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Journal of Diabetes and Endocrinology

Letter to the Editor

Could the antiglycemic role of vinegar be investigated in a double-blind trial?

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Accepted 19 November, 2013

We read with great interest Mahmoodi et al.'s (2013) article published in the January issue of the Journal of Diabetes and Endocrinology. The authors investigated some hematological and blood biochemical factors in type 2 diabetic patients in a double blind randomized controlled trial (RCT).

One of the queries about this study is the random allocation. According to the standard criteria for RCT study design protocols (Schulz and Grimes, 2002), the authors did not mention any details about the vital sections of the protocol in their study. Though matching cases between two groups in an endocrinological trial is critical, the authors matched groups based on sex and body mass index (BMI) while for example the duration of morbidity could play an essential role.

It is well-known that vinegar contains about 3 to 9% acetic acid. The authors did not determine the dosage of the product they used. Besides, why did the authors try a single volume for vinegar? On the other hand, using 15 ml as a single volume is unknown. For example in the study of Ostman et al. (2005), different amounts of vinegar; 18, 23 and 28 g (6% acetic acid) were used in their investigation. In another crossover trial, individuals with either insulin resistance (n = 11) or type 2 diabetes (n = 10) consumed a vinegar processed drink (20 g apple cider vinegar, 40 g water, 1 tsp saccharine) or placebo drink before the consumption of a mixed meal (Johnston et al., 2004).

Another controversial aspect of the study is the placebo use. It is obvious that the unique taste of vinegar cannot be blinded by single water. According to ethical considerations, all the subjects must be informed about the study's intervention at the beginning of the study, however the introduction of vinegar/water (placebo) for the subjects definitely failed the blinding objective. The only way to eliminate this issue is designing a cross-over RCT. According to the review of Johnston et al. (2010) on four randomized crossover trials, they evidently indicated that two teaspoons of vinegar (10 g) effectively reduced postprandial glycemia. It seemed that the only way for achieving intellectual data is cross-over design. Otherwise, pharmacologists should produce a placebo with the same taste and without any side effects.

Besides, in the statistical analysis the authors declare that they performed analysis of variance (ANOVA) test. However, according to the presented data the study was designed based on analyzing different parameters between 2 groups (intervention vs. placebo), thus the ANOVA test is not indicated.

Altogether, RCT studies are known for producing one the highest level of evidences among research studies and thus require extra attention in its study design. It seems that authors failed to achieve this goal.

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Case Report

Conjunctive group therapy: A case study of an adult type I diabetes mellitus patient

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A 30-year-old woman diagnosed with type 1 diabetes mellitus attended 2-year Conjunctive Group Therapy in parallel with medical treatment at a Greek state hospital. The study focuses on the patient's changes in terms of attitudes and metabolic control after termination of the intervention. Qualitative data was collected from focused interviews before and after the intervention and thematic analysis was performed; blood samples were collected for the measurement of glucose levels. Findings showed that by termination of the group therapy, the patient improved her adjustment to diabetes, engaged in self-care behaviors, and achieved better stress management; her overall mood, social relationships and quality of life were improved; she redefined the role of diabetes in her life and achieved good metabolic control.

Key words: Type 1 diabetes mellitus, group therapy, conjunctive group therapy, psychological adjustment, self-care, stress, quality of life, social environment, diabetes redefinition, metabolic control.

INTRODUCTION

Diabetes mellitus (DM) is a chronic condition and a significant public health problem; diabetes complications are responsible for high morbidity and in many cases premature mortality. About 8% of the Greek population suffers from DM, of which 10% suffers from type 1 DM (Jörgens et al., 2002) (DM1). DM1 has an early onset in the patient's life and insulin injection is an integral part of the medical therapy of this medical condition.

The onset of DM1 generates various biological and psychological changes, which affect a patient's life in many ways (Cox and Gonder, 1992). DM1 may bring patients up against complicated challenges, such as maintaining optimal physical health, managing diabetes, coping, self-care, meeting the demands of the medical condition, accepting a new reality, confronting the social environment, and dealing with possible diabetes complications, and unpredictable symptoms (Shilitoe, 1994; Siousioura, 2012b; Stenström et al., 1993). As a

chronic condition, DM1 demands radical changes in a patient's lifestyle, in order for the patient to achieve effective adjustment. Patients' individual differences play a significant role in the course of the condition regarding adjustment and lifestyle changes; nevertheless, patients share common psychological reactions to diabetes, such as denial, stress over the diagnosis, prognosis, and treatment, interpersonal stress, diabetes related distress, depressive symptoms and also a need to redefine DM and integrate it into a new identity (the "unified self") (Charmaz, 1987; Penn, 2001; Weigner and Jacobson, 2001).

According to Gliedman and Roth (1980), during the initial stage of the course of diabetes the sense of the patient's "unified self" is lost, because the boundaries between the individual's external image and the real self become indistinguishable (Gliedman and Roth, 1980). Furthermore, Sachs et al. (1993) argue that patients,

especially in the western world, usually fail to realize the connection between control of glucose levels and control of their body or self (Sachs et al., 1993). In other words, patients fail in perceiving the connection and interaction between the condition and their body/self. Thus, the patient perceives the condition as an "enemy" or a "rival" towards the self. Charmaz (1987) supports that patients diagnosed with a chronic condition go through the process of finding a new identity, which involves the patient's efforts to reconstruct the self image, manage everyday life, maintain social relations, find a new meaning in life and integrate the condition into the self. Based on the earlier notions, DM1 treatment is a process that requires a holistic approach, namely, one that combines medical monitoring and regimen compliance on one hand, and psychological intervention on the other.

Group therapy for patients with physical illnesses is based on the biopsychosocial model and has been broadly used in applied clinical research and practice (Yalom, 2006). Group therapy in particular has been used for its effectiveness as a therapeutic approach, and also because as a process it enables simultaneous treatment of a large number of patients (Yiannitsi, 1997). Numerous studies have found group therapy to be an effective treatment for chronic conditions (Mensing and Norris, 2003; van der Ven, 2003; Yalom, 2006), and more specifically for DM (Weigner, 2003) and DM1 (Mannucci et al., 2005; Siousioura, 2012a; Snoek et al., 2001).

The purpose of this article is to present the case of a DM1 patient who participated in a 2-year Conjunctive Group Therapy (CGT) (Tsamparli and Siousioura, 2009a, 2009b), while receiving parallel medical treatment for DM1, and more specifically to focus on the changes that took place in terms of the following areas: expectations from the group, psychological adjustment to type 1 DM, self-care, everyday life, stress, quality of life and depressive symptoms, family and friends, redefinition of DM, and metabolic control.

CASE STUDY

A 30-year-old woman outpatient attended 2-year group intervention in parallel with medical treatment for DM1 at a Greek state hospital (Diabetes Clinic of Evangelismos General Hospital/Department of Endocrinology, Diabetes and Metabolism) in Athens. The patient's demographic and clinical characteristics are presented in Table 1. She was diagnosed with DM1 at the age of 18 and had followed intensive medical treatment with the use of pump since then. Medical treatment and monitoring was never ceased. The group intervention started in the beginning of 2010 and ended in the beginning of 2012. Therapy was based on the principles of CGT (Tsamparli and Siousioura, 2009a, 2009b; Yiannitsi, 1997), which involved eight members including the patient, the meetings took place at "Evangelismos" Hospital, each session lasted two hours, and the group met twice per month. The patient's participation in the group was based on referral from the endocrinologist and her own consent and personal request for a psychotherapeutic intervention. The participant was informed: (a) that the intervention regarded the psychological aspects of the condition; (b) that an endocrinologist was going to be present at the group meetings as a participative observer; (c) in case that medical or nutritional issues of the condition came up during the group meetings, there would be a common decision on arranging an extra session with the doctor or dietician, respectively, and (d) about the rules and regulations of the group psychotherapeutic procedure: discretion, confidence, open expression, and non-guided topics of discussion.

Research data was obtained with the use of focused interview by Merton and Kendall (Cohen and Manion, 1994) at two different times (before and after the intervention), and the patient's answers were content-analyzed using Grounded Theory methodology (Kumagai et al., 2009; Lundin, 2008; Strauss and Corbin, 1998). Grounded theory seeks to derive thematic categories from initial data. The basic thematic categories that emerged were expectations from the group, psychological adjustment to type 1 DM, selfcare, everyday life, stress, quality of life and depressive symptoms, family and friends, redefinition of DM, and metabolic control. The process was reiterated several times in order to examine emerging thematic categories. Validation of the approach was considered to have been achieved when repeated data analysis revealed no new thematic categories (Strauss and Corbin, 1998). The same analysis was followed for focused interview before and after the group intervention.

Data concerning metabolic control was collected by HbA1c blood measurements. HbA1c is a biological index, which indicates the average plasma glucose concentration over prolonged periods of time. The index is produced using High Performance Liquid Chromatography (HPLC) and a high percentage value of HbA1c indicates poor DM regulation during the last weeks (good regulation: <48 mmol/mol (6.5%) to 53 mmol/mol (7%); marginal regulation: 53 mmol/mol (7%) to 58 mmol/mol (7.5%); and poor regulation: > 58 mmol/mol (7.5%) (Strauss and Corbin, 1998). Blood samples for HbA1c measurement were collected prior to, and after the termination of the therapeutic intervention.

The results of the focused interviews are presented in Table 2. The first column contains the thematic categories: expectations from the group, psychological adjustment to type 1 DM, self-care and everyday life, stress, quality of life and depressive symptoms, family and friends, redefinition of DM, and metabolic control; the second and third column contain the patient's emotional state, beliefs and attitudes towards the aforementioned categories and her own characteristic phrases, before the patient's participation in the group and after termination of the group, respectively. The results of HbA1c measurements are presented in Table 3. The patient's HbA1c measurement before the intervention was 56 mmol/mol (7.26%), and after the intervention HbA1c value was 46 mmol/mol (6.39%). The patient gave an oral ethical clearance for this case study; her basic demographic characteristics have been altered, for confidentiality purposes.

DISCUSSION

Although, the patient's participation in the group was voluntary; at the beginning of the process she displayed strong resistance, emotional inhibition and was reluctant to disclose. Nevertheless, as therapy progressed she became actively involved by initiating group discussions and interacting with group members with assertiveness. Furthermore, she developed thorough insight, identified the role of diabetes in her life in relation to herself and her social environment, and also managed to reflect on the group processes effectively. All the earlier mentioned, combined with the patient's verbal ability to express herself in a poetic way and to provide arguments on the issues that concerned her, gave her a very strong role in

 Table 1. Patient's demographic and clinical characteristics.

Parameter	
Sex	Female
Marital status	Single
Living with family	No
Age	30
Age at the time of diabetes diagnosis	18
Duration of disease (years)	12
Nationality	Greek
Level of education	University
Occupation	Professional
Modality of DM1 medical treatment	Pump
Type of DM1 medical treatment	Intensive
Diabetes complications	No
History of antidepressant therapy	No

Table 2. Patient's beliefs, attitudes and characteristic phrases before and after participation in Conjunctive Group Therapy.

Phrase	Before participation	After termination
Expectations from the group	The patient's concern was to be released of the stress she experienced in various occasions in her life. "I would like to see what I can do when I feel tensed"	It was as if an internal revelation had taken place and the disease itself was eventually affected by the procedures of the group, namely the interaction among the members - which was void of judgment and excuses - , the learning of every-day behaviors and the answers that were given regarding many doubts. These answers helped the patient understand her extreme behaviors on various areas such as eating habits, which had had a direct impact on diabetes. "it feels as if there was an internal process, which was guided by an expert diabetes changed, and this change is not an end in itself, but the result of the group dynamic before the group, stress was made the scapegoat, but after the participation I felt that when the mind is treated, then diabetes is treated too before I had good and bad periods in my life and I would inevitably take revenge on diabetesthat means that I was not aware of my extreme behaviors, whereas now I can fully realize my "delusion""
Psychological adjustment to type 1 DM	She would go beyond her limits in order to be able to integrate the disease into her life. She had reached her absolute low in order to get to know her disease. However, she would not hide it from the others. She was not afraid of the implications, she was only afraid of her fears/phobias. "I did not have a hard time because I like changesI cannot imagine my life without tests (that is, medical tests)"	There was a change in the way of thinking, and an increase of her self-respect and self-awareness. She recognized her dysfunctional behaviors regarding disease management and was adjusted to the demands of self-care such as: medical tests and regular monitoring, and also selection of diabetologist. Diabetes implications seemed not to be her number one concern unless she was in a bad mood. "the improved care did diabetes goodit was the result of this intervention which continued as a dominothe unconscious errors "soul-sugar" were reduced"

Table 2. Contd.

Self-care, everyday life and type 1 DM

She used to handle self-care and mainly nutrition, without panicking, but only when she was in a good mood. When her blood glucose levels were unstable her mood would be seriously disrupted. Therefore she started using a pump, changed her physician in order to have more efficient advising and communication and decided to participate in

- "...when I feel well, I control my nutrition ... I get very frustrated when glucose levels are bad ...
- ...pump has helped treatment, it is like a nice car that takes you to work, it is not to blame if I drive badly..."

She recognized her extreme behaviors regarding eating habits and emotional fluctuation.

"... I do not destroy my nature ... I consciously want my nature to be in line with the environment whether internal or external..."

Stress and metabolic control

Stress used to reinforce her weaknesses and her fear of implications and would lead her to binge eating and increase of blood sugar levels. She tried to control her many episodes of hypoglycaemia with the pump.

"...my stress brings out my weaknesses...

implications..."

...when I have an episode of hypoglycaemia I see myself as completely weak, which is rather bad for me, because I am a strong person, I don't want things to be half done... ...when I am not well, I think about my fear of

She had had periods of sadness not only because of the disease. She had become vulnerable and selective in the sense that she had limited travelling and friendly contacts, and neglected her academic obligations, as she would

choose to do only specific things every day in an attempt to control stress. However her character prevailed over her

disease. Quality of life and depressive

"... I was sad over times, but not about diabetes, it was diabetes on top of others, like when you open a bottle of champagne and the cork pops out too ...

...diabetes increases and lowers the standards of life...

- ...due to diabetes my sense of rationale was in the center and became a habit...
- ...my character is above everything, even above diabetes..."

She was still not ready to move out her family's house and create a family of her own. She used to believe that the disease and its unpredictable consequences, such as hypoglycaemic episodes, were some of the reasons for this choice. However, her partner and her friends were supportive to her.

"...I am the strong member of my family, but I am still not ready to go away...

...I am an independent person even in my relationship or my friendships ... I am also selective I don't compromise..."

Her way of thinking changed, she met her limits and priorities. She considered that controlling stress is something that contributes to her emotional equilibrium.

"...my thoughts are more positive and productive ...things are clearer now... everything takes what it deserves ...this means I am starting to recognize my limits ... "

and this led to the improvement of her life. "...tension is reduced. I used to hold the sword and without knowing why, I used to attack... ...there are changes taking place inside me

She recognized her mother's overprotection towards her, and her family's agony. She felt strong to handle confrontation with the family and not to integrate her family's problems into her life and her disease. These changes also had an impact on her friendships.

"...now I do not get affected by my environment however stressful it may be ...l am ready to accept myself..."

Family, friends and type 1 DM

symptoms

She used to believe that the disease brought hidden elements of one's character - such as patience, balance, and organization - to light

"...I am very selective all the time..."

Redefinition of type 1 DM

Through group therapy she realized the importance of living for the present and of reconciliation with the difficult parts of herself, such as her disease.

"... I let the disease be affected by my new profile and my self-awareness..."

She learned how to live with diabetes by trying to experience "here and now" without concerns about her long term plans. She learned how to manage her psychosomatic well-being. She changed her criteria in making friends. She obtained self-awareness

- ...I experience every moment ...I don't plan for the future, I live for today ... "

Metabolic control	She used to consider that stress affected her hormones and thus their regulation. "stress and hormones work like guiltif it is not for them I do not confront a "trial"when I feel well in my mind and my soul, my blood sugar levels do not scare me, they become the springboard"	She managed to make the connection between the quality of her life and the feeling of "catharsis" (that is, purification/cleansing) of her soul and her physical health. "good life, catharsiscatharsis of the soul is comes before good regulation"
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Table 3. Mean and standard deviation of HbA1c measures before and after the intervention.

Parameter	Before the intervention	After the intervention
HbA1c Value	56 mmol/mol (7.26%)	46 mmol/mol (6.39%)

to focus on the factors that previously impeded self-care; therefore, she modified her behavior and further achieved spectacular progress regarding diabetes regulation. Finally, she achieved significant changes in her life (change of occupation and city of residence), a fact that indicates that she became more autonomous and improved the quality of her life.

More specifically, as shown by the results, prior to the intervention, the patient's expectations of diabetes treatment were very low, as she thought that the group's function would be to soothe everyday distress caused by the condition. Moreover, she perceived diabetes as an external factor that affected herself and her life in a negative way, by compromising her health, dreams, actions and potential in general. In terms of emotional state, the patient's core feelings were a continuous and generalized fear, stress and anxiety that emerged from a constant sense of threat. In terms of behavior, the patient had great difficulty in displaying stable self-care behaviors and used to attribute this inconsistency to external factors, such as the physician or the regimen. Additionally, over the years, she had dropped out of a variety of activities such as friendly contacts, travelling and academic obligations. Before the intervention, she used to live with her parents and feel dependent on them. She had also given up the choice of creating a family of her own, attributing this attitude to the unpredictability of DM1. Finally, for many years, she had poor metabolic control as shown by HbA1c value prior to the intervention (Table 3).

Gradually, as the intervention progressed, there were numerous changes observed. First of all, diabetes treatment became a more tangible target as she realized that the group taught her new behaviors regarding everyday self-care and answered critical questions regarding the condition, her feelings and her perspective, and also offered her a clear picture of her dysfunctional behaviors, such as binge eating, which used to have a negative impact on diabetes. The previous generalized fear and constant vague sense of threat that fed her anxiety was eliminated and she engaged in stress management, which also decreased the sense of vulnerability. She gradually recognized her responsibility regarding self-

care and the amount of control she could have over it; therefore, she managed to stabilize self-care behaviors. Furthermore, she regained contact with lost friends and engaged in new relationships, reinforcing in this way social support; she began travelling again and continued her studies, which boosted self- efficacy. She also recognized the impact of her mother's overprotection on her and the degree of her dependency. She learned how to handle confrontation with the family, managed to set personal boundaries, and became more autonomous. She managed to redefine the role of diabetes in her life and most important to integrate it in her everyday life and achieve reconciliation with diabetes. Finally, she achieved good metabolic control.

The changes in attitudes, beliefs, emotional state, behavior and disease outcome that the patient displays are in line with the principles of CGT, as the intervention addresses both the psychological and biological aspects of DM1 and attempts to orientate care towards the 'whole person', the 'psychosomatic wholeness' and the 'unified self' (Shillitoe, 1988; Tsamparli and Siousioura, 2009a, 2009b). The notion of the "whole" or the "one" (holon) was raised by Socrates in the context of a holistic perception about health (Zalokostas, 1996).

The areas where group therapy focused were: (a) patients' emotional expression and exploration of beliefs, (b) gradual accomplishment of realistic targets regarding regimen and every-day activities, which give patients' life a positive meaning (Greer et al., 1992), (c) provision of information and advice, not only about the condition itself, but also about various aspects of life (Cain et al., 1986), and finally (d) replacement of dysfunctional behaviors with alternative functional ones. The aforementioned targets aim at making the course of diabetes less unpredictable and therefore more stable, and at reducing the possibilities of diabetes implications, comorbidity with depression or other mental disorders, and potential hospitalizations. In CGT, the patient's request, which is primarily diabetes regulation, is modified to a request for self-awareness, insight, and improvement of quality of life. The supportive atmosphere of the group facilitates the diffusion of patients' negative emotions. This means that patients are able to express and elaborate on negative

emotions such as insecurity due to the threat of the condition, fear of hypoglycemic episodes, loss of control regarding levels of blood sugar, which may often lead to extreme behaviors such as alcohol abuse, binge eating, insulin avoidance, giving up physical exercise or medical monitoring, a sense of inferiority and stigmatization, and fear of death. At the same time, CGT enables patients to focus on self-awareness and individual responsibility, in order to engage in self-care behaviors and eventually incorporate diabetes into every-day life. Furthermore, the patient is guided to redefine diabetes in a way that it can be more naturally integrated into their life. The patient begins to consider diabetes as the reason for searching about the meaning of life, existence, and death. Anderson and Wolpert (2004) refer to the aforementioned procedure as an opportunity for change (Anderson and Wolpert, 2004). As the patient obtains deeper self-awareness, the perception of the condition is modified and this leads the patient to eventually redefine diabetes: the individual discovers new potentials and gives a new meaning to life in general (Meleiset al., 2000). The examination of one patient who participated in a group therapeutic intervention for DM1 does not allow generalizations about the use of CGT in DM1 treatment and does not account for treatment outcomes for other DM1 patients. The focus was to emphasize on the changes achieved in a patient's attitudes, emotions, behavior and DM1 outcome after participation in an intervention that addresses both the physical and psychological aspects of diabetes. Further research is required in order to examine the causes of change.

ABBREVIATIONS

DM, Diabetes mellitus; **DM1**, type 1 diabetes mellitus; **CGT**, conjunctive group therapy.

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