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Title – Close Reading and Creative Writing – CrewD Program. An alternative educational method for Group Care Intervention in type 2 diabetes management. A Randomized Trial.

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Running Head: Group Care Intervention using Close Reading and Creative Writing

Key Messages:

- This is the first structured education program for diabetes that incorporates close reading and creative writing.
- Close reading of literary texts followed by creative writing in a diabetes Group Care may stimulate patients' awareness and empowerment.
- This is the first randomized trial designed to evaluate a Group Care intervention to manage type 2 diabetes using close reading and creative writing. A significant reduction of A1c was observed in the intervention group, showing non-inferiority in relation to the classical approach.

Keywords: Narrative Medicine; Diabetes; Education; Group Care; Randomized Trial

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Abstract

Aims: Group Care for individuals with diabetes is a recognized educational practice, but techniques from narrative medicine using of literary works have never been incorporated in these programs. We designed a new educational model of Group Care for individuals with Diabetes (CrewD Program) incorporating close reading and creative writing in group education. A randomized trial was designed to evaluate this intervention.

Methods: A total of 49 individual with type 2 diabetes, aged <85 years old and >6 years school education were randomized to two different Group Care dynamics: (a) one “control group”, with a classical structured educational approach currently used in our institution and (b) an “intervention group”, with the introduction of literary texts, narrative skills, close reading and creative writing. Evaluation included anthropometrical measures, A1c and questionnaires for psychological evaluation. Individual A1c levels in the six years period prior the trial were collected from clinical records.

Results: A significant reduction of A1c was observed in the intervention group, showing non-inferiority in relation to the classical approach. A significant decrease in A1c was observed in relation to the six previous years. A significant increase in satisfaction with therapist and group process was observed.

Conclusions: This is the first randomized trial designed to evaluate a Group Care intervention to manage type 2 diabetes using narrative techniques. The results suggest that this may be a useful model for more highly schooled individual, and may constitute an alternative for the educational process.

Trial Registration: ClinicalTrials.gov number: NCT03678896; Available at: <https://clinicaltrials.gov>

1. Introduction

Diabetes is a holistic experience comprised of psychological, intellectual, clinical, financial, cultural, spiritual, and social elements (1). Diabetes self-management education and support (DSMES) is a critical element of care for persons with diabetes (2). Although there are several effective methods reported in the literature, they differ with respect to the types of intervention and population involved (3). There is a need to assess methods that can generate clinically significant changes in various real world clinical and community settings, relatively low-cost and cost-effective, as well as a satisfying experience for recipients (3).

Incorporating behavioral and psychosocial strategies demonstrate improved outcomes. (2). The development of creative, patient-centered experience-based delivery methods is relevant for supporting informed decision-making and behavior change that go beyond the acquisition of knowledge (4) to sustain improvements (4-6) as a diminishing effect of educational interventions after the end of the intervention is observed (6-7). There is often the claim for new models to empower people with diabetes and build strategies that enable them to cope with chronic diseases (8).

DSMES is routinely delivered in our Institution for several years as group sessions with an organized educational program. A structured curriculum about living with diabetes is addressed using a dynamic interaction of patients among themselves and with healthcare providers within a group setting. Several authors have shown that it is easier for individuals to modify their opinion and behavior when taking part in a small group than when they are alone (9). It is a recognized practice with positive outcomes in terms of metabolic control, quality of life parameters and knowledge acquisition (10-13).

Narrative medicine is using narrative skills with literary texts, such as close reading and creative writing, in medical education and patient care (14-15). In our own experience, after publishing a short story book about persons with diabetes (16), we witnessed individual reports in which they identified themselves with some of the characters and situations represented. When the reading process succeeds in apprehending otherness, in registering the singularity and inventiveness of the work, we may call this a creative work (17). Hannah Arendt mentioned that storytelling reveals the meaning without committing the error of defining it (18). Writing, as one form of representation, allows an individual to achieve his or her perception. To write is not only to report or record but also to discover (14). The positive impacts of expressive writing on health are well documented (19-20).

As Anderson and Funnell argue *“There is a significant benefit to sharing one’s story with trusted friends and colleagues. In fact, it is the power of telling (and hearing oneself tell) one’s story that makes the counseling relationship between diabetes educators and patients so potent. Telling our story to others evokes the emotional components of those stories in ways that just*

thinking about them usually does not. Also, when we tell our story to others, it allows them to ask questions that may lead us deeper into our experience and stimulate new insights” (1, p104).

In recent years some published reports demonstrated beneficial effects of using narrative approach, patient centered, in diabetes and in other chronic diseases. Examples of these are storytelling groups (21-27), photo stories (28-29), autobiographical narratives (30), artistic and creative expression (31). This kind of approach has the potencial, as Gucciardi noted, to provide patients with a more active role in their health care, while allowing them to form strong bonds with peers who share similar disease-related experiences (22). However this kind of approach that values the individual experience in people with Diabetes was not yet been evaluated in randomized trials.

With this in mind, we improved a structured educational model of Group Care for individual with diabetes using Literary Texts, Close Reading and Creative Writing. According to Rita Charon, close reading is a generic term for attentive, critical, careful reading that can result in therapeutic dividends to the reader who integrates conflicting perceptions into an aesthetic whole (32). Literary texts are chosen as life sketches that could be related to life experience of people with diabetes. In each session, a short story written by the first author about a person with Diabetes (16) is discussed and two other literary texts are read. These can be narrative excerpts or poems, not necessarily about diabetes and the authors are well known writers of the Portuguese and international literature (such as Anton Tchekov, Rainer Marie Rilke, Wislawa Szymborska or Eudora Welty). The three texts were chosen by the Team leaders (one healthcare professional and one literature professor) and are somehow related to the session theme. For example, in 2nd session, dedicated to Nutrition, the short story is about an old lady with diabetes since childhood who publishes candy recipes in cooking contests with a pseudonym. The two other texts are one narrative excerpt, about a man who returns at their parent house after a great journey and is presented with a delicious and huge dinner, and one poetic text about preparing the dinner table for a party.

A Group dynamic using close reading and creative writing about those texts would possibly trigger different insights, promote discussion between participants, autobiographical narratives and motivate health behavior changes. Concerning chronic disease, regardless of the stage (33), change is a fundamental step towards disease acceptance and consequent individual activation and engagement in managing their health. (34). Stories are a universal form of communication that create engagement, embrace complexity and function as sense-making devices (23). Expressive writing and narratives allow patients to identify their specific needs as well as gaps in knowledge and skills (19, 22). As a consequence, the level of perceived control over the disease should increase. Additionally, it should reduce stigma associated with disease and facilitate peer support (22). Consequently, narratives incorporate information, communication

and persuasion to encourage behavior change (25). Stories promote the patient-centered paradigm, focusing on the patient 's perception of their needs and self-management ability (22). Additionally, knowing that diabetes management is relatively impaired by differences in the explanatory models of disease used by people with diabetes or by their physicians (35), narrative might help to bridge these differences. By sharing narrative ways of knowing and experiencing the world and self, health care professionals and patients will be closer (36) and will interact in a more humanized and empathic way. Besides, a positive and supporting group atmosphere should facilitate communication and the narrative flow.

A randomized trial was designed to determine whether group dynamic strategies using narrative and reading produce the same positive outcomes as a conventional group approach.

2. Methods

2.1. Trial Design

This study consisted of a two-arm parallel design with four assessment points. The allocation ratio was one third in the control group, two third in the intervention group.

2.2. Participants and Recruitment

Participants were recruited from the institution where the intervention was conducted. Inclusion criteria for participants were: Individuals with type 2 diabetes of >1 year known duration, aged <85 years old, with a follow-up in our outpatient clinic for at least 6 months and >6 years-school education, without diagnosed psychiatric disease. Individuals that don't meet these criteria were excluded. Patients were identified from clinical recordings according to inclusion criteria. Recruitment was carried out by phone contact during one month. They were invited to participate in an intervention to improve self-management of diabetes. Individual that agreed to participate gave their written consent. During intervention all participants maintained the usual clinical care, similar in both arms. Each participant maintained the habitual individual counselling every 6 months in Diabetes outpatient clinic, unless they had intercurrent problems, seen separately by their usual doctor and by a nurse. Observations by a dietician may eventually occur, if necessary. Ophthalmology and podologist follow-up was maintained. They were treated either with diet and oral administration of hypoglycemic agents or insulin in addition to the former. No individual started insulin therapy during the trial period.

A total of 49 participants, 27 men, with a mean age of 66,7 years (SD = 7.99), were randomized to two different Group Care dynamics (Table 1). All participants have Portuguese as their native language and all have participated in previous individual or group educational sessions. Mean diabetes duration was 16 years (SD = 7.8). The control group consisted of 17 participants, presented with the classical structured educational approach. The intervention group consisted of 32 participants, divided in 2 similar subgroups, was presented with close reading and creative writing. This group was divided in two equal groups for practical reasons at different time schedules. Participants were evaluated before the first session and after the third and the sixth session. 3 months later after the last session, a follow-up final evaluation was performed. Participant A1c levels in the six previous years were also collected from clinical records. No differences were found at baseline between the experimental and the control group as regards to socio-demographic and anthropometrical variables.

We assisted to 7 drop-outs, 5 in the intervention group and 2 in the control group. 5 other individual did not complete the four evaluations by medical reasons (4 in the intervention group and 1 in the control group; 3 underwent surgical interventions, 2 initiated chemotherapy for

cancer disease).

2.3. Interventions

All participants provided written informed consent before participating in the study, which was conducted after being approved by Portuguese Diabetes Association Ethics Committee and conforms the Declaration of Helsinki. The study was conducted between January 2017 and October 2017.

Six sessions were included in this intervention, delivered in a one a month periodicity over a 6-month period. The intervention was divided in two different approaches: (a) the classical structured educational model using Group Care that is currently used in our institution. and (b) the CrewD Program - Creative reading and writing in Diabetes Program, as described below.

Classical structured educational approach

Each session was 90 minutes long, with a similar internal structure in all of them. The contents and methods are according to published Standards for Diabetes Self-Management Education and Support (4). Each session included the following topics: a) Chronic Disease; b) Nutrition; c) Exercise; d) Complications; e) Self-management; and f) Diabetic foot. The sessions were held in a large room, in which the seats were arranged in circle. Every session was chaired by two healthcare providers, who worked as group leaders.

There was a different visual presentation in each session, with relevant theoretical information. A board with sheets of paper was available for use in the discussion along with brochures about the disease. Participants were encouraged to actively participate and take part in group-problem solving. Group leaders guided the discussion by asking questions and encouraging the discussion, but avoiding being judgmental (Figure 1).

CrewD Program approach

Our aim with this approach was to improve such sessions using narrative skills like close reading and creative writing through the development of the CrewD Program (Creative reading and writing in Diabetes Program). Close reading is a generic term for attentive, critical, careful reading that can result in therapeutic dividends to the reader who integrates conflicting perceptions into an aesthetic whole (32). After closely examining a text together, participants were invited to write for a few minutes to a prompt that arises from the piece that has just been examined. After writing, they are invited to share what they have written with one another and to respond to what they hear in one another's work (32). This creative writing process brings to words feelings or experiences that previously were not concrete and allow new insight (32).

Local environment and the number of participants were the same in control and intervention groups. There were also two group leaders: a health professional and a literature professor manager of creative writing groups. Group leaders guided the sessions with similar dynamics.

Each session had a title, which parallels the classical structured educational approach, which was known in advance by the subjects: a) Who I am in diabetes?; b) Nutrition; c) The body where I live; d) Fears; e) Can attention change things?; and f) Roots.

Text choice was a dynamic issue. It was decided by the team leaders considered the subject's level of understanding and its relation to the session's topic. Texts were not necessarily related to diabetes (except the short stories) and they were written in the participants' native language.

Three different texts were used in every session: one short story about a person with diabetes, from our short story book (16), one excerpt of a narrative (a letter, a novel or a chronicle) and one poem. The short story was not discussed in the first session, as we present it at the end of session one to be read at home before the following session, where it would be discussed.

The short story was discussed for fifteen minutes at the session start. To structure the discussion, participants were invited to answer three different questions at home and then to express publically their opinions. Then, the excerpt from a narrative was read out loud by one of the group leaders and the participants were asked to do a close reading (five minutes). Next, they were asked to write a small text related to the previous reading (five minutes), which they read to the audience (10 minutes). Afterwards, team leaders directed a discussion with the participants focusing on their feelings and on how the texts relate to themselves and to their diabetes. Individual were encouraged to participate and freely express their opinion but participation was not mandatory.

The poem was read out loud by the other team leader, followed by a five-minute close reading. Following this reading, participants were asked to write a brief text (five minutes). Next, participants were organized into groups of 3-4 and shared among themselves the essays they wrote (15 minutes). A fifteen-minute discussion with all the groups was then conducted.

Every session ended with a five-minute period during which a short story and three questions about it were handed to the participants, to be discussed in the following session.

In the first session, as there was no short story to discuss, during the first 15 minutes, participant were invited to introduce themselves and to state their strengths and weakness related to diabetes control (Figure 1).

General procedure was the same for all the six sessions performed in both groups.

Team Leaders

Team leaders are facilitators. There are two Team leaders in every session, both in the control and in the intervention group. In the Control Group (Classical structured model) they were both health professionals with a large experience in leading Group Care with people with Type 2

Diabetes; one of them, a medical doctor (FR) was always present, the second element was an educator nurse or an educator dietician. In the Intervention Group (CrewD Approach), a medical doctor (FR) was always present with a literature professor (DA) with a large expertise as manager of creative writing groups.

Team leaders primary role consisted in supporting group process and encouraging the sharing of life experiences and disease management, avoiding being judgmental. In the Classical structured model, promoting problem solving was central for this objective. In CrewD setting, using Close Reading, Team leaders encourage personal interpretations of the texts, sharing of different insights´ and bringing up individual narratives. As in every group there are healthcare professionals as Team leaders, they validate and correct information if necessary. Eventually they may intervene with their own experience.

2.4. Outcomes

Individual evaluation included anthropometrical assessment (primary outcomes) and self-reports for psychological variables (secondary outcomes). Regarding the anthropometrical profile, the assessment included weight, fat mass, waist circumference and A1c levels. A1c was measured by high-performance liquid chromatography (HPLC) with boronate affinity. The evaluation of adipose mass was performed with Tanita SC-330® bioimpedance equipment. Other anthropometric parameters were measured using calibrated balance and measuring tape. As for the self-reports, the measures were on quality of life, locus of control, empathy and group satisfaction; respectively, through the Diabetes Quality of Life Questionnaire – DQOL (37); the Short Form of the State of Health Questionnaire SF-36 (38); Jefferson Scale of Physician Empathy – JSPE - R (39); Locus of Control – LOC (Diabetes Specific Locus of Control Scale) (40); and the Group Satisfaction Scale – GSS (41).

These evaluation measures were applied equally to both groups.

2.5. Sample size

Sample size was calculated according to a priori power analysis with G*power software. The minimum sample size to detect a moderate effect size (f) for a mixed statistical design given significance level (.05) and statistical power (.95) was n=45.

2.6. Randomization and allocation

Random allocation sequence was conducted based on simple randomization with random number generation. The random allocation sequence was generated by the statistician that participated in the study, whereas the enrollment and the assignment of participants to intervention done by the first author of the study.

2.7. Statistical methods

The statistical analyses were conducted in SPSS (v.22). The statistical procedures were based on repeated measures ANOVA to determine the differences between assessment points in each group condition. Effect size for the ANOVA was reported as eta-squared (η^2) for each significant test. The eta-squared was given by $\eta^2 = SS_B/SS_T$, where SS_B and SS_T , depict the Sum of Squares between factors and the SS_T , respectively for between-subjects factors and for the total model. According to Cohen (42) a small effect size corresponds to 0.01, medium to 0.06 and large to 0.14. Pearson bivariate correlations were then conducted to explore the relationships between significant outcomes and anthropometrical variables at baseline. Furthermore, a moderated linear regression model was also tested for each significant outcome to identify the best predictors of change between the baseline and follow-up. The effect size measures in the regression analyses were based on Cohen's f^2 that was given by $f^2 = R^2/1-R^2$. According to Cohen (43) a small effect size for f^2 corresponds to 0.02, medium to 0.15 and large to 0.35. The significance level adopted was .05.

3. Results

Descriptive analysis to anthropometrical variables

The entire sample had an initial BMI of 29.16 (SD=4.67) and A1c of 7.51% (59 mmol/mol) (SD=1.13). The two groups were very similar either in the physical and the psychological variables at baseline. The effects of the socio-demographic variables regarding gender, education and age as well as the variables concerning the anthropometrical data (weight, fat mass, waist circumference) were controlled by conducting the analysis on A1c separately for each of these factors. No significant effects were found in A1c levels ($p>.05$).

Comparisons between assessments for A1c levels

Both groups showed a significant ($F(3, 93) = 19.78$; $\eta^2=0.63$; $p<.001$) reduction of A1c between the first and the last session (intervention group initial A1c of 7.55% (59 mmol/mol) (SD=1.13); last session A1c of 6.83% (51 mmol/mol) (SD=0.94) $p<.001$; control group initial A1c of 7.44% (58 mmol/mol) (SD=1.49); last session A1c of 7.21% (55 mmol/mol) (SD=1.48).

In the follow-up evaluation both groups showed a non-significant A1c reduction (Figure 2).

Moderating effects of locus of control on the relation between BMI and A1c levels

Pearson bivariate correlations show that individual with a superior BMI present a more significant reduction in A1c ($p<.001$). However, this relationship was moderated by external locus of control as tested in a moderated linear regression model ($B = -0.503$; $t(33) = -2.435$; $f^2 = 0.15$; $p<.05$), suggesting that this association is true only for individual with lower levels of external locus of control. The BMI explained 13.7% of the variance of A1c levels ($\Delta R^2_a = .137$).

Comparisons of A1c levels in the six years' period prior the trial

The aim of this analysis was to understand whether A1c levels decreased throughout time (prior and during trial periods). This analysis shows a significant decrease ($p<.05$) in A1c levels throughout time irrespective of intervention group ($F(9, 189) = 2.81$; $\eta^2=0.13$; $p<.01$), specifically from 2011 to 2012, while the other variations that occurred within this period were non-significant. At the trial period, the decrease is significant (all p 's<.05) with exception for the comparison between the third assessment and the follow-up. (Figure 3).

Self-reported satisfaction with therapist and with content/group process

The Group Satisfaction Scale is a self-report instrument that was used to assess the level of satisfaction with the professionals that conducted both the CrewD approach and the Classical Structured Educational approach. This instrument was not completed until the second assessment. Thus, the data available for the remaining three assessments show a significant

increase between assessments ($p < .05$) in satisfaction with therapist ($F(2, 70) = 5.31; \eta^2 = 0.15; p < .01$) and satisfaction with content/group process ($F(2, 70) = 5.13; \eta^2 = 0.15; p < .01$) throughout the study (Table 2).

Comparisons between assessments for psychological variables

The ANOVAs were also conducted for each self-report measure. The dependent variables in this analysis were the Diabetes Quality of Life Questionnaire, the Short Form Health Survey, the Jefferson Scale of Physician Empathy, and the Locus of Control scale. The results showed no differences between assessments in each of these domains (all p 's $> .05$), suggesting that quality of life, health perception, locus of control, and empathy did not change throughout the study.

4. Discussion

DSMES is effective (3) and considered as an integral aspect of care for people with diabetes (2). Demographic variables, such as ethnic background, age, formal educational level, reading ability and other barriers to participation must be considered when developing an educational intervention (2). New models are needed to empower people with diabetes and build strategies that enable them to cope with chronic diseases (8).

In order to answer this need, this study aimed at developing a new educational program using an innovative technique from narrative medicine. Narrative skills stimulate creativity and a deeper understanding of reality (1, 14-15, 23). As Hinyard refers, narrative approaches are emerging as a promising set of tools for motivating and supporting health-behavior change (44). Health benefits were already clearly demonstrated in a population with a chronic disease as hypertension when storytelling was used (27). We expected that close reading of literary texts followed by creative writing in a Diabetes Group Care would stimulate individuals to share their stories together with their peers, allowing new insights, developing greater awareness, stimulating empowerment and engagement in managing their health. Taking this into account, we developed a new structured educational program – CrewD Program. A randomized trial was conducted comparing a CrewD Program with the classical approach that was already in use in our Institution.

Both groups showed a significant reduction of A1c between the first and the last session of the intervention. In the follow-up evaluation both groups showed a non-significant A1c reduction. Regarding the individual clinical records in the six years prior to this trial, a decrease of A1c levels was observed in the trial period. These results give support to the intervention carried out in our study, but do not provide evidence for long-lasting effects of this approach at the level of A1c levels.

Participants with a superior BMI present a more significant reduction in A1c but this association with BMI is true only for individual with lower levels of external locus of control. A significant increase in satisfaction with therapist and satisfaction with content/group process was observed. No effects were observed in the other psychological outcomes studied. This was an unexpected result but was probably related with the lack of statistical power of our sample or with the instruments used to assess change. In future research a qualitative approach such as the one used by Guciardi et al (21) could be added to a more comprehensive analysis of the process.

The results should be interpreted with caution given the study's limitations. It was conducted in a relatively small sample of subjects. They were invited and selected according their availability, introducing a potential selection bias. Participant health literacy was not assessed. This study was based on a two-arm design, but three different groups were created for practical reasons. The size of each group was the largest that is possible according to the group dynamics.

Given that the methods followed in the experimental groups were equal, these two groups were merged for statistical purposes. Further studies using larger samples will be needed to validate this procedure for clinical intervention in diabetes. However, this quantitative and controlled approach to the impact of narratives on health was innovative and the results are encouraging. We hope to inspire other to continue.

5- Conclusion

This is the first randomized trial evaluating a Group Care intervention to manage type 2 diabetes using narrative skills. A significant reduction of A1c in the intervention group showed non-inferiority in relation to the classical approach. A significant decrease in A1c was observed in relation with the A1c levels of the previous six years. A significant increase in satisfaction with therapist and with group process was observed. This may be a useful model for patients with several years of school education, and may constitute an alternative for the long term educational process.

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The study described in the manuscript has been previously presented at 78th American Diabetes Association Meeting as a poster presentation.

FR is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Authors contributions:

FR was responsible for the first draft of the manuscript. FR, DA, JR were responsible for CrewD development. FR and ML prepared the evaluation protocol and JO did the statistical analysis. FR, DA, JO, ML, JR were responsible for text revision, with FR being responsible for the final version of the manuscript. All authors contributed to and have approved the final version of the manuscript.

Disclosures:

The authors do not present any possible conflicts of interest.

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List of Table:

Table 1. Demographic table comparing intervention with control group. No significant differences were found.

Table 2. The Group Satisfaction Scale shows a significant increase between assessments in satisfaction with therapist and satisfaction with content/group process throughout the study ($p < .05$).

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Figure 1. Classical structured educational approach vs CrewD Program approach.

Figure 2. Comparisons between assessments for A1c levels .

Figure 3. Comparisons of A1c levels in the six years' period prior the trial.

