Cognitive−behavioural therapy for health anxiety in a genitourinary medicine clinic: randomised controlled trial

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Background
Little is known about the management of health anxiety and hypochondriasis in secondary care settings.

Aims
To determine whether cognitive–behavioural therapy (CBT) along with a supplementary manual was effective in reducing symptoms and health consultations in patients with high health anxiety in a genitourinary medicine clinic.

Method
Patients with high health anxiety were randomly assigned to brief CBT and compared with a control group.

Results
Greater improvement was seen in Health Anxiety Inventory (HAI) scores (primary outcome) in patients treated with CBT (n=23) than in the control group (n=26) (P=0.001). Similar but less marked differences were found for secondary outcomes

of generalised anxiety, depression and social function, and there were fewer health service consultations. The CBT intervention resulted in improvements in outcomes alongside higher costs, with an incremental cost of £33 per unit reduction in HAI score.

Conclusions
Cognitive–behavioural therapy for health anxiety within a genitourinary medicine clinic is effective and suggests wider use of this intervention in medical settings.

Declaration of interest
P.S. adapted the CBT intervention for health anxiety and developed the Health Anxiety Inventory. P.T. is the Editor of the *British Journal of Psychiatry* but had no part in the evaluation of this paper for publication. Funding and trial registration detailed in Acknowledgements.

Health anxiety – and the related condition, hypochondriasis – is a relatively common problem in both primary and secondary medical care settings, with at least 1 in 20 of all attendees satisfying the diagnostic criteria for the condition.[1,2] Anxiety over health also places a substantial burden on health services[3] and impairs quality of life.[4] In genitourinary clinics we have previously found (using a standard scale)[5] that nearly 1 in 10 of consecutive attendees has significant health anxiety and that this was associated with persistent morbidity.[6] Although there has been a tendency to regard hypochondriacal concerns as difficult to treat, cognitive–behavioural therapy (CBT) has been shown to be effective.[7,8] In view of the conspicuous morbidity created by hypochondriasis and its impact on services we felt a randomised controlled trial of this treatment in secondary care was justified. Our study was carried out in patients with abnormal health anxiety with the hypothesis that CBT would reduce health anxiety to a greater extent than control management and that the extra cost might be offset by savings on health service consultations.

Method

The study was carried out with out-patients presenting to the genitourinary medicine clinic at King's Mill Hospital, Sutton-in-Ashfield, Nottinghamshire, between April 2002 and February 2005. Patients were not screened but those felt to be suffering from health anxiety were given the Health Anxiety Inventory (HAI)[5] and those with a score of 20 or more were invited to take part in the study if they satisfied all the criteria listed below. Randomisation was made to either CBT supplemented by a booklet (bibliotherapy) or to a single assessment interview with ordinary care in the clinic, supplemented by the offer of CBT after 1 year if this was still desired. In addition to assessment of health

anxiety, self-ratings were made of anxiety using the Beck Anxiety Inventory (BAI)[9] and the Hospital Anxiety and Depression Scale – Anxiety (HADS–A),[10] of depression using HADS–D,[10] of social function using the Social Functioning Questionnaire (SFQ)[11] and of premorbid personality status recorded using the Personality Assessment Schedule.[12] Self-ratings were chosen because H.S. saw patients in both groups and was not masked to treatment allocation. All assessments of symptoms were repeated after 3, 6 and 12 months.

The cost-effectiveness analysis took a health service perspective, because patients with health anxiety are known to be high users of both primary and secondary care services.[3] Health service use in primary and secondary care was collected after the 12-month follow-up from examination of medical records by staff unaware of treatment allocation. Unit costs in GBP (£) for the financial year 2004–05 were attached to each individual service and summed to generate total costs.[13,14] The cost of CBT was based on the time spent by the therapist with each patient plus relevant overheads. As a key element of total costs, the cost of CBT was varied in sensitivity analysis by increasing it and decreasing it by 50%.

The primary outcome was chosen in advance as the improvement in the mean HAI score between baseline and 6 months, with secondary outcomes of HAI at 12 months, and changes in social function, anxiety and depression scores at 3, 6 and 12 months.

Procedure

Attendees at the clinic suspected of having significant health anxiety were given the short form of the HAI[5] with symptoms assessed over the previous 6 months. Those with a score of 20 or more were given a simple explanation of the nature of health anxiety, an information sheet about the study and invited to take

part if they satisfied the other inclusion criteria described. A score of 20 or more on the HAI was chosen because a previous study had established that people scoring above this threshold had persistent symptoms over a 6-month period.[6] Patients allocated to CBT were seen by H.S. and given separate allocated times for their treatment sessions at the clinic. Each patient also received a manual prepared by P.S. on the principles of treatment.

Patients who satisfied the criteria for inclusion were randomised within 48 h from a remote centre (London) to the two arms of the trial in a 1:1 ratio based on a computerised randomisation sequence of permutated blocks of size 20. Patients allocated to CBT received the booklet and up to seven sessions of CBT each lasting up to 1 h, with additional booster sessions given if sufficient improvement had not been made. Those allocated to the control arm continued to be seen in the clinic as necessary (by any staff member) but received no psychological input apart from their initial interview.

H.S. also audiotaped her interviews with patients; these were assessed and feedback given by J.G. during treatment, but none of this involved further face-to-face training.

Statistical analysis

Main analysis

Statistical analysis was carried out using STATA version 10 for Windows primarily by analysis of variance at each time point with adjustment for baseline differences for each variable. A further regression analysis for longitudinal data using random effects models was carried out for each measuring score, with outcomes of repeated measures of the assessment scores at 6 and 12 months adjusted for the baseline scores, treatment, follow-up and interaction between follow-up and treatment. These models are essential in the analysis of panel data-sets with high variability between participants and low variability within participants. These models produce a matrix-weighted average of these results. Assessment for baseline scores took place before randomisation to treatment; however, adjustment for baseline was essential to correct for the possibility of differences in baseline scores between treatments.

Missing data

The follow-up scores were incomplete for the HAI, BAI, HADS–A and HADS–D assessments. The method of multiple imputations was used to account for missingness in these scores. These method imputes m plausible values for each missing value, under the assumption of 'missing at random'. Missing at random holds when missing data are different from the observed data, but the pattern of missing data is traceable from the observed data.[15] Results were then combined using the rules of multiple imputation. Sensitivity analysis was carried out to compare differences in the imputed outcome estimates of the repeated measures of the assessment scores at 6 and 12 months adjusted for the baseline, to the repeated measures analysis of the incomplete scores.

The cost-effectiveness analysis combined the primary outcome (HAI score) with total service-use costs and the cost of the intervention at 12-month follow-up. Differences in cost were first compared using standard t-tests, despite the skewed distribution of the cost data, as this method enables inferences to be made about the arithmetic mean.[16] Non-parametric bootstrapping was used to assess the robustness of confidence intervals to non-normality of the cost distribution.[17] Incremental cost-effectiveness ratios were calculated.

The trial focused specifically on the treatment of health anxiety in order to compare with a previous study.[7] Abnormal

health anxiety is not necessarily the same condition as hypochondriasis as defined in standard classifications and may include conditions such as abridged hypochondriasis[18] that fall short of the criteria for full hypochondriasis status. The nomenclature and status of these disorders remains controversial with none of the labels for the somatoform disorders achieving diagnostic confidence,[19] but it is likely that most of those with persistent health anxiety would also satisfy the diagnostic requirements for hypochondriasis.

Sample size and randomisation

The study was carried out specifically to determine whether CBT adapted for health anxiety is feasible in a medical clinic and to provide pilot data for an effect-size calculation for a large pragmatic trial, so a formal calculation of sample size was considered unnecessary.

Inclusion and exclusion criteria

Inclusion criteria: Patients who in addition to having significant health anxiety (HAI=20) were: (a) aged between 16 and 65 years; (b) were permanent residents in the immediate area; (c) had sufficient understanding of English to read and complete the questionnaires; and (d) gave written consent for the interviews. Audiotaping of treatment sessions and access to their medical records was requested but not obligatory.

Exclusion criteria: Patients who were: (a) currently under active psychiatric treatment; (b) on psychotropic drugs that had been newly prescribed in the previous 6 months; and (c) actively being investigated for suspected pathology. However, those who had active or pre-existing pathology were not excluded.

Results

Figure 1 shows the flow of participants through the study. In total, 65 patients were selected, mainly by H.S., as likely to have health anxiety: 60 completed the HAI and 59 of these had a score of 20 or more; there was a delay in baseline assessment with one patient, whose score fell to 18 at this time. Ten patients were excluded because three had current psychiatric care and seven declined participation after reading the information sheet and asking questions. Of the remaining 49 patients (26 male, 23 female), 23 were allocated to CBT and these received a mean of 4.3 sessions (range 0–13) of 45–60 min over the 6-month period, with 4 patients receiving a total of 6 sessions between 6 and 9 months. One patient refused access to her general practice records, supplying data on the number of contacts she had with primary care herself; this was also the case for one other participant with respect to consultations in both primary and secondary care. Two patients declined audiotaping because of the risk of discovery of them having attended a genitourinary medicine clinic.

One patient withdrew from the study immediately after allocation to the CBT arm; one other did not turn up for treatment or follow-up (but returned 18 months later and was taken on for treatment – this intervention was not included in the study). Two patients withdrew in the control arm: one before their 3-month assessment and one later. Four other patients did not have assessments at all time points. Fifteen (31%) of the 49 patients (8 in the CBT group and 7 in the control group) had at least one follow-up assessment by telephone (n=8) or by posted letter (n=7). At 6 months, the primary end point, 44 patients were assessed and able to provide some data. Of the 26 patients in the
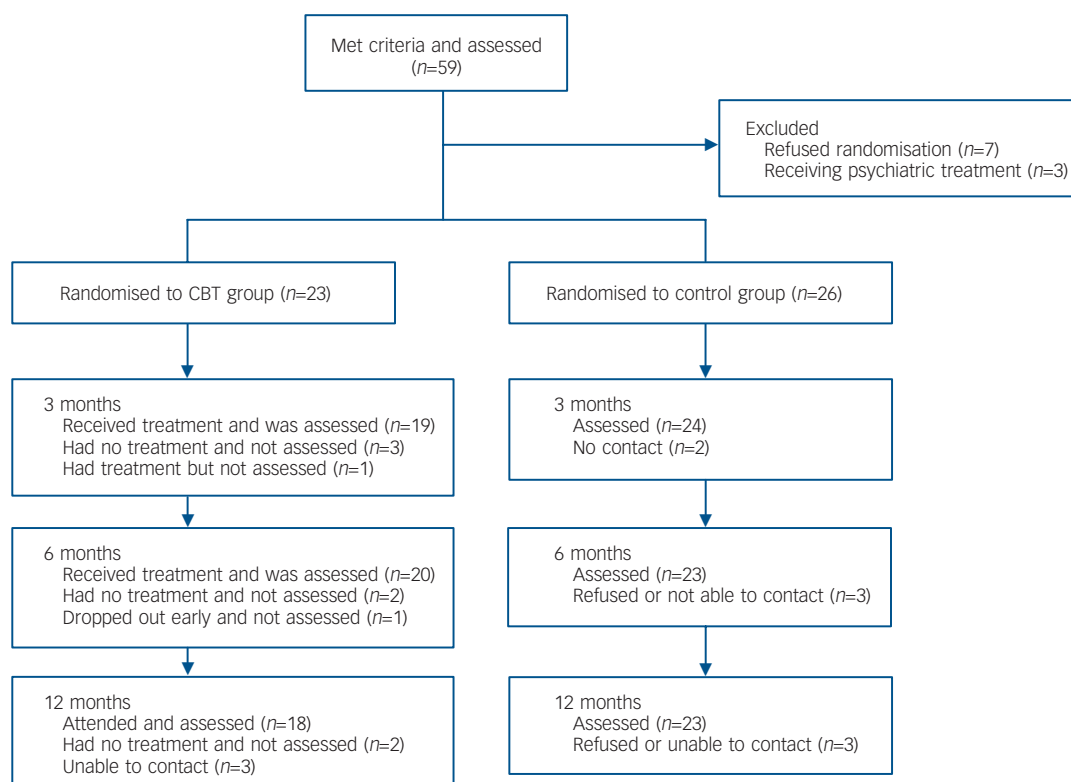
Fig. 1 Flow of patients through trial.

control group, 4 asked to have CBT after 1 year and were treated at that time; their data are not included here. Of the 44 patients who provided data, personality assessment showed that 10 (48%) in the CBT group and 14 (61%) in the control group had a personality disorder. As the economic data were collected from patient records, data on 48 of the 49 patients were available for all follow-up periods, though where data are matched to outcomes in the cost-effectiveness analysis, the sample was correspondingly reduced in size. Further details of the characteristics of the patients, their comorbid disorders and their treatment are given in the online Tables DS1 and DS2.

Efficacy

Using repeated measures analysis of variance with baseline, 6-month and 12-month data, and with imputed missing values, there was significantly greater improvement for health anxiety ($P=0.001$), generalised anxiety with the HADS–A ($P=0.036$) and depression with the HADS–D ($P=0.002$) in the CBT group compared with the control group, with non-significant improvement in the BAI and social functioning (SFQ) over these time scales (Table 1 and online Table DS3), although social function was significantly more improved at 3 months than in the control group ($P<0.01$).

Because the assessments were not masked, even though they were all self-ratings and therefore not subject to observer bias, it was felt important to evaluate the outcome in those assessed by telephone and post only. It was postulated that if H.S. was demonstrating any bias in assessments this would show most prominently in telephone interviews and least in those completed by post. This hypothesis was not supported for any measure. For example, for the health anxiety scores the relative reductions in scores after 1 year for interview ratings in CBT and control groups were 56% and 17%, for telephone ratings 47% and 42%, and postal ratings 43% and 19% respectively.

Economic evaluation

In the CBT group, primary care contacts and out-patient appointments fell over the 12-month period of the study, whereas contacts in the control group remained at largely the same level or fell only slightly (Table 2). The greater part of the reduction in contacts in the CBT group was in the second 6 months, after most of the treatment had been completed (online Table DS2).

The lower levels of service use over follow-up in the CBT group were reflected in £150 lower mean total service costs per patient (£634 v. £484) (Table 3). However, this difference in cost was not sufficient to offset the cost of the CBT sessions, which were on average £427 per patient. Thus, mean costs per patient over 12 months follow-up were £911 in the CBT group and £634 in the control group. None of these differences in costs was statistically significant.

The CBT intervention resulted in improvements in outcomes alongside higher costs, so the incremental cost-effectiveness ratio was calculated at £33 per unit reduction in HAI score. The cost of the CBT intervention was found to be an important cost-driver. When the cost of the intervention was lowered by 50%, the difference in cost between control and CBT groups fell to only £63, generating an incremental cost-effectiveness ratio of only £8 per unit reduction in HAI score. Conversely, when the cost of the intervention was increased by 50%, the difference in cost between the CBT and control group was substantial (£490) and reached statistical significance ($P=0.02$) and the incremental cost-effectiveness ratio increased to £59 per unit reduction in HAI score.

Discussion

Synthesis of results

The results showed that CBT for health anxiety given for a mean of 4.3 sessions per patient over a mean period of 15 weeks

Table 1 Significance of random effects models of panel data[a]

| Assessment | Regression on longitudinal data at 3, 6 and 12 months adjusting for baseline, Coefficient (*P*) | | |
	Treatment	Significance of follow-up at 6 and 12 months	Interaction of treatment and follow-up
Health Anxiety Inventory	6.60 (0.001)	−1.64 (0.172)	0.98 (0.565)
Beck Anxiety Inventory	5.81 (0.055)	−0.98 (0.639)	2.29 (0.417)
HADS–Anxiety	2.93 (0.036)	−0.323 (0.742)	0.428 (0.737)
HADS–Depression	3.79 (0.002)	0.46 (0.506)	−0.55 (0.557)
Social Functioning Questionnaire	1.63 (0.138)	0.39 (0.549)	0.60 (0.523)

HADS, Hospital Anxiety and Depression Scale.
a. After accounting for missing data using multiple imputation with each outcome the repeated measure of the score at 6 months and 12 months adjusted for baseline, treatment groups, follow up (6 and 12 months) and interaction between treatment and follow up.

Table 2 Mean (s.d.) service use over 12 months of study

| | CBT (*n*=18) | | | Control (*n*=23) | | |
	6 months	12 months	Total	6 months	12 months	Total
CBT sessions	4.1 (2.7)	0.3 (0.8)	4.4 (3.2)	0	0	0
Primary care contacts[a]	2.7 (2.8)	2.1 (2.8)	4.7 (5.1)	3.6 (4.3)	3.7 (5.8)	7.3 (9.7)
Out-patient appointments	2.8 (2.4)	1.2 (2.0)	3.9 (3.4)	3.0 (3.8)	1.9 (2.9)	4.9 (6.3)
In-patient stays	0	0	0	0	0.2 (0.7)	0.2 (0.7)
A&E attendances	0.1 (0.5)	0.2 (0.4)	0.3 (0.8)	0.1 (0.3)	0.3 (0.7)	0.3 (0.9)

A&E, accident and emergency; CBT, cognitive–behavioural therapy.
a. Includes general practitioner and practice nurse.

Table 3 Mean (s.d.) total costs per patient in GBP (£) over 12 months of study

Source of cost	CBT group (*n*=18)	Control group (*n*=23)	CBT costs minus control costs	95% CI	*P*
CBT sessions	427 (304)	0	427		
Service costs	484 (354)	634 (602)	−150	−174 to 474	0.354
Total costs	911 (560)	634 (602)	276	−648 to 95	0.141

CBT, cognitive–behavioural therapy.

significantly reduced symptoms of the primary outcome of health anxiety, and the secondary outcomes of generalised anxiety and depression after 6 and 12 months compared with a control group. These findings suggest that CBT for health anxiety is likely to be of value in secondary as well as in primary care.

Limitations

The trial had limitations: its numbers were small, the selection of patients was more opportunistic than systematic, the assessments were not masked (even though all were self-ratings), and only one therapist gave the treatment. However, before the trial, H.S. did not have any experience of any form of psychological treatment although she had carried out previous research as an assessor in psychiatric studies. The control group received no treatment apart from a single interview and so therapy time was not equivalent; a recent study has shown that the effects of CBT (in a similar population with medically unexplained symptoms) are largely attenuated when treatment time is equivalent.[19]

Implications

Our findings are encouraging and one of their most striking aspects was the maintenance of therapeutic benefit beyond the period of active treatment. Only four patients had any treatment after 6 months, yet the differences in scores between the groups were as great at 12 months as they were at 6 months (online Table DS3). This is somewhat unusual, as although CBT has been shown to be effective in the short- and medium-term treatment of many anxiety disorders, including those with medically related conditions common in liaison settings,[21–23] there is also evidence that its effects diminish in the medium and long term.[23–25] Part of this apparent loss of efficacy is the natural tendency for many of these disorders to improve over time irrespective of specific treatment, but this may not apply to health anxiety as it is more persistent.[6] The level of improvement was substantial and at 12 months the levels of anxiety in the treatment group (mean HAI score=10.4) were generally well within the normal range (mean HAI for controls=9.4).[5] This symptomatic improvement also extended to social functioning as the mean scores at 6 months (5.1) and 12 months (5.2) were only marginally greater than the mean of 4.6 found in a large random sample in a national survey.[11]

As these gains were achieved with a mean of 4.3 sessions of treatment it appears that this adaptation of CBT for health anxiety in such clinics could offer a significant opportunity to reduce, if not eliminate, an unpleasant, persistent and often undetected form of morbidity, especially in some clinics where health anxiety is particularly severe.[26] However, it is not clear to what extent the bibliotherapy component contributed to the improvement. Most of the patients regarded the written material as helpful (online

Table DS2), but verbal feedback suggested this was being used as an aid to recognition of abnormal health perception and to work done in therapy. A preliminary study has, however, suggested that bibliotherapy alone may be of benefit without the need for face-to-face contact.[27]

It is also well known that early trials of many interventions generally demonstrate greater effect sizes than later large trials, for a variety of reasons,[28] and it would be unreasonable to expect the same active/control difference in a large trial. H.S. was not masked and this constitutes a limitation to the study, but the fact that all assessments were self-reports and the evidence that there were no differences in the telephone and postal active-control treatment differences suggestive of bias gives more credence to the findings. Although the benefits of this approach, which we accept might accrue from other structured psychological treatments, could be influenced by many factors, we feel that the administration of treatment within the framework of the clinic by one of its regular practitioners was an important one. In this setting there is also the possibility of booster sessions, or even simple reminders, of the essential aspects of treatment that can ward off significant relapse, and the bibliographic component of the treatment may also help in this task. The continuing benefit is also important in offsetting the cost of treatment through reduced consultation.

Planned developments

The results suggest there is no reason, in principle, why future treatment for health anxiety should not include many other secondary care doctors having this expertise. This would require much greater training to increase awareness of psychological aspects of health anxiety as well as teaching health service staff to use the technique. Such a development is in keeping with recent recommendations about the expansion of CBT away from classical psychiatric locations[29] and, more radically, could be the start of what Rief & Sharpe[30] have called 'a move toward a psychologically sophisticated healthcare system in which psychological assessment and intervention are fully (re)integrated into medical care'. This would lead to liaison psychiatric services acting not just as a secondary referral source for a minority of patients, but as an integrated service within secondary medical care in which both identification and treatment of health anxiety would be improved and expensive investigations reserved for those that really require them rather than as a procedure driven by defensive medicine and clinical doubt.

Our findings also suggest that benefit is likely to be achieved not only in terms of reduced morbidity but in improvement of clinic function by reducing the number of (unnecessary) consultations, although a much larger study would be necessary to have the power to confirm this. Service use by participants in the CBT group was substantially lower than by those in the control group in the second 6 months of the study after treatment had been completed, suggesting that over a longer follow-up period, the cost of the CBT could be offset, but only if the improvements seen over 12 months were maintained. Cognitive–behavioural therapy for health anxiety improved outcomes, but the costs were not entirely offset by reduced service use elsewhere in the health system, and so the total costs were slightly higher. The incremental cost of the intervention was £33 per unit reduction in HAI score. Adoption of CBT for health anxiety would thus depend on decision-makers' willingness to pay for improvements in outcomes. The sensitivity analysis demonstrated that the cost of CBT has a substantial impact on the cost-effectiveness of the intervention. If the costs of CBT can be kept low without having an impact on its effectiveness, then there is an increasing possibility that the costs will be offset by lower levels of service use, as seen in the CBT group, elsewhere in the health system.

The results suggest that CBT is significantly more effective and may have a more positive effect on health service costs than simple control measures, so that the cost per unit improvement effectiveness outcome is low. A pilot study such as this can only provide limited evidence of efficacy and cost equivalence; however, a large-scale study is currently being carried out on the efficacy of this treatment in other medical clinics (www.controlled-trials.com/ISRCTN14565822).

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Psychiatry in the Old Testament

Lost in translation: the biblical classification of personality disorder

George Stein

The Book of Proverbs gives advice on the best way to achieve a contented life and a high standard of personal morality. Those who can achieve this are called 'the wise' who are righteous, but those who cannot are 'the fools' who are wicked. Psychiatric interest lies in the description of the latter. Unfortunately, the single word 'fool' in the St James's version (as well as in all later editions) was used as the English translation for eight separate Hebrew words, each of which described a quite distinct character. In this way the elaborate ancient Hebrew character typology was effectively lost in translation.

The main types of Hebrew fool were: *kesil* (literally, stupid and over-confident), an unintelligent person frequently involved in quarrels; *ewil*, a morally blind individual, but more intelligent than *kesil*; *pethi*, a simpleton, perhaps with intellectual disability, who cannot plan for the future; the *hasar-leb* (literally, empty-hearted), also of poor intelligence, who neglects himself and his property. Other characters are also occasionally mentioned: *ba-ar*, a crude individual; *nabal*, a brutal and depraved man (the word *nabal* also means wine skin suggesting a link with alcoholism); *holel*, an irrational madman; *les*, also translated as a scoffer, was a contemptuous narcissistic individual while *belial* (a scoundrel) was an aggressive psychopath who shows most of the features of DSM–IV antisocial personality disorder. Finally, a female character *essa zarah*, the strange woman or loose woman, a loud, rebellious person, constantly on the go, has numerous affairs and shows both borderline and histrionic features.

A much more detailed description and analysis of each of these character types, some of whom resemble DSM–IV personality disorder types, is given by Fox (*Proverbs 1–9. The Anchor Bible*, vol. 18A; Doubleday, 2000), who wrote that the fools of the Book of Proverbs were 'aberrant individuals, just stupid folk who [caused] harm above all to themselves and whose punishment [was] inevitable'. This definition will seem familiar to most psychiatrists who work with people with personality disorders. It is also not too far from Schneider's original definition (in his 1923 title *Die Psychopathischen Personlichkeiten*) of an individual with a personality disorder as 'a person who suffers or makes others suffer because of his abnormal personality'. The Book of Proverbs and its character typology was written more than 2500 years ago.