TITLE

Motiva.DM2 Project. A Pilot Behavioral Intervention on Diet and Exercise for Individuals with Type 2 Diabetes Mellitus.

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ETHICAL APPROVAL

This study was approved by the Ethics Committee of the Principality of Asturias, Spain (reference number: 16/18).

CONFLICT OF INTEREST

The authors declare that they have no conflict interests.

FUNDING

The authors received no funding.

Abstract

Aim: The purpose of this study was to assess the efficacy of an educational intervention based on the Behavior Change Wheel (BCW) framework for individuals with type 2 diabetes mellitus (DM2) on dietary and exercise behavior in a Spanish region.

Methods: A two-arm pilot research was developed. The intervention consisted of a 6-month period with guidelines and 4 in-person interventions. The outcome was changes in behaviors, motivation, competence, autonomy, social support to implement the recommendations, HbA1c, and body composition.

Results: n=111 patients were recruited. Individuals in the intervention experienced a significative improvement on adherence to dietary recommendations (+1.23; p=0.026), exercise (+0.86; p=0.001), and a decrease in HbA1c levels (-0.6%; p=0.002) and BMI (-0.73; p<0.001).

Conclusion: The intervention for DM2 individuals, based on the BCW framework, developed, and implemented by primary care nurses has been effective in improving the adherence to healthy eating, exercise, HbA1c levels, and body composition.

Keywords: Diabetes Mellitus, Type 2; Diet; Exercise; Health Education

1. Introduction

Diabetes Mellitus (DM) is a non-committable disease that can be managed as a priority [1]. Globally, there are approximately 463 million adults diagnosed with DM, and by 2045 this number will rise to 700 million [2]. Among the different types of this disease, type 2 diabetes mellitus (T2DM) is the more frequent, representing 90-95% of the total cases [3].

T2DM patients are more at risk of developing cardiovascular diseases [4,5], nephropathies, retinopathies, neuropathies, and amputations [6]. With the aim of avoiding these complications, good glycemic control is essential [3], the most commonly used indicator of which is glycated hemoglobin (HbA1c).

A healthy lifestyle has an impact on this control [7]. There is enough evidence to confirm that HbA1c levels can be lowered with a healthy diet [8,9], maintaining an adequate weight [10], or exercising regularly [7,8]. Moreover, interventions that improve these behaviors are effective in glycemic control and the reduction of cardiovascular risk [12,13], especially when both behaviors are targeted [14] and patients are motivated [15,16].

The efficacy of behavioral interventions depends greatly on an adequate design and implementation. It is therefore essential to develop interventions according to an effective theoretical framework [17], as the Behavior Change Wheel (BCW) [18]. The backbone of this model is known as COM-B, which stands for capability, opportunity, motivation, and behavior. The authors of the model indicate that a change in behavior

requires changes in at least one of the other 3 components and determines which interventions may be implemented to modify each of the components (18).

Considering firstly that a lifestyle that includes a healthy diet and exercise is associated with good outcomes for T2DM patients, secondly that Primary Care is essential in Spain (as they are in charge of monitoring individuals with T2DM), and thirdly that no intervention with the BCW framework had been found in Spain, we chose to carry out the present study with the aim of analyzing the effectiveness of an educational intervention based on the BCW model for T2DM patients targeting dietary and exercise behavior and developed and implemented by Primary Care nurses. Then, we evaluated the influence of the intervention on motivation, social opportunity, HbA1c, and body weight.

2. Methods

2.1. Study setting and selection criteria

This was a two-arm pilot research, developed between March 2018 and June 2019, in T2DM patients from 4 health care centers in the sanitary area 3 of the Principality of Asturias (Spain). Measurements were taken at baseline and at 6 months post-intervention, in both arms.

The study included individuals over 18 years of age, who voluntarily chose to participate, were fluent in Spanish, were receiving care during the time of the study at the selected healthcare centers, and suffered no terminal diseases or severe psychiatric disorders.

One hundred and twenty individuals (120) met the criteria and were invited to join the study. Of these, 9 (7.5%) chose not to participate: 2 because they lacked the time, 2 because they did not feel empowered to participate, 1 because they did not trust the usefulness of the research, and 4 because they were not interested.

A non-probabilistic sampling strategy was used to avoid cross-contamination between groups, using the healthcare center where they were treated as a randomization unit, between two groups: intervention group (IG) and control group (CG).

In this study, structured group education was an independent variable, and the recommendations related to diet and exercise, motivation, competence, autonomy, social support for healthy eating and exercise, HbA1c, and body weight were dependent variables.

2.2. Data collection

Data were collected before (Pre-intervention) and 6 months after the beginning of the intervention (Post-intervention) by 4 nurses from our research group, who previously studied and rehearsed the data collection protocol and intervention to homogenize the process and avoid biases.

2.3 Information related to behavioral recommendations, competences, autonomy, and social support

The questionnaire Motiva.Diaf-DM2 [22] was used to analyze adherence to and motivation of behaviors linked to healthy eating, exercise, and information related to personal variables. The questionnaire has three parts:

The first one collects sociodemographic and personal data, and information on the individual's disease: sex, age (at the beginning of the study), level of education, time since T2DM diagnosis, and type of treatment.

The second part includes 17 questions (11 about diet, and 6 about exercise) to measure adherence to behavioral recommendations. The answer to each of these recommendations was dichotomic and analyzed as such (follows recommendation=1; doesn't follow recommendation=0). Additionally, participants from the IG were asked during Pre-intervention to note the number of recommendations they wanted to achieve (agreed recommendations) and the number of achieved recommendations was registered in Post-phase.

The last part of the questionnaire includes questions related to the degree of satisfaction of basic psychological needs (BPNs) (competence, autonomy, and social support) for each behavior ranging from 0 (worst level of satisfaction) to 4 (best level of satisfaction). Scores of competence and autonomy were considered indications of capacity and motivation, and social support and the number of visits to Primary Care nurses as indicators of social opportunity.

2.4 Information related to HbA1c and body weight

Anthropometric measurements of weight (kg) and size (m) were performed to calculate body weight according to the Body Mass Index (BMI): "BMI= weight (kg)/size^2 (m)."

Determination of HbA1c levels was obtained with venous blood work and interpreted quantitatively (levels from blood work) and qualitatively (control number ≤ 7%; control number >7%) [23].

2.5 Educational Intervention

IG patients received a 6-month educational intervention about dietary and exercise habits designed according to the BCW framework [18] and delivered by the nurses in our research group. Interventions on psychological capacity, automatic and reflective motivation for diet, psychological and physical capacity, and autonomic and reflective motivation for exercise (Table 1) were specifically targeted. The BCW was selected due to the effectivity shown in previous behavioral interventions in T2DM patients [19, 20], and in Primary Care [21].

The intervention included the administration of written guidelines specifically designed for the study. The content, validated by T2DM experts and T2DM patients selected with the same criteria used in the study, was elaborated according to the behavioral recommendations included in the Motiva.Diaf-DM2 [22] questionnaire. Also, nursing professionals in the team made verbal recommendations to the participants, which included a standardized part for all the patients, and a customized one targeting everyone's specific needs.

The different activities of the intervention were developed in 4 nursing visits to Primary Care, lasting between 10 and 20 minutes each. In the first visit, coinciding with the start of the study, patients were explained the aim of the study and their collaboration was requested. Those who expressed their intention to participate signed the informed

consent form. Subsequently, they were measured (anthropometric measurements), blood work was performed, and they filled out the questionnaire (baseline measurements).

In the second visit, 1 week after the first one, guidelines were administered to the participants and the nurses provided them with information through an educational-persuasive intervention about the importance of diet and exercise for the management of T2DM. Likewise, the recommendations to be achieved during the intervention were agreed upon with each patient.

In the third visit, 3 months after the start of the program, adherence to behavioral recommendations was reviewed, facilitators and barriers encountered were analyzed, and progress was positively reinforced.

In the last visit, 6 months after the beginning of the program, anthropometric assessments and blood work were repeated, participants filled in a questionnaire (Post) and the achievement of the objectives agreed upon at the beginning of the study was evaluated.

In all the visits, both in the 4 programmed visits and in those requested by the participants, the nurses answered any doubts raised by individuals in relation to T2DM. The usual care was delivered to CG patients, following guidelines and protocols previously established.

2.6. Data Analysis

For the description of the personal characteristics of the sample, percentages, means, and standard deviations (SD) were calculated according to the nature of the variables. The assumption of normality was checked using the Kolmogorov-Smirnov test, and after corroborating it was met, the corresponding parametric tests were used.

Mixed ANOVA intervariability analysis (between-subject factors: intervention with two levels, CG and IG) and intravariability analysis (within-subject factors: time with two levels, Pre-intervention and Post-intervention) were performed to determine the impact of the intervention on behavioral recommendations and BPNs. The Pearson correlation coefficient and the Kappa index were used to calculate the association among agreed recommendations. Finally, Student's t was used to analyze the impact of the intervention on HbA1c and BMI.

Analyses were performed using IBM® SPSS® Statistics version 24.0 software.

2.7. Ethical considerations

This study was approved by the Clinical Research Ethics Committee of the Principality of Asturias (numbered 16/18).

3. RESULTS

3.1 Population included in the study

The sample was constituted by 111 participants, 63 (56.76%) belonged to the IG, and 48 (43.24%) to the CG. The characteristics of the study population are shown in Table 2.

Of the 111 individuals initially included in the study, 106 finished the study, with an abandonment rate of 4.5% (n=5; 4 from the IG and 1 from the CG) (Figure 1).

3.2 Impact of the intervention on behavioral recommendations

In the Post, CG participants achieved a mean of 9.43 dietary recommendations (SD=1.612) and 2.11 (SD=1.645) exercise recommendations. In the IG, participants achieved a mean of 9.78 (SD=1.415) and 2.47 (SD=1.490) for diet and exercise recommendations, respectively.

Mixed ANOVA intervariability (intervention with two levels: CG and IG) and intravariability (time with two levels: Pre-intervention and Post-intervention) analyses were performed. Regarding diet, the F value for interaction was 5.074 ($p=0.026$; Cohen's d=0.444-intermediate effect) and the F value for intravariability was 22.773 ($p<0.001$; Cohen's d=0.937- strong effect) (Figure 2). For exercise, the F value for interaction was 11.958 ($p=0.001$; Cohen's d=0.678- intermediate effect), and the F value for intravariability was 10.986 ($p=0.001$; Cohen's d=0.648- intermediate effect) (Figure 3).

IG participants agreed to achieve an average of 1.24 (SD=0.773) recommendations during the time of the study, of which they finally achieved 0.88 (SD=0.311) ($r=0.788$; $p<0.001$). As seen in Table 3, 66.10% of the agreed recommendations were achieved ($k=0.495$, moderate degree of agreement; $p<0.001$).

3.3 Impact on competence, autonomy, and social support

Mixed ANOVA analysis for diet and exercise separately only showed significative differences in relation to intervention, competence, and autonomy for exercise.

For dietary behavior, in competence the F value for interaction was 0.025 (p=0.874) and the F value for intravariablity was 0.822 (p=0.367); in the case of autonomy, the F value for interaction was 0.853 (p=0.358) and the F value for intravariability was 2.546 (p=0.367). For social support, the F value for interaction was 0.021 (p=0.884), and the F value for intravariability was 2.472 (p=0.119).

For the BPNs related to exercise, in competence the F value for interaction was 4.941 (p=0.029; Cohen's d=0.449, intermediate/low effect), and the F value for intravariability was 0.058 (p=0.811); in autonomy the F value for interaction was 5.128 (p=0.025; Cohen's d=0.459, intermediate/low effect) and the F value for intravariability was 0.197 (p=0.658); and in the case of social support from the environment the F value for interaction was 1.445 (p=0.232), and the F value for intravariability was 0.015 (p=0.903).

The mean numbers of T2DM-related nursing visits requested by the participants were of 0.30 (SD=0.976) and 1.10 (SD=5.162), for the CG and IG respectively, with no statistically significant differences found between the two groups (t=1.052; p=0.295).

3.4 Impact of the intervention on HbA1c and body weight

Mixed ANOVA, intervariability and intravariability analyses were also performed for Hba1C value. The F value for interaction was 10.243 (p=0.002; Cohen's d=0.444-

intermediate effect) and F value for intravariability was 4.190 ($p<0.043$; Cohen's $d=0.937$- strong effect) (Figure 4). The percentage of controlled HbA1c in the CG were 70.2% and 68.1% in Pre-intervention and Post-intervention respectively ($p=1.000$). In the IG it increased from 62.7% to 83.1% ($p=0.008$).

Finally, a mixed ANOVA analysis showed an insignificant decrease in BMI in IG participants, while an increase was observed among CG participants (intervariability $F= 0.370$, $p=0.544$; intravariability $F=1.686$; $p= 0.197$).

4. Discussion

The current pilot study assessed the effect of an intervention based on the BCW, developed in a primary care setting, *versus* usual care in adults with T2DM, and explored various behavioral and clinical outcomes. IG members experienced an improvement in their adherence to recommendations for both behaviors, in their capability related to exercise, and in their HbA1c and BMI values. Therefore proving the effectiveness of the intervention.

It should be noted that both participation (similar to or higher than that observed in previous studies with similar characteristics [24, 25]), and the percentage of abandonment (lower [26, 27] or similar [25] to that of previous studies) were very satisfactory, which highlights the viability of the intervention.

The number of recommendations achieved by participants was very positive and consistent with the results of previous studies [27-29]. Including both behaviors in the

intervention may be one of the reasons that could have influenced the results. According to Huang et al., [14], intervening both behaviors simultaneously is often more effective than targeting each behavior separately.

Another circumstance that may have influenced the success of the intervention was the inclusion of in-person interaction so that the nurse could assess the specific needs of each participant. Previous studies show that the fact that the guiding and orientation offered by a professional, whom patients consider a reference, towards the achievement of objectives contributes significantly to the achievement of said objectives [26]. Moreover, the information contained in the guidelines given to the participants could have also had an influence on the success of the intervention. The combination of personal intervention with written material has demonstrated to be effective in previous studies among adult patients with chronic diseases, on the same behaviors and in the same community in which this study was carried out [30] and in populations diagnosed with T2DM [31].

Michie et al. [32] indicate that a credible source's persuasive actions and education influence the motivation and the enablement, sources of behavior that influence the adoption of healthy behaviors. It is important to remember that behavior changes are more likely to happen when T2DM patients are motivated [33]. Therefore, education and persuasion by the nurses in the intervention, as well as the establishment of a professional-patient commitment to a specific number of recommendations, could have contributed to motivating the participants, hence improving adherence to the recommendations.

Another aspect to highlight which contributed to the effectiveness of the intervention was the active participation of patients throughout the process. The design used was based on previous experiences in which patients participated in collaborative problem solving, identification of needs or commitment to change [28]. In addition, the literature suggests that diabetes experts support the involvement of patients in their own care [34], which in turn is associated with improved outcomes for interventions [35].

Two notable achievements are the reductions in HbA1c and BMI levels experienced by IG participants. Based on this, it could be said that the results could have contributed to reducing the risk of complications in the IG, since, as previous findings suggest, adequate glycemic control [36-38] and maintaining an adequate weight [39] or decreasing it [40, 41] reduces the risk of complications related to T2DM.

In relation to BPNs, an improvement was observed in those specifically targeted during the exercise intervention, particularly, competence and autonomy, indicators of capability and motivation, but not social support. This finding is not surprising since the intervention only included nursing visits for participants when necessary, an option already available in Primary Care, and no other actions of recognized effectiveness were carried out, such as changes in the context [42], elimination of barriers [43] or the promotion of family support [43, 44].

The overall analysis of the results corroborates the importance of implementing programs aimed at improving dietary behavior and exercise performance in T2DM patients as a strategy to improve glycemic control and reduce the risk of complications [12-14].

5. LIMITATIONS

While the piloting has been effective, interventions on important sources of behavior for behavioral change, such as social and physical opportunity, social and/or environmental variables, have not been included. On the other hand, the selection of patients from a limited geographical area prevents us from extrapolating the results to other locations.

6. IMPLICATIONS FOR CLINICAL PRACTICE AND RESEARCH

This pilot study suggests the possibility of completing the model of care received by T2DM patients with an intervention on diet and exercise, which combines face-to-face interventions and the delivery of written information in order to improve behavioral adherence, and HbA1c levels, thus contributing to better outcomes. Additionally, the intervention seemed easy to deliver, low cost, well-received by the patients, and could be incorporated as usual care in Primary Care Center visits.

In order to contrast these results, future RCTs should be implemented using the same design and theoretical framework in order to reinforce the results observed and provide an answer to certain circumstances which may be difficult to explain, such as the results obtained regarding BPNs.

7. CONCLUSIONS

The intervention for T2DM patients based on the BCW model and developed and implemented by Primary Care nurses has been effective in improving adherence to healthy eating, exercise, and HbA1c levels.

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The authors received no funding from an external source.

Author Contributions
RMP, CPC & XGM contributed to the planning of the study; CPC, ISG, RFR & XGM develop the intervention; RMP & MC had access to data and conducted analyses; RMP, CPC & XGM wrote the first draft; All authors critically reviewed the intellectual content of manuscript drafts and approved the final version for submission.

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Declaration of Competing Interest
The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

[1] World Health Organization. Global Report Diabetes, 2016, https://apps.who.int/iris/bitstream/handle/10665/204871/9789241565257_eng.pdf?sequence=1; 2016 [accessed 20 July 2020].

[2] International Diabetes Federation. Diabetes Atlas. 9th ed. https://www.diabetesatlas.org/en/; 2019 [accessed 20 July 2020].

[3] American Diabetes Association. 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes-2019. Diabetes Care. 2019;42(Suppl 1):S13-S28.

[4] Zheng Y, Ley SH, Hu FB. Global aetiology and epidemiology of type 2 diabetes mellitus and its complications. Nat Rev Endocrinol. 2018;14(2):88-98.

[5] Ares Blanco J, Valdés Hernández S, Botas P, Rodríguez-Rodero S, Morales Sánchez P, Díaz Naya L, et al. Gender differences in the mortality of people with type 2 diabetes: Asturias Study 2018. Gac Sanit. 2019:S0213-9111(19)30088-3.

[6] Pérez-Pevida B, Llavero M, Gargallo J, Escalada J. Microvascular complications of diabetes. Medicine. 2016;12(17):958-70.

[7] Davies MJ, D'Alessio DA, Fradkin J, Kernan WN, Mathieu C, Mingrone G, et al. Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2018;41(12):2669-701.

[8] Franz MJ, MacLeod J, Evert A, Brown C, Gradwell E, Handu D, et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. J Acad Nutr Diet. 2017;117(10):1659-79.

[9] Saintrain MVL, Sandrin RLESP, Bezerra CB, Lima AOP, Nobre MA, Braga DRA. Nutritional assessment of older adults with diabetes mellitus. Diabetes Res Clin Pract. 2019;155:107819.

[10] Rothberg AE, McEwen LN, Kraftson AT, Ajluni N, Fowler CE, Nay CK, et al. Impact of weight loss on waist circumference and the components of the metabolic syndrome. BMJ Open Diabetes Res Care. 2017;5(1):e000341.

[11] Colberg SR, Sigal RJ, Yardley JE, Riddell MC, Dunstan DW, Dempsey PC, et al. Physical Activity/Exercise and Diabetes: A Position Statement of the American Diabetes Association. Diabetes Care. 2016;39(11):2065-79.

[12] Chen L, Pei JH, Kuang J, Chen HM, Chen Z, Li ZW, et al. Effect of lifestyle intervention in patients with type 2 diabetes: a meta-analysis. Metabolism. 2015;64(2):338-47.

[13] Barreira E, Novo A, Vaz JA, Pereira AMG. Dietary program and physical activity impact on biochemical markers in patients with type 2 diabetes: A systematic review. Aten Primaria. 2018;50(10):590-610.

[14] Huang XL, Pan JH, Chen D, Chen J, Chen F, Hu TT. Efficacy of lifestyle interventions in patients with type 2 diabetes: A systematic review and meta-analysis. Eur J Intern Med. 2016;27:37-47.

[15] Ryan RM, Patrick H, Deci EL, Williams GC. Facilitating health behavior change and its maintenance: Interventions based on self-determination theory. The European Health Psychologist. 2008;10:2–5.

[16] Deci EL, Ryan RM. Self-determination theory in health care and its relations to motivational interviewing: a few comments. Int J Behav Nutr Phys Act. 2012;9:24.

[17] Bully P, Sánchez Á, Zabaleta-del-Olmo E, Pombo H, Grandes G. Evidence from interventions based on theoretical models for lifestyle modification (physical activity, diet, alcohol and tobacco use) in primary care settings: A systematic review. Prev Med. 2015;76 Suppl:S76-93.

[18] Michie S, van Stralen MM, West R. The behavior change wheel: a new method for characterising and designing behavior change interventions. Implement Sci. 2011;6:42.

[19] Brooksbank K, O'Donnell J, Corbett V, Shield S, Ainsworth R, Shearer R, et al. Discussing Weight Management With Type 2 Diabetes Patients in Primary Care Using the Small Talk Big Difference Intervention: Protocol for a Randomized Controlled Trial. JMIR Res Protoc. 2019;8(2):e12162. doi: 10.2196/12162.

[20] Moore AP, Rivas CA, Stanton-Fay S, Harding S, Goff LM. Designing the Healthy Eating and Active Lifestyles for Diabetes (HEAL-D) self-management and support programme for UK African and Caribbean communities: a culturally tailored, complex intervention under-pinned by behavior change theory. BMC Public Health. 2019;19(1):1146. doi: 10.1186/s12889-019-7411-z.

[21] Westland H, Bos-Touwen ID, Trappenburg JC, Schröder CD, de Wit NJ, Schuurmans MJ. Unravelling effectiveness of a nurse-led behavior change intervention to enhance physical activity in patients at risk for cardiovascular disease in primary care: study protocol for a cluster randomised controlled trial. Trials. 2017;18(1):79.

[22] Martín Payo R, González Méndez X, Papín Cano C, Suárez Álvarez J. Development and validation of a questionnaire for assessing the characteristics of diet and physical activity in patients with type 2 diabetes. Psicothema. 2018;30(1):116-122.

[23] American Diabetes Association. 6. Glycemic Targets: Standards of Medical Care in Diabetes-2020. Diabetes Care. 2020;43(Suppl 1):S66-S76.

[24] Jutterström L, Hörnsten Å, Sandström H, Stenlund H, Isaksson U. Nurse-led patient-centered self-management support improves HbA1c in patients with type 2 diabetes-A randomized study. Patient Educ Couns. 2016;99(11):1821-9.

[25] Gamboa Moreno E, Mateo-Abad M, Ochoa de Retana García L, Vrotsou K, Del Campo Pena E, Sánchez Perez Á, et al. Efficacy of a self-management education programme on patients with type 2 diabetes in primary care: A randomised controlled trial. Prim Care Diabetes. 2019;13(2):122-133.

[26] Wayne N, Perez DF, Kaplan DM, Ritvo P. Health Coaching Reduces HbA1c in Type 2 Diabetic Patients From a Lower-Socioeconomic Status Community: A Randomized Controlled Trial. J Med Internet Res. 2015;17(10):e224.

[27] Halvari H, Healey J, Olafsen AH, Byrkjeland R, Deci EL, Williams GC. Physical activity and motivational predictors of changes in health behavior and health among DM2 and CAD patients. Scand J Med Sci Sports. 2017;27(11):1454-69.

[28] Jayasuriya R, Pinidiyapathirage MJ, Jayawardena R, Kasturiratne A, de Zoysa P, Godamunne P, et al. Translational research for Diabetes Self-Management in Sri Lanka: A randomized controlled trial. Prim Care Diabetes. 2015;9(5):338-45.

[29] do Valle Nascimento TM, Resnicow K, Nery M, Brentani A, Kaselitz E, Agrawal P, et al. A pilot study of a Community Health Agent-led type 2 diabetes self-management program using Motivational Interviewing-based approaches in a public primary care center in São Paulo, Brazil. BMC Health Serv Res. 2017;17(1):32.

[30] Del Valle MO, Martín-Payo R, Cuesta-Briand B, Lana A. Impact of two nurse-led interventions targeting diet among breast cancer survivors: Results from a randomized controlled trial. Eur J Cancer Care (Engl). 2018;27(4):e12854.

[31] Lepard MG, Joseph AL, Agne AA, Cherrington AL. Diabetes self-management interventions for adults with type 2 diabetes living in rural areas: a systematic literature review. Curr Diab Rep. 2015;15(6):608.

[32] Michie S, Atkins L, West R. The Behavior Change Wheel: A Guide to Designing Intrerventions, Silverback. 1st ed. Great Britain: Silverback Publishing; 2014.

[33] Juul L, Rowlands G, Maindal HT. Relationships between health literacy, motivation and diet and physical activity in people with type 2 diabetes participating in peer-led support groups. Prim Care Diabetes. 2018;12(4):331-7.

[34] Gee JP, Scarbrough J, Bowker D, Keller T. Diabetes Educators Beliefs About Patient Self-Management and Strategies Used to Support Persons With Diabetes. Diabetes Educ. 2019;45(2):174-83.

[35] Almutairi N, Hosseinzadeh H, Gopaldasani V. The effectiveness of patient activation intervention on type 2 diabetes mellitus glycemic control and self-management behaviors: A systematic review of RCTs. Prim Care Diabetes. 2020;14(1):12-20.

[36] Mostafa SA, Coleman RL, Agbaje OF, Gray AM, Holman RR, Bethel MA. Modelling incremental benefits on complications rates when targeting lower HbA1c levels in people with Type 2 diabetes and cardiovascular disease. Diabet Med. 2018;35(1):72-7.

[37] Mitsios JP, Ekinci EI, Mitsios GP, Churilov L, Thijs V. Relationship Between Glycated Hemoglobin and Stroke Risk: A Systematic Review and Meta-Analysis. J Am Heart Assoc. 2018;7(11):e007858.

[38] Güner TA, Coşansu G. The effect of diabetes education and short message service reminders on metabolic control and disease management in patients with type 2 diabetes mellitus. Prim Care Diabetes. 2020:S1751-9918(20)30184-4.

[39] Schmidt AM. Diabetes Mellitus and Cardiovascular Disease: Emerging Therapeutic Approaches. Arterioscler Thromb Vasc Biol. 2019;39(4):558-68.

[40] Wing RR, Lang W, Wadden TA, Safford M, Knowler WC, Bertoni AG, et al. Benefits of modest weight loss in improving cardiovascular risk factors in overweight and obese individuals with type 2 diabetes. Diabetes Care. 2011;34(7):1481-6.

[41] Cradock KA, ÓLaighin G, Finucane FM, Gainforth HL, Quinlan LR, Ginis KA. Behavior change techniques targeting both diet and physical activity in type 2 diabetes: A systematic review and meta-analysis. Int J Behav Nutr Phys Act. 2017;14(1):18.

[42] Frieden TR. A framework for public health action: the health impact pyramid. Am J Public Health. 2010;100(4):590-5.

[43] Park S, Zachary WW, Gittelsohn J, Quinn CC, Surkan PJ. Neighborhood Influences on Physical Activity Among Low-Income African American Adults With Type 2 Diabetes Mellitus. Diabetes Educ. 2020;46(2):181-90.

[44] Wooldridge JS, Ranby KW, Roberts S, Huebschmann AG. A Couples-Based Approach for Increasing Physical Activity Among Adults With Type 2 Diabetes: A Pilot Feasibility Randomized Controlled Trial. Diabetes Educ. 201;45(6):629-41.

Dear Dr Sesti, thank you very much for getting back to us so quickly, and please thank the reviewers on our behalf for such constructive recommendations. Below are the responses to the reviewers. Additionally, the changes appear in red color in the manuscript.

Reviewer #1:

We have no answers for this reviewer. We would like to reiterate our thanks for the time spent in the review and the value that it adds to our research.

Reviewer #2:

Comment 1 & 2: The English language should be thoroughly revised; The overall clarity of presentation should be improved (for instance, the lack of verbs and commas in many sentences describing result details are confusing).

We sent the paper to an official English translator.

Comment 3 & 4: I suggest to have the Behavior Change Wheel method at least briefly described within the text rather than only cited and to have the questionnaire validation method detailed (the generic description "validated by DM2 experts and by individuals diagnosed with DM2, selected with the same criteria in the study" is not acceptable as such).

We include a brief description of the BCW in the introduction and in method (epigraph 2.5). Regarding the second recommendation, "the generic description validated by DM2 experts and by individuals diagnosed with DM2, selected with the same criteria in the study" refers the intervention, not the questionnaire. The questionnaire information appears in epigraph 2.3 and it is detailed in reference number 22.

Comment 5: As a minor comment, please remember to explain the term "IG" at its first presentation.

Thank you very much. We forgot to do it in the first version of the paper. First time presented is in page 5 and it has been explained.

Reviewer #3:

1, 9 & 11: It is better to show a Flow diagram showing the process of selecting cases. In addition, since the selection criteria and exclusion criteria for cases are

unclear, they should be described in detail. If the final study population is 106, it is recommended that all baseline data in Table 2 be shown as 106.
Thanks for the comment. We changed data and included HbA1c and BMI information at baseline for the 106 participants. The number of complications wasn't included in the first version of the paper and we consider that it is more sensitive to use the value of HbA1c than the number of complications. Also, we included the figure 1 "Flow Chart Selection Process".

Comment 2. Does this include people with chronic conditions other than cognitive impairment and type 2 diabetes who are receiving exercise and nutrition guidance? Does it include people who are unable to exercise (e.g., those who have an exercise disorder or have a cardiac condition that limits exercise)?

Thanks for the comment. The exercise recommended is non-risk low intensity (such as walking) and daily activities, which can be done by most of the population, or are specific to prevent complications due to type 2 diabetes such as "When performing any physical activity, eat high-carbohydrate food to prevent hypoglycemia". Because of that reason, we did not include other exclusion criteria than "terminal diseases or severe psychiatric disorders"

Comment 3: Page3, line 14: Why has no BCW intervention been implemented in Spain? Also, has the efficacy of BCW in patients with type 2 diabetes been shown in other countries?

We do not know the reasons why the BCW wasn't found in any intervention for type 2 diabetes in Spain. Probably this theory is not as popular as others traditionally used. In other countries we found papers describing the utilization of this theory in research with aims similar to the ones included in our research. We include commentaries in the section 2.5 (refs 19 & 20).

Comment 4. In what ways is the BCW intervention expected to have a positive impact on patients with type 2 diabetes? I would like to have you present a hypothesis.
This study tried to demonstrate the hypothesis that an educational intervention was effective in improving dietary and physical activity behaviors in people diagnosed with type 2 diabetes (T2DM).

Also, as a hypothesis and according to the BCW, the acquisition of knowledge and the support of nursing professionals should be effective in improving psychological capacity, motivation, and social opportunity. Therefore, improving these determinants would contribute to improving behaviors.

The hypothesis that this research presents is the effectiveness of an educational intervention based on the BCW model for individuals diagnosed with T2DM targeting dietary and exercise behavior and developed and implemented by Primary Care nurses. Secondly, we

evaluated the influence of the intervention on motivation, social opportunity, HbA1c, and body composition.

Comment 5. The method of grouping subjects is unclear. Please show in detail how it was assigned to 2 groups (IG, CG).

In section "method"(page 4) we wrote: "A non-probabilistic sampling strategy was used to avoid cross-contamination between groups, considering the healthcare center where they were treated as a randomization unit, between two groups: intervention group (IG) and control group (CG)". We consider that it is explained already.

Comment 6. The questionnaire Motiva.Diaf-DM2 [22] has 20 questions (14 diets, 6 exercises), but 17 items (11 diets, 6 exercises) are used in this study. Please provide details of the items used and why they were limited to 17 items.

Thanks to the comment of the reviewer we found an erratum in the original work where the development of the questionnaire was published. Psicothema´s editor was informed.

The original paper (page 119) includes the following text "Except for item 1, which had a factor loading of .27, all items had factorial weights > .30. Values between .30 and .50 are commonly accepted in the literature (Izquierdo, Olea, & Abad, 2014) and, consequently, no items were eliminated". What really must include is this "Values between .30 and .50 are commonly accepted in the literature (Izquierdo, Olea, & Abad, 2014) and, consequently items 1, 8 & 13 were eliminated".

7. The method of the intervention in each of the two groups is unclear. This information is important, and thus please describe the intervention method in detail separately for IG and CG. I recommend you to describe BCW in detail, which is the basis of the intervention method in this study, in the text. Also, it would be easier to understand if you show the flow of the intervention protocol in a diagram.

Thanks for the suggestion. In this case we consider that epigraph 2.5 describes in detail the intervention, which allows, along with the information from Table 1, the understanding of its development. However, we have made a more succinct description.

8. It is unclear what Figure 1 shows. Please enter the item name and unit on the vertical axis and add a description for the abbreviation. If the graph shows the mean values for each group, you need to show error bars such as standard deviation or standard error. Which is the same in Fig. 2.

Thanks for the recommendations. Data and text have been added to the figure.

10. It is unclear what Table 3 shows. Please provide a concrete explanation of what the score indicates and the content of the "Agreed Recommendations". Also, please add it in the text.

Text in table 3 has been modified according with the text that appear in page 9 of the manuscript.

12. Although there is no statistically significant difference at baseline in this study, IG is highly educated compared to CG, has a short duration of diabetes, has a high proportion of oral drug therapists, and has a large social support system for diet. Didn't these differences affect the results of this study? It is also recommended to consider whether changes in medication in each group affected the study results. In addition, it is recommended to perform multivariate analysis such as multiple regression analysis and logistic regression analysis to adjust confounding factors such as age, gender and educational background.

Regarding the first question raised by the reviewer about the verification of the non-existence of statistically significant differences between the two groups, it is understood that both groups can be considered equivalents. It is however true, as the reviewer points out, that from a descriptive point of view there are some differences between the groups, but the authors consider such differences not to be qualitative relevant nor do challenging to the results. Regarding medication, no change related to therapeutic regimens has been registered.

Following the recommendations made by the reviewer, multiple regression series were included using stepwise procedures [dependent: diet, physical activity or HbA1c post-intervention; independent variables: diet, physical activity or HbA1c pre-intervention (as applicable), sex, age, time since diagnosis and educational level]. The variables observed by the reviewer are not included in the final models because, as such results point out, variables did not impact on the model.

Modelo		Non standardized coefficient		Standardized coefficient	t	Sig.	95,0% CI	
		B	Error estándar	Beta			Lower limit	Upper limit
1	(Constante)	6,088	,631		9,642	,000	4,836	7,341
	Diet Pre- Intervention	,400	,070	,496	5,716	,000	,261	,538
2	(Constante)	5,668	,652		8,695	,000	4,374	6,961
	Diet Pre- Intervention	,413	,069	,513	5,981	,000	,276	,550
	Group	,554	,262	,181	2,114	,037	,034	1,074

a. Dependent: Diet in post-intervention

Modelo		Non standardized coefficient		Standardized coefficient	t	Sig.	95,0% CI	
		B	Error estándar	Beta			Lower limit	Upper limit
1	(Constante)	1,246	,211		5,920	,000	,829	1,664
	AFPRE	,581	,089	,549	6,569	,000	,406	,757
2	(Constante)	,759	,265		2,866	,005	,233	1,284
	AFPRE	,623	,087	,589	7,189	,000	,451	,795
	Intervención	,746	,260	,235	2,871	,005	,230	1,262

a. Dependent variable: physical activity post-intervention

Modelo		Non standardized coefficient		Standardized coefficient			95,0% CI	
		B	Error estándar	Beta	t	Sig.	Lower limit	Upper limit
1	(Constante)	3,997	,378		10,585	,000	3,248	4,746
	HbA1c pre-intervention	,376	,052	,584	7,193	,000	,273	,480
2	(Constante)	3,765	,380		9,906	,000	3,011	4,519
	HbA1c pre-intervention	,370	,051	,575	7,248	,000	,269	,472
	Physical activity post-intervention	,118	,048	,196	2,472	,015	,023	,213
3	(Constante)	3,843	,373		10,292	,000	3,102	4,584
	HbA1c pre-intervention	,382	,050	,592	7,599	,000	,282	,482
	Physical activity post-intervention	,133	,047	,220	2,811	,006	,039	,226
	Group	-,350	,150	-,183	-2,326	,022	-,648	-,051

a. Dependent variable: HbA1c post-intervention

13. Page 8, Line 15: Finally, Student's t was used to analyze the impact of the intervention on HbA1c and BMI. Why isn't the analysis of HbA1c and BMI a mixed ANOVA?

Done. Table 4 & 5 have been deleted, and a new figure has been added.

14. Were there any major treatment changes in IG and CG that would affect HbA1c at 6 months?

No changes in medication were registered during the study period time.

15. In this study, a questionnaire was used to see changes in the degree of compliance with diet and exercise therapy. But it is desirable if changes in actual dietary intake and physical activity be evaluated quantitatively. A discussion on this point should be done and add it to the limitations of research.

As indicated by the reviewer, there are other methods to evaluate changes in dietary habits, as well as other methods to assess physical activity performance. Quantifying the changes is an option using, for example, an FFQ or a diary, but we consider that the aim of the research was successfully assessed using the Motiva.Diaf DM2 (MMDM2) questionnaire. The reasons were: it responds effectively the aim of our research; it guarantees the feasibility to develop the research; and it is adequate to be used by the participants; specifically by type 2 diabetes patients.

16. Page13, Line 12: "In relation to BPNs, an improvement was observed in those specifically targeted during the exercise intervention." This sentence shows that exercise BPN had a positive effect on BPN. Why couldn't similar results be achieved with dietary BPN?

That is a good comment. We had the same question after developing the analysis. We are going to develop more research to clarify this point and others that we consider need to be

clarified. We added a commentary in appendix 6 (implications for clinical practice and research).

Minor issues.

Minor Comment 1, 4 & 5. There are two abbreviations for Behavior change wheel, BCW and BGC, so please unify them to either one. The description of Control group is CG in the text, but both CG and GC are mixed in the chart. Please unify to either. In addition, it is recommended to unify the notation of IG and CG in figures and tables by showing them in the order of IG and CG. It is recommended to use T2DM as the abbreviation for type 2 diabetes is generally T2DM.

Change incorporated. Thank you.

Minor Comment 2. In this paper, it seems that body composition is defined as BMI, but in general, body composition refers to the constituents of the human body such as body fat percentage, skeletal muscle mass, bone mass and body water content. Therefore, it is recommended to change the notation such as body weight instead of body composition.

Thanks for the comment. We changed the term composition for weight.

Minor Comment 6. Please add information such as acknowledgments, author contributions, and whether you have received research grants.

Thanks for the suggestions. This information was added after conclusions.

Reviewer #4:

This article discusses the efficacy of an educational intervention based on the behavior change wheel for individuals with type 2 DM in a Spanish region. Patients were randomized to intervention or standard of care and results like adherence, exercise, A1C and BMI were collected at 6 months. Patients on the intervention group had a significant improvement on the outcomes.

This article benefits from an English revision. For example, what does it mean DM is a non-committable disease? there are many other passages with similar issues.

In the introduction it is important to mention that we should aim for behavior interventions that are sustainable to be able to make long-term lifestyle changes. there is no mention if the authors would plan to offer this type of intervention on the long-term for the patients. what is the main goal?

We agree. Due to the design this research (pilot design) the aim was to analyze the effectiveness of an educational intervention. Additionally, we indicate in epigraph number 6 that future RCTs are going to be implemented, using the same design and theoretical framework, to reinforce the results observed.

Offer this behavioral intervention a regular basis when patients return for follow up appointments?

The results are going to be presented to the Health authorities to suggest the implementation of the intervention as usual care in Primary Care Centers. Nonetheless, due to COVID pandemic we had to delay the presentation of the results as well as the suggestion.

It is well known that behavioral changes benefit the patients and lead to positive results. In fact all patients should receive this type of intervention and this is well documented in the literature. While we all agree that lifestyle interventions should be one of the most important intervention for patients with DM I don't believe this study brings much more new evidence on this topic. The authors could pivot and explain that this type of behavioral intervention is easy to deliver, low cost, and well-received by the patients and can be coupled with regular doctor visits. lot's of available interventions are very costly and demanding to the patients. If this type of intervention can be coupled with the regular doctor visit it may be worthwhile.

Thanks for the comment. We added the suggestion to epigraph number 6.

it was not clear on table 2 the time to the diagnosis. was that on months or years? this study would be more impactful if the inclusion criteria was for patients recently diagnosed with diabetes. the results would also be more impactful if patients had started with a higher A1C from the beginning.

We modified the table number 2. We clarified the aspect suggested by the reviewer and added information related to HbA1c.

could the authors comment on the importance of figure 1 and figure 2. not sure if really adds to the article.

We agree. Figures 1 and 2 were redundant following the results presented in page 8. Their aim is to facilitate a visual interpretation of the interactions, but obviously they could be deleted.

On the discussion the authors state that the reduction of the A1C and BMI contributed to reducing the risk of complications. while this may be possible on the long-term if patients maintain a healthy lifestyle this study is not powered to state

that the risk of complications of type 2 DM while I agree with the importance of implementing programs aimed at improving dietary behavior/exercise… at no point the authors discussed the effects of this intervention on the long-term. can we extrapolate that this behavioral intervention will affect patients on the long-term?

Thanks for the suggestion. That is true and we will rewrite the text where the affirmation appears.

Are the authors planning to do another study. will they follow patients long-term. We all know that lot's of intervention can be successful on the short term but once done patients go back to previous lifestyles. are the authors considering this type of intervention as standard of care for all patients of diabetes? if not, which subset of the population would benefit the most? for how long this type of intervention should last? and the implementation on the implications for clinical practice and research I would say it would be very important to follow this patients longer than 6 months, proceed with future RCTs looking beyond a 6 month time frame to make sure these changes are sustainable.

Yes, we developed the pilot test as methodology. Nonetheless, as we indicated above, we are planning to develop more research in the future. Following the results presented in the study, we are going to contact to the health authorities and get authorization to implement the design in all primary health centers of the region, which would potentially give us access to more than 7000 persons diagnosed with Type 2 Diabetes for a long period time.

Abstract

Aim: The purpose of this study was to assess the efficacy of an educational intervention based on the Behavior Change Wheel (BCW) framework for individuals with type 2 diabetes mellitus (DM2) on dietary and exercise behavior in a Spanish region.

Methods: A two-arm pilot research was developed. The intervention consisted of a 6-month period with guidelines and 4 in-person interventions. The outcome was changes in behaviors, motivation, competence, autonomy, social support to implement the recommendations, HbA1c, and body composition.

Results: n=111 patients were recruited. Individuals in the intervention experienced a significative improvement on adherence to dietary recommendations (+1.23; p=0.026), exercise (+0.86; p=0.001), and a decrease in HbA1c levels (-0.6%; p=0.002) and BMI (-0.73; p<0.001).

Conclusion: The intervention for DM2 individuals, based on the BCW framework, developed, and implemented by primary care nurses has been effective in improving the adherence to healthy eating, exercise, HbA1c levels, and body composition.

Keywords: Diabetes Mellitus, Type 2; Diet; Exercise; Health Education

TITLE

Motiva.DM2 Project. A Pilot Behavioral Intervention on Diet and Exercise for Individuals with Type 2 Diabetes Mellitus.

AUTHORS:

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ETHICAL APPROVAL

This study was approved by the Ethics Committee of the Principality of Asturias, Spain (reference number: 16/18).

CONFLICT OF INTEREST
The authors declare that they have no conflict interests.

FUNDING
The authors received no funding.

Abstract

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1. Introduction

Diabetes Mellitus (DM) is a non-committable disease that can be managed as a priority [1]. Globally, there are approximately 463 million of adults diagnosed with DM, and by 2045 this number will rise to 700 million [2]. Among the different types of this disease, type 2 diabetes mellitus (DM2) is the more frequent, representing 90-95% of the total cases [3].

Individuals diagnosed with DM2 are more at risk of developing cardiovascular diseases [4,5], nephropathies, retinopathies, neuropathies, and amputations [6]. With the aim of avoiding these complications, a good glycemic control is essential [3], the most commonly used indicator of which is glycated hemoglobin (HbA1c).

A healthy lifestyle has an impact on this control [7]. There is enough evidence to confirm that HbA1c levels can be lowered with a healthy diet [8,9], maintaining an adequate weight [10] or exercising regularly [7,8]. Moreover, interventions that improve these behaviors are effective in glycemic control and the reduction of cardiovascular risk [12,13], especially when both behaviors are targeted [14] and are motivating for patients [15,16].

The efficacy of behavioral interventions depends greatly on an adequate design and implementation. It is therefore essential to develop interventions in an effective theoretical framework [17], as the Behavior Change Wheel (BGC) [18], which has proven effective in both the design and the evaluation of behavioral interventions [19, 20], some of them successfully implemented in Primary Care [21].

Since a lifestyle that includes a healthy diet and exercise is associated with good outcomes for DM2 patients, Primary Care is essential in Spain—as they are in charge of monitoring individuals with DM2—; and no intervention with the BCW framework has been found in Spain, we chose to carry out the present study with the aim of analyzing the effectiveness of an educational intervention based on the BCW model for individuals diagnosed with DM2 targeting dietary and exercise behavior and developed and implemented by Primary Care nurses. Secondly, we evaluated the influence of the intervention on motivation, social opportunity, HbA1c, and body composition.

2. Methods

2.1. Study setting and selection criteria

This was a two-arm pilot research, developed between March 2018 and June 2019, in individuals diagnosed with DM2 from 4 health care centers in the sanitary area 3 of the Principality of Asturias (Spain). Measurements were taken at baseline and at 6 months post intervention, in both arms.

The study included individuals over 18 years of age, who voluntarily chose to participate, were fluent in Spanish, were receiving care during the time of the study at the selected healthcare centers and suffered no terminal diseases or severe psychiatric disorders.

One hundred and twenty individuals (120) met the criteria and were invited to join the study. Of these, 9 (7.5%) chose not to participate: 2 because they lacked the time, 2 because they did not feel empowered to participate, 1 because they did not trust the usefulness of the research, and 4 because they were not interested.

A non-probabilistic sampling strategy was used to avoid cross-contamination between groups, considering the healthcare center where they were treated as a randomization unit, between two groups: intervention group (IG) and control group (CG).

In this study, structured group education was an independent variable, and the recommendations related to diet and exercise, motivation, competence, autonomy, social support for healthy eating and exercise, HbA1c, and body composition were dependent variables.

2.2. Data collection

Data was collected before (Pre-intervention) and 6 months after the beginning of the intervention (Post-intervention) by 5 nurses from our research group, who previously studied and rehearsed the data collection protocol and intervention with the aim of homogenizing the process and avoiding biases.

2.3 Information related to behavioral recommendations, competences, autonomy, and social support

The questionnaire Motiva.Diaf-DM2 [22] was used to analyze adherence to and motivation of behaviors linked to healthy eating, exercise, and information related to personal variables. The questionnaire has three parts:

The first one collects data on sociodemographic, personal, and the individual's disease: sex, age (at the beginning of the study), level of education, time since DM2 diagnosis, and type of treatment.

The second part includes 17 questions (11 about diet, and 6 about exercise) with the aim of measuring adherence to behavioral recommendations. The answers to each of these recommendations was dichotomic and analyzed as such (follows recommendation=1; doesn't follow recommendation=0). Additionally, participants from the IG were asked during Pre-intervention to note the number of recommendations they wanted to achieve (agreed recommendations) and the number of achieved recommendations was registered in Post-phase.

The last part of the questionnaire includes questions related to the degree of satisfaction of basic psychological needs (BPNs) (competence, autonomy, and social support) for

each behavior ranging from 0 (worst level of satisfaction) to 4 (best level of satisfaction). Scores of competence and autonomy were considered indications of capacity and motivation, and social support and the number of visits to Primary Care nurses, as indicators of social opportunity.

2.4 Information related to HbA1c and body composition

Anthropometric measurements of weight (kg) and size (m) were performed to calculate body composition according to the Body Mass Index (BMI): "BMI= weight (kg)/size^2 (m)."

Determination of HbA1c levels was obtained with venous blood work and interpreted quantitatively (levels from blood work) and qualitatively (control number ≤ 7%; control number >7%) [23].

2.5 Educational Intervention

IG patients received a 6-month educational intervention designed according to the BCW framework [18] delivered by the nurses in our research group involving dietary and exercise habits. Interventions on psychological capacity, automatic and reflective motivation for diet, and psychological and physical capacity, autonomic and reflective motivation for exercise (Table 1) were specifically targeted. The usual care was delivered to CG patients.

The intervention included the administration of written guidelines specifically designed for the study. The content, validated by DM2 experts and by individuals diagnosed with DM2, selected with the same criteria in the study, was elaborated according to the

behavioral recommendations included in the Motiva.Diaf-DM2 [22] questionnaire. Also, nursing professionals in the team made verbal recommendations to the participants, which included a standardized part for all patients, and a customized one for each individual's specific needs.

The different activities of the intervention were developed in 4 nursing visits at the healthcare center, lasting between 10 and 20 minutes each. In the first visit, coinciding with the start of the study, patients were explained the aim of the study and their collaboration was requested. Those who expressed their intention to participate signed the informed consent form. Subsequently, they were measured (anthropometric measurements), blood work was performed, and they filled out the questionnaire (baseline measurements).

In the second visit, 1 week after the first one, guidelines were administered to the participants and the nurses provided information about the importance of diet and exercise for a good management of DM2 with an educational-persuasive intervention. Likewise, the recommendations to be achieved during the intervention were agreed upon with each patient.

In the third visit, 3 months after the start of the program, adherence to behavioral recommendations was reviewed, facilitators and barriers encountered were analyzed, and progress was positively reinforced.

In the last visit, 6 months after the beginning of the program, anthropometric assessments and blood work were repeated, participants filled in a questionnaire (Post)

and the achievement of the objectives agreed upon at the beginning of the study was evaluated.

In all the visits, both in the 4 programmed visits and in those requested by the participants, the nurses answered any doubts raised by individuals in relation to DM2.

2.6. Data Analysis

Percentages, means, and standard deviations (SD) were calculated for the description of each individual's characteristics in the sample according to the nature of the variables. The assumption of normality was checked using the Kolmogorov-Smirnov test, and after corroborating it was met, the corresponding parametric tests were used.

Mixed ANOVA intervariability analysis (between-subject factors: intervention with two levels, CG and IG) and intravariability analysis (within-subject factors: time with two levels, Pre-intervention and Post-intervention) were performed to determine the impact of the intervention on behavioral recommendations and BPNs. The Pearson correlation coefficient and the Kappa index were used to calculate the association among agreed recommendations. Finally, Student's t was used to analyze the impact of the intervention on HbA1c and BMI.

Analyses were performed using IBM® SPSS® Statistics version 24.0 software.

2.7. Ethical considerations

This study was approved by the Clinical Research Ethics Committee of the Principality of Asturias (numbered 16/18).

3. RESULTS

3.1 Population included in the study

The sample was constituted by 111 participants, 63 (56.76%) belonged to the IG, and 48 (43.24%) to the CG. The characteristics of the study population are shown in Table 2.

Of the 111 individuals initially included in the study, 106 finished the study, observing an abandonment rate of 4.5% (n=5; 4 from the IG and 1 from the CG).

3.2 Impact of the intervention on behavioral recommendations

In the Post, CG participants achieved a mean of 9.43 dietary recommendations (SD=1.612), and 2.11 (SD=1.645) exercise recommendations. In the IG, 9.78 (SD=1.415) and 2,47 (SD=1.490) for diet and exercise, respectively.

Mixed ANOVA intervariability analysis (intervention with two levels: CG and IG) and intravariability (time with two levels: Pre-intervention and Post-intervention) were performed. For the diet, F=5.074 (p=0.026; Cohen's d=0.444-intermediate effect) for interaction, and F=22.773 (p<0.001; Cohen's d=0.937- strong effect) for intravariability (Figure 1). For exercise, F=11.958 (p=0.001; Cohen's d=0.678- intermediate effect), and F=10.986 (p=0.001; Cohen's d=0.648- intermediate effect) for intravariability (Figure 2).

IG participants agreed to achieve an average of 1.24 (SD=0.773) recommendations during the time of the study, of which they finally achieved 0.88 (SD=0.311) (r=0.788;

p<0.001). As seen in Table 3, 66.10% of the agreed recommendations were achieved (k=0.495, moderate degree of agreement; p<0.001).

3.3 Impact on competence, autonomy, and social support

Mixed ANOVA analysis for diet and exercise separately only showed significative differences in relation to the intervention, competence, and autonomy for exercise.

For dietary behavior, for competence F =0.025 (p=0.874) for interaction, and F=0.822 (p=0.367) for intravariability; in the case of autonomy, F=0.853 (p=0.358) for interaction, and F=2.546 (p=0.367) for intravariability. In the case of social support, F=0.021 (p=0.884) for interaction, and F=2.472 (p=0.119) for intravariability.

For the BPNs related to exercise, for competence F= 4.941 (p=0.029; Cohen's d=0.449, intermediate/low effect) for interaction, and F=0.058 (p=0.811) for intravariability; in autonomy F=5.128 (p=0.025; Cohen's d=0.459, intermediate/low effect) for interaction, and F=0.197 (p=0.658) for intravariability; and in the case of social support from the environment F=1.445 (p=0.232) for interaction, and F=0.015 (p=0.903) for intravariability.

The mean numbers of DM2-related nursing visits requested by the participants were of 0.30 (SD=0.976) and 1.10 (SD=5.162), for the CG and IG respectively, with no statistically significant differences found between the two groups (t=1.052; p=0.295).

3.4 Impact of the intervention on HbA1c and body composition

The average HbA1c value in Pre-intervention was 6.89 (SD=1.095), and 6.75 (SD=0.959) in Post-intervention (t=1.300; p=0.200) for the CG. In the IG, mean HbA1c decreased significantly from 7.16 (SD=1.701) in the Pre-intervention to 6.56 (SD=0.935) (t=0.200; p=0.002) in Post-intervention (table 4). The percentage of controlled HbA1c in the CG was 70.2% and 68.1% in Pre-intervention and Post-intervention respectively (p=1.000). In the IG it increased from 62.7% to 83.1% (p=0.008).

As shown in Table 5, body composition of IG participants decreased significantly during the intervention, with this decrease being very significant.

4. Discussion

The current pilot study assessed the effect of an intervention based on the BCW, developed in primary care settings, versus usual care in adults with DM2, exploring various behavioral and clinical outcomes. IG members experienced an improvement in adherence to recommendations for both behaviors, in the capability related to exercise, in the HbA1c and BMI values. Therefore, proving the effectiveness of the intervention.

It should be noted that both in terms of participation, similar to or higher than that observed in previous studies with similar characteristics [24, 25], and the percentage of abandonment, lower [26, 27] or similar [25] to that of previous studies, were very satisfactory, which highlights the viability of the intervention.

The number of recommendations achieved by participants was very positive and consistent with the results of previous studies [27-29]. Including both behaviors in the

intervention may be one of the reasons that could influence the results. According to Huang et al., [14], intervening both behaviors simultaneously is often more effective than targeting each behavior separately.

Another circumstance that may have influenced the success of the intervention was the inclusion of in-person interaction, so that the nurse could assess the specific needs of each participant. Previous studies show that the fact that a professional, whom patients consider a reference, who guides and orients them towards the achievement of objectives contributes significantly to the achievement of the objectives [26]. On the other hand, the information contained in the guidelines given to the participants could have also had an influence. This combination of personal intervention with written material has demonstrated to be effective in previous studies among adult patients with chronic diseases, on the same behaviors, in the community in which this study was carried out [30] and in populations diagnosed with DM2 [31].

Michie et al. [32] indicate that a credible source's persuasive action and education influence the motivation and the enablement, sources of behavior that influence the adoption of healthy behaviors. It is important to remember that behavior change is more likely to happen when people diagnosed with DM2 are motivated [33]. Therefore, education and persuasion by the nurses in the intervention, as well as the establishment of a professional-patient commitment through a commitment to a specific number of recommendations, could have contributed to motivating the participants hence improving adherence to the recommendations.

Another aspect to highlight which contributed to the effectiveness of the intervention has been the active participation of patients throughout the process. The design used was based on previous experiences in which patients participated in collaborative problem solving, identification of needs or commitment to change, [28]. In addition, the literature suggests that diabetes experts support the involvement of patients in their own care [34], which in turn is associated with improved outcomes for interventions [35].

Two notable achievements are the reduction in HbA1c and BMI levels experienced by IG participants. Based on this, it could be said that the results have contributed to reducing the risk of complications in the IG, since, as previous findings suggest, adequate glycemic control [36-38] and maintaining an adequate weight [39] or decreasing it [40, 41] reduces the risk of complications related to DM2.

In relation to BPNs, an improvement was observed in those specifically targeted during the exercise intervention. Particularly, competence and autonomy, indicators of capability and motivation, but not social support. This finding is not surprising since the intervention only included nursing visits for participants if necessary, an option already available in Primary Care, and no other actions of recognized effectiveness were carried out, such as changes in the context [42], elimination of barriers [43] or the promotion of family support [43, 44].

The overall analysis of the results corroborates the importance of implementing programs aimed at improving dietary behavior and exercise performance in people diagnosed with DM2 as a strategy to improve glycemic control and reduce the risk of complications [12-14].

5. LIMITATIONS

While the piloting has been effective, interventions on important sources of behavior for behavioral change, such as social and physical opportunity, social and/or environmental variables, have not been included. On the other hand, the inclusion of patients from a limited geographical area prevents us from extrapolating the results to other locations.

6. IMPLICATIONS FOR CLINICAL PRACTICE AND RESEARCH

This pilot study suggests the possibility of completing the model of care received by patients diagnosed with DM2 with an intervention on diet and exercise, which combines face-to-face interventions and the delivery of written information in order to improve behavioral adherence, HbA1c and BMI levels, and thus contributes to better outcomes.

In order to contrast these results, future RCTs should be implemented, using the same theoretical framework, in order to reinforce the results observed.

7. CONCLUSIONS

The intervention for patients diagnosed with DM2, based on the BCW model and developed and implemented by Primary Care nurses, has been effective in improving adherence to healthy eating, exercise, HbA1c levels and body composition.

[1] World Health Organization. Global Report Diabetes, 2016, https://apps.who.int/iris/bitstream/handle/10665/204871/9789241565257_eng.pdf?sequence=1; 2016 [accessed 20 July 2020].

[2] International Diabetes Federation. Diabetes Atlas. 9th ed. https://www.diabetesatlas.org/en/; 2019 [accessed 20 July 2020].

[3] American Diabetes Association. 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes-2019. Diabetes Care. 2019;42(Suppl 1):S13-S28.

[4] Zheng Y, Ley SH, Hu FB. Global aetiology and epidemiology of type 2 diabetes mellitus and its complications. Nat Rev Endocrinol. 2018;14(2):88-98.

[5] Ares Blanco J, Valdés Hernández S, Botas P, Rodríguez-Rodero S, Morales Sánchez P, Díaz Naya L, et al. Gender differences in the mortality of people with type 2 diabetes: Asturias Study 2018. Gac Sanit. 2019:S0213-9111(19)30088-3.

[6] Pérez-Pevida B, Llavero M, Gargallo J, Escalada J. Microvascular complications of diabetes. Medicine. 2016;12(17):958-70.

[7] Davies MJ, D'Alessio DA, Fradkin J, Kernan WN, Mathieu C, Mingrone G, et al. Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2018;41(12):2669-701.

[8] Franz MJ, MacLeod J, Evert A, Brown C, Gradwell E, Handu D, et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. J Acad Nutr Diet. 2017;117(10):1659-79.

[9] Saintrain MVL, Sandrin RLESP, Bezerra CB, Lima AOP, Nobre MA, Braga DRA. Nutritional assessment of older adults with diabetes mellitus. Diabetes Res Clin Pract. 2019;155:107819.

[10] Rothberg AE, McEwen LN, Kraftson AT, Ajluni N, Fowler CE, Nay CK, et al. Impact of weight loss on waist circumference and the components of the metabolic syndrome. BMJ Open Diabetes Res Care. 2017;5(1):e000341.

[11] Colberg SR, Sigal RJ, Yardley JE, Riddell MC, Dunstan DW, Dempsey PC, et al. Physical Activity/Exercise and Diabetes: A Position Statement of the American Diabetes Association. Diabetes Care. 2016;39(11):2065-79.

[12] Chen L, Pei JH, Kuang J, Chen HM, Chen Z, Li ZW, et al. Effect of lifestyle intervention in patients with type 2 diabetes: a meta-analysis. Metabolism. 2015;64(2):338-47.

[13] Barreira E, Novo A, Vaz JA, Pereira AMG. Dietary program and physical activity impact on biochemical markers in patients with type 2 diabetes: A systematic review. Aten Primaria. 2018;50(10):590-610.

[14] Huang XL, Pan JH, Chen D, Chen J, Chen F, Hu TT. Efficacy of lifestyle interventions in patients with type 2 diabetes: A systematic review and meta-analysis. Eur J Intern Med. 2016;27:37-47..

[15] Ryan RM, Patrick H, Deci EL, Williams GC. Facilitating health behaviour change and its maintenance: Interventions based on self-determination theory. The European Health Psychologist. 2008;10:2–5.

[16] Deci EL, Ryan RM. Self-determination theory in health care and its relations to motivational interviewing: a few comments. Int J Behav Nutr Phys Act. 2012;9:24..

[17] Bully P, Sánchez Á, Zabaleta-del-Olmo E, Pombo H, Grandes G. Evidence from interventions based on theoretical models for lifestyle modification (physical activity, diet, alcohol and tobacco use) in primary care settings: A systematic review. Prev Med. 2015;76 Suppl:S76-93.

[18] Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci. 2011;6:42.

[19] Gould GS, Bar-Zeev Y, Bovill M, Atkins L, Gruppetta M, Clarke MJ, et al. Designing an implementation intervention with the Behaviour Change Wheel for health provider smoking cessation care for Australian Indigenous pregnant women. Implement Sci. 2017;12(1):114.

[20] Munir F, Biddle SJH, Davies MJ, Dunstan D, Esliger D, Gray LJ, et al. Stand More AT Work (SMArT Work): using the behaviour change wheel to develop an intervention to reduce sitting time in the workplace. BMC Public Health. 2018 Mar 6;18(1):319..

[21] Westland H, Bos-Touwen ID, Trappenburg JC, Schröder CD, de Wit NJ, Schuurmans MJ. Unravelling effectiveness of a nurse-led behaviour change intervention to enhance physical activity in patients at risk for cardiovascular disease in primary care: study protocol for a cluster randomised controlled trial. Trials. 2017;18(1):79.

[22] Martín Payo R, González Méndez X, Papín Cano C, Suárez Álvarez J. Development and validation of a questionnaire for assessing the characteristics of diet and physical activity in patients with type 2 diabetes. Psicothema. 2018;30(1):116-122.

[23] American Diabetes Association. 6. Glycemic Targets: Standards of Medical Care in Diabetes-2020. Diabetes Care. 2020;43(Suppl 1):S66-S76..

[24] Jutterström L, Hörnsten Å, Sandström H, Stenlund H, Isaksson U. Nurse-led patient-centered self-management support improves HbA1c in patients with type 2 diabetes-A randomized study. Patient Educ Couns. 2016;99(11):1821-9.

[25] Gamboa Moreno E, Mateo-Abad M, Ochoa de Retana García L, Vrotsou K, Del Campo Pena E, Sánchez Perez Á, et al. Efficacy of a self-management education programme on patients with type 2 diabetes in primary care: A randomised controlled trial. Prim Care Diabetes. 2019;13(2):122-133..

[26] Wayne N, Perez DF, Kaplan DM, Ritvo P. Health Coaching Reduces HbA1c in Type 2 Diabetic Patients From a Lower-Socioeconomic Status Community: A Randomized Controlled Trial. J Med Internet Res. 2015;17(10):e224.

[27] Halvari H, Healey J, Olafsen AH, Byrkjeland R, Deci EL, Williams GC. Physical activity and motivational predictors of changes in health behavior and health among DM2 and CAD patients. Scand J Med Sci Sports. 2017;27(11):1454-69.

[28] Jayasuriya R, Pinidiyapathirage MJ, Jayawardena R, Kasturiratne A, de Zoysa P, Godamunne P, et al. Translational research for Diabetes Self-Management in Sri Lanka: A randomized controlled trial. Prim Care Diabetes. 2015;9(5):338-45.

[29] do Valle Nascimento TM, Resnicow K, Nery M, Brentani A, Kaselitz E, Agrawal P, et al. A pilot study of a Community Health Agent-led type 2 diabetes self-management program using Motivational Interviewing-based approaches in a public primary care center in São Paulo, Brazil. BMC Health Serv Res. 2017;17(1):32.

[30] Del Valle MO, Martín-Payo R, Cuesta-Briand B, Lana A. Impact of two nurse-led interventions targeting diet among breast cancer survivors: Results from a randomized controlled trial. Eur J Cancer Care (Engl). 2018;27(4):e12854.

[31] Lepard MG, Joseph AL, Agne AA, Cherrington AL. Diabetes self-management interventions for adults with type 2 diabetes living in rural areas: a systematic literature review. Curr Diab Rep. 2015;15(6):608.

[32] Michie S, Atkins L, West R. The Behaviour Change Wheel: A Guide to Designing Intrerventions, Silverback. 1st ed. Great Britain: Silverback Publishing; 2014.

[33] Juul L, Rowlands G, Maindal HT. Relationships between health literacy, motivation and diet and physical activity in people with type 2 diabetes participating in peer-led support groups. Prim Care Diabetes. 2018;12(4):331-7.

[34] Gee JP, Scarbrough J, Bowker D, Keller T. Diabetes Educators Beliefs About Patient Self-Management and Strategies Used to Support Persons With Diabetes. Diabetes Educ. 2019;45(2):174-83.

[35] Almutairi N, Hosseinzadeh H, Gopaldasani V. The effectiveness of patient activation intervention on type 2 diabetes mellitus glycemic control and self-management behaviors: A systematic review of RCTs. Prim Care Diabetes. 2020;14(1):12-20.

[36] Mostafa SA, Coleman RL, Agbaje OF, Gray AM, Holman RR, Bethel MA. Modelling incremental benefits on complications rates when targeting lower HbA1c levels in people with Type 2 diabetes and cardiovascular disease. Diabet Med. 2018;35(1):72-7.

[37] Mitsios JP, Ekinci EI, Mitsios GP, Churilov L, Thijs V. Relationship Between Glycated Hemoglobin and Stroke Risk: A Systematic Review and Meta-Analysis. J Am Heart Assoc. 2018;7(11):e007858.

[38] Güner TA, Coşansu G. The effect of diabetes education and short message service reminders on metabolic control and disease management in patients with type 2 diabetes mellitus. Prim Care Diabetes. 2020:S1751-9918(20)30184-4.

[39] Schmidt AM. Diabetes Mellitus and Cardiovascular Disease: Emerging Therapeutic Approaches. Arterioscler Thromb Vasc Biol. 2019;39(4):558-68.

[40] Wing RR, Lang W, Wadden TA, Safford M, Knowler WC, Bertoni AG, et al. Benefits of modest weight loss in improving cardiovascular risk factors in overweight and obese individuals with type 2 diabetes. Diabetes Care. 2011;34(7):1481-6.

[41] Cradock KA, ÓLaighin G, Finucane FM, Gainforth HL, Quinlan LR, Ginis KA. Behaviour change techniques targeting both diet and physical activity in type 2 diabetes: A systematic review and meta-analysis. Int J Behav Nutr Phys Act. 2017;14(1):18.

[42] Frieden TR. A framework for public health action: the health impact pyramid. Am J Public Health. 2010;100(4):590-5.

[43] Park S, Zachary WW, Gittelsohn J, Quinn CC, Surkan PJ. Neighborhood Influences on Physical Activity Among Low-Income African American Adults With Type 2 Diabetes Mellitus. Diabetes Educ. 2020;46(2):181-90.

[44] Wooldridge JS, Ranby KW, Roberts S, Huebschmann AG. A Couples-Based Approach for Increasing Physical Activity Among Adults With Type 2 Diabetes: A Pilot Feasibility Randomized Controlled Trial. Diabetes Educ. 201;45(6):629-41.

Figure

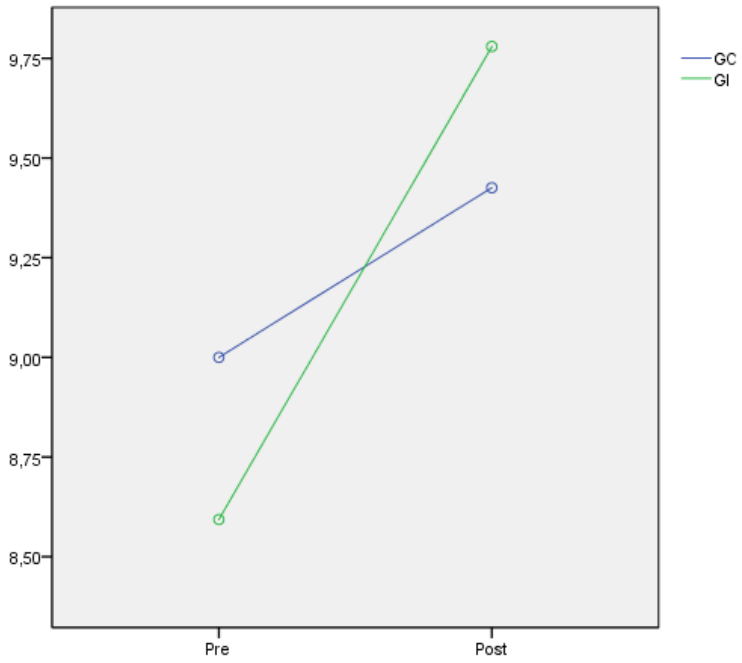


Fig. 1- Mean number of dietary recommendations Pre-intervention and Post-intervention for CG and IG separately.

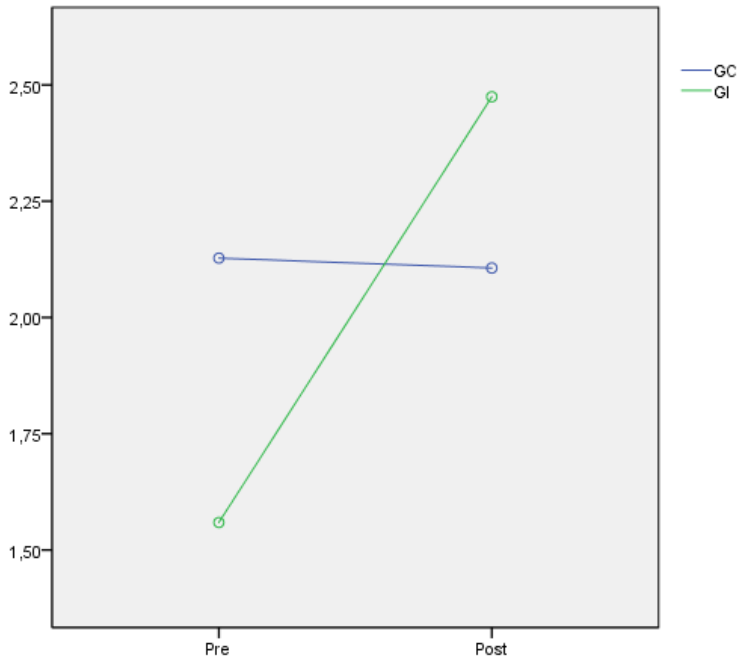
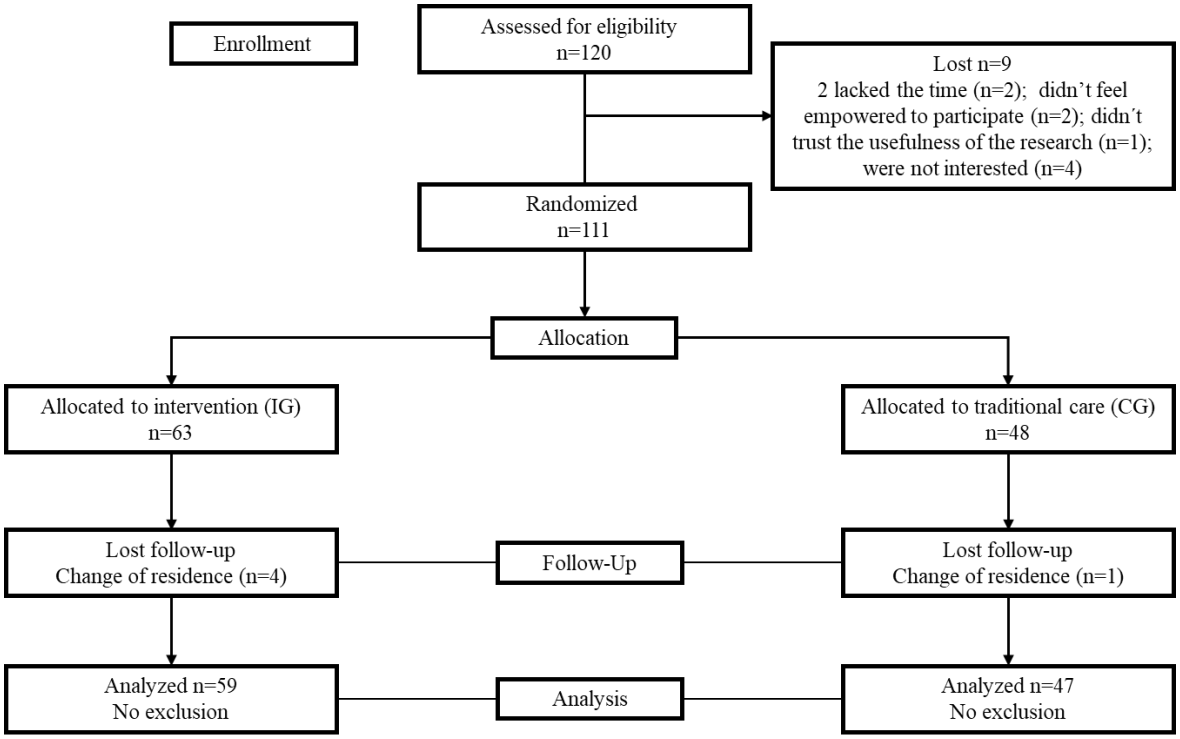


Fig. 2- Mean number of recommendations related to exercise Pre-intervention and Post-intervention for CG and IG separately.

Figure



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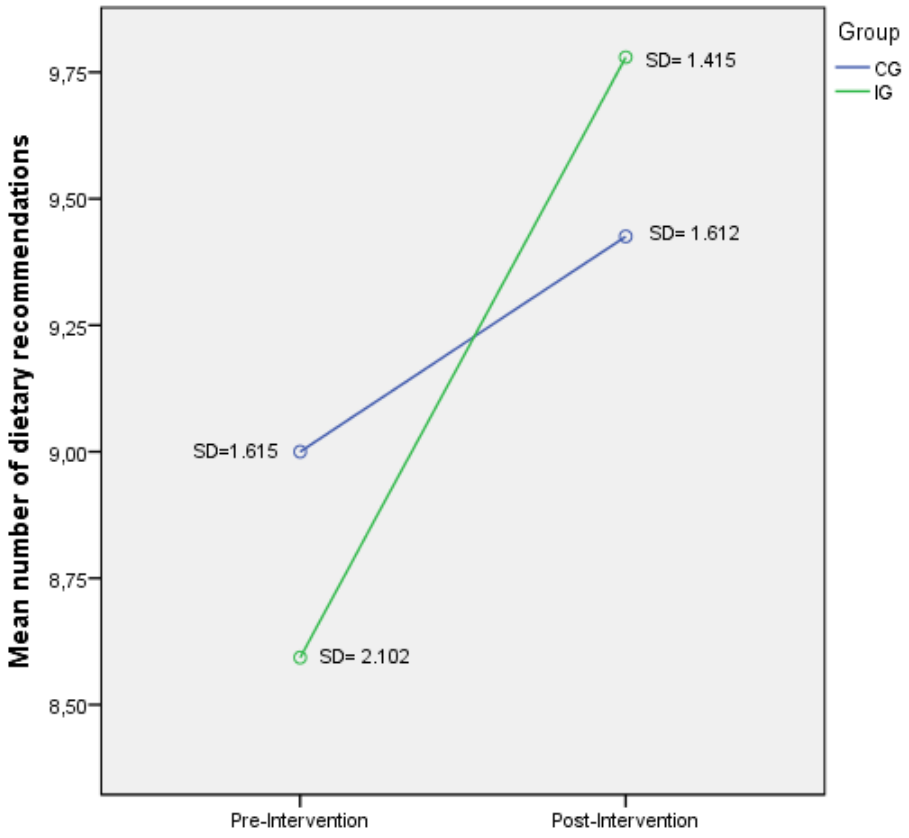

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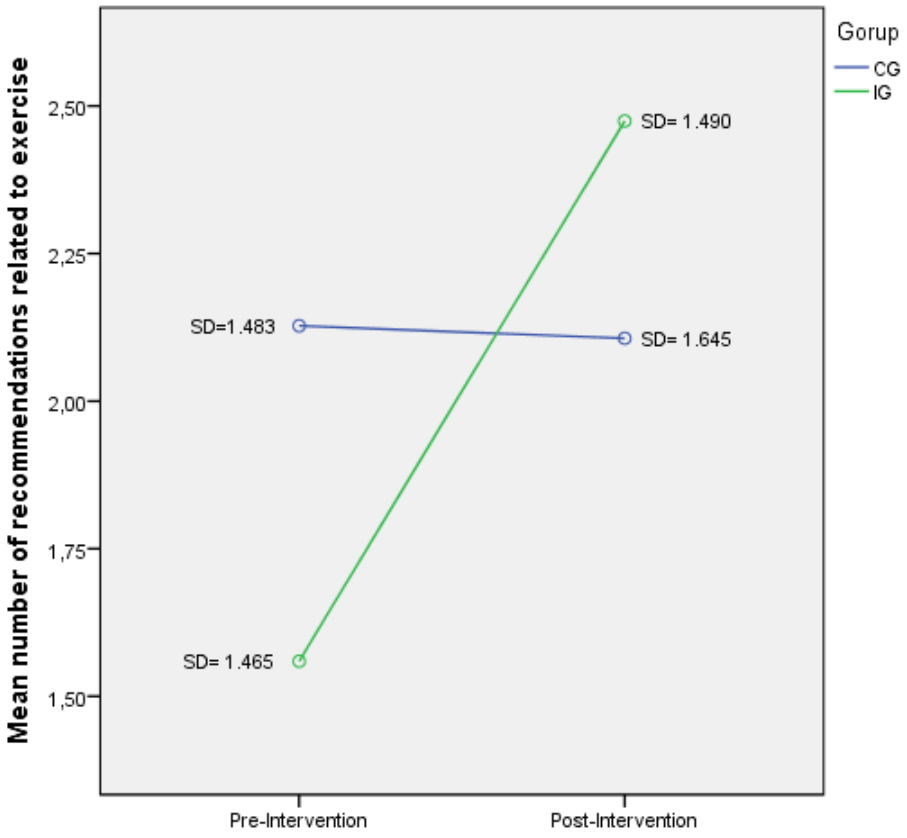

Fig. 3- Mean number of recommendations related to exercise Pre-intervention and Post-intervention for CG and IG separately.

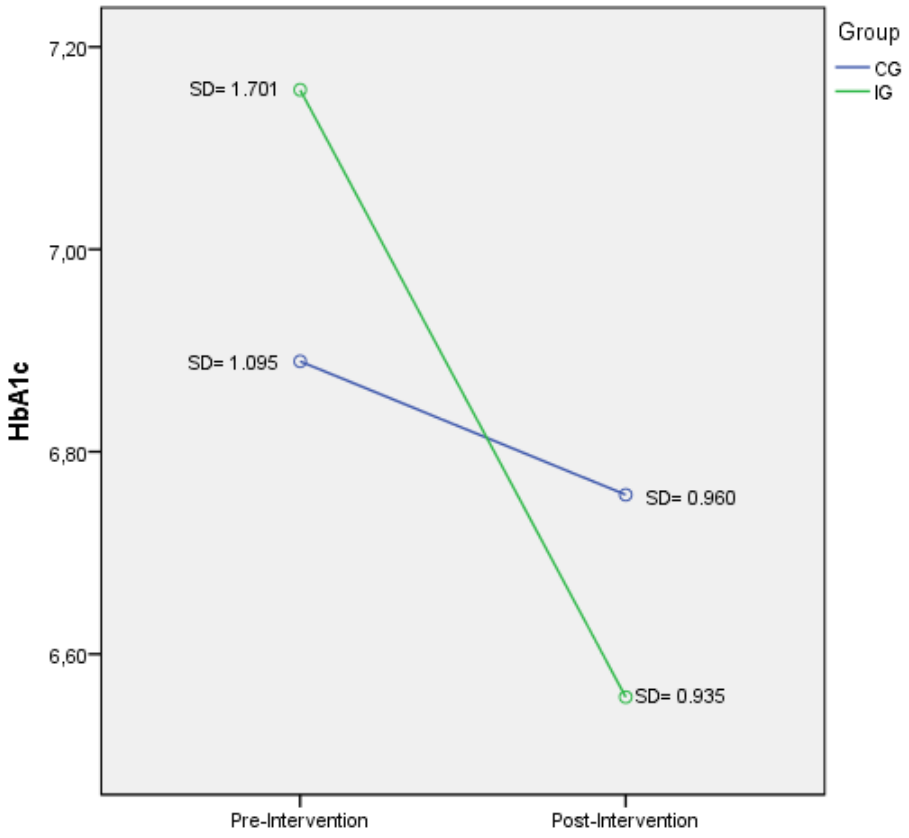

Fig. 4- Mean number of HbA1c value Pre-intervention and Post-intervention for CG and IG separately.

Table

Table