158 [106–218] vs. 135 [106-215]; control: 128 [100-215] mg/dl vs. 146 [102-203] mg/dl, p between groups=0.03) reduced overtime only in intervention group.

Conclusion: In this sample of type 2 DM patients attending a primary care unit, a significant decrease in HbA1c was observed during the follow-up, but it was similar in intervention and control groups. The DM education course delivered to CHW was able to improve patients' lipid profile.

Introduction

Diabetes mellitus (DM) affects 8.3% of the world population¹, and establishing effective public health policies to control it challenges governments worldwide. DM treatment is demanding, and its effectiveness relies mainly on patients' adherence to lifestyle changes and continuous anti-hyperglycemic medication intake.² A complex set of social, political, historical, environmental, cultural and behavioral factors influence both the management of DM and the sustainability of diabetes self-care practices.³ Multiple interventions that include education, social support, and community programs are then needed to achieve success in DM care and control.^{3,4} Culturally relevant interventions may be particularly important for those who have traditionally lacked access to care.^{3,4,5}

Many health promotion and DM programs are engaging community health workers (CHW) to strengthen the links and facilitate communication between healthcare providers and individuals.^{3,6} The CHW is defined as a member of a particular community who works as a bridge between the healthcare system and community members. Commonly, CHW do not have formal health training and provide cultural mediation, informal counseling and social support, culturally appropriate health education, advocating for individual and community needs, increasing access to care, and building individual and community capacity.⁷ CHW are individuals who represent their ethnic, cultural, or geographic communities and provide a link between these communities and health care providers.³

Previous studies have demonstrated the role of CHW in health outcomes, especially in improving maternal and child health.^{8,9} In DM field, CHW have an important role in collaborating with DM educators and other health care providers in preventing and controlling diabetes and its complications through education, lifestyle change, self-management and social support.³ Improving CHW literacy upon DM important issues may

have an impact on patients metabolic control. Thus the aim of this study is to evaluate the effect of a structured diabetes education training provided to CHW in metabolic control of patients with type 2 DM assisted by these professionals.

Research Design and Methods

Trial design and study settings

This study is a randomized controlled trial conducted in the primary care unit São Pedro, in Porto Alegre, Rio Grande do Sul, Brazil. This primary care unit operates on the model of Family Health Strategy, a government program for primary care health services in Brazil, which includes actions for health promotion, prevention, recovery, rehabilitation of diseases and injuries. This health unit attends a bounded area with an estimated population of 4340 persons and which is divided into eight micro-areas, each one assisted by one specific CHW. The complete health team also includes 2 primary care physician, 2 nurses and 4 nurse technicians.

Participants

All CHW accepted to participate the study and signed the informed consent. Each CHW is responsible for monitoring and conducting monthly home visits of approximately 18 patients with type 2 DM. The primary care team in this service was responsible for the care of 147 adult patients with type 2 DM, who were all invited to participate in the study. Type 2 DM diagnosis was based on the ADA's criteria.¹⁰ All included patients agreed to participate in the study after signing an informed consent.

Baseline assessments

Patients assessment consisted on clinical (age, gender, ethnicity, diabetes duration,

history of hypertension and blood pressure [BP] levels, smoking and physical activity), and anthropometrical (weight, height, and waist circumference) data. BP was measurement with automatic digital sphygmomanometer (Omron), after a 5 minute rest in the sitting position, and the average of two measurements held on the left arm, with 1 minute interval, were considered for analysis. Patients were diagnosed as hypertensive when systolic BP was greater than 140 mmHg and/or diastolic greater than 90 mmHg on 2 occasions or if the individual was on antihypertensive therapy. The body mass index (BMI: weight/height²) was also calculated. Blood sampling for HbA1c, lipid profile, creatinine measurements and a spot urine sample for albuminuria were collected.

Interventions

After initial evaluation of patients, the 8 CHW and their respective areas were randomly divided into two groups: intervention and control. Randomization was performed by the website randomization.com. Intervention group (CHW n = 4) received training on structured diabetes education and were taught to transmit their knowledge during their visits. Control group (CHW n = 4) received training in different public health issues, not related to DM. The only components of the health team aware of CHW group of randomization were the CHW themselves, as primary care doctors, nurses and nurses technicians were blinded to study allocation.

The DM education program, adapted from Gagliardino et al¹¹, included 4 theoretical sessions, 60 minutes long, taught once a week for 4 weeks, developed in the form of group classes, and given by one of the authors (CBL). Classes took place at the primary care unit, in the boardroom, containing appropriate teaching material for this purpose. The educational method used was collaborative in that the CHW were encouraged to participate actively in the learning process. The educational program content comprises

(1) definition of DM, and identification of modifiable risk factors for type 2 DM, (2) non-pharmacological treatment, with emphasis on diet and exercise, (3) pharmacological therapy, including mechanism of action and side effects of anti-hyperglycemic medications provided by the Brazilian public health system (metformin, glyburide, NPH and regular insulin) and (4) an overview of chronic DM complications.

Knowledge of participants and CHW about DM was assessed before and after training with appropriate questionnaire composed by 22 questions addressing the information discussed in the meetings and will be referred as DM knowledge score.¹² Stress related to DM was assessed by the scale Problem Areas in Diabetes (PAID)¹³, which is a questionnaire of 20 items, focused on the negative emotional aspects experienced by patients living with diabetes. Each item can be scored from 1 (meaning "no problem") to 6 (corresponding to "serious problem"). The score is transformed into a scale ranging from 0 to 100; high score indicates greater damage. PAID questionnaire has been translated to Portuguese language and has been validated for use in Brazil.¹⁴

Three months after CHW training, patients were reassessed for BMI, BP, lipid profile and HbA1c, as well as for DM knowledge score and PAID scale. The training effect of CHW was measured through the variation of these parameters between intervention and control groups. The primary endpoint was changes in HbA1c 3 months after the course.

Laboratory analysis

Blood sampling (10 ml) was taken for analysis of fasting plasma glucose (glucose-peroxidase enzyme colorimetric method), creatinine (Jaffe method), total cholesterol, HDL cholesterol and triglycerides (enzymatic colorimetric method). Albuminuria was measured in a urine sample (turbidity). Measurement of HbA1c was performed by the high-performance liquid chromatography on Merck-Hitachi 9100 machine by column cation

exchange method and the reference values are <6%. LDL cholesterol was calculated by Friedewald equation [LDL = total cholesterol – (HDL + Triglycerides/5)]¹⁵.

Statistical analysis

Calculations and graphics were performed with the Excel and SPSS 18.0 for Windows software's. Continuous variables are presented as mean \pm standard deviation and median (interquartile range), and categorical as absolute (number of cases) and relative frequency (percentage). Variables with non-normal distribution were analyzed after logarithmic transformation. Categorical variables were compared using the chi-square test and continuous variables with the Student t test for analysis related to baseline measurements. To evaluate changes in variables overtime and between groups, ANOVA for repeated measures was used. A p value (two-tailed) <0.05 was considered significant.

A sample size of 106 individuals, with a power of 80% and alfa-error of 5%, was required to find a difference of 0.8% in HbA1c, based on results of Scain et al¹² and Spencer et al¹⁶. All the 147 individuals with DM attending the primary care unit were invited to participate and 118 accepted. Results are reported based on intention-to-treat analysis, as all patients were included on analysis regardless they received or not regular visits from the CHW. For patients lost from follow-up we chose to consider the worst scenario, and baseline HbA1c value was repeated at the end of the study. We also analyzed the data excluding lost from follow-up patients.

Results

Baseline characteristics

Of the 118 patients included, 35% (n=41) were men and 62% (n=73) were whites. Participants mean age was 61 \pm 11 years with mean diabetes duration was 10.1 \pm 9.9 years

(median: 6 years; 3 – 5 years), Included subjects had a mean of 5.0 ± 3.6 years of formal literacy and 41.6% (n = 49) had a mean family income of less than U\$ 450 per month. Mean BMI was 31 ± 6 kg/m² and mean HbA1c was $9.1\pm 2.1\%$. Clinical and laboratory characteristics of patients according to randomization groups (intervention and control) are depicted in **Table 1**. No differences between groups regarding these variables were observed.

Follow-up results

The 8 CHWs assisting 118 patients were randomized in two groups to receive the Diabetes Education Program (intervention group, 4 CHWs, n = 62 patients) or an education course in other health issues (control group, 4 CHWs, n= 56 patients). Four months after the baseline assessment (3 months after the education course), 94 individuals were reevaluated (80%). Patients lost from follow-up were similar to those completing the trial regarding age, DM duration, gender and HbA1c at baseline. No change in DM's knowledge scores was observed between groups (intervention: 10.8 ± 3.5 vs. 10.9 ± 4.0 ; control: 9.8 ± 3.8 vs. 10.9 ± 4.1 , p= 0.08).

A significant reduction in HbA1c levels was observed in both groups (intervention: 9.1 ± 2.2 vs. 7.9 ± 1.9 %; control: 9.1 ± 2.1 vs. $8.4\pm 2.5\%$, p overtime <0.001), but was not different between groups was observed (p between groups =0.13) (**Figure 1**). HDL cholesterol reduced in both groups overtime, with no differences between groups (intervention: 47 ± 13 vs. 44 ± 11 ; control: 45 ± 13 vs. 44 ± 12 , p overtime =0.001; p between groups =0.33). Also, stress related to DM (PAID) score decreased during the follow-up in both groups (intervention: 44 ± 19 vs. 39 ± 19 and control group: 47 ± 19 vs. 45 ± 19 , p overtime =0.02; p between groups =0.32). Notably, intervention group presented a reduction in total cholesterol (intervention: 192 ± 43 vs. 182 ± 39 mg/dl; control: 197 ± 44 vs.

191±45 mg/dl, p overtime=0.40; p between groups=0.035) and triglycerides (intervention: 158 (106 – 218) vs. 135 (106 - 215) mg/dl; control: 128 (100 -215) vs. 146 (102 - 203) mg/dl, p overtime=0.70; p between groups = 0.03) at the end of the trial in comparison with control group (**Table 2**). No differences in others outcomes of interest (BMI and BP) were observed between groups. Similar results were found when patents lost from follow-up were excluded from analysis (data not shown).

Discussion

In this sample of subjects with type 2 DM from a primary care unit in which its CHW underwent a DM education program, in order to transmit their knowledge to the community, there was a reduction in HbA1c in both groups, but no difference was observed between groups. HDL cholesterol and stress related to DM reduced in both groups overtime, with no differences between groups. Interestingly, total cholesterol and triglycerides reduced significantly only in intervention group.

CHW are also denominate as community health agents, community health advocates, community health representatives, lay health educators, peer health promoters, community health outreach workers, and in Spanish, *promotores de salud*, and have been recognize as important components of the health team attending patients in the primary care setting, especially when considering culturally distinct as well as low income populations.³ There is already evidence of their benefits improving maternal and child health⁸, improving tuberculosis treatment outcomes and reducing child morbidity and mortality⁹ and disease prevention, such as asthma management and cervical cancer screening and mammographic screening⁴.

However, the effectiveness of CHW in DM care is still controversial. Gary et al¹⁷ demonstrated a reduction in diastolic BP and triglycerides in an African American urban

population when patients received a combination of nurse plus CHW counseling, but no changes were seen in HbA1c. As well, in Holtrop et al¹⁸ study no significant reductions in HbA1c or BMI were observed after six months of a lay health advisor intervention, in which an educational program was provided for women with type 2 DM in rural areas. Nevertheless, Perez-Escamilla et al¹⁹ demonstrated that a CHW education program for Latino patients with type 2 DM have a significant effect on HbA1c levels (-0.55%), that was more pronounced at 12- and 18-month visits; but no effect on blood lipids, BP, and weight was reported. Spencer et al¹⁶ also demonstrated the benefit of a culturally tailored, behavioral theory-based CHW intervention for Latino and African American patients with type 2 DM control, as HbA1c reduced 0.8% after intervention.

A systematic review showed a great variability in CHW roles and duties in DM care, which ranged from a large involvement in providing support to patient's care to implementing education sessions taught by other health care professionals.²⁰ Studies examining the role of CHW were not sufficient in number to determine conclusions about the best roles for CHW in community interventions. There was also a great variability in the number and nature of intervention components. This makes difficult to determine what intervention characteristics led to positive outcomes and the role of the CHW in producing the observed effect. That systematic review²⁰ demonstrated that improvements in metabolic status were noted for interventions where CHW were actively involved in care¹⁷, provided assistance for interventions delivered by other health care providers^{21, 22} and assumed a direct teaching role^{17, 23, 24}. Some of the successful interventions involved other health professionals than CHW^{22, 25} and other successful interventions primarily or exclusively involved the CHW^{17, 21, 23, 24}.

In Brazil, CHW work in educational processes of the community in a wide range of health issues, and not exclusively in DM. Their monthly home visits addresses education

for individuals with chronic or infectious diseases, such as hypertension, DM, cardiovascular diseases and tuberculosis, as well as for individuals at risk or vulnerability, such as pregnant women and children 0-5 years. At the same visit they may have to talk about all of these topics in a particular family. This may influence the effectiveness of DM education, which is itself a broad topic to be addressed at each visit.

In our study, control group participants did not receive the CHW intervention but were also visited at home for data collection, including HbA1c assessment. This may explain why HbA1c also declined in this group, biasing findings toward the null hypothesis. Another difference between our population and those from studies reporting benefits in HbA1c was that the majority of the studies took place in racial and ethnic minority communities and included individuals who have traditionally lacked access to adequate health care. These communities may have culturally stronger and well-developed community networks and social ties among members, including community leaders, which may lead to a better commitment and engagement in this kind of educational intervention. This is not the case of the community in this study. Therefore, future research is needed to identify populations in which the model works best and on how to tailor interventions to participants from diverse cultures and social conditions.

DM patients have lower quality of life than patients without this disease.²⁶ Evidence also suggests that stressful experiences might affect DM, in terms of both onset and exacerbations.²⁷ The stress related to DM score used in this study (PAID score) have been associated with higher HbA1c and is an important predictor of poor adherence to treatment not involving general emotional distress.^{14, 28} In our study, stress related to diabetes reduced in both groups. This effect may be explained by participation in the study, as patients received physical examinations, filled questionnaires, had blood drawn for exams, and when were not able to walk to the health unit, were visited at home for data

collection, which probably established in participant patients a sense of being cared. In addition, as CHW were participating in a study, maybe their intervention were more effective, even in the control group, since CHW proved to be essential not only for delivering education on topics directly relevant to type 2 DM self-management but also for providing care coordination and social support services to patients. Thus, CHWs filled huge vacuums of needs that are currently not being addressed by healthcare, public-care, and social assistance systems surrounding the target community.

This study has some limitations. The education course was provided only to intervention group, but one cannot assure that CHW randomized to intervention group did not share the acquired knowledge about DM with their colleges from control group. Another important aspect is that CHW are supposed to visit DM patients monthly, but not all of them receive regular visits, as is the case of productive age patients because visits are schedule during working hours.

In conclusion, improving CHW literacy regarding DM was associated with lower total cholesterol and triglycerides of patients with type 2 DM. HbA1c also decreased during the follow-up, but was similar in intervention and control groups. Additional studies are needed to identify specific, replicable characteristics of successful interventions involving CHW.

Conflict of interest statement

All authors declare no conflict of interests.

Acknowledgments

The authors gratefully acknowledge the support of the collaborating organizations: CNPq and Fundo de Incentivo à Pesquisa (FIPE). CBL and JLG were recipients of a scholarship

from CNPq. The Authors are also grateful to the health care professionals and patients of the primary care unit São Pedro and to Hospital de Clínicas de Porto Alegre, Porto Alegre, Rio Grande do Sul, Brazil, for their support in the conduction of this research.

This study was partially sponsored by FIPE of Hospital de Clínicas de Porto Alegre.

References

- 1) Diabetes Atlas. Disponible at: <http://www.idf.org/diabetesatlas>. Accessed in April 2015.
- 2) Standards of Medical Care in Diabetes 2015. Diabetes Care 2015; 38 (1): S1–94.
- 3) American Association of Diabetes Educators. Community Health Workers in Diabetes Management and Prevention American Association of Diabetes Educators (AADE) Position Paper, 2011.
- 4) Viswanathan M, Kraschnewski J, Nishikawa B, Morgan LC, Thieda P, Honeycutt A, Lohr KN, Jonas D. Outcomes of community health worker intervention. AHRQ Publication No. 09-E014, June 2009.
- 5) CDC's Division of Diabetes Translation Community Health Workers/ Promotores de Salud: Critical Connections in Communities. Disponible at: <http://www.cdc.gov/diabetes/projects/pdfs/comm.pdf>.
- 6) Davis KL, O'Toole ML, Brownson CA, Llanos P, Fisher EB. Teaching How, Not What: the contributions of community health workers to diabetes self-management. The Diabetes Educator 2007; 33: 208–215S.
- 7) Look MA, Baumhofer NK, Ng-Osorio J, Furubayashi JK, Kimata C. Diabetes training of community health workers serving Native Hawaiians and Pacific people. The Diabetes Educator 2008; 34: 834–840.
- 8) Giugliani C, Harzheim E, Duncan MS, Duncan BB. Effectiveness of community health workers in Brazil: a systematic review. J Ambulatory Care Manag 2011; 34 (4): 326–338.
- 9) Lewin S, Munabi-Babigumira S, Glenton C, Daniels K, Bosch-Capblanch X, van Wyk BE, Odgaard-Jensen J, Johansen M, Aja GN, Zwarenstein M, Scheel IB. Lay health workers in primary and community health care for maternal and child health and the

management of infectious diseases. *Cochrane Database Syst Rev* 2010. The Cochrane Library, (11), CD004015. doi: 10.1002/14651858. CD004015.pub1.

10) Standards of Medical Care in Diabetes 2010. *Diabetes Care* 2010; 33(1): S11–61.

11) Gagliardino JJ, Etchegoyen G. A model educational program for people with type 2 diabetes: a cooperative Latin American implementation study (PEDNID-LA). *Diabetes Care* 2001; 24 (6): 1001–1007.

12) Scain SF, Friedman R, Gross JL. A structured educational program improves metabolic control in patients with type 2 diabetes: a randomized controlled trial. *Diabetes Educ* 2009; 35 (4): 603–11.

13) Polonsky WH, Anderson BJ, Lohrer PA, Welch G, Jacobson AM, Aponte JE, Schwartz CE. Assessment of diabetes-related distress. *Diabetes Care*. 1995; 18 (6): 754–60.

14) Gross CC, Scain SF, Scheffel R, Gross JL, Hutz CS. Brazilian version of the problem areas in diabetes scale (B-PAID): validation and identification of individuals at high risk for emotional distress. *Diabetes Res Clin Pract*. 2007; 76 (3): 455–9.

15) Cordova CMM, Achneider CR, Juttel ID, Cordova MM: Avaliação da dosagem direta do colesterol-LDL em amostras de sangue de 10.664 pacientes em comparação com o uso da fórmula de Friedewald. *Arquivos Brasileiros de Cardiologia* 2004; 83 (6): 476–481.

16) Spencer MS, A Rosland AM, Kieffer EC, Sinco BR, Valerio M, Palmisano G, Anderson M, Guzman JR, Heisler M. Effectiveness of a Community health worker intervention among African American and Latino adults with type 2 diabetes: a randomized controlled trial. *J Public Health*. 2011; 101: 2253–2260.

17) Gary TL, Bone LR, Hill MN, Levine DM, McGuire M, Saudek C, Brankati F. A randomized controlled trial of the effects of nurse case manager and community health

worker interventions on risk factors for diabetes-related complications in urban African Americans. *Prev Med* 2003; 37: 23–32.

18) Holtrop JS, Hickner J, Dosh S, Noel M, Ettenhofer TL. ‘Sticking to it—diabetes mellitus’: a pilot study of an innovative behavior change program for women with type 2 diabetes. *J Health Educ* 2002; 33: 161–166.

19) Pérez-Escamilla R, Damio G, Chhabra J, Fernandez ML, Segura-Pérez S, Vega-López S, Kollannor-Samuel G, Calle M, Shebl FM, D’Agostino D. Impact of a community health workers–led structured program on blood glucose control among latinos with type 2 diabetes: The DIALBEST Trial. *Diabetes Care* 2015; 38 (2): 197–205.

20) Norris SL, Chowdhury FM, Van Le K, Horsley T, Brownstein JN, Zhang X, Jack Jr L, Satterfield DW. Effectiveness of community health workers in the care of persons with diabetes. *Diabetic Medicine* 2006; 23: 544–556.

21) Brown S, Garcia A, Kouzekanani K, Hanis CL. Culturally competent diabetes self-management education for Mexican-Americans: the Starr County Border Health Initiative. *Diabetes Care* 2002; 25: 259–268.

22) Heath GW, Leonard BE, Wilson RH, Kendrick JS, Powell KE. Community-based exercise intervention: Zuni Diabetes Project 5858. *Diabetes Care* 1987; 10: 579–583.

23) Lorig KR, Ritter PL, Gonzalez VM. Hispanic chronic disease selfmanagement: a randomized community-based outcome trial. *NursRes* 2003; 52: 361–369.

24) Philis-Tsimikas A, Walker C, Rivard L, Talavera G, Reimann JO, Salmon M et al. Improvement in diabetes care of underinsured patients enrolled in Project Dulce. *Diabetes Care* 2004; 27: 110–115.

25) McDermott R, Tulip F, Schmidt B, Sinha A. Sustaining better diabetes care in remote indigenous Australian communities. *BMJ* 2003; 327: 428–430.

- 26) Edelman D, Olsen MK, Dudley TK, Harris AC, Oddone EZ. Impact of diabetes screening on quality of life. *Diabetes Care*. 2002; 25 (6): 1022–6.
- 27) Lloyd C, Smith J, Weinger K. Stress and Diabetes: a review of the links. *Diabetes Spectrum* 2005; 18 (2): 121–7.
- 28) Nichols GA, Hillier TA, Javor K, Brown JB. Predictors of glycemic control in insulin-using adults with type 2 diabetes. *Diabetes Care* 2000; 23: 273–277.

Table 1: Baseline clinical and laboratory characteristics according to group of randomization.

	Control n= 56	Intervention n= 62	p
Age (years)	58.9±11.5	62.6±11.2	0.08
Diabetes Duration (years)	10.7±11.0	9.5±8.5	0.55
Whites n (%)	33 (59)	40 (65)	0.53
Men n (%)	22 (39)	19 (31)	0.33
BMI* (Kg/m ²)	30.6±6.0	30.7±5.4	0.89
Systolic BP (mmHg)	136.5±24.4	142.9±21.7	0.13
Diastolic BP (mmHg)	80.9±12.5	79.7±12.3	0.61
DM knowledge score	9.4±3.8	10.7±3.6	0.08
Fasting Plasma glucose (mg/dL)	165±64	156±64	0.43
HbA1c (%)	9.1±2.1	9.1±2.2	0.95
Total Cholesterol (mg/dL)	197.1±44.3	191.8±43	0.56
HDL- Cholesterol (mg/dL)	45.5±13.2	46.7±12.6	0.61
Creatinine (mg/dL)	0.86±0.27	0.88±0.33	0.69
Triglycerides	128 (100-215)	158 (106-218)	0.44
Albuminuria	15 (5-63)	19 (5-60)	0.50

Data expressed in mean ± standard deviation or median (interquartile interval)

BMI = body mass index; BP = blood pressure; DM = diabetes mellitus

Table 2: Changes in clinical and laboratory variables before and after intervention

	CONTROL		INTERVENTION		P between groups	P overtime
	n=56		n=62			
	BASAL	FINAL	BASAL	FINAL		
Systolic BP (mmHg)	136±24	137±22	143±22	139±22	0.36	0.16
Diastolic BP (mmHg)	81±12	83±11	80±12	79±10	0.11	0.58
BMI (kg/m ²)	30.6±6.0	30.6±5.9	30.7±5.4	30.8±5.4	0.82	0.96
Total Cholesterol (mg/dl)	197±44	191±45	192±43	182±39	0.035	0.40
HDL (mg/dl)	45±13	44±12	47±13	44±11	0.33	0.001
Triglycerides (mg/dl)	128 (100-215)	146 (102-203)	158 (106-218)	135 (106-215)	0.03	0.70

Data expressed in mean ± standard deviation or median (interquartile interval)

BP = blood pressure; BMI = body mass index

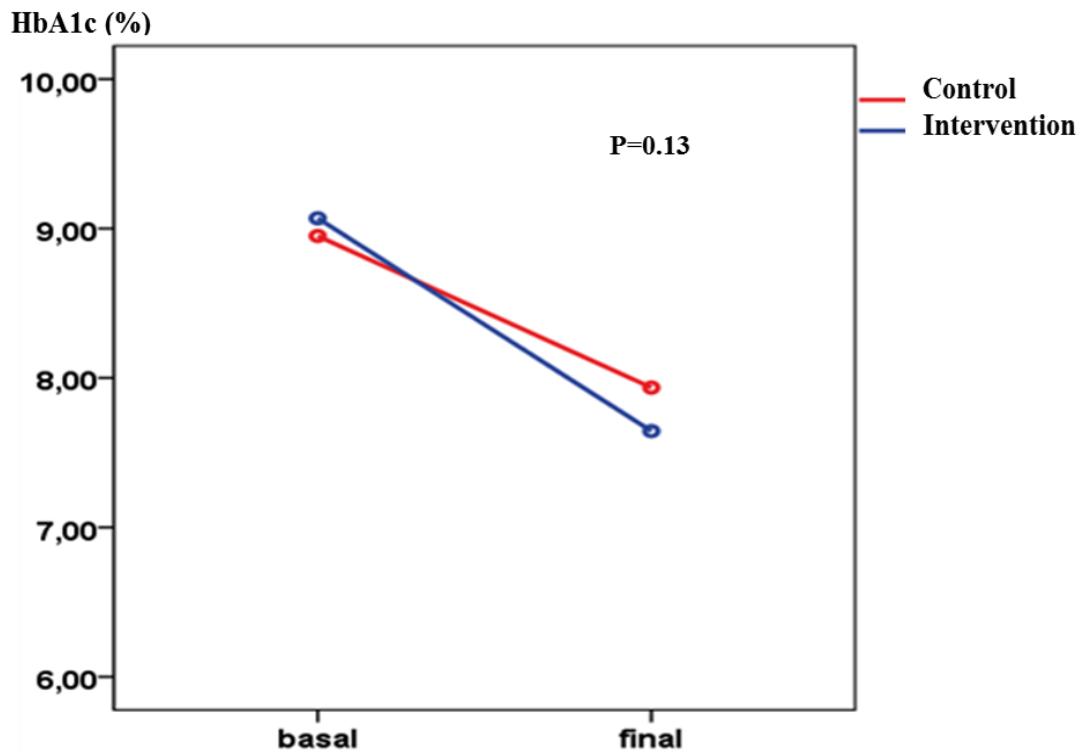


Figure 1: HbA1c values in control and intervention groups.

P < 0.001 for decrease in HbA1c overtime in both groups. P = 0.13 for differences between groups.