Evaluating the effectiveness of guided CCBT in the Netherlands (Beating the Blues): design of a randomized trial

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Beating the Blues

- CCBT program for mild to moderate depression
- NICE approved, and
- → clinically effective
- → cost effective
- → acceptable
- Characteristics
- o web-based
- o (inter)active
- o CBT techniques
- o 8 modules; 50' each
- o case studies
- Dutch version recently introduced, but
- → with three f2f contacts
- → i.e. guided CCBT

http://beatingtheblues.nl/ demo

Control treatment

- Treatment as usual: f2f therapy based on CBT
- → integrity check with CTS

Trial registration

 Dutch Cochrane Centre NTR2621

Objectives

- Primary objective
- determine clinical and cost effectiveness of guided CCBT for mild to moderate depressive symptoms
 - → hypothesis: guided CCBT is not inferior to f2f therapy based on CBT (tolerated maximum effect difference δ=0.2)
- · Secondary objectives
- o influence on anxiety symptoms
- o acceptability to clients
- o predictors/ moderators of outcome

Design

- Non-inferiority randomized clinical trial
- → two active interventions; parallel
- → blocked randomization
- → 374 participants
- → blinding not possible

Procedure

- Enrolment (screening, baseline)
- Allocation (after randomization)
- Follow-up (6w, 12w, 6m, 12m)
- Analysis (clinical, economical)

Study period

- 01-02-2011 until 01-02-2014
 - → pilot just started

Participants

- Recruited from Mentaal Beter practices
- Inclusion criteria: BDI-II-NL range 14-28, duration complaints ≥ 2m, 18-65 years-of-age, proficient speaker of Dutch, access to internet and e-mail at home
- Exclusion criteria: other psychological treatment for depressive complaints, suicide ideation, severe co-morbid disorders, substance abuse (alcohol/ drugs)
- Participants can leave the study at any time for any reason without any consequences



Questionnaires

- Online available
- BDI-II-NL, PHQ-9, DAS, BADS, GAD-7, CORE-34, WSAS (clinical analysis); EQ5D/VAS, TiC-P (economical analysis)
- Feedback and acceptability questionnaires are also administered

Statistics

- Clinical analysis
- primary outcome measure: presence/ severity of depressive symptoms as measured with BDI-II-NL
 - → compare difference scores
- → improvement and between group effect sizes
- → reliable and clinically significant change
- Economical analysis: costeffectiveness and cost-utility
- primary outcome measure:
 QALY based on EQ-5D/ VAS

Steering group

 Added to the study to provide feedback and advice

Discussion

- Inflow? Adherence?
- Comments?

References

 See hand-out; for more information, e-mail to e.m.parigger@interhealth.nl



Interhealth is the holding company of Mentaal Beter and Innohealth. Mentaal Beter started in 2004 as a franchise organization for private mental health care professionals. It holds approximately 400 franchisees all over the Netherlands. To date, over 1100 professionals are connected to Mentaal Beter. Innohealth started in 2007 and is bringing innovative health care solutions to the Dutch market. One of these is Beating the Blues. In the near future, Fearfighter will also be introduced.