Journal of Affective Disorders 183 (2015) 221–228

Contents lists available at ScienceDirect

Journal of Affective Disorders

journal homepage: www.elsevier.com/locate/jad

Research report

Lifestyle change recommendations in major depression: Do they work?

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ARTICLE INFO

Article history:
Received 3 March 2015
Received in revised form
29 April 2015
Accepted 30 April 2015
Available online 14 May 2015

Keywords:
Depression
Lifestyle recommendations
Exercise
Diet
Sunlight exposure
Sleep patterns

ABSTRACT

Background: Modifying some lifestyle factors can be useful in depression, at least as an adjuvant treatment. Combining different lifestyle interventions seems to be an adequate strategy to increase their antidepressant efficacy according with preliminary studies, but this issue has not been enough investigated.
Methods: The present study is a randomized, double-blinded, multicentre, two arm-parallel clinical trials, with a 12 month follow-up. The sample consisted of 273 Primary Care patients. Four combined hygienic-dietary written recommendations were given to the patients about diet, exercise, light exposure and sleep hygiene.
Results: Both active and control interventions were associated with improvement on BDI (Beck Depression Inventory) scores. However, there were not statistically significant differences (7.0 vs. 7.6; $p=0.594$).
Limitations: We were unable to monitor whether patients carry out recommendations. Intervention could be too difficult to accomplish for depressed patients without enough support and supervision.
Conclusions: Just giving written lifestyle recommendations are not enough for depressive patients to benefit from them, so perhaps lifestyle change recommendations work or do not work on Depression depending on how they are presented to patients and on monitoring systems of their implementation.

1. Introduction

Major depression has become the second most prevalent cause of illness-induced disability worldwide (Ferrari et al., 2013; Gabilondo et al., 2010; Stegmann et al., 2010). In addition, depression increases the risk for early mortality and is the most expensive mental disorder in Europe representing a 1% of the total economy of Europe (Mykletun et al., 2009; Sobocki et al., 2006).

The identification of modifiable risk factors for depression is an important research objective nominated as a challenge in global mental health (Collins et al., 2011; Hidaka, 2012). Given that significant numbers of patients do not satisfactory respond to first-line antidepressant treatments (pharmacological or psychological); this is an area of psychiatric research that deserves continuous attention (Cooney et al., 2013; Walsh, 2011). Major depression etiopathogenesis is related with a wide variety of biological and psychosocial factors, including many associated with lifestyle (Hidaka, 2012; Kupfer et al., 2012; Lopresti et al., 2013; Oliver-Quetglas et al., 2013; Patten et al., 2009). Some studies are suggesting that modifying lifestyle factors can be useful in depression, at least as an adjunctive treatment (Lopresti et al., 2013; Sarris et al., 2014; Walsh, 2011). Therefore, the influence of diet (Jacka et al., 2011; Kiecolt-Glaser et al., 2014; Quirk et al., 2013; Sánchez-Villegas et al., 2012), physical exercise (Azevedo Da Silva et al., 2012; Conn, 2010; Daley, 2008; Song et al., 2012), sleep (Baglioni et al., 2011; Hayley et al., 2015; Manber et al., 2008), and light exposure (Even et al., 2008; Leppämäki et al., 2004; Milaneschi et al., 2014), among others, on the course of depression, has been independently investigated, but the evidence based remains patchy and without definitive conclusions (De Moor et al., 2008; Sarris et al., 2014). Although it has been scarcely proved, combining different lifestyle interventions seems to be an adequate strategy to increase efficacy of lifestyle-based interventions (Daubenmier et al., 2007; García-Toro et al., 2012a; Sarris et al., 2014). Results of a preliminary study showed a significant improvement in depressive symptoms after a

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http://dx.doi.org/10.1016/j.jad.2015.04.059
0165-0327/

combined but simple intervention was added to first line treatment (García-Toro et al., 2010; García-Toro et al., 2012a). Patients who were given four hygienic-dietary recommendations about exercise, diet, sun exposure and sleep evolved better than a control group. These previous findings encouraged further research and the need of replication with a larger sample and a longer follow-up in a pragmatic and ecologically valid study, to confirm the positive antidepressant effects of this simple antidepressant procedure.

The aim of this study was to test in a controlled study the add-on antidepressant efficacy of four structured hygienic-dietary recommendations in Primary Care depressed patients after a 12 months intervention period.

2. Methods

The study was approved by the Ethic and Clinical Research Committees of three Spanish regions (Balearic Islands, Catalonia and Aragon). A detailed research protocol has been registered (ISRCTN73931675) and published elsewhere (García-Toro et al., 2012b).

The present study is a randomized, double-blinded, multicenter, two arm-parallel clinical trial, with a year follow-up. The sample consisted of patients, aged 18 or more, with a diagnosis of Major Depressive Disorder as stated by the DSM-IV-TR (APA, 1994), mild to moderate depressive symptoms for at least two months of duration, and having sufficient physical and cognitive aptitudes to understand and give written informed consent. Exclusion criteria were: suffering any other severe disease that affects the Central Nervous System (neurological disease such as Alzheimer, Parkinson or any other neurodegenerative brain pathology) which would interfere with the study; uncontrolled or potentially medical condition which would interfere with affective symptomatology or the adherence to the hygienic-dietary recommendations; delusion or hallucinations at the time of the study; significant risk of suicide; and pregnancy or lactation.

A total of 62 General Practitioners participated in the study and included 273 patients at Primary Health Centers from January 2012 to December 2013.

Patients were recruited from Primary Care health centers. GPs included patients fulfilling the study criteria and participants were also required to score 11 or higher on the Beck Depression Inventory II (Beck et al., 1996) at the initial diagnostic screening made by the GPs. In case of refusal or exclusion, the next patient attending the Primary Care unit who fulfilled the inclusion criteria was enrolled. Other patient information was collected by trained psychologists, after consenting to the study, using a Case Report Form (CRF) that included data on sociodemographic features and history of psychiatric and medical illnesses. All outcome variables were assessed 3 times: prior to start of the study (baseline), after 6 and 12 months after inclusion (first and second follow-up respectively) in individual and face-to-face data collection.

An independent researcher was responsible for managing the randomization lists. Patients were randomly assigned to the active treatment or control group, by randomization blocks of 10, after signed informed consent. Patients assigned to the active treatment received an envelope containing a sheet of paper with four detailed hygienic-dietary recommendations under consideration. The control group received an identical envelope, but the advice was to "perform the pattern of eating, sleeping, exercise and exposure to sunlight, which they thought would fit their needs best". General Practitioners took the randomized envelope and asked the patient to follow the recommendations written inside.

Study design, procedures and reporting followed guidance from the CONSORT statement (Schulz et al., 2010).

2.1. Blinding

GPs were blinded to the random allocation of their patients. The main outcome was assessed by trained psychologists, blind to patient allocation. The statistician and data-entry staff were also blinded.

2.2. Intervention

The lifestyle measures, active and control, were the same ones used by our group in a previous study in which active recommendations were associated with greater improvement in patients with depression (García-Toro et al., 2012a).

Active group intervention

In order to try to accelerate the improvement of your depression we recommend you to follow these lifestyle measures:

1. Go to bed when sleepy and not before 11 o'clock at night. Use your bed and bedroom only for sleep and sexual activities (do not read, watch TV or lie on the bed during the day). If you do not fall asleep after 15 or 20 min, get up and start an activity until you feel sleepy enough to go back to bed. Get up early, never later than 9 a.m., no matter how well you have slept the night before. Do not lie down or take a nap during the day.
2. Walk at least 1 h a day, at a good pace but without becoming short of breath or being unable to talk while walking. If you think you have a medical problem which makes walking difficult or uncomfortable consult your doctor. Use appropriate footwear for walking and have a shower or a bath afterwards.
3. Be exposed to sunlight at least 2 h per day, taking precautions to avoid sunburn or sunstroke (sunscreen, hat, etc.).
4. Try to eat a healthy and balanced diet. Eat at regular hours without snacking between meals. Avoid especially sweet or sugary drinks. Eat fish at least three times per week, plus fruit, cereals, nuts and vegetables daily.

Control group intervention

In order to try to accelerate the improvement of your depression we recommend you to follow these lifestyle measures

1. Sleep the hours that you feel your body needs in order to meet your needs best.
2. Adapt the pace of daily physical activity to meet your needs best.
3. If exposed to sunlight take precautions to avoid sunburn or sunstroke (sunscreen, hat, etc.).
4. Try to eat a healthy and balanced diet.

2.3. Primary and secondary outcomes

The primary outcome was Depression score using the validated Spanish version (Sanz et al., 2003) of the Beck Depression Inventory (BDI-II) (Beck et al., 1996) at 12 months. This instrument is widely used as it allows patient self-rating of depressive symptoms, avoiding evaluation bias, and determines a cut-off for mild or moderate depression.

Secondary outcomes were Depression severity at 6 months, the Psychiatric comorbidity by the Spanish validated version (Ferrando et al., 1998) of Mini International Neuropsychiatric Interview (MINI, Sheenan et al., 1998) and the State-Trait Anxiety Inventory (STAI, Spielberger et al., 1982) at 6 and 12 months. The STAI is a 40-item