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**Intervention with feedback using
Outcome Questionnaire 45 (OQ-45)
in a Swedish psychiatric outpatient population.
A randomised controlled trial.**

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ABSTRACT

Aim

The objective of the study was to evaluate the efficacy of the Outcome Questionnaire 45 (OQ-45) with feedback in a Swedish psychiatric outpatient population using a randomised controlled design.

Method

In all 1,720 patients made at least one regular visit to the clinics in the period 12 February 2007 to 10 February 2008 and received information about the study. Of these, 374 patients (22%) agreed to participate. After written consent, 188 patients were randomised to the feedback group and 186 patients to the control group. Those constituted the intention to treat, ITT group. 262 patients (70%) completed the OQ-45 questionnaire at least twice, and they were included in the per protocol analysis. Those who improved less than expected and were at risk for treatment failure were called alerted patients.

Results

There was a tendency that patients who received feedback improved more than the controls in OQ-45 total score. In the ITT analysis the p-value was 0.061 and the effect size $g=0.21$. In the per protocol analysis the p-value was 0.076 and the effect size $g=0.24$.

In the intervention group, 27% of the patients were alerted because of risk of treatment failure versus 28% in the control group (reaching level of alertness). The OQ-45 differences between the intervention and control groups did not significantly differ for patients who were alerted/reaching level of alertness and for non-alerted patients ($g=0.17$ and $g=0.28$, respectively).

Conclusions

The feedback group had a tendency to improve more than the control group, possibly indicating that the method is effective, and the result (basically) supports previous findings.

KEYWORDS

Outcome Questionnaire 45 (OQ-45), Randomised controlled trial, Psychiatric treatment, Psychiatric outpatient population, Feedback, Intervention

INTRODUCTION

The prevalence of mental illness is increasing worldwide [1], increasing the demand for psychiatric treatment. In order to meet this demand, well-functioning methods to evaluate and guarantee the treatment effects and achievements in psychiatry are necessary. Evaluation is important both during ongoing treatment and at discharge.

The response of patients to different treatments within different diagnoses is a broad area of research. Results are highlighted in guidelines and recommendations on screening, effective care and intervention as well as diagnoses and treatment of each group of diagnoses [2]. However, forecasting the effect of psychotherapy treatment in individual cases is complicated and other factors besides diagnosis influence the outcome [3].

A large review of treatment results for different types of therapy shows that around half, 40-60%, have improved after completed therapy. A fairly large group, 35-40%, remain unchanged, and 5-10% of the patients are in a worse condition when treatment is completed. The last group is usually in a worse psychological condition when treatment is initiated and has a higher attrition rate compared with the two other groups [4-5].

Therapists generally tend to be overly optimistic in assuming that what they are doing is right, even when, in fact, it is not [6], and patients do not voluntarily tell their therapists when they are not improving. According to previous research [6-7], an important innovation in psychotherapy research is the concept of patients providing feedback to their therapists about their progress.

There are currently few methods allowing quality control and evaluation of the treatment given to patients suffering from mental health problems during ongoing treatment [7]. One such method is the Outcome Questionnaire-45 (System) which provides therapists with their patients' feedback online. This has been shown to improve treatment outcomes, identify patient deterioration before it goes too far, and shorten the length of treatment [4, 8].

Evaluations of the OQ-45 method have shown positive results. Patients had significantly better outcome if the therapist used this method during treatment and read the feedback message before the counselling sessions, compared to patients of therapists who did not read the feedback before counselling. The proportion of patients who improved increased and the proportion of patients whose condition worsened decreased. The effect is most pronounced for those patients at risk of treatment failure. Risk of treatment failure is defined based on results from previous OQ-45 studies. Those with OQ-45 scores over a certain level during ongoing treatment are at risk for treatment failure, the others are not at risk [18, 19].

A recent meta- and mega-analytic review [8] of data from six large studies [9-14] reported that different feedback procedures were effective in enhancing treatment outcome, especially for those patients at risk of treatment failure. A total of 6,151 subjects were included and, of these, 1,382 (22%) were at risk of treatment failure.

The subjects at risk of treatment failure were analysed separately in the meta-analyses. Three types of feedback (*a*: feedback to therapist only, *b*: feedback to both therapist and patient, and *c*: feedback to both therapist and patient including clinical support tools) had significantly higher effect than the group with no feedback. The Hedge's *g* concerning OQ-45 changes

were -0.28, -0.36 and -0.44 respectively in the ITT analyses and -0.53, -0.55 and -0.70 respectively in the per protocol analyses.

The patients at risk thus have stronger effects than those not at risk but the effects in the later group were also significant. In the patients who were not in the risk for treatment failure, the mean post treatment OQ score difference was for the group with only therapist feedback, ITT $g = -0.12$ and per protocol $g = -0.30$, and with both therapist and patient feedback, ITT $g = -0.18$ and per protocol $g = -0.32$.

In our study we did randomization for the individual patient and not for the therapists, as was the case in the Hawkins's study. Thus a therapist could have both feedback and control patients.

The Hawkins et al study (2004) [12] differs in several aspects from the other studies. The study was performed in a hospital outpatient setting, while the other studies were conducted at a large university counselling centre. The mean intake OQ-45 score was larger in the Hawkins et al [12] sample (83 points versus 70 points with SDs of 22-23 in all other studies).

Because of the similarities between the study by Hawkins et al and our study, some additional details from their study will be presented. Of the 715 patients who were offered the intervention, 313 (44%) accepted. One hundred and eleven patients (36%) did not answer OQ-45 at least twice and were excluded from the analysis. The mean number of sessions in the included subjects was 8.2. The effect size for all types of feedback versus treatment as usual was $d = 0.31$ and for therapist/patient feedback versus treatment as usual $d = 0.33$. The feedback interventions in this study enhanced the outcomes of both on-track and not-on-track patients alike. Testing the effects of feedback among the patients at risk of treatment failure only, they found no significant differences.

Objectives: The purpose of the present study was to evaluate the efficacy of the technique based on the results of Outcome Questionnaire 45 (OQ-45) with feedback [15] in a Swedish psychiatric outpatient population using a randomised controlled design. The clinical support tool available with the Outcome Questionnaire 45 (OQ-45) was not used in this study.

The specific objectives were:

- To compare efficacy in the patients, where both therapist and patient received feedback (feedback group) with the patients where there was no feedback to therapist and patient (control group) regarding:
 - Changes in the OQ-45 total scale (primary outcome measures).
 - Changes in OQ-45 subscales of psychiatric symptoms, interpersonal problems and social functioning (secondary outcome measures).
 - Frequency of OQ-45 scores indicating alert status (secondary outcome measure).

METHODS

Participants

The study was performed in two general psychiatry out-patient clinics in Psychiatry Skåne in Malmö, Sweden, between 12 February 2007 and 10 February 2008. The two clinics cover a geographical catchment area of 200,000 inhabitants. The clinics assess and treat patients with mental disorders with the exception of substance use disorders, schizophrenia and other psychotic disorders. The patients are offered medical treatment and various types of psychotherapeutic treatment.

Settings

The outpatient clinics consist of psychiatric teams with staff including psychiatrists, qualified mental hospital nurses and nurses' assistants, clinical psychologists, social workers, physiotherapists and occupational therapists. Any of these professional categories could be the primary therapist, i.e. responsible for the patient's treatment. Usually, the primary therapist assesses the patients and often initiates treatment in the same session. The total number of patients in 2007 was 1,495 for one clinic (Drottninggatan) and 1,882 patients for the other (Fosievägen). Some of these persons were only assessed by an expert at the clinic, but not offered further treatment in the psychiatric clinics. This group constituted a minority of the patients, but exact numbers are not available. The patients were divided into new admissions (no contact in the last three months) and others (contact in the last three months). However, the results did not differ between patients with new admissions and others. In addition there were no differences between the two settings (Drottninggatan and Fosievägen). Therefore all patients were treated as one group in the analyses.

Outcome Questionnaire 45

Outcome Questionnaire 45 with feedback (OQ-45) [16] aims to improve treatment results by continuously monitoring the patient's progress during treatment. By simple OQ-45 ratios, this method offers feedback to the therapist and patient about the patient's level of function regardless of the severity of the psychiatric conditions, by comparing the patient's current response with the expected response to the treatment.

There is a module, clinical support tool, available with the OQ45. This module provides clinical support in cases where the patient does not follow the expected response to the treatment, with additional questions regarding the therapeutic alliance, the patient's motivation to change and the patient's social network. This clinical support tool was however not used in our study.

Implementation of the OQ-45 methodology

From autumn 2006 until the project launch on 12 February 2007, extensive preparation work, including information to the staff, was conducted.

Group training sessions were held. In addition individual introduction to the study and the OQ-45 method was provided when the therapist was assigned his/her first patient from the feedback group. Detailed information about the implementation is presented in Hansson et al 2009 [17].

Trial Design

At their first visit to the clinic during the study period, all patients were offered participation in the study. They received an information letter about the study on arrival at the reception. The reception staff made a note in the patient's record to avoid repeated information. The information letter was available in Swedish only and translation was not offered, for economic reasons.

Patients agreeing to participate signed a letter of consent which was handed in at the reception. The patient received the OQ-45 questionnaire for completion, and this was returned to the receptionist. In return the patient was given a new envelope with information on which group (feedback or control group) he/she was randomised into. The decision to participate was registered, along with information about the primary therapist (some patients had several therapists and in such cases one was appointed as the primary therapist).

At each further visit to the clinic, the receptionist gave the OQ-45 questionnaire to the patient. Patients who saw their primary therapist more than once weekly were asked to complete the questionnaire once a week. The receptionist received the completed questionnaire for scanning before the patient met with the therapist. The process was identical for patients in feedback and control groups and the receptionists were not aware of group to which the patient had been allocated.

Interventions by OQ-45

For patients belonging to the feedback group, the therapist received a feedback message showing total score on OQ-45, the subscales and a diagram of treatment progress. From the second visit the feedback was available to the therapist via a web application as soon as the questionnaire had been scanned by the reception staff. The therapist read the feedback before the patient was asked to enter for counselling.

Patients in the feedback group also received feedback themselves, consisting of the treatment progress diagram. The patient feedback was handed out to each patient by the therapist. For this group the design also included an increased cooperation with the Swedish Social Insurances Agency (SIA). In Sweden there is a close cooperation between psychiatry as well as somatic care and Social Insurance Agency. Possible effects of the SIA technique on sickness benefits is therefore of relevance and will be presented in a separate paper. Like the patients in the feedback group, patients in the control group completed the OQ-45 prior to each treatment session, but neither patient nor therapist had access to any feedback.

The study was approved by the Ethical Review Committee at Lund University.

Sample size calculation

We included all subjects in the calculations, not only those at risk of deterioration. Assuming the same effect sizes as in psychotherapy research in general [6], with 15% difference of successful cases between the intervention and control groups, a power of 0.80 and a significant level of $p < .05$ would necessitate a sample of 600 subjects.

Randomisation, sequence generation, allocation concealment and blinding

Two different versions (feedback and control) of patient information were put into envelopes in a pre-randomised order. The randomisation list was prepared using a computer program which assigned the patient to one of the two groups at random. The randomisation was balanced in blocks of 8, 10 or 12 patients where the size and the order of the blocks were drawn.

The sealed envelopes were available at the reception and handed out in the same order as the patients were registered. Everyone involved – patient, receptionist, therapist and researcher – were blinded to the allocation.

OQ-45 Measures

OQ-45 – The questionnaire consists of 45 statements (subscales *Symptom distress*, *Interpersonal difficulties* and *Social function*) and the response options *never*, *seldom*, *occasionally*, *often* or *almost always*.

Each item receives a score on a five point scale (range 0-4). Some of the items are asked in reversed order. The total score (TOT) is achieved by summing up the patient's responses to all 45 items, 0-180 points. The higher the score, the higher the level of dysfunction found.

Changes of 14 points or more in the total score are considered reliable [15].

Missing values were replaced with the rounded average of the items answered by the individual in the subscale concerned.

The manual (OQ Measures, 2004) [18] uses the following intervals for classification of mental health: 0-63 points (low), 64-84 points (medium) and 85-180 points (high).

The OQ-45 has proved to contain good test qualities. Reliability has been tested in both non-patient and patient populations. The internal consistency reliability is good; alphas varied for the different subscales between 0.70-0.92 and for the total scale 0.93 in both non-clinical and the clinical populations. A three-week test-retest gave a reliability value of 0.84 for the total scale [19]. The Swedish version of the scale has also been analysed in terms of psychometric characteristics by Wennberg et al (2010) [20]. They studied 227 subjects with substance use disorders. The test properties were satisfactory except for a somewhat low internal consistency in the social role subscale.

Diagnoses

Diagnoses according to ICD-10 should be given to all patients attending the clinics. However only 212 (57%) of 374 patients received a diagnosis. We therefore used the diagnoses available from the sickness absence/benefit certifications in the SIO charts of the 202 study

participants receiving sickness benefit when entering the study. These diagnoses were considered reliable. Diagnoses for the remaining 172 study participants were extracted from the patients' computerised medical charts (MELIOR) at the Psychiatric Services, Skåne University Hospital. After this procedure, only 32 (9%) individuals lacked diagnoses.

The diagnostic procedure is obviously not optimal. However, we chose to present our diagnostic data to add additional information on our sample.

Statistical methods

The statistical analysis was carried out with SPSS for Windows 14.0 [21] and the significance level set at $p < 0.05$.

For nominal data, a chi-square test was used when comparing proportions.

The change from the initial to the last assessment in each group was measured with a paired sample t-test. A univariate analysis of variance was used to analyse the difference between the feedback group and the control group concerning treatment results [22-23]. The value of the last assessment has been used as the dependent variable, the randomisation group as a fixed variable and the value of the first assessment as covariates. Hedge's effect size was calculated with the Comprehensive Meta-Analysis version 2.0.

We analysed both the intention-to-treat, ITT, effect (including all subjects with initial assessment with OQ-45) and the per-protocol effect (including all subjects with two assessments with OQ-45). The 'last observation carried forward' technique was used, and in the ITT analysis this meant that if there was only one assessment it was used as both initial and final score.

RESULTS

Participants flow [24] (FIGURE 1)

Recruitment

In all 1,720 patients received information about the study. Of these, 374 patients (22%) agreed to participate. After written consent, 188 patients were randomised to the feedback group and 186 patients to the control group.

Of the in total 83 possible therapists, 56 actively participated in the study, in so far as that they had at least one patient participating in the study. The therapists did not give informed consent.

The therapists could not choose whether they should participate in the study or not. The therapists' participation was completely dependent on the participation of their patients (see trial design).

The number of patients participating in the study per therapist ranged from 1 to 21, with a median value of 4.

Ambivalence among therapists concerning the method is probably the explanation why many of them did not use the method. The therapists' attitude with regard to usefulness of feedback reports was not evaluated in our study but there were no indications, from neither therapists nor patients, that the method was harmful to the therapeutically alliance.

Baseline data

Baseline data regarding the study population is presented in *Table 1*.

Only 7% of the participants made their first visit to the clinics during the study year. No significant differences were found between first visits and other study participants concerning the number of visits during the study year, sex and age.

There was a non-significant higher rate of unemployment in the intervention group but no other important tendencies.

Number of visits and assessments with OQ-45

Twenty-one patients (6%) visited the clinics only once during the study period, 6 (3%) in the intervention group and 15 (9%) in the control group. The number of visits did not differ between the intervention group and the control group (1-10 visits 50% and 52% respectively, 11-20 visits 21% and 21% respectively and >20 visits 30% and 28% respectively).

Of all 374 patients, 262 (70%) assessed themselves on more than one occasion. Among the subjects with only one assessment, 52 were in the intervention group and 60 in the control groups. The mean number of assessments in the intervention group was 6.1 vs 4.7 in the control group.

Main outcome: change in OQ-45

In the ITT analysis the intervention group had a larger reduction in the total OQ-45 than the control group, but this did not reach a significant level ($p=0.061$). The effect size was $g=0.21$. The intervention group decreased 2.4 points more than the control. The symptom distress subscale showed larger differences between the groups than the interpersonal and social functioning scales (*Table 2*).

In the per protocol analysis the results were similar compared with the ITT analysis with a larger improvement in the intervention group than the control group ($p=0.076$). The effect size was 0.24. The intervention group decreased 3.2 points more than the control group. The symptom distress subscale showed the largest difference between the groups (*Table 2*).

Outcome related to severity categories

The group with high initial total scores (85-180 points) on OQ-45 in the ITT analysis included 70% and, in the per protocol analysis, 71% of the patients. In the group with medium total scores (64-84 points) the figures were 27% and 27% respectively, and in the group with low total scores (0-63 points) 3% and 2% respectively.

There were no significant outcome differences between the intervention or control group in any of the severity groups. In the high initial score group the ITT effect size was $g=0.17$ and the per protocol effect size was $g=0.16$. Corresponding figures for the medium total score groups were $g=0.25$ and $g=0.30$ respectively.

Outcome in alerted and non-alerted patients

Only per protocol analyses are presented. A total of 37 (27%) patients in the intervention group and 35 (28%) in the control group were alerted/reaching the level of alertness. Of these, 20 and 16 respectively were alerted/reaching the level of alertness several times. In the alerted/reaching the level of alertness group, OQ-45 increased in the intervention group with 0.57 (14.5) points and in the control group with 3.26 (17.0) points. In the non-alerted groups, corresponding figures were -8.7 (12.4) and -5.5 (10.89) respectively. The corresponding effect sizes were $g=0.17$ and $g=0.28$ respectively.

Outcome related to diagnosis

Only per protocol analyses are presented. The effect sizes were not significant because of small sample sizes. Effect sizes were in the depressive group $g=0.33$, in the anxiety group $g=0.11$ and in the personality disorders group $g=-0.03$.

DISCUSSION

The main finding of the study was the tendency that the intervention group reduced the OQ-45 scores more than the control group (ITT-analysis, $p=0.061$ effect size $g=0.21$, per protocol analysis, $p=0.067$ effect size $g=0.24$).

Limitations

Only 22% of all patients attending the clinics participated in the study. This acceptance rate was lower than expected. Providing information about the study in an envelope at the clinic reception as opposed to personal information by the therapist may have yielded a sense of non-importance and thus non-participation.

Some of the previous studies using OQ-45 have been designed to either measure therapist effect [25] or to evaluate the OQ-45 tool [26]. In these studies therapists directly recruited the patients, which may have increased participation rates. However, other studies have used similar recruitment procedures to our study [9-14]. They have achieved higher participation rates than in our study possibly because the OQ-45 was a standard tool for all patients in those studies. However in the Hawkins et al study [12], which has many similarities with our study, the acceptance rate was 44%, which is rather low considering that OQ-45 was a standard tool in their setting.

Another limitation was that only 262 (70%) out of 374 study participants rated themselves on more than one occasion. We did not measure whether the individual therapist used the OQ-45 tool according to the study design. The Hawkins et al study [12] had even lower rates. A mere 64% filled in the OQ-45 at least twice in their study, perhaps indicating that responding to OQ-45 may be a general problem, at least in patients with moderate to severe psychiatric disorders.

Further, most patients in our study were engaged in treatment prior to enrolment in the study. The proportion of first visits in the present study was only 7%. Two aspects are crucial in the treatment course: the initial symptom/function level and the level of change within the first 3 treatment occasions [6]. Thus the analysis of differences between the feedback and control groups became more difficult to illustrate/show.

Previous studies have found that the level of change within the first three treatment occasions is important for the treatment course and that the method is more efficient if applied from first visit [6]. In our study, the patients were measured a while after beginning of treatment which may account for the marginal progress of patients in both conditions. Thus the change did not exceed measurement error in any of the two conditions. The time between beginning of treatment and first measurement makes the comparison with studies by Lambert and co-workers difficult.

The most remarkable difference between our study and the US studies was the mean number of sessions – 18.2 in our sample versus 8.2 in the Hawkins et al study and similar number of sessions in the other US studies. The difference in addition to the low number of new patients may indicate that our patient sample probably has more longstanding and severe symptoms than the US samples. This is supported by the mean initial OQ-45 score in our sample of 92 compared with 83 in the Hawkins' sample and 70 in the other US studies. In addition a sample of psychiatric inpatients in US had a mean score of 89 [15].

Generalisability

The key finding was a tendency to a larger improvement in the feedback group than the control group, indicating that the method is effective and basically supports the finding of Shimokawa et al. (2010) [8]. The lower effect size in our study compared with Hawkins and

coworkers (2004) [12], 0.21/0.24 versus 0.30/0.31, could be explained by the limits of our study presented above.

Furthermore, those with medium initial scores had larger effect sizes than those with high scores (ITT/ per protocol, 0.25/0.30 versus 0.17/0.16, indicating that perhaps those with medium score have greater potential to change compared to those with high scores.

Feedback effect

We found no differences between patients at risk of worsening (alert/reaching the level of alertness patients) and those who were not. Hawkins et al. reported similar results. This indicates that feedback procedures *per se* facilitate improvement in patients in general, not only those at risk of deterioration (alert patients). However in samples with less severity than our and Hawkins study [12] the effects in patients with risk for deterioration (alert patients) are considerably greater than in patients with no risk [8].

CONCLUSION

The main finding was a tendency for feedback intervention to facilitate improvement in psychotherapy in general, both in patients with risk of deterioration (alert patients) and other patients. The largest improvement tended to be in patients with moderate level of impairment.

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LEGEND

Figure 1 - Participants flow.

CONSORT 2010 statement: Guidelines for reporting parallel group randomised trials.

Participants flow

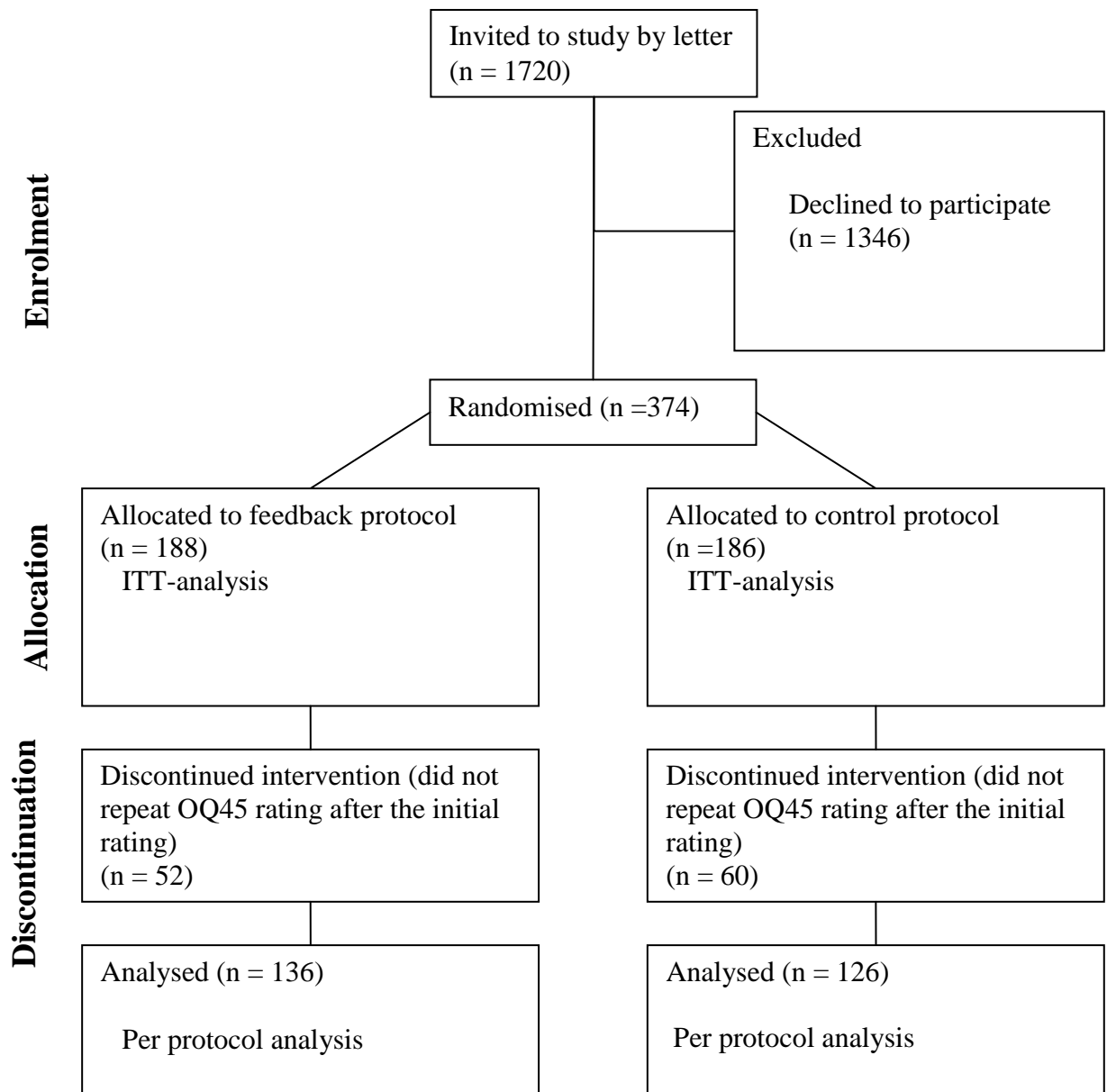


Table 1 – Baseline data regarding the study population. Diagnoses with rates lower than 5% are not reported

N	Total	Feedback	Control
	374	188	186
Mean age (\pm SD)	39 (13)	38 (12,8)	39 (14,06)
Men	100 (27%)	43 (23%)	57 (31%)
Women	274 (73%)	145 (77%)	129 (69%)
Single	233 (62%)	111 (59%)	122 (66%)
Unemployed	168 (45%)	96 (51%)	72 (39%)
First visits (no contact with psychiatric services during last 3 months)	25 (7%)	15 (8%)	10 (5%)
Individuals at the SIA.	238 (64%)	125 (66%)	113 (61%)
Individuals not born in Sweden (SIA data)	32/238 (13%)	16/125 (13%)	16/113 (14%)
Sickness benefits from the social insurance system (SIA data)	205/238 (85%)	109/125 (87%)	96/113 (85%)
<i>Diagnosis axis I:</i>			
Depression	119 (32%)	58 (31%)	61 (33%)
Bipolar disorder	29 (8%)	10 (5%)	19 (10%)
Anxiety syndrome	94 (25%)	49 (26%)	45 (24%)
Personality disorder	45 (12%)	23 (12%)	22 (12%)
Missing/No diagnosis	32 (9%)	13 (7%)	19 (10%)
Number of subjects attending the clinics 2006	318 (85%)	154 (82%)	162 (87%)
Number of visits in 2006 among attendants (mean)	15.8	16.7	14.9

Table 2 - Improvement of OQ-45 total scales and subscales by intervention group. ITT and per protocol analysis. Two-tailed significance levels and Hedge's g.

	<i>Intervention group (ITT/Per protocol)</i>		<i>Control group (ITT/Per protocol)</i>		<i>Significant level</i>	<i>Effect size (g)</i>
	<i>N=188/136</i>		<i>N=186/126</i>			
	<i>Initial data</i>	<i>Change</i>	<i>Initial data</i>	<i>Change</i>		
<i>ITT analysis</i>						
<i>Total score</i>	93.0 (15.3)	-4.5 (11.9)*	91.0 (16.6)	-2.1 (11.1)*	<i>p=0.061</i>	<i>0.21</i>
<i>Symptom distress</i>	56.2 (12.1)	-3.0 (8.4)*	54.5 (13.0)	-1.4 (7.1)*	<i>p=0.066</i>	<i>0.21</i>
<i>Interpersonal difficulties</i>	21.9 (3.1)	-0.7 (3.0)*	21.4 (3.9)	-0.3 (3.7)	<i>ns</i>	<i>0.12</i>
<i>Social function</i>	14.9 (4.8)	-0.7 (4.5)*	15.1 (4.3)	-0.3 (4.1)	<i>ns</i>	<i>0.09</i>
<i>Per protocol analysis</i>						
<i>Total score</i>	93.5 (14.2)	-6.2 (13.6)*	92.0 (16.7)	-3.0 (13.4)*	<i>p=0.067</i>	<i>0.24</i>
<i>Symptom distress</i>	56.9 (11.1)	-4.2 (9.6)*	55.3 (12.9)	-2.1 (8.5)*	<i>p=0.087</i>	<i>0.23</i>
<i>Interpersonal difficulties</i>	21.7 (3.2)	-1.0 (3.5)*	21.3 (3.0)	-0.5 (4.5)	<i>ns</i>	<i>0.12</i>
<i>Social function</i>	14.9 (4.6)	-1.0 (5.3)*	15.4 (4.1)	-0.5 (5.0)	<i>ns</i>	<i>0.10</i>

** significant at the 5% level between pre-treatment and post-treatment levels*