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Siemonsma, P.C.

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CHAPTER 8

General discussion and epilogue
INTRODUCTION
In this thesis I have taken on the challenge of integrating theoretical, methodological and clinical considerations into the design of a study. We rose to this challenge using as our case study Cognitive Treatment of Illness Perceptions (CTIP), a rehabilitation treatment for patients suffering from chronic low back pain (CLBP). In this chapter we reflect on the difficulties that we encountered in making use of theory-driven methods in rehabilitation. Three dilemmas were faced: (1) how to give primacy to theory without weakening the methodological quality of the study, (2) whether to give primacy to proving or improving CTIP, and (3) whether to give primacy to research needs or to clinical practice needs. Subsequently, the results are discussed of (1) the prospects of transferring the research results to other environments and situations, (2) the prospects for the structural implementation of the treatment in rehabilitation practice and (3) the aspects that are worth further research. Finally, I reflect on the overall gain in knowledge that results from this thesis in the epilogue.

Dilemmas in making use of theory-driven research in rehabilitation
The first dilemma in making use of theory-driven research in rehabilitation was how to give primacy to theory without weakening the methodological quality of the study. Usually, researchers give primacy to methodological issues. In such methodology-driven research the randomized controlled trial is advocated as the optimal design for examining treatment effectiveness, because it comes with a clear set of requirements to counter threats to internal validity. Within this perspective theory comes into play at the end of the research process to understand and interpret the results, also called post-hoc theorizing. Theory-driven research explicitly integrates theory in the research design from the very start of the study. In the CTIP study, for example, Leventhal’s Common sense Self-Regulation Model (CSRM) leads to a strong focus on the individual’s illness perceptions in explaining the limitations in physical activity. CTIP, therefore, aimed at increasing patient-relevant activities. These activities were hypothesized to be best measured with PSFL, rather than a more generic measure such as Quebec. However, such measures that specifically matches with the treatment outcomes are generally more time-consuming to administer, are not as well researched on methodological issues (such as reliability and validity) and are, therefore, not as well accepted in the international research community. As a result, these measures, such as PSFL, that most accurately assess the specific outcome of a particular treatment are also more difficult to compare between studies. In this thesis we have balanced theory and methodology by including
both types of outcome for physical activity in the RCT.

A second dilemma was whether to give primacy to proving or improving CTIP. Trying to prove the effects of CTIP by the conduct of an RCT would be first choice in a methodology-driven approach. The key question in such a pragmatic trial is whether or not CTIP is effective on certain parameters. An added benefit of conducting an RCT is that the results are relatively easy to publish because journals have put RCTs high on their priority lists. Moreover, RCTs are likely to result in a high number of citations because they form the basis of systematic reviews. A limitation is that such pragmatic trials are not designed to answer clinically relevant questions such as ‘How, for whom and under what circumstances is treatment effective?’ We tackled this dilemma by combining a traditional pragmatic RCT with a theory-driven explanatory study of predictors of CTIP effectiveness. In fact, instead of choosing between proving or improving, we integrated them.

A third dilemma was whether to give primacy to research needs or to clinical practice needs. This dilemma emerged at the very beginning of this study, i.e. at the point of writing the research proposal to gain funding for the study. It took extensive explanation of why a pre-determined, fixed, research design was not included in the proposal. In theory-driven research it is advocated to plan for environmental intrusions such as clinical procedures that influence treatment, clinicians who are unable or unwilling to comply with the treatment protocol or adaptations to the treatment protocol. For an optimal implementation of the experimental treatment in clinical practice an open-system mode is advocated in which such potential implementation problems can be reduced. The open-system mode allowed us to integrate clinical needs, concerns, and theoretical notions regarding CTIP in the research design. In this phase necessary adaptations were made to fit the novel treatment to stakeholders’ needs.

During the experimental phase of the trial a closed system mode prevailed. In this mode we buffered environmental intrusions that might compromise the internal validity of the trial, bias measurements and, as a consequence, prevent the study from generating valid and reliable results. However, this did not mean that the open system mode was totally eliminated, given that the research setting was far from being a laboratory. Describing our theory-driven proposal in terms of open system and closed system modes convinced the fund provider that the study would generate relevant results and was, therefore, worthwhile.
During the trial, in the closed system mode, we studied the fidelity to the treatment protocol in clinical practice, with the aim of generating a better understanding of the research results and creating a broader evidence base. There are many factors that may lead to deviation from the treatment protocol, such as the therapists introducing new treatment ingredients or not delivering essential ingredients. The actual provision of treatment can be quite different from the one which was intended to be studied. This may lead to misleading results. The fidelity to the treatment protocol was, therefore, investigated. The fidelity study turned out to be time consuming, costly and a labour intensive endeavour. Factors that are serious barriers for the advancement of our knowledge and understanding of rehabilitation in a time when the number of publications and dissertations are performance indicators (rather than knowledge gained or impact on clinical practice). So, we not only had to try and balance research needs and clinical practice needs within the study, but we also had to balance the need for publications with that of clinical relevance outside the study.

In this thesis we experienced that science is not just practised on Olympus - the lonely scientist, far removed from everyday practice and in an unselfish quest for truth - (although it helped significantly to withdraw at times and sit on a virtual mountain to think), but science turned out to be practised at Agora - a societal practice tightly bound with other societal practices - (such as those of scientists, clinicians, and fund providers). What was gained from struggling with these dilemmas, from withdrawing to Olympus and from walking around at Agora? The results can be found in the summary section and its implications are discussed below.

RESULTS
What are the prospects of transferring the research results to other environments and situations?
The CLBP patients studied in this thesis are quite similar to those in other rehabilitation intervention studies, for example in (Leeuw, Goossens et al., 2008b; Smeets, Vlaeyen et al., 2006). The patients are quite comparable regarding their level of physical activity limitations (on average 12 limitations indicated on the RDQ), with regard to age (on average 46 years), to gender (56% females) and to work status (43% working). In addition, the selection process used in our studies closely followed our clinical routine, i.e. patients visiting the rehabilitation physician and psychologist and filling in screening questionnaires before a decision as to treatment was made. Therewith, the recruitment procedures
allowed for the usual clinical variations, such as variation in recruitment rates, personal factors of the physician/psychologist and patients. We have attracted the attention of several newspapers and did some advertising towards the end of the study. This could have resulted in patients being more motivated to participate in research. However, the percentages of patients withdrawing from treatment (18%) and dropping out of the study (8%) are quite comparable with other studies. Taking these factors into account, we are confident that the population is representative of the population of patients with CLBP that commonly visits rehabilitation physicians and that the clinical selection process was not unduly influenced by the study taking pace. On these grounds, we do not hesitate to suggest that these results can be generalized for the CLBP population that visit rehabilitation physicians in the Netherlands.

The therapists in this study were specifically trained to treat patients according to the CTIP protocol. They were experienced in multidisciplinary treatment of patients suffering from chronic pain. The results of the fidelity study showed that they were able to work well within the protocol. For this reason we assume that experienced therapists in other settings can be trained to deliver the treatment as well. However, a concern for consistent provision of the treatment is the availability of supervision in these settings. Supervision is needed to assist therapists to work accurately with the treatment, for example by using the Socratic style dialogues and having an open-minded approach towards the patient’s illness perceptions. Therapists may also be tempted to introduce ingredients that they use more routinely in other methods, but which are not included in the treatment protocol. Therefore, we think that the results should only be generalized for trained and experienced therapists in settings where structured supervision is available.

Several methodological issues have to be considered. We have strived to attain a broad evidence-base for CTIP by studying the effectiveness, predictors of outcome and the actual implementation of the experimental treatment during the trial. This kind of implementation is not to be confused with structural implementation of treatments with proven effectiveness. This attempt to create a broad evidence-base resulted in using a mix of methods, each of the methods having their own strengths (and limitations). Effectiveness can indicate whether or not the treatment was effective, but fails to explain how and why. The predictor study indicated what factor was most relevant for predicting the treatment effect of CTIP, but did not focus on more general predictive factors. The fidelity study identified how the treatment protocol (i.e. the planned treatment) was actually implemented in the experimental setting by the therapists and which parts of the
treatment were more difficult to implement. Together this resulted in clinically relevant information about the treatment as well as knowledge of the conditions of implementation of the treatment.

The choice of control group for the trial on effectiveness provoked long debates. In the end we decided to use a waiting list control group. Although one might consider this ‘weak competition’ (how hard can it be to do better in comparison to doing nothing?), we are very happy with the choice for two reasons. The first reason is that, contrary to the expectation that a chronic condition does not change all by itself, the control group did change for the better. We were thus able to statistically adjust these changes and thereby get a more accurate estimation of CTIP effect. A second reason is that the contrasting treatments that we considered, which were Graded Activity (GA) and Gradual Exposure in Vivo (GEiV), were thought to have many ingredients in common with CTIP, and, therefore, the resulting difference (i.e. greater effectiveness) would be small and hard to prove. The overlap between GA and GEiV was later confirmed by research by Leeuw et al. (Leeuw, Goossens et al., 2008a; Leeuw et al., 2008b).

The power of the study estimating the effectiveness of CTIP was calculated with the information available at the time and resulted in 135 patients being required for the trial. Re-calculating the power with the actual numbers, mean and standard deviation (n=139, -19.1 and 26.16) resulted in 120 patients. Therewith the power of the study was sufficient to make a reliable statement about the effectiveness. In retrospect, the initial power calculation had two flaws. First, it was assumed that the level of physical activities in the waiting list control group would not change, and second, there was no correction included for unequal groups. When recalculating the power using this additional information (including the -5.4 mm improvement in the waiting list control group and including the proportion of 0.5 waiting list controls to the intervention group), then the power of the study is 0.8.

For the predictor study the power was calculated that a maximum of 9 variables could be included in the regression model to obtain a reliable regression equation in the prognostic study, i.e. allowing 15 patients per predictor. However, for the predictor study only three predictors were studied in 136 patients, resulting in 45 patients per predictor. This is sufficient to study the effects of the predictors reliably. For the fidelity study the power was likely to be insufficient to estimate its impact on the outcome. This is due to consistent high fidelity rating and associated lack of variance. Therefore, no reliable estimation could be calculated for the impact of fidelity ratings on the outcome. As the primary aim of the fidelity study was to verify the actual delivery of the experimental treatment
as opposed to the treatment as planned, we did not consider this a serious problem.

The theoretically best measurement instruments were not always readily available. Two types of general problems concerning measurement instruments were encountered: (1) unavailability of instruments to measure some constructs of the treatment and (2) if there were instruments that measured the construct, they did not always measure it to the degree of detail required. An example of the first type was the measurement of the patient’s characteristic ‘being problem-focused’. Being problem-focused, rather than emotion-focused, was theorized to be a predictor of treatment success. However, because of the lack of suitable measurement instruments, we decided not to include this treatment-specific predictor in the study. An example of the second sort was the measurement for illness perceptions (IPQ-R) which was included to objectify the process of therapeutic change. However, specification of the content of CTIP indicated that this instrument was not appropriate to measure the changes in illness perceptions that one hopes to achieve with CTIP. The IPQ-R does, indeed, measure changes in the number of illness perceptions, but fails to detect in-depth changes in the content of the perceptions (French & Weinman, 2008). These issues limited the level of detail to which certain treatment aspects could be investigated. Potentially, this might have led to the underestimation of effects or predictors.

Although the length of the recruitment period was three and a half years, the procedures were highly standardized using forms, which make it unlikely that this has introduced drift in the selection procedures of the trial. A positive impact of the study duration is that we have been able to keep to normal clinical routines while recruiting patients. If the study had been of a shorter duration, normal routines would have been disrupted, at least as far as the number of patients that needed to be seen are concerned. The patients were asked to participate in the study for at least a year, as we included longer term follow-up (one year). The results are not included in this thesis, but they might have influenced the patients’ decision to participate. However, we have no indication that this has led to more recruitment bias than in other studies, as inclusion rates are comparable with other studies.

In conclusion, we are quite confident that the results can be generalized as regards the CLBP patients treated in rehabilitation settings by experienced therapists who are trained to treat according to the protocol and where structured supervision is provided.
What are the prospects for the structural implementation of the treatment in rehabilitation practice?
CTIP is best applied to CLBP patients who have a rational problem-solving style. Especially the patients who score > 43 points on the SPSI-RPS are highly likely to show a clinically significant change in physical activity. These results are true for any patient with CLBP that is judged to have an indication for rehabilitation treatment. Although the study of fidelity to the treatment protocol was unable to provide quantitative proof for this assumption, one may theorize that these effects may be greater in patients with maladaptive illness perceptions that are related to the CLBP or physical activity.

The results of this thesis also invite both therapists and professionals who are involved in prescribing treatments to add criteria for selecting patients that are ‘suitable for a specific treatment’ to their existing list of criteria for selecting patients that are ‘suitable for rehabilitation’. Such treatment-specific criteria should consider what skills and abilities a patient needs for particular treatments and should lead to a more specific and uniform assessment of the treatments to prescribe. Thus, a clinical implication of this thesis is that clinicians are urged to critically reflect on the content of their treatment and to apply this knowledge in their selection criteria and procedures.

CTIP was demonstrated to be effective in improving physical activity in patients with CLBP, and was shown to be worthwhile to co-exist with available rehabilitation treatments for CLBP, such as GA and GEiV. The average treatment intensity for CTIP was 8.5 hours (n=142 as only patients who received more than one treatment are included). For GA and GEiV approximately 16 and 26 hours of treatment were planned to be given in the study by Leeuw et al. (Leeuw et al., 2008b). An average of 100 and 78 hours were reported for multidisciplinary and for combination treatment by Smeets et al. (Smeets, Vlaeyen et al., 2008). In this comparison CTIP, consequently, has a very low treatment intensity. Compared to the available rehabilitation treatments, CTIP has a more narrow treatment target, because it is specifically targeted at maladaptive illness perceptions. The targets of rehabilitation treatment are more multifaceted, including treatment targets aimed at improving coping skills, time-management, self-efficacy, physical re-conditioning, etcetera. In the ideal patient for CTIP, maladaptive illness perceptions play an important role in the perseverance of activity limitations in chronic low back pain.

An important issue for clinicians is how to give CTIP a place in the rehabilitation of CLBP. This issue cannot be readily solved based on the knowledge of this thesis. Instead, we urge clinicians to discuss the aims, ingredients and ideal
patients for the treatments that they have available and to make rational choices about what to apply and to whom. In these discussions the rationales of the treatments should be discussed: do the rationales still fit if the treatments are mixed? This contrasts with the current practice of intuitively mixing treatments or adding one treatment to another. We also urge clinicians to consider the timing and interaction of treatments: treatments might be like pills in this respect that more is not always better and some combinations are better than others. The outcome of these discussions should be anchored in the whole rehabilitation process: from treatment indication, to application and evaluation.

A requirement for application of CTIP is that therapists are well-trained and supervised. Supervision is important to ensure that therapists closely follow the structure of the protocol, that new skills are applied correctly (such as Socratic dialogues) and that the treatment is focused on illness perceptions (and not on general perceptions such as ‘it is important to help other people’). Under these conditions, the treatment can be implemented in other rehabilitation settings. On the basis of our fidelity study we recommend the training of therapists to have a strong focus on formulating illness perceptions. The application of CTIP requires that the rehabilitation team is willing to review the whole treatment process: from the selection procedure (as mentioned above) to working according to protocol (which impedes therapists in their personal freedom, such as mixing treatments and adding ingredients) and the assignment of tasks (CTIP prescribes one therapist, whereas simultaneous treatment by several professions is more commonly used). This will result in a new and effective treatment option being available to patients, a treatment that has a clear treatment structure and content and a limited duration.

Given the available treatment protocol and the nature of illness perceptions, future clinical applications involving CTIP may consider tele-rehabilitation as part of the treatment. This could make the treatment more cost-effective and will be in accordance with societal changes that face us, such changes include an aging population, shortage of staff (CBS, 2010) and financial constraints. Tele-rehabilitation, taken as treatment-from-a-distance, might also be beneficial to the individual patients, as they do not have to travel to the rehabilitation centre, can respond to their home assignments at their own convenience and will have more time to reflect before having to react. Evidence is mounting concerning the efficacy and effectiveness of tele-rehabilitation (Kairy, Lehoux et al., 2009) and, therefore, seems to be an opportunity for future application of CTIP.
General discussion and epilogue

The results of this thesis are encouraging for the (future) clinical application of CTIP. However, some caution is warranted because these are the initial results from a single series of studies. More knowledge about how to optimize the treatment, patient characteristics and interaction with other treatments is needed.

**What aspects are worth further research?**
The longer-term effectiveness and cost-effectiveness are well worth taking into account before considering CTIP as a treatment option in routine care. Data have been collected on the one year outcome and information on costs were collected using cost-diaries to study cost-effectiveness of CTIP. The results of these studies are forthcoming.

We analyzed and compared the treatment content of CTIP, GA and GEiV. Based on this analysis, comparative trails could be designed to estimate what works best for whom. Given the large proportion of overlapping and non-specific treatment components an effectiveness trial seems less promising. More promising than a general comparison of the treatments would be a comparison of the treatments on well theorized distinct features. For example, on the issue that currently clouds the comparison of the effects of GA and GEiV: physical exposure. The physical exposure component is included in both treatments and might explain the lack of differential effects on the outcome. In this case CTIP might shed light on this issue as this treatment mainly relies on mental experimentation. It would also be well worth considering Acceptance and Commitment Therapy (ACT) in these equations, as this treatment is quite new in the Netherlands and is increasingly used in rehabilitation treatment.

Further studies of CTIP’s treatment components and working mechanism are strongly recommended. This should include a study of the phase-effects and determination of which phase is most useful to which patient. Our experience so far suggests that some patients have benefitted from merely mapping the illness perceptions, some from adding identification of maladaptive illness perceptions, some were sufficiently helped by formulating alternatives, whereas others substantially benefitted from the phase of experimenting. Therefore, it is well worth exploring if a treatment containing fewer phases may be just as effective for some patients. And, as suggested in the previous section, other types of application of the treatment, such as tele-rehabilitation, are worth considering from the perspective of cost-effectiveness. The design of the treatment, as formulated in the treatment protocol, is just one way of translating Leventhal’s common sense self-regulation model (CSRM) into a rehabilitation treatment,
Another tempting area for research is the application of CTIP to patients with chronic benign pain (CBP). Further research should focus on what specific requirements of this population need to be addressed in CTIP. The current protocol has a strong focus on avoidance of physical activity, whereas both CLBP and CBP patients are known to use persistent activity or overload strategies. Adaptation of the protocol to other diseases is also feasible for the future.

More research on implementation problems is recommended to assist in the optimal implementation of CTIP in other settings (such as other rehabilitation settings and primary care) and to explore other delivery modes. Moreover, determining the best way to teach therapists essential skills for CTIP and gaining insight into the requirements for supervision would be helpful. In studying the best ways to teach therapists it is recommended to explore the possibilities of E-learning in order to reduce the costs of training.

**EPILOGUE**

A thesis, in a way, is a small world within self-set boundaries. Therefore this thesis adds some knowledge to a restricted world. Important boundaries for this thesis were theory, chronic low back pain and rehabilitation treatment. In this epilogue I look past these boundaries to see where the gains of this thesis fit in the larger picture.

Chronic low back pain rehabilitation is a specialist area within the field of rehabilitation and comprises a number of treatments. By focusing on the patients’ common sense beliefs about their illness (illness perceptions) I have added a new perspective, a unique ingredient, to the available treatments. Unique ingredients are those ingredients that are used exclusively in one treatment and not in comparison treatments. Cognitive Treatment of Illness Perceptions (CTIP) was developed to include the unique ingredient of illness perceptions. In this thesis, much of our effort was aimed at identifying and researching the unique ingredients of CTIP.

Besides unique ingredients, rehabilitation treatments have a (large) nonspecific effect and a specific effect (Donovan, Kwekkeboom et al., 2009). Nonspecific effects rely on the fact that something is done by a credentialed professional which elicits the belief that one is getting an effective treatment (Bowers & Clum, 1988; Whyte & Hart, 2003; Lilienfeld, 2007), and depend on a positive patient-provider interaction and provider variables (Borrelli, Sepinwall et al., 2005). Nonspecific effects do not rely on what exactly is done in treatment. No doubt these effects have emerged in CTIP as well. The treatment effect emerges
in full if specific effects of treatment are added to the nonspecific effects. These specific effects can be attributed to not-unique and to unique treatment ingredients. Not-unique are those treatment ingredients that are common to many treatments (Perepletchikova & Kazdin, 2005; Santacroce, Maccarelli et al., 2004), such as structured experience and teaching-interaction (Whyte et al., 2003).

In this way I have added some knowledge to a very small field of treatments in the larger area of rehabilitation. Rehabilitation, in turn, involves only a small part of medical knowledge, let alone of human knowledge. So, is this attempt to gain new knowledge futile? The philosopher Karl Popper described the search for new knowledge as carefully touching around in a dark room, searching for a black hat – that might not be there (Popper, Onrust et al., 1988). The only option is to try and make mistakes. Especially the mistakes are important in the view of Popper, as those can be learned from. Mistakes tell us where the hat is not. To me this thesis is best described as a careful attempt to touching around using theory in the dark room of knowledge, in the corner of rehabilitation. By doing so, I have added some knowledge as to the direction in which knowledge (hat) may be found, but mostly I have pointed out where it cannot be acquired.

REFERENCE LIST


