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Behaviour therapy for obesity treatment considering approved drug therapy

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Obesity is a worldwide health problem whose prevalence is on the increase. According to the Robert Koch Institute, in Germany, 67 % of all men over the age of 18 and 54 % of all women are overweight or obese, with 17 % of men and 20 % of women being classified as obese.
Obesity is considered to be a risk factor for numerous metabolic and cardiovascular diseases such as Type 2 Diabetes or cardiac failure. Many obesity-associated diseases require intensive medical treatment and are the cause of a large proportion of health-related expenditures in Germany. From a health policy aspect, the significance of obesity therefore lies particularly in its high prevalence and the associated costs of avoidable secondary diseases. Treatment of obesity includes nutritional, exercise and behaviour therapy, usually in combination. Under certain circumstances, drug treatment or surgical procedures may be indicated. In Germany, Sibutramin, Orlistat and Rimonabant have been approved as treatment drugs.
The goal of behaviour therapy for obesity is to bring about a long-term alteration in the eating and exercise habits of overweight and obese individuals. Long-term weight loss and maintenance can be achieved through learning self controlled eating habits. Essential features of such treatments are self observation, self control and self evaluation of one's own eating habits and physical activity. Included in the treatment are stress management, social support and relapse prevention and management.

All HTA reports are available for free of charge as full texts in the DAHTA database (only in German) and at German Medical Science (gms).

Objectives

Medical questions

- Can behaviour therapy alone or in conjunction with the approved drugs reduce weight in subjects when compared with other therapeutic measures (advice or instruction on nutritional changes, physical activity or a combination of the two)?
- Can weight maintenance be observed during the follow-up period after the intervention with behaviourally based obesity treatment, either with or without the employment of approved drugs?

Economic questions

- How cost effective is behaviourally based obesity treatment in conjunction with the approved drugs when compared with other therapeutic measures (advice or instruction on nutritional changes, physical activity or a combination of the two)?

Ethical, social and legal questions

- What ethical-social and legal aspects must be considered in evaluating behaviour therapy in conjunction with the approved drugs?

Methodology

We performed a systematic review using the following databases: MEDLINE, EMBASE previews, EMBASE Alert, AMED, SCISEARCH, MEDIKAT, BIOSIS, GMS, SOMED, CAB Abstracts, ISTP+ISTP/ISSHP, ETHMED, GLOBAL Health, Deutsches Ärzteblatt, CCMed, Social SCISEARCH, Karger-Verlagsdatenbank, Kluwer-Verlagsdatenbank, Springer-Verlagsdatenbank, Springer-Verlagsdatenbank PrePrint, Thieme-

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Verlagsdatenbank, Cochrane-Library CDSR, NHS-CRD-DARE, International Agency for Health Technology Assessment NHS-CRD-HTA, National Health Service NHS-EED and HTA-Datenbank der Deutschen Agentur für Health Technology Assessment.
On the basis of previously defined inclusion criteria randomized, controlled studies, HTA reports and guidelines which examine behaviour therapy alone or in conjunction with drug treatment in comparison to other forms of treatment (advice or instruction on nutritional changes, physical activity or a combination of the two) were included in the evaluation. In this regard, the behaviour therapy must be defined in the studies by an indication of its most important contents. A systematic, qualitative evaluation of the studies was then carried out in accordance with recognized standards of evidence-based medicine.

Results

To evaluate the effectiveness of behaviour therapy overall 18 studies, included one HTA and one meta-analysis could be identified according to the predefined inclusion criteria.
Only three studies compare behaviour therapy to other therapy forms (advice or instruction on nutritional changes, physical activity or a combination of the two). Of these, two studies support the positive effects of behaviour therapy with an adequate analysis of the statistical uncertainty. One study merely employs pre/post comparisons to present the effectiveness of behaviour therapy. All other studies comparatively assess various types and intensities of behaviour therapy. These studies are divided into studies which examine the various types and intensities of behaviour therapy, behaviour therapy based on media support and behaviour therapy with additional drug treatment. The HTA provides adequate evidence for its assessment of behaviour therapy as an effective method of weight reduction.
Studies which assess the various therapeutic approaches or the intensities of behavior therapy all indicate an effect with regard to weight reduction. A comparative analysis of the studies reveals the greater effectiveness of intensive behaviour therapy when compared with “normal” behaviour therapy, and the greater effectiveness of group therapy when compared with individual treatment.
Studies related to behaviour therapy based on media support demonstrate a weight reduction both through the interventions of media alone as well as through the intervention of media in conjunction with personal support within the groups. However, analyses of the inter-group comparisons offer no statistically significant difference.
Comparative analyses confirm the effectiveness of behaviour therapy coupled with additional drug treatment when compared to behaviour therapy alone. However, the three studies with “behaviour therapy plus drug treatment” intervention method, lack of any long-term assessment of this form of treatment.
In all the studies presented here, relevant changes in weight of -5 % to -10 % are only partially achieved. High weight losses of less than -10 % were found among the intervention group in two of the studies. One study reported a weight loss of -11.4 % with the “group therapy” intervention method, while another study reported a weight loss of -11.2 % with the “behaviour therapy plus drug treatment” intervention method. In both studies, the weight losses differ significantly from the comparison groups.
A total of eight studies include an intervention period with a subsequent follow-up period during which the subjects are only monitored for the purpose of weight determination. The duration of these follow-up periods varies

from three to twelve months. Nearly every study indicates a clear weight loss at the end of the intervention followed by a renewed weight gain towards the end of the follow-up period.

Discussion

A comparative assessment among the studies proved difficult due to their heterogeneous nature. Little conformity can be detected in either the contents of the behavior therapy or in the treatment plans. The length of the follow-up periods also varies from study to study. The three studies of the "behaviour therapy plus drug treatment" intervention method are comparable with regard to the study duration. However, the limitation of drug intervention to 12 months can be seen as the result of the treatment period for the employed drug, Sibutramin, being limited to one year. Many studies only analyse weight changes within one group or for the entire study population. However, the results of these analyses all indicate a significant weight loss at the end of the intervention.

Ethical, social and legal aspects

No literature which deals with the ethical-social or legal aspects of behaviour therapy, possibly under the inclusion of drug treatment, could be identified.
Behaviour therapy, possibly under the inclusion of drug treatment represents but a fragment of the available treatments for obesity. Thus, the ethical-social aspects relate to the entire problem area of obesity and not merely specifically to behaviour therapy in cases of obesity. However, in comparison with nutritional therapy, exercise or surgical procedures, successful behaviour therapy can make the obese individual aware of their adipogenic behaviour and permanently strengthen self responsibility for health promoting behaviour.
If drug treatment were employed without being accompanied by nutritional, exercise or behaviour therapy, it could easily give the adipose patient the impression that a change to a more health promoting behaviour is not necessary. In this case, the aspect of self fault and the promotion of self responsibility for a more health conscious behaviour remain unaddressed.
Legal aspects relate primarily to the reimbursement practices for obesity treatment of both the legally mandated as well as private health insurers. While all providers provide reimbursement for from 20 to 30 sessions of behaviour therapy for obesity, weight loss drugs are excluded from reimbursement by legally mandated health insurers under § 34 SGB V if it is primarily the "life-style" aspect which stands in the foreground. While private health insurers have no definite exclusion clause for these drugs, the obese patient must, however, prove that he or she is suffering from a disease which requires treatment. Thus, both the legal as well as the privately insured patient is presented with the problem of defining the obese condition as a disease.

Conclusion/recommendations

Despite the small number of studies which evaluate the effectiveness of behaviour therapy alone in comparison with other forms of treatment for obesity (advice or instruction on nutritional changes, physical activity or a combination of the two), the effects of behavior therapy on a reduction in weight can be shown. However, relevant weight changes of -5 % to -10 % are only achieved to a certain extent. The extremely heterogeneous nature of the interventions makes a comparison of the study results very difficult.

However, a greater effectiveness of intense forms of therapy when compared with “normal” behavior intervention and for group therapy when compared with individual therapy can be recognized. Further, a trend can also be detected indicating that those methods which offer drug treatment in addition to behaviour therapy are more effective than behaviour therapy alone. Few adequate data are available which show the long-term success of behaviour therapy. However, all studies have in common that the successes with regard to weight reduction gradually weaken over time.
For a more precise assessment of behaviour therapy and behavior therapy under the inclusion of additional drug treatment, the necessary long-term studies with consistent contents with respect to the behaviour therapy and consistent treatment methods are lacking.