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A randomized controlled trial of a 10 week group psychotherapeutic treatment added to standard medical treatment in patients with functional dyspepsia

M. Orive [a,h,*], I. Barrio [b], V.M. Orive [c], B. Matellanes [d], J.A. Padierna [e], J. Cabriada [f], A. Orive [f], A. Escobar [g,h], J.M. Quintana [a,h]

[a] Research Unit, Galdakao-Usansolo Hospital, Galdakao, Bizkaia, Spain
[b] Department of Applied Mathematics, Statistics and Operational Research, University of the Basque Country UPV/EHU, Leioa, Spain
[c] Digestive Service, Basurto University Hospital, Bilbao, Bizkaia, Spain
[d] Psychology Department of Personality, Assessment and Treatment, University of Deusto, Bilbao, Bizkaia, Spain
[e] Department of Psychiatry, Galdakao-Usansolo Hospital, Galdakao, Bizkaia, Spain
[f] Digestive Service, Galdakao-Usansolo Hospital, Bilbao, Bizkaia, Spain
[g] Research Unit, Basurto University Hospital, Bilbao, Bizkaia, Spain
[h] Health Services Research on Chronic Patients Network (REDISSEC), Bilbao, Bizkaia, Spain

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ABSTRACT

Objective: Epidemiological evidence suggests an association between psychological factors and functional dyspepsia (FD). Yet few randomized controlled trials (RCTs) of psychological interventions have been conducted for FD. We conducted an RCT to evaluate the efficacy of psychotherapy among chronic FD.
Methods: One hundred fifty-eight consecutive patients with FD were randomized to medical therapy plus psychotherapy consisted in 8 group and 2 individual sessions focused on teaching techniques for coping with FD (intensive treatment (IT); n = 76) or medical therapy alone (conventional treatment (CT); n = 82). Patients completed validated self-reported questionnaires before and after the 10-week treatment and 6 months later. Linear mixed-effects models were used, in intention-to-treat analysis.
Results: At the end of treatment period, statistically significant improvements were observed for IT compared with CT for dyspepsia-related quality of life (DRQoL). *DRQoL mean changes of 6.09 and 3.54 were obtained in IT and CT patients, respectively ($p = <0.0001$); and SS mean changes of 11.55 and 4.57 were obtained in IT and CT patients, respectively ($p = 0.0013$).* Those improvements, measured by minimum clinically important difference (MCID), were clinically significant (DRQoL: 77% of the IT patients exceeded the MCID vs the 45% of the CT; SS: 75% vs 48%). Six months after treatment, those statistically significant improvements persisted for DRQoL ($p = 0.0067$) and for SS ($p = 0.0405$). Clinical improvements persisted for SS (63% vs 41%).
Conclusions: These findings suggest that adding psychotherapy to standard medical therapy improves short-term outcomes in patients with FD and may have long-term effects as well. The cost-effectiveness of intensive therapy needs to be evaluated.
Registration number and name of trial registry: NCT01802710

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Introduction

According to the ROME III Diagnostic Criteria [1], functional dyspepsia (FD) is defined as symptoms thought to originate in the gastroduodenal region in the absence of any organic, systemic, or metabolic disease likely to explain the symptoms. FD is the most common gastrointestinal problem seen in primary care settings [2], with a prevalence of 12–15% [3]. Common symptoms include epigastric pain or discomfort, belching, heartburn, bloating, post-prandial nausea, pressure or fullness, and/or early satiety [3].

Although the cause of FD is unclear, it is likely to be multifactorial [4,5]. Because there is no standard recognized treatment, FD is a difficult condition for both clinicians and patients. Current treatment generally focuses on medical therapy, emphasizing pharmacological interventions and dietary changes [6,7]. However, most patients do not fully respond to this approach [5]. Psychological interventions

* Corresponding author at: Research Unit, Hospital Galdakao-Usansolo, Bo. Labeaga s/n, Bizkaia 48960, Spain. Tel.: +34 94 4007105; fax: +34 94 4007132.
E-mail addresses: miren.orivecalzada@osakidetza.net (M. Orive), irantzu.barrio@ehu.es (I. Barrio), victormanuel.orivecura@osakidetza.net (V.M. Orive), b.matella@fice.deusto.es (B. Matellanes), jesusangel.padiernaacero@osakidetza.net (J.A. Padierna), joseluis.cabriadanuno@osakidetza.net (J. Cabriada), aitor.orivecalzada@osakidetza.net (A. Orive), antonio.escobarmartinez@osakidetza.net (A. Escobar), josemaria.quintanalopez@osakidetza.net (J.M. Quintana).

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[5,7] have been proposed as alternative or additional management options.

Epidemiological evidence suggests an association between psychological factors and FD [5]. Psychotherapy has proven to have beneficial effects for similar indications, such as irritable bowel syndrome [8], unexplained physical symptoms, chronic fatigue syndrome, and peptic ulcer disease [5]. Psychotherapy has also been shown to reduce health-care costs in patients with functional gastrointestinal disorders [5,8]. These successes have encouraged the use of psychological intervention in patients with FD. However, the benefits of such interventions remain unclear in this population [5].

Few randomized controlled trials of psychological intervention have been conducted for FD [5,9]. A recent well-established systematic review [5] identified only four eligible trials that demonstrated benefits of psychotherapy on dyspepsia symptoms, which persisted for 1 year. Those results should be interpreted with caution, as Soo et al. [9] suggested, because different methodologic problems limit the interpretation of these results.

We performed a parallel-group randomized controlled trial to evaluate the efficacy of psychotherapy among patients with FD. We also evaluated the magnitude of differences, evaluating patient reported outcomes that are easy to interpret clinically. Primary outcome variables included disease specific instruments and a global outcome measure. Psychological status measured by Hospital Anxiety and Depression Scale (HADS) [10,11] was included as secondary outcome.

Materials and methods

Participants

Patients from the digestive services of Galdakao-Usansolo and Basurto University Hospitals between the ages of 18 and 80 years with chronic upper abdominal symptoms consistent with ROME III criteria [1] for FD were recruited for this study. To be eligible for this parallel randomized controlled trial, all patients were required to have an endoscopy to exclude structural organic causes for their symptoms at the time of recruitment. Patients were excluded if they had any organic pathology that could explain the FD symptoms; if they were regularly using non-steroidal anti-inflammatory drugs (NSAIDs); or if they had physical or psychological impairments that prevented them from completing the questionnaires. Patients with heartburn as the main symptom were also excluded as they are not included in the ROME definition [1]. Patients with prominent FD symptoms but also some concomitant irritable bowel syndrome (IBS)'s symptoms were not excluded, provided that they did not fulfill ROME III criteria for IBS.

Procedure

Patients attending the endoscopy units at participating hospitals with inclusion criteria (described above) were contacted from November 2009 to September 2011 by an investigator (MO or VMO) who explained the purpose of the study. Patients who agreed to participate and signed the inform consent were randomly allocated to the control or experimental group in a 1:1 ratio in blocks of 4 according to a computer generated random assignment sequence stratified by hospital site, prepared in advance by a statistician. Patients in the control group received standard medical treatment (*conventional intervention*) while those in the experimental group received standard medical treatment plus psychotherapy (*intensive intervention*). Following current guidelines for the treatment of FD, medical therapy (40 g of prokinetic a day, 1 mg of antisecretory agent 3 times day or a combination of both) focused on the most bothersome symptom (see Appendix 1). On the other hand, psychotherapy was based on the principles of cognitive behavioral therapy, and it was adapted from the script of Sank and Shaffer. It consisted of one 50-minute session per week for 10 weeks (the first eight were group sessions and the last two individual meetings) (see Appendix 1). In both the control and experimental groups, patients were assessed at the same time, at baseline (T0), at the end of 10 weeks of treatment (T1) and six months after treatment ended (T2), with mailed questionnaires. Reminders were mailed at two and four weeks to participants who did not return their questionnaires. Given the nature of the intervention, neither patients nor individuals collecting the data were blinded to the treatment assignment. At the end of the study, each control group patient was invited to undergo the psychological treatment, if interested. All Basurto University Hospital patients were followed by their physicians every three months for at least one year, while Galdakao-Usansolo Hospital patients met with their physician just once during the year after endoscopy, unless the patient requested another consultation. Physicians involved in the recruitment and in the medical treatment were blinded to patients' randomization.

The trial was approved by the Ethics Committees of both hospitals. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki (6th revision, 2008); registration number and name of trial registry: NCT01802710; clinical improvement and in Quality of Life-Functional Dyspepsia-(Clinical Trial.gov).

Measurements

The following assessments were performed in both the experimental and control group, at T0, T1 and T2. *Sociodemographic and clinical background*. Data on age, sex, educational level, marital status, time with FD, current use of psychiatric and/or digestive medications, and attending hospital were recruited at T0.

Disease specific instruments

To evaluate dyspepsia related-health outcomes two disease-specific questionnaires were used. The Glasgow Dyspepsia Severity Score (GDSS) [12] and the Dyspepsia Related Health Scale (DRHS) [13]. The 8-item GDSS yields a global score that ranges from 0 to 20, with higher scores indicating more severe dyspepsia. The Spanish version of this questionnaire, validated by Monés et al. [14] showed acceptable internal consistency (0.60) and good consistency for patients at the 6-month follow-up evaluation (0.80). The DRHS questionnaire consists of four scales: severity of common symptoms, pain intensity, pain disability, and satisfaction with dyspepsia-related health. The responses to the questions in each domain are added to provide four scores between 0 and 100, with 0 representing the worst health status possible and 100 the best. The Spanish version of this questionnaire, validated by Ruiz et al. [15] displayed good psychometric properties (Cronbach alpha of 0.70–0.94 and test–retest correlation of 0.90–0.94) [15].

Psychological status

Psychological status was rated using the Hospital Anxiety and Depression Scale (HADS) [11]. It is a 14-item measure: 7 items evaluate depression (the HADS-D subscale) and 7 evaluate anxiety (the HADS-A subscale). A subscale score of 0–7 indicates the absence of anxiety or depression; a score of 8–10 indicates a possible case of anxiety or depression; and a score of 11 or higher indicates the presence of anxiety or depression. It has been adapted and validated in a Spanish population (Cronbach alpha: 0.86 for HADS-A and 0.86 for HADS-D and high concurrent validity) [10].

Global outcome measure

Subjective clinical improvement (SCI) was assessed in both the control and experimental groups at T1 and T2, asking patients to decide whether he or she has remained the same, improved, or deteriorated in regard FD related health and general health. Improvement or worsening is rated on a seven point ordinal scale. One question was about FD related health (see Appendix 2).

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