Author's response to reviews

Title: A real-life observational study of the effectiveness of FACT in a Dutch mental health region

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Author's response to reviews: see over
Author reply

Please find enclosed the revised version of our manuscript "A real-life observational study of the effectiveness of FACT in a Dutch mental health region". We have incorporated all comments. Below we give further details per comment.

REVIEWER 1 J. Remmers van Veldhuizen

We thank J. Remmers van Veldhuizen for his valuable comments.

Major Compulsory revisions:
1. The FACT model needs some more explanation in the context of Dutch Mental health care. In this article it becomes not clear how FACT works with two approaches from one multidisciplinary recovery-oriented team:
   a) individual casemanagement and home visits from a multidisciplinary team for SMI who are rather stable.
   b) shared caseload with full ACT approach (with patients on the digital FACT-board and daily staff meetings and handovers to coordinate the intensive ACT treatment and care).

These approaches/methods are integrated in one team, working in a system with close cooperation with hospital and daycentre facilities.


The model started in 2004 and at this time more than 60 FACT teams in the Netherlands have been started (versus 25 ACT teams) on a population of 16.000.000. An increase to 200 FACT teams is expected.

FACT is now better defined in the introduction. Page 5, second paragraph:
In The Netherlands, a Dutch variant of ACT was developed: ‘function-ACT’ (FACT) [7]. Members of FACT teams conduct a style of assertive outreach by paying both announced and unannounced home visits, and by using supportive legal measures when needed [8]. The difference with ACT is that FACT can be a comprehensive care system. FACT combines two approaches for SMI patients within one multidisciplinary recovery-oriented team: (a) individual case management and home visits for extensive care SMI-patients who are mostly stable; (b) shared caseload with intensive full ACT approach for patients in need for intensive care. These are discussed in daily staff meetings similar to the practice conducted in ACT. When, over time, the care needs of these patients change, they remain in the same multidisciplinary team (continuity of care). These teams are in charge of the transition between various intramural and extramural institutions [7]. In Maastricht, the FACT teams remain responsible for care even when patients are admitted. Thus, FACT teams serve a diverse population of SMI patients with various levels of need for care. On the other hand, “classic” ACT serves only those SMI patients who are in crisis or have the highest needs for care. As patients in crisis need more guidance than more stable patients do, the average frequency of contacts
**is lower and caseload is higher for a FACT team than for an ACT team.** Although FACT was developed for the Dutch mental health care system, it has been noted that its features may also be applicable in other countries, such as the U.S. [9].

In addition, we refer to Bond&Drake 2007. Page 5, line 23-25: *Although FACT was developed for the Dutch mental health care system, it has been noted that its features may also be applicable in other countries, such as the U.S. [9].*

**Minor essential revisions:**

2. In the discussion and conclusions they could consider some hypotheses regarding mediating mechanisms to explain their findings. In the Dutch discussion we are focusing on some possible effective aspects of FACT:
   1) FACT (with intensive ACT and stepped down treatment in the same team) arranges more continuity of care in comparison with a system with ACT teams and so called stepped down teams. Early signs of relapses can be treated, support can be given in episodes of life events etc.
   2) FACT pays more than in the past attention to the EBM treatment of the 80% group (relatively stable SMI) with the different EBP by psychiatrist, psychologist, addiction workers and IPS (Individual Placement and Support), working as team members in the multidisciplinary team.
   3) FACT focuses on 100% of the SMI in a specific region 45-55,000 inhabitants and includes the traditional ACT-patients and the other 80% of SMI as well. This gives more incentives for working with the community towards social inclusion.

We elaborated on these 3 points in introduction and discussion, when discussing differences in effect between studies.

Discussion page 15, line 5, 6  
*Because of the continuity-of-care principle these interventions are continued when treatment by the psychiatrist is finished.*

Discussion, page 16, line 4, 5  
*First, the focus of FACT on early detection of worsening of symptoms in order to prevent further exacerbation may be responsible for this discrepancy [7].*

Discussion page 14 last line and page 15 line 1-3  
*In FACT, a multidisciplinary team, including psychiatrist, psychologist, addiction workers, vocational rehabilitation workers using Individual Placement and Support (IPS), and case managers, provides treatment based on evidence-based practices for all SMI-patients rather than only for those SMI-patients who need intensive care.*

Introduction, page 6, line 6-11:  
*In addition, in FACT the focus of treatment is the community rather than the clinic, not only for the 80% less intensive SMI patients but for all SMI patients. The aim is that the more severely ill SMI patients also benefit from social inclusion in the community [7]. In addition, ambulatory SMI patients can access*
resources needed for recovery and rehabilitation that were often only available for clinical patients.

3. The authors have cited at two places “De Vugt” and colleagues; I suppose that they mean “Vugt” and colleagues. Page 13; Formally The FACT Fidelity Scale (FACTs) is under development by Bähler, van Veldhuizen, Vugt and others.

We asked Maaike van Vugt for her exact name and it is now printed correctly in the paper (Van Vugt).

Discretionary Revisions
4. The authors could give more recent information regarding the development of implementation of FACT teams in the Netherlands and regarding certification.

This work is being done by the centre for certification ACT and FACT in the Netherlands. They can mention the website: www.ccaf.nl

We added a section on the start of new FACT teams and development of FACT in the Netherlands, and added the website for further information. Page 6, line 12, 13: Currently, more than 60 FACT (and 25 ACT) teams are in operation in the Netherlands (population 16.4 million); an increase to 200 FACT teams is expected [7].

Page 16, line 8-10: A Dutch expert group is evaluating working ingredients and formulates fidelity criteria to maximize the development of a standard for care (www.ccaf.nl).

REVIEWER 2 Gary Cuddeback

We thank Gary Cuddeback for his useful comments.

Design
1. With respect to the study design, was there not an opportunity to use propensity score matching here given the wide array of data available through the two administrative databases? [Discretionary Revisions]

We thank the reviewer for this excellent suggestion. We redid the matching and the analyses and were now able to match more of the FACT patients (also see comment #6). In addition, we were now able to include measurements from the last half of 2007. In the new analyses effects of FACT were reduced, but a strong interaction was apparent in line with our original hypotheses flowing from the specific way FACT integrates ACT treatment and less intensive care forms.

In the revised version we rewrote part of the introduction, methods and discussion as well as the complete results paragraph.

2. Matching can be problematic if not done carefully. How similar were the groups before matching began? Also, how reliable and stable were the variables on
which subjects were matched? In particular, the GAF has mixed reviews with respect to its reliability and validity. [Minor Essential Revisions]

In theory, only the more severe mentally ill patients receive FACT. Therefore, matching was the only possibility to select a sub group of similar severity.

We know that reliability of the GAF-scores is not always perfect. Because of the resulting noise in the data a FACT-patient may not be matched with the patient that would have been the best matched in the hypothetical situation that there was no measurement error. However, the patient is still matched with a control patient that is quite similar.

Page 20, last paragraph:
Furthermore, reliability of the GAF at the individual level is not sufficient and this could lead to random misclassification in the propensity scores [44]. Some FACT patients may, therefore, not have been matched to the "closest" control patient. However, because this misclassification is random it only leads to noise and a larger confidence interval, while the effect size remains.

Page 11, line 17-23:
Before matching, FACT patients differed significantly from all non-FACT patients with respect to age (mean age FACT-patients 38 years, others 43 years) and GAF (mean symptoms FACT-patients 52.9, others 50.7). Positive symptoms and negative symptoms were higher in the FACT group and depression/anxiety was lower, but differences were not statistically significant. After the matching, matching variables were more balanced than before, although there was still a small difference in age (mean 37 years vs 39 years, p=0.08).

3. Can the authors describe the services that the patients in the comparison group were receiving, in general? [Discretionary Revisions]

We agree with the reviewer that this was lacking in the previous version and we added a sentence in the methods. Page 8, line 2-4:
Standard treatment of patients with SMI - the control condition - includes inpatient treatment, sheltered residential treatment and community treatment with broker-type case management.

Sample
4. There are a number of clarifications that could be made about the samples in the study. For example, the authors describe FACT as a service team that will take ACT consumers (i.e., individuals with severe and persistent mental illness [SMI]) plus others who are less severely impaired. How many FACT patients were SMI versus those who were less severe? And, with respect to the additional patients that were added to the sample because of a low GAF and a minimum of 2 domain needs, were these patients also considered SMI? How many of these individuals were in the sample? [Minor Essential Revisions]
FACT is not designed for non-SMI patients and these were excluded from all analyses. The less severe patients, the 80% group (Remmers van Veldhuizen) are still diagnosed with SMI. SMI is a patient level variable; if a patient was diagnosed as an SMI patient once he was categorised in the SMI-group for all his assessments even if he was in remission. MMI patients were also included in the analyses because they were only slightly less severely ill than SMI patients. Table 1 presents the percentage of SMI patients in the group of SMI and MMI patients.

The definition of SMI was not only based on diagnosis, but also other criteria, such as low GAF and 2 needs, because diagnoses lagged behind. Thus, by definition, these patients were also considered SMI.

Of all 440 subjects included in the present analysis 299 (68%) were diagnosed with schizophrenia or psychotic disorder. Of the remaining 141 subjects, 7 scored >15 on the positive symptoms scale and 36 met the criteria for SMI based on GAF and CAN, while another 98 met the criteria for MMI (also based on GAF and CAN).

In order to make more clear that we did not study non-SMI patients we added a sentence to the introduction and a sentence to the methods. Introduction: Page 4, line 11-15:

FACT combines two approaches for SMI patients within one multidisciplinary recovery-oriented team: (a) individual case management and home visits for extensive care SMI-patients who are mostly stable; (b) shared caseload with intensive full ACT approach for patients in need for intensive care.

Methods: Page 11, line 7-8:

All patients not meeting the above criteria for MMI and SMI were excluded from the analyses, even if they were treated by a FACT-team.

5. The authors were forthcoming about their inability to distinguish ACT versus FACT recipients among the four teams. Were the less severely impaired FACT patients eliminated from the FACT sample for the purposes of this study? If not, could this partially explain the findings? [Minor Essential Revisions]

There were some non-SMI patients that did receive FACT, but these were excluded from the analysis. In order to make this more clear we added an extra sentence in the methods (also see comment #9). Methods: Page 11, line 7-8:

All patients not meeting the above criteria for MMI and SMI were excluded from the analyses, even if they were treated by a FACT-team.

6. Why were there relatively few FACT patients (n = 34) if the four teams have been existence since 2002? [Discretionary Revisions]

In the previous version of the paper only a sub group could be matched with controls because they had missing values for the matching variables or because there were no controls in the stratum. Using propensity score matching (see comment #1) we could match a much larger proportion of the FACT-patients. The data set used in the revised version of the paper contained 349 FACT patients. One hundred and nine
could not be matched because of missing propensity scores. The other 240 were matched.

7. Can you describe the samples (FACT and comparison) with respect to length of time in treatment? Were FACT patients receiving treatment longer? If available, this information could be added to Table 1. [Minor Essential Revisions]

Eighty percent of the patients were chronic with their first mental health contact more than 4 years before baseline and there was no difference between FACT patients and controls ($\chi^2=0.78$, $p=0.68$, df=2). This is now added to Table 1. There was also no interaction between FACT and level of chronicity ($\chi^2=4.3$, df=2, $p=0.12$).

8. Also, how many FACT subjects came from each team? Were the subjects equally distributed among the four teams? [Discretionary Revisions]

Information on the team was not available from all patients, because FACT patients were also scored by other teams. Patients that were scored by a member of their FACT-team were distributed over three teams (76: 52: 57). In the revised version of our paper, the fourth team was excluded, because it served a different patient population and FACT was only partly implemented.

Measures

9. Can the authors provide any information about the convergent validity of the CGI and BPRS? Also, the authors state that when subjects couldn’t be matched on the BPRS, they were matched on the CGI. How often did this occur? [Discretionary Revisions]

In the revised version data were based on propensity score matching. Therefore, the CGI was no longer used in the matching procedure.


BPRS was scored at every assessment (between 1 and 5 assessments per patient) and these scores were recoded into remission, using the Andreasen criteria. This is the outcome variable in the present analysis.

Statistical analysis, page 12, line 10, 11.

The dependent variable was symptomatic remission (yes/no) a variable at measurement-level, while the independent variable was FACT (yes/no).

Data Analysis

11. Can the authors describe the data analysis in more detail? Was hierarchical linear modeling used? Logistic regression with generalized estimating equations to control for dependent observations? [Minor Essential Revisions]
Logistic regression with generalized estimating equations (Stata xtgee command) was not possible because we needed a command to analyse data with 3 levels. Stata xtgee and xtreg can only analyse data with two levels. A set of commands that is new in Stata 10 can handle more than 2 levels, as is also possible in MLwiN.

We added a sentence on the used commands within Stata. Page 12, line 8, 9: **The xtmelogit command is the logistic regression variant of the Stata xtmixed command with 2 or more levels.**

12. *Could more be said about the multiple observations per subject? At what time points were these observations collected? [Minor Essential Revisions]*

Data were collected within routine clinical practice, resulting in a variable number of measurements per person.

Page 8, line 13-17: **Data are cumulatively and routinely collected in clinical practice with intervals of 1 to 2 years and with every major change in treatment or setting. There is no specific baseline in the flow of the illness history and the number of follow-up measurements differs per person as this is a naturalistic study [29].**

**Discussion**

13. *The authors state that FACT patients are more likely to be in remission compared to patients who are receiving standard care. However, given the limitations in the design and questions about the comparability of the samples, the authors should caution their readers that causal inferences cannot be made. [Minor Essential Revisions]*

We agree with the reviewer that one should always be careful in formulating conclusions and causal interferences are difficult even in longitudinal research. We changed some sentences in order to make sure that our conclusions are not too strong.