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SUMMARY

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IN CHAPTER 1 a general introduction to this thesis is presented. A short description of the terms used is given, and key concepts are introduced. After a short description of the aetiology of phobias, the contemporary diagnoses of phobias and their prevalence are discussed, and background information on the treatment of phobias is described. As an extension of phobia treatment, the advent of Internet-based interventions is described. The chapter concludes by describing the rationale for, and general framework of, this dissertation.

In CHAPTER 2 the scientific protocol for the RCT of the study is given, which describes the design of the trial and publicly announces procedures, outcome measures and analyses to be performed as a preregistration. The aim of the study was to establish the effectiveness and cost-effectiveness of a five-week Internet-based guided self-help intervention for phobias, which was offered to patients already on a waiting list to receive face-to-face psychotherapy at a specialised outpatient clinic. The intervention was adapted from an existing self-help book for phobias, which is based on cognitive behavioural therapy and exposure exercises. Eligible and consenting participants were randomised to one of two groups: 1) the five-week Internet-based intervention followed by face-to-face psychotherapy; 2) waiting list as usual follow by face-to-face psychotherapy. Measurements of costs and effects (primary outcome measure: the Fear Questionnaire) were performed pre-randomisation, and at 5-week, 3 months, 6 months, 9 months and 12 months. Moreover, secondary outcome measures included general anxiety (BAI), depression (CES-D), quality of life (EQ-5D) and satisfaction (CSQ-8). Ultimately, the goal of the trial was to ascertain whether it is possible for a short Internet-based pre-treatment to shorten face-to-face therapy and speed up recovery without sacrificing clinical effectiveness.

In CHAPTER 3 the impact and treatment of specific phobias (the pathological fear for specific things or situations) is described. Specific phobias are a heterogeneous and very broad group of disorders. They are highly prevalent and can pose a considerable burden on patients, yet they are often seen as a mild disorder and patients are often met with disbelief, dismissal or even ridicule. We undertook a systematic review and random-effects meta-analysis to pool the available evidence on psychological treatments for specific phobias,

including 22 studies which compared some form of psychological treatment to a wait-list or no treatment control condition. The results showed that virtually every treatment comprised some form of exposure treatment, and that on the whole treatments attained very high effect sizes (Hedges' $g=1.21$; 95% CI: $0.98 - 1.44$). However, as seen previously in psychotherapy literature, studies that used a wait-list control group design had significantly larger effect sizes, moreover, the methodological quality of the studies was suboptimal and sample sizes were generally very low. Meta-regression analyses of effect size and number of psychotherapy sessions per week suggested that therapies using more intensive session planning also attained higher effect sizes. Although the risk of bias was high and methodological quality lacking, psychotherapy for specific phobias seems very effective, and brief intensive treatments seem preferable.

In CHAPTER 4 we describe the short-term outcomes of the randomised controlled trial described in chapter 2. In just over three years, we screened 481 patients and recruited 212 into the intervention (105 in the intervention condition, 107 in the control group). At post-test, five weeks after randomisation, we found a small but significant between-groups effects for the intervention. The intention-to-treat analyses indicated a small and significant effect on the primary phobia outcome (the FQ, Cohen's $d=0.35$; $p=.02$, and the secondary depression outcome (CES-D, $d=0.34$; $p=.03$); and a small but nonsignificant effect on the secondary general anxiety outcome (BAI, $d=0.28$; $p=.05$). However, although participants were enthusiastic about enrolling into the trial, the adherence to the intervention was low. Only 14 out of 105 participants (13.3%) finished all five weeks of the intervention, and 86 out of 212 participants (40.5%) were lost to follow-up at five weeks. We conclude that the Phobias under Control intervention has a modest short-term effect, but needs additional work to prevent participant drop-out.

In CHAPTER 5 the cost-effectiveness and longer term effects of the intervention are described. At one year after randomisation, we compared the differences between the intervention group and the control group – after both groups had received face-to-face psychotherapy – and found small and nonsignificant between-group differences in the primary phobia outcome

measure (the FQ, Cohen's $d = -0.15$; 95% CI $-11.51 - 4.46$). Furthermore, we found no significant differences in costs from a societal perspective between both groups (mean difference = $-\text{€}481$, 95% CI $\text{€} -1343 - \text{€}4401$). Intervention participants did use fewer face-to-face psychotherapy sessions (on average, 4.8 fewer sessions of psychotherapy valued at $\text{€}180.50$ per session), but this difference was also not statistically significant. We conclude that the intervention in its current form or setup is not cost-effective when compared to care-as-usual (i.e., waiting list followed by face-to-face psychotherapy). However, there may be secondary benefits of implementing the intervention, such as providing a service to patients or motivating and preparing patients for treatment. Furthermore, although not statistically significant, the reduction in number of face-to-face sessions is encouraging.

In CHAPTER 6, we explore some of the reasons of the strikingly low adherence to the intervention, as found in chapter 4. Using the demographic and clinical information from the participants in the intervention group, we performed exploratory analyses to find out whether there are certain factors that can predict non-adherence to the intervention. As previously reported in chapter 4, the adherence to the intervention was very low, only 13.3% of 105 patients completed all five weeks. In total, there were 8 exercises in the intervention and the median number of completed exercises was 3, indicating that most participants did not get to the point where they had to perform in-vivo exposure exercises (which was from exercise 6 onwards). We attempted to build a multi-predictor model, where several factors combined predicted whether a participant was adherent, i.e. would complete at least 50% of the exercises. In this model, the most important risk factor was a higher baseline score of anxiety (OR = 0.94, 95% CI 0.90 – 0.99). A protective factor against dropping was a higher age (OR = 1.05, 95% CI 1.00 – 1.09). Additionally, the participants who were more likely to complete the intervention were also more significantly more likely to complete the post-test assessment ($\chi^2 = 17.68$, $p = .000$). Of the participants who were non-adherent, only 38.5% completed the post-test assessment, while 86.7% of adherent participants completed the post-test assessment. This means that the outcomes that were measured during at post-test are possibly biased towards 'good' patients, i.e., those

that were motivated and compliant. The results of this secondary analysis suggest that underlying motivation is an important factor to consider when offering Internet-based interventions to a clinical population.

In CHAPTER 7 we present a broader overview of the state of Internet-based interventions. During when the Phobias under Control project was being run, the implementation of Internet-based interventions in the Netherlands expanded rapidly. However, it would appear that many of the implementation and upscaling efforts rely on untested assumptions about the interventions being implemented, especially with regards to effectiveness and cost-effectiveness. This is an obvious violation of the commitment to evidence-based practice in routine mental healthcare. In this chapter, we describe four of the most common reasons we encountered for implementing untested Internet-based interventions: 1) Internet-based interventions are effective and ready for implementation; 2) the interventions are evidence-based because they are made of evidence-based elements; 3) a seeming lack of negative findings does mean they are not there; 4) science cannot keep up with the pace of technological developments. We argue that the implementation of untested interventions is practically irreversible due to sunk cost effects and clinical inertia in de-implementing unsuccessful interventions, and propose better cooperation between clinical practice and academia. In short, this chapter sums up some of the issues and 'lessons learned' in 7 years of working in the field of Internet-based interventions.

In CHAPTER 8 the findings, strengths and limitations of this dissertation are summarised and discussed. It is divided in two parts: the first part is a summary and general conclusion about the findings of the Phobias under Control project in terms of clinical and scientific implications. Topics that are covered are the acceptability of the intervention in terms of adherence, motivation and patient preferences; the clinical effectiveness and the cost-effectiveness of the intervention, also in context of other research; the process of embedding the project in routine mental healthcare; limitations of the study; and implications for clinical practice. In the second part, offers a broader discussion about the context of Internet-based interventions; and how the lessons learned from the Phobias under Control project could inform,

strengthen and inspire future research into Internet-based interventions. Topics covered are recent developments, in particular blended therapy; the implementation of Internet-based interventions; trial design and research methodology, in particular pilot testing; research issues pertaining to how we measure intervention adherence; and intervention content development.

The main conclusions are that the Phobias under Control project was modestly effective over a short term, but that its beneficial influence appears to fade over time. Moreover, other than a non-significant reduction in sessions of FtF psychotherapy, we could not show cost-effectiveness of the intervention. However, there may be reasons other than cost-effectiveness for implementing Internet-based interventions. Furthermore, it is argued that research into Internet-based interventions would benefit greatly by the appropriate use of pilot testing; and some suggestions are given to increase the probability of these interventions being successful, science-based, and sustainable. In conclusion, Internet-based interventions have grand challenges, but also a grand potential to improve routine mental healthcare.