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Haanstra, T.M.

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CHAPTER 1

General introduction

Patients' expectations: a brief introduction

The primary goal for medical treatment is to produce the best possible outcomes for each patient. Traditionally, most clinicians have worked from a biomedical viewpoint, and thus try to achieve that goal by administering a treatment that addresses the physiological illness or complaints of the patient. In the last decades however, there has been a gradual shift towards a biopsychosocial view of medical treatment. The biopsychosocial model recognizes that besides physiological (or biological) factors, psychological and social factors are also important in the development, progress, prognosis, experience and outcome of illness and treatment¹. Increasing acceptance of the biopsychosocial model has seen growing interest in the specific role of psychosocial factors within the context of health care.

A promising psychosocial factor is the patient's expectations and beliefs about the treatment they are about to receive. A number of individual studies and literature reviews, coming from various medical disciplines suggest that patients' expectations in general are an important variable affecting treatment outcomes²⁻⁴. For example Goossens et al⁵ showed that patients who believed that cognitive behavioral therapy would help them cope with their chronic pain had more positive scores on 5 different outcomes namely motoric behavior, negative affect, health-related quality of life, pain coping and pain catastrophizing⁵. Expectations about treatment outcome have also been shown to be associated with outcome for more invasive treatments, like surgery⁶⁻⁸.

Broadly speaking, expectations can be defined as 'the anticipation of future events', and as such are recognized as inevitable and essential components of daily life. Many of our decisions and actions are preceded by the expectation that certain events are going to occur or certain outcomes are going to be achieved. Expectations of individuals have therefore been the subject of research in many fields and from many perspectives. Unsurprisingly, the longest-standing research interest in expectations has probably been in the field of psychology⁹. Expectations research in psychology is primarily concerned with the question how individuals' beliefs and evaluations of beliefs can influence their behavior. Based on early psychological theories, expectations have been recognized as an important variable in the field of marketing. Marketers have so far focussed on ways to promote new and repeated purchasing by understanding and creating expectations, which can then be met through provision of goods and services¹⁰⁻¹¹. Further, expectations have been subject of research in education¹² and sociology¹³. A well known example is the phenomenon called pygmalion effect: if teachers expect enhanced performance from children, then the children's performance was enhanced¹⁴.

Expectation related research in health care has been performed since the second half of the 20th century, but references to the power of the mind in the cure of disease were made long before that. For example, early in the 19th century Haygarth reported on the results of what now is known as possibly the first placebo controlled trial. He studied 'Perkins tractors' (metallic rods that were supposed to work through electromagnetic

influence) a commonly used therapy for many diseases at that time, and treated 5 patients with real tractors and another five with tractors with no metal in them. In both groups 4 out of 5 patients found their symptoms to be relieved. Haygarth wrote with respect to this result: "an important lesson in physics is here to be learnt, the wonderful and powerful influence of the passion of the mind upon the state and disorder of the body. This is often overlooked in the cure of diseases"⁹.

In the biomedical domain research on expectations has traditionally been performed within the context of placebos and placebo effects. A placebo is defined by Shapiro and Shapiro as "any therapy or part of therapy deliberately used for non-specific psychological or psychophysiological effect and without specific activity of the condition being treated"¹⁵. Consequently, the placebo effect is defined as the non-specific psychological or psychophysiological effect produced by a placebo. When applying this definition, the placebo does not necessarily need to be an inert pill, injection or other substance, but can be any part of therapy that is not specific to the condition being treated, therefore in literature the effects produced by placebos are also referred to as non-specific effects or contextual effects¹⁶. Thus, the placebo concept actually represents a black box of effective components or mechanisms of a treatment that are not clearly identified and understood yet. To improve treatment outcomes it is important to understand the contents of the black box by identifying the mechanisms underlying placebo effects. One of the mechanisms through which placebos are believed to work is via the expectation of the person receiving the placebo¹⁷⁻¹⁸.

With increasing interest in patient centered care, patients' expectations have also been found to be relevant from a health services perspective. Patient centered care is defined by the institute of medicine as "*providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions*"¹⁹. Within health services research, patient satisfaction is a key concept and researchers in several medical disciplines have shown patients' expectations to be associated with satisfaction with care. This may be very important from an economic point of view as dissatisfaction is associated with health care shopping and higher healthcare costs²⁰. It has also been suggested that patients' expectations play an important role in effective patient-practitioner communication, another key aspect of patient centered care²¹⁻²².

Theoretical frameworks

Expectations play a role in many of the theories and frameworks relevant to health and health care. These theories and frameworks have been applied to various areas of medical research namely; placebo research, health behavior research and health services research. Without aiming to be exhaustive, a short overview of theories is provided below to illustrate how expectations fit within these theories.

Theories and frameworks aimed at explaining or predicting behavior

Expectations play a prominent role in several theories of health behavior such as Bandura's self-efficacy theory, Fishbein and Ajzen's theory of planned behavior and Leventhal's common sense model. All these theories are concerned with how beliefs can influence behavior. Such beliefs include expectations about all aspects of medical treatment and disease. Although they have a common basis, there are also differences between these models, specifically regarding the type and definitions of beliefs that are part of the model and the specific role of those beliefs.

Bandura's self-efficacy theory focusses on the interrelationships between outcome expectancy, self-efficacy and behavior²³ and forms a part of the social cognitive theory. Self-efficacy theory states that behavior and changes in behavior are determined by a person's expectation of what the outcome of that behavior will be (outcome expectation) and the confidence or expectation that the person can successfully perform the behavior (self-efficacy expectations). According to Bandura, judgements of self-efficacy are derived from various sources including previous successful behavior, observations of others' successful behavior, verbal persuasion and physiological and affective states at the time of the self-efficacy assessment. Bandura proposes that self-efficacy expectations causally influences outcome expectations but that outcome expectations cannot causally influence self-efficacy expectations. For example when a person feels capable of exercising three times a week after work this may influence the expectation that exercising will be beneficial for his health, however the expectation that exercise is beneficial for one's health does not influence the feeling of capability to exercise three times a week. Both the person's judgement of self-efficacy and the outcome expectation determine that the person will actually exercise three times per week.

The theory of reasoned action²⁴ and its later extension, the theory of planned behavior²⁵ suggest that a person's intention to perform certain behavior depends on his attitude to the behavior and subjective norms. If a person intends to perform the behavior then it is likely that the person will do so. In this model the concept 'attitudes', being defined as the sum of beliefs about (the outcome of) a particular behavior weighted by evaluations of the importance of these beliefs, shows conceptual similarities to expectations. For example, a person may expect that regular exercise is beneficial for his health and will make him lose weight, but also that it is uncomfortable and time-consuming, the expectation that exercise is healthy may overrule the negative expectations because being healthy is more important to the person.

In contrast to Bandura and Fishbein²⁴ and Ajzen²⁵ theories that are applicable to a wide range of human behaviors, Leventhal's common sense model²⁶⁻²⁷ is specifically aimed at understanding health behavior. It proposes that when a person is confronted by a health threat (e.g. experiencing low back pain) the person's subsequent health-related behavior is determined by emotional and cognitive perceptions about their illness. Perceptions about

the consequences of the disease; how long the illness will last, and whether it is curable and controllable show considerable overlap with the concepts outcome expectations and self-efficacy expectations as used by Bandura. The common sense model however differs from the other models by proposing a feedback loop. After evaluating the results of the health behavior, the person will reconsider the health threat and form altered illness perceptions and adjust his behavior based on them.

Theories and frameworks aimed at explaining the placebo phenomenon

Research into the role of expectations as a mechanism of the placebo phenomenon has been dominated by Kirsch's response expectancy theory¹⁷⁻¹⁸. This theory proposes that what people experience depends partly on what they expect to experience. Kirsch called the expectations that produce or mediate these experiences 'response expectancies' which are defined as anticipation of the occurrence of non-volitional responses like emotions, pain or pleasure'. Response expectancies can be distinguished from stimulus expectancies which are 'the anticipation of the occurrence of external consequences'. The response expectancies that produce the outcomes can be induced by verbal (or non-verbal) suggestions and rituals, but also by prior experience. Although this theory has been empirically confirmed in experimental research and the neuropsychological mechanisms behind this theory have been identified, there is very little translational research that demonstrates how to harness the placebo effect in clinical practice²⁸.

Theories and frameworks aimed at explaining or predicting patient satisfaction
Expectation related theories have also been developed within marketing and health services research, as expectations are believed to play a central role in determining patients' perceptions of, and satisfaction with, health services. For example, the expectancy-disconfirmation theory²⁹ posits that satisfaction is the result of a comparison between prior expectations and perceptions of the actual product or outcome. When the perceived outcome exceeds the original expectations the disconfirmation is positive which contributes to satisfaction, when the outcome is poorer than the expectation the disconfirmation is negative which contributes to dissatisfaction.

A framework which is widely used to guide research on patient expectations in the context of satisfaction with healthcare was proposed by Thompson and Sunol³⁰. Their model integrates expectancy-disconfirmation theory with other models including the response expectancy theory. They suggest that there are four types of expectations that influence the level of satisfaction post-treatment namely 1. Ideal expectations which refer to an idealistic state of beliefs 2. Predicted expectations which refer to what patients actually believe will happen 3. Normative expectations which refer to what should or is ought to happen 4. Unformed expectations which refer to the expectations that patients are unable or unwilling to formulate. According to this theory satisfaction occurs when the outcomes is positioned in the zone between normative and minimal predicted expectations. Outside this zone, satisfaction will be low when the outcome falls short of the minimal predicted

expectations and satisfaction will be high when the outcomes exceed the normative expectations. Maximum satisfaction occurs when the level of ideal expectations are achieved as an outcome.

The need for an integrative framework

The previously described theories and frameworks all have proven useful in their own area. However, in clinical practice all these ‘areas’ are relevant. A patient comes into the office of the clinician with a range of expectations that do not exist in isolation, nor are they relevant to one models only. For example the expectation that massage is effective for alleviating back pain but exercise is not, may be relevant for patient satisfaction (if a physiotherapist recommends exercise the patient may be dissatisfied) but also to non-specific effects of treatment (which won’t be enhanced if the patient does not get massage) and to behavior (the patient probably won’t engage in his exercise). Further this expectation is relevant to patient-practitioner interaction and communication as the practitioner will probably try to explain why exercise may be more beneficial than massage thereby attempting to change the patients’ beliefs and expectations.

Thus, from a clinical perspective it would be useful to have a model that integrates aspects from multiple models and places the patients’ expectations regarding his illness and treatment at the centre. A preliminary framework by Crow et al³¹ is an attempt at creating such an integrated framework in which the expectation of the patient is the central construct. Crow and colleagues conducted a systematic review in which literature on expectancies in medical treatment (N=85 papers) was reviewed to assess the nature and magnitude of placeboeffects and consider how placebo effects could be harnessed to improve the quality and cost-effectiveness of health care³¹. Based on this systematic review a conceptual framework was proposed to describe the relationships between determinants and outcomes related to patient expectations, expectations being regarded as the central mechanism of the placebo effect. For this framework and review Crow et al did not only use placebo related literature but also used concepts and definitions from Bandura’s self-efficacy theory and outcomes relevant to health services research. The framework divides determinants into four broad categories: Factors related to the patient (e.g. pre-existing beliefs); factors related to the practitioner (e.g. a warm and empathetic attitude); factors related to the interaction between patient and practitioner (e.g.the extent of interaction that takes place); and the setting and characteristics of the treatment (e.g. the way in which an intervention is delivered (injections, pills etc.). Crow et al divides the outcomes into three broad categories: changes in physical health status (e.g. less swelling or more optimal blood parameters); patient self-reports (e.g. well-being or pain); and measures of health service utilization (e.g. length of hospital stay) (fig 1).

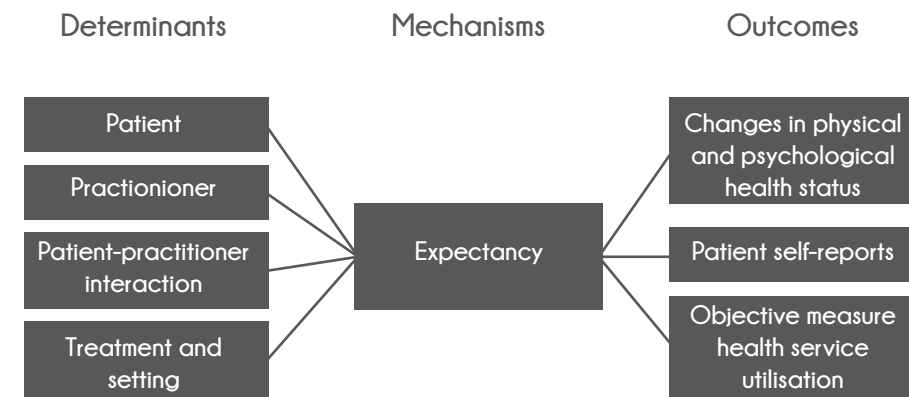


Figure 1: Crow’s preliminary framework

Research themes of this thesis

As described above there is a long history of research on patients’ expectations in various disciplines and fields. While it is clear that patients’ expectations are a promising avenue of research, a complete understanding of the specific roles that patients’ expectations play within a medical treatment setting has not yet been reached. Actually using the patients’ expectations to improve the effectiveness of treatment is a step even further away. In order to approach this goal we identified four research themes that need more attention. These research themes inspired the research questions and aims for this thesis and are outlined in turn below.

Theme 1: Definition, typology and measurement

Two terms used regularly in the literature are ‘expectancy’ and ‘expectation’. Both terms find their root in the latin word ‘expectare’ which means ‘to look out for’ but in the English language there are subtle differences in definition between the two. According to the Oxford dictionary; expectation is “*a strong belief that something will happen or be the case*”; expectancy is “*the state of thinking or hoping that something, especially something good, will happen*”. This suggests that an expectation corresponds to the belief itself, while expectancy refers to the state of holding the belief. According to The American Psychological Association’s (APA) Dictionary of Psychology³², expectation is a state of tense, emotional anticipation; while expectancy is an attitude or mental set that determines the way in which a person approaches a situation. This definition suggests expectation is a more emotional while expectancy is a more cognitive construct. Although the definitions in these dictionaries suggest that expectancy and expectation are slightly different concepts, in the medical and psychological literature often they are used interchangeably and there is no consensus as to when to use which term. Furthermore, in many other languages there is no distinction between expectancy and expectations. For example in the Dutch

language, both are referred to as ‘verwachtingen’. In this thesis the terms expectancy and expectation will be used interchangeably.

It is well-accepted that patient expectations are a complex and multifaceted construct which, despite a long research history, lacks conceptual clarity³¹⁻³³. The published literature contains many inconsistencies and a wide variety of definitions of patients expectations. There are models that describe similar concepts but give them different names, and conversely, different concepts are given the same or a similar names. Several authors have^{31,33-35} reviewed the clinical literature in different clinical areas and noted that authors often do not specifically define what they mean by expectations, nor do they refer to the theoretical model that underpins their hypotheses. This makes it difficult to interpret findings and compare results across studies. The extent of the problem is illustrated by the description of the typologies of expectations used in different frameworks and models. A typology proposed by Kravitz³⁴ distinguishes the emotional (value expectations; which are expressions of desires, necessities, entitlements or importance) and cognitive components (probability expectations which are the probabilistic beliefs that something will occur) of expectations. Kravitz proposes that expectations have three key features namely the definitional orientation (value versus probability expectations), level of specificity (e.g. expectations for health care in general versus expectations for a specific treatment), and their content (structure, process or outcomes of care). The typology by Thompson and Sunol³⁰ is based on whether expectations are ‘predicted’ or ‘idealized’ or even ‘unformed’. Crow³¹ follows the typology of Bandura by distinguishing expectations related to the treatment outcome (outcome expectations) and to patients themselves (self-efficacy expectations).

The lack of conceptual clarity of the patient expectations construct has implications for its measurement. Recently, researchers systematically reviewed the literature regarding measurement instruments for expectations of patients with musculoskeletal disorders³⁶ and patients undergoing orthopedic surgery³⁷. Both these systematic reviews concluded that the current standard of measurement of expectations is poor. The majority of measurement instruments used in clinical literature were developed for the purpose of the single study and lacked proper clinimetric evaluation of validity and reliability. Several questionnaires have been developed according to good clinimetric standards, but they vary highly in the content addressed by the items, in the nature of expectations assessed (value or probability expectations) and the specificity of the items³⁶.

Finally, it is noteworthy that patients were involved in development of only very few theories, frameworks, typologies and measurement instruments. As patients themselves are self-evidently essential to any conceptualisation of the construct, their inclusion in validation of existing typologies or development of ones is appropriate.

Theme 2: Determinants of patients’ expectations

The ultimate goal of expectation research is to be able to use patient expectations to optimise clinical situations, for instance by manipulating them to increase the therapeutic benefits of a treatment. In order to do so it is necessary to know how expectations develop and what the determinants of expectations are and whether and how they change. To date, relatively little is known about the determinants of expectations. Most clinical studies have investigated only a few patient characteristics (e.g. gender and age) and psychological variables such as anxiety and depression as correlates of pre-treatment expectations. Crow et al’s model however, suggests four broad categories of important determinants of expectations; the patient, the practitioner, the patient-practitioner relationship, and the treatment and setting. Experimental work has indicated that previous ‘learned’ experiences (classical condition paradigm) inform expectations as do verbal suggestions by the practitioner³⁸. It is noted though that the majority of this evidence comes from experimental, as opposed to clinical settings. The categories suggested by Crow et al lack empirical clinical evidence and are too broad to be practically applicable. Moreover, it is largely unknown whether findings from experimental settings can be translated to clinical situations.

Theme 3: The relationship between patients’ expectations and treatment outcomes

In the last decades there has been an increase in clinical studies investigating the association between treatment expectations and clinical outcomes. For musculoskeletal disorders positive associations have been found for this relationship in patients with osteoarthritis undergoing total knee or hip arthroplasty⁶⁻⁷, patients with low back pain undergoing physiotherapy², manual therapy³⁹, acupuncture⁴⁰ or surgery⁴¹, in patients with neck pain undergoing manual therapy⁴² and in patients with chronic pain undergoing cognitive behavioral therapy⁵. The strength of the association in these studies varies widely. There are also some studies which showed no relationship between expectations and outcomes. Reasons for this variation may be methodological and conceptual differences; e.g. design of the studies (cross sectional versus longitudinal), the outcomes (patient reported versus observer-rated outcomes), the type and content of the expectations, the measurement approach taken, and the statistical models used to define the relationship. As yet it is still unclear which exact type of expectations have a relationship with which outcomes under which circumstances.

Theme 4: the mechanisms through which patients’ expectations influence treatment outcomes

The mechanisms through which expectations can be translated to health outcomes have mainly been studied in the context of investigation of placebo effects. Experimental studies have focused primarily on placebo analgesia and have identified several possible neurobiological pathways that mediate the relationship between expectations and

nonvolitional outcomes such as pain⁴³ and itch⁴⁴. However, theoretical models from behavioral psychology suggest that behavioral aspects and motivation may also mediate the relationship between expectations and outcomes^{23,45}. For instance if a patient with low back pain believes that exercise helps relieve the pain, he may be more motivated to perform the exercises and better adhere to treatment recommendations which results in better outcomes. Flood et al⁴⁶ hypothesized that there are at least 5 possible pathways that may explain why expectations are associated with outcomes, namely: 1. triggering of a physiological response, 2. conditioning the patient psychologically to observe certain types of outcomes and ignore others 3. changing the understanding of the disease (by information and education) 4. moderation of anxiety and 5. motivating patients to achieve better outcomes. It is likely that multiple pathways simultaneously play a role and interact, and perhaps the dominant pathway varies according to type of treatment, disorder or individual. It is therefore important that these and other potential pathways are investigated in clinical studies.

Aims and outline of this thesis

Summarizing the above it may be clear that there is scientific evidence suggesting a relationship between patients' expectations and treatment outcomes, the exact role of different types of expectations and the pathways linking expectations to outcomes are neither well-defined nor understood. The three research fields in which expectations have been most investigated; placebo research, behavioral research and health services research, have worked from separate theoretical models and frameworks. In order to fully benefit from the role that expectations can play within medical treatment, it is necessary to integrate knowledge from all these three fields. One way of doing this is to establish a heuristic theoretical framework in which perspectives from the three areas are taken into account informed by the perspective of the patient.

The aim of the work presented in this thesis is to advance the scientific understanding by proposing a refinement and extension of Crow et al's framework (figure 1). This will involve addressing aspects of the four themes related to the role of patients expectations within treatment settings. Specifically the following research questions will be addressed:

Theme 1: How do patients themselves conceptualize the construct expectations? Do currently available measurement instruments capture the conceptual differences between patients' outcome expectations, treatment credibility, optimism, pessimism and hope?

Theme 2: Can we identify determinants of patients' expectations based on interviews with low back pain patients about which factors have influenced their expectations?

Theme 3: Do expectations predict health outcomes above and beyond other clinically relevant predictors? Which type of expectations is related to which type of outcomes? Are changes in expectations related to changes in outcomes?

Theme 4: Does adherence to treatment mediate the relationship between patients' outcome expectations and treatment outcomes?

Most studies described in this thesis are performed within the musculoskeletal area. There has been particular interest in the biopsychosocial model and context effects of treatment in this area, probably because for a majority of patients no specific pathology has been identified for some of the most prevalent disorders like low back and neck pain. Given this, and the modest effects associated with established treatments, it may be even more important to harness the non-specific effects of treatment.

Chapter 2 of this thesis addresses themes 1 and 2. It contains the report of a qualitative study on the conceptualization of expectations by low back pain patients enrolled in a RCT comparing three different treatment options. In this study we also explored the factors that patients' believed had influenced their expectations (determinants from the patients perspective). In **Chapter 3** an aspect of theme 1 is investigated. The purpose of this study was to examine whether the measurement instruments used to assess expectations in clinical research studies can distinguish between expectation, credibility, optimism, pessimism and hope, in patients undergoing an invasive surgery (total hip or total knee arthroplasty; TKA or THA). These psychological factors show conceptual similarities and it is questioned whether patients can distinguish between them. In **Chapter 4** an aspect of theme 3 is investigated by reviewing the literature regarding the relationship between patients' pre-operative expectations, and outcome following TKA or THA. Two different types of expectations, five different outcomes and three different time-points were assessed to explore whether these aspects could be the cause of variation in the relationship between expectations and outcomes in TKA and THA. In **Chapter 5** an aspect of theme 3 is studied. It describes the expectations that patients have concerning the outcomes of a total hip or total knee arthroplasty and the extent to which each of these expectations are fulfilled 1 year postoperative. In **Chapter 6** another aspect related to theme 3 is investigated; it describes a study on the predictive value of preoperative outcome expectations on post-operative pain and function in patients undergoing TKA and THA. Two expectation measurements with different levels of specificity regarding the content of expectations assessed (regarding the general outcome of the surgery, and regarding very specific functional outcomes) were included to explore the differential effects of the specificity of the measurement of expectations on the outcomes. Further, we explored the relative importance of expectations as compared to other well-known predictors of outcomes for TKA and THA surgery. In **Chapter 7** another aspect of theme 3 is explored, specifically we investigated the relative importance of multiple psychosocial factors, including treatment expectancy, credibility, fear avoidance beliefs and locus of control beliefs for predicting the outcome of manual or physical therapy in patients with neck pain. **Chapter 8** addresses theme 3 but takes a step outside of the field of musculoskeletal disorders. It is concerned with the cognitive illness perceptions of diabetes patients and the relationship of these perceptions and changes in these perceptions with changes in the two most important outcomes in diabetes care, those being; self-

reported quality of life and the blood glucose marker HbA1c. In **Chapter 9** one of the hypothesized pathways that may explain part of the relationship between expectations and health outcomes is investigated. This aim fits within theme 4. We examined whether more positive expectations for treatment outcome led to better adherence to treatment which subsequently led to better treatment outcomes for acute low back pain patients treated with paracetamol or placebo paracetamol. Finally, in **Chapter 10**, the general discussion, we propose a refinement and extension of Crow et al preliminary model. This extension takes into account perspectives from our own work as well as others. We will further discuss the results of the studies described in chapter 2 to 9 with respect to this framework and present promising avenues for further research.

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