Preference Effects in the Treatment of Panic Disorder

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Patient preferences have drawn considerable attention as a potential moderator of treatment outcome. The Doubly Randomised Controlled Preference Trial (DRCPT) in which patients are randomised to a choice between two or more treatments or random assignment to one of these same treatments is considered one of the most rigorous tests of the effects of patient preferences on outcomes. To date, there have been no DRCPTs involving the choice between two psychological treatments for any psychiatric disorder.

The Project Psychotherapy Outcome and Self-selection Effects (POSE), from which this program of PhD research is drawn, was a DRCPT carried out in the southern part of Sweden between 2010 and 2019. In the Project POSE, 221 adults with a primary diagnosis of Panic Disorder with or without Agoraphobia (PD/A) were randomly allocated to choose between Panic Control Treatment (PCT) and Panic Focused Psychodynamic Psychotherapy (PFPP), or to random assignment to these two treatments.

The result show that contrary to expectation, there were no differences on the primary and secondary outcomes at post-treatment or long-term follow-up for patients randomised to the treatment choice and random allocation to treatment conditions. However, a disordinal interaction, albeit non-significant, on the PDSS, suggested that the effect of treatment preferences on outcomes for PD/A may have been moderated by treatment type (PCT or PFPP).

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LUND
UNIVERSITY

DOCTORAL DISSERTATION

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Abstract

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Project POSE, from which this program of PhD research is drawn, had two primary aims: 1) to assess the effects of patient treatment preferences on the primary and secondary outcomes at post-treatment and follow-up; and 2) to compare outcomes for PCT and PFPP on the primary and secondary outcomes at post-treatment and follow up. The primary aims of this PhD were: 1) to assess the effects of patient choice of treatments on the primary outcomes at post-treatment and follow-up; and 2) via qualitative and quantitative methods to better understand why participants randomised to the choice condition chose either PFPP or PCT; and 3) to evaluate the validity of the Swedish version of the PDSS, which served as the primary (interview version) and secondary (patient-report version) measures of PD/A severity in the trial.

Study I identified an important gap in the literature with respect to a need for studies that could experimentally test the role of patient treatment preferences on outcomes in psychotherapy. Study II established that that the Swedish translations of the PDSS and PDSS-SR possessed high levels of internal consistency and concurrent validity, as well as a factor structure similar to the English-language original, suggesting they were valid for use as a primary/secondary measures in the DRCPT. Study III found that when offered a choice between PCT and PFPP, the resulting choice was primarily a function of the individual's beliefs about the chosen therapy, its potential for success, and their own learning style. Contrary to expectation, Study IV found no differences for the primary and secondary outcomes at post-treatment or long-term follow-up for patients randomised to the treatment choice and random allocation to treatment conditions. However, a disordinal interaction, albeit non-significant, on the PDSS, suggested that the effect of treatment preferences on outcomes for PD/A may have been moderated by treatment type (PCT or PFPP).

Key words
Preference effects, Doubly randomised controlled preference trial, Panic disorder, Cognitive behavioural therapy, Psychodynamic therapy

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Table of Contents

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Lund, januari 2021

Martin Svensson

Abstract

Patient preferences have drawn considerable attention as a potential moderator of treatment outcome. The Doubly Randomised Controlled Preference Trial (DRCPT) in which patients are randomised to a choice between two or more treatments or random assignment to one of these same treatments is considered one of the most rigorous tests of the effects of patient preferences on outcomes. To date, there have been no DRCPTs involving the choice between two psychological treatments for any psychiatric disorder. A DRCPT was conducted in which 221 adults with a primary diagnosis of Panic Disorder with or without Agoraphobia (PD/A) were randomly allocated to choose between Panic Control Treatment (PCT) and Panic Focused Psychodynamic Psychotherapy (PFPP), or to random assignment to these two treatments. The primary outcome measures were the Panic Disorder Severity Scale (PDSS), work status and sick leave assessed at post-treatment, 6-, 12-, and 24-month follow-ups. A range of secondary outcomes were assessed at these same intervals. The DRCPT, titled Project POSE (Psychotherapy Outcome and Self-selection Effects), was carried out in the southern part of Sweden between 2010 and 2019.

Project POSE, from which this program of PhD research is drawn, had two primary aims: 1) to assess the effects of patient treatment preferences on the primary and secondary outcomes at post-treatment and follow up; and 2) to compare outcomes for PCT and PFPP on the primary and secondary outcomes at post-treatment and follow-up. The primary aims of this PhD were: 1) to assess the effects of patient choice of treatments on the primary outcomes at post-treatment and follow-up; and 2) via qualitative and quantitative methods to better understand why participants randomised to the choice condition chose either PFPP or PCT; and 3) to evaluate the validity of the Swedish version of the PDSS, which served as the primary (interview version) and secondary (patient-report version) measures of PD/A severity in the trial.

Study I identified an important gap in the literature with respect to a need for studies that could experimentally test the role of patient treatment preferences on outcomes in psychotherapy. Study II established that that the Swedish translations of the PDSS and PDSS-SR possessed high levels of internal consistency and concurrent validity, as well as a factor structure similar to the English-language original, suggesting they were valid for use as a primary/secondary measures in the DRCPT. Study III found that when offered a choice between PCT and PFPP, the resulting choice was primarily a function of the individual's beliefs about the chosen therapy, its potential for success, and their own learning style. Contrary to expectation, Study IV found no differences for the primary and secondary outcomes at post-treatment or long-term follow-up for patients randomised to the treatment choice and random allocation to treatment conditions.

However, a disordinal interaction, albeit non-significant, on the PDSS, suggested that the effect of treatment preferences on outcomes for PD/A may have been moderated by treatment type (PCT or PFPP).

Summary in Swedish

Patienters behandlingspreferenser har under de senaste tre decennierna uppmärksammats som en potentiell moderator för behandlingsresultat. En dubbelrandomiserad forskningsdesign, ”Doubly Randomised Controlled Preference Trial” (DRCPT), där patienter randomiseras antingen till ett val mellan behandlingar eller till slumpmässig fördelning till en av behandlingarna, anses vara en av de mest lämpliga studiedesignerna för att undersöka effekterna av patienters behandlingspreferenser. Projektet ”Psykoterapeutiskt utfall och självvalseffekter” (POSE) var en DRCPT som genomfördes i södra Sverige under åren 2010-2019. Detta var den första DRCPT studien att jämföra två former av psykoterapi. Patienter började inkluderas till projektet 2011, och den sista tvåårs uppföljningen genomfördes våren 2019. I projektet behandlades patienter med en primär diagnos av paniksyndrom med eller utan agorafobi (PS/A). PS/A är vanligt i befolkningen och har en livstidsprevalens på 1 % till 3,5 % och är ett kroniskt tillstånd förknippat med lägre livskvalitet och minskad arbetsförmåga. Patienter med PS/A utnyttjar sjukvården i hög grad, de har en ökad sjuklighet och en ökad dödlighet. Kognitiv beteendeterapi (KBT), antingen som enskild behandling eller i kombination med psykofarmaka, är förstahandsvalet vid behandling av PS/A. Dessvärre avslutar en betydande del av patienterna behandlingen i förtid (avhopp), eller uppnår inte en kliniskt meningsfull minskning av symtomen. Det finns vetenskapligt stöd även för andra psykologiska behandlingar, däribland psykodynamisk terapi (PDT), som behandling för PS/A. Att undersöka och tillmötesgå patienters behandlingspreferenser för olika behandlingsalternativ kan vara en möjlighet att öka effekten av befintliga psykoterapiformer för PS/A. De två psykoterapiformer som prövades i Projekt POSE var ”Panic Control Treatment” (PCT), en form av KBT för PS/A med omfattande forskningsstöd, och ”Panic Focused Psychodynamic Psychotherapy” (PFPP), en form av PDT som visat goda behandlingsresultat i tre randomiserade kontrollerade studier för PS/A.

Projekt POSE hade två övergripande mål: 1) att bedöma effekterna av patientens val av behandling på de primära utfallsmåtten (allvarlighetsgrad av PS/A, status på arbetsmarknaden, sjukfrånvaro) och på de sekundära utfallsmåtten (t.ex. co-morbida tillstånd och frekvens av vårdsökande) vid behandlingens avslut, och vid 6, 12 och 24 månader efter behandling; 2) att jämföra behandlingseffekterna av PCT och PFPP på de primära utfallsmåtten (allvarlighetsgrad av PS/A, status på arbetsmarknaden, sjukfrånvaro) och på de sekundära utfallsmåtten (t.ex. co-morbida tillstånd och frekvens av vårdsökande) vid behandlingens avslut, och under uppföljningsperioden.

Föreliggande avhandling hade följande mål: 1) att undersöka effekterna av patientens val på utfallet i DRCPT-studien vid behandlingsavslut och under hela två-års uppföljningen; 2) att undersöka karaktäristika för vilka patienter som valde PCT eller PFPP och hur de motiverar behandlingsvalet; 3) en psykometrisk utvärdering av de svenska översättningarna av ”Panic Disorder Severity Scale”, i intervjuversion (PDSS) och i självskattningsversion (PDSS-SR). PDSS var ett av de primära utfallsmåtten och PDSS-SR ett av de sekundära utfallsmåtten för allvarlighetsgrad av PS/A. Kvantitativa och kvalitativa metoder applicerades på datamaterialet. En parallell avhandling författad av Thomas Nilsson (Institutionen för psykologi, Lunds universitet) fokuserar på behandlingsjämförelsen mellan PCT och PFPP och potentiella moderatorer för behandlingsresultatet. Med anledning av detta adresseras inte behandlingsjämförelsen i diskussionen i föreliggande avhandling.

Studie I: I artikeln presenteras den teoretiska och empiriska bakgrunden för Projekt POSE, detaljer vad gäller forskningsdesign och vetenskaplig metod i DRCPT. Studien publicerades (online) i den refereegranskade tidskriften BMC Trials den 31:e mars 2015.

Studie II: I artikeln utvärderas faktorstrukturen och de psykometriska egenskaperna för de svenska översättningarna av ”Panic Disorder Severity Scale” i dess intervju (PDSS) och självrapporteringsversion (PDSS-SR) för de 221 deltagarna i preferensstudien. PDSS var det primära utfallsmåttet och PDSS-SR var ett av de sekundära utfallsmåtten på paniksymptom i preferensstudien. Artikel publicerades (online) i den refereegranskade tidskriften Nordic Journal of Psychiatry den 14:e januari 2019.

Studie III: Artikeln undersöker vilka variabler som är förknippade med patientens val emellan PCT och PFPP och hur detta val motiveras av patienten. Deltagarna var de 109 personer som randomiserades till självvalsalternativet i preferensstudien. Artikeln publicerades (online) i den refereegranskade tidskriften Psychotherapy Research den 5:e november 2020.

Studie IV: I artikeln presenteras resultaten vid behandlingsavslut och två års uppföljning av de 221 vuxna patienter med en PS/A som deltog i DRCPT studien. Artikeln publicerades (online) i den refereegranskade tidskriften Psychotherapy and Psychosomatics den 23:e november 2020.

Studie I identifierade en lucka i litteraturen avseende bristen på studier som experimentellt testat betydelsen av behandlingspreferenser för utfallet av psykoterapi. Studie II bekräftade att de svenska översättningarna av PDSS och PDSS-SR har goda psykometriska egenskaper och en faktorstruktur liknande de engelskspråkiga originalen. Resultatet styrker frågeformulärens användning som mått på allvarlighetsgrad av paniksyndrom i forskning. Studie III utforskade valet mellan två

evidensbaserade psykoterapiformer för PS/A, PCT och PFPP. Valet var främst en funktion av individens värdering av den enskilda terapins innehåll, dess potential för framgång och patientens egen inlärningsstil. I studie IV fann vi mot förväntan inga skillnader, vare sig för primära eller sekundära utfallsmått, vid behandlingsavslut eller uppföljning, för patienter som randomiserade till självval respektive slumpmässig fördelning till behandling. En icke-signifikant, disordinal interaktion kan förklara nollresultatet och antyder att effekten av behandlingspreferenser modereras av behandlingstyp (PCT eller PFPP).

List of Studies

I. Sandell, R., Svensson, M., Nilsson, T., Johansson, H., Viborg, G., & Perrin, S. (2015). The POSE study - panic control treatment versus panic-focused psychodynamic psychotherapy under randomised and self-selection conditions: Study protocol for a randomised controlled trial. Trials, 16(130). Published (online) 31 March 2015. [PMID: 25873067]. DOI: 10.1186/s13063-015-0656-7

II. Svensson, M., Nilsson, T., Johansson, H., Viborg, G., Perrin, S., & Sandell, R. (2019). Psychometric analysis of the Swedish panic disorder severity scale and its self-report version. Nordic Journal of Psychiatry, 73(1), 58-63. Published (online) 14 January. [PMID: 3063646]. DOI: 10.1080/08039488.2018.1554699

III. Svensson, M., Nilsson, T., Perrin, S., Johansson, H., Viborg, G., & Sandell, R. (2020). Preferences for panic control treatment and panic focused psychodynamic psychotherapy for panic disorder - Who chooses which and why? Psychotherapy Research. Published (online) 5 November. [PMID: 33148129]. DOI: 10.1080/10503307.2020.1839686

IV. Svensson, M., Nilsson, T., Perrin, S., Johansson, H., Viborg, G., Falkenström, F. & Sandell, R. (2020). The effect of patients' choice of cognitive behavioural or psychodynamic therapy on outcomes for Panic Disorder: A doubly randomised controlled preference trial. Psychotherapy & Psychosomatics. Published (online) 23 November. [PMID: 33227785]. DOI: 10.1159/000511469

Abbreviations

PD = Panic Disorder

PD/A = Panic Disorder with or without Agoraphobia

PDT = Psychodynamic Therapy

CBT = Cognitive Behavioural Therapy

PFPP = Panic Focused Psychodynamic Psychotherapy

PCT = Panic Control Treatment

RCT = Randomised Controlled Trial

DRCPT = Doubly Randomised Controlled Preference Trial

PRPT = Partially Randomised Preference Trial

POSE = Psychotherapy Outcome and Self-selection Effects

SDM = Shared Decision Making

STS = Systematic Treatment Selection

SMD = Standardized Mean Difference

SCID = Structured Clinical Interview for DSM-IV

DSM = Diagnostic and Statistical Manual

PDSS = Panic Disorder Severity Scale

PDSS-SR = Panic Disorder Severity Scale – Self Report

CORE-OM = Clinical Outcome in Routine Evaluation—Outcome Measure

MADRAS-S = Montgomery Åsberg Depression Rating Scale, Self-Report Version

SDS = Sheehan Disability Scale

BSQ = Bodily Sensations Questionnaire

MI = Mobility Inventory for agoraphobia

WAI = Work Ability Index

IIP = Inventory of Interpersonal Problems

PEX = Psychotherapy Experience Questionnaire

LSI-II = Learning Style Inventory-II

Introduction

Treatment Preferences

Patient Preferences for Treatment

The term 'patient preference' refers to sometimes distinct but overlapping constructs in the treatment literature. The term is sometimes used in relation to behaviours or attributes of the therapist or therapy that are valued or desired by the patient (Glass et al., 2001). Adamson et al. (2005) define treatment preference as the choice of treatment a patient would have made had they been asked. Research on patient treatment preferences identify factors that are associated with or assumed to influence patient motivation to engage in (and their level of satisfaction with) various treatments, and has an overall aim to improve the efficacy of individual treatments and the patient's experience of healthcare delivery (Swift & Callahan, 2009). Identifying patient treatment preferences is also an important aspect of the Evidence Based Practice (EBP) paradigm, defined by the American Psychological Association as "…the integration of the best available research with clinical expertise in the context of patient characteristics, culture, and preferences" (American Psychological Association, 2006, p. 273). During the last ten years there has been an increasing number of published studies investigating patient treatment preferences, partly reflecting the positive evidence linking outcomes to such preferences (Swift et al., 2018). Patient treatment preferences have been evaluated with respect to outcomes for different treatments, aspects of treatment methodology, and methods of delivery (e.g. internet vs. face to face, group vs. individual) for different mental and physical conditions, and the extent to which patients of different demographic backgrounds (e.g., age, gender, ethnicity) express a preference for specific treatments or treatment modalities (Cole et al., 2018; Farrell & Deacon, 2016; Glock et al., 2018; Hanson et al., 2016; Kirk et al., 2016; McHugh et al., 2013; Moffitt et al., 2015; Patel & Simpson, 2010; Perreault et al., 2014; Price, 2016; Seidler et al., 2018; Swift & Callahan, 2010; Swift et al., 2015; Tzur Bitan & Lazar, 2019). Little is known about factors beyond demographic characteristics that may influence patient preferences for specific treatments or treatment modalities (McHugh, Whitton, Peckham, Welge, & Otto, 2013; Steidtmann et al., 2012). In addition, the studies that have been carried out to evaluate the relationship between

treatment preferences and outcomes are relatively few in number and highly heterogeneous in terms of sample characteristics and design, i.e. the methods for eliciting patient treatment preferences (Swift et al., 2018). Nevertheless, when asked, there is evidence that patients have well-developed ideas about what constitutes effective and unhelpful psychotherapeutic approaches to their own difficulties (Bowie et al., 2016; Nilsson et al., 2007).

Shared Decision Making (SDM)

Kunneman et al. (2016) defines Shared Decision Making (SDM) as a process in which clinicians and patients work together to understand the patient's problems and to determine how best to address them when two or more reasonable treatment options exist. The authors stress the importance of making the treatment decision together with the patient so that the patient does not feel abandoned in the decision making process. To support this process, conversation and decision aids have been developed to assist healthcare professionals to elicit patient treatment preferences and to jointly guide treatment decisions as part of an 'ongoing' conversation about the patient's healthcare (Kunneman et al., 2016). This approach can be contrasted with the way that patient treatment preferences are elicited in the psychotherapy literature, i.e. either before or after the patient has been offered a single treatment or chosen between two treatments, and usually on the basis of written information about the alternative treatments, not as part of a discussion with the healthcare provider (Glass et al., 2001). SDM is recommended in the UK's National Institute for Health and Care Excellence guidelines (NICE, 2011) for PD/A. However, further research is needed to estimate the extent to which SDM is associated with different health related outcomes, including illness reduction, patient involvement in and satisfaction with their healthcare, and the cost of care (Montori et al., 2017).

Systematic Treatment Selection (STS)

Systematic Treatment Selection (STS) is defined by Beutler et al. (2006, p. 29) as a "procedure for identifying the mix of therapist, treatment strategies, and psychotherapeutic interventions that are most likely to produce a favorable response in any given patient. Two basic assumptions underlie this approach: (a) There is no treatment method or model that works well on all patients, and (b) most treatment methods work well on some patients". In STS, patient treatment preferences are one of several aspects influencing the treatment decision. The sole example of an STS study involving both CBT and PDT is a study by Watzke et al. (2010) who compared STS and randomization to either non-manualized CBT or PDT in a diagnostically mixed inpatient sample (N = 291). STS in this trial was based on a clinician assessment of the

patient's diagnoses and treatment goals; actual patient treatment preferences played a minor role in the selection of treatment.

Concepts Relating to Preferences

In the literature there are many concepts relating to preferences, most of which have been studied in relation to measurement of preferences. Some examples among these are: etiological beliefs (El Amiri et al., 2018; Tompkins et al., 2017); treatment credibility (Bragesjo et al., 2004; Cohen et al., 2015; Devilly & Borkovec, 2000; Frovenholt et al., 2007); treatment expectations (Cohen et al., 2015); and helpfulness beliefs (Bragesjo et al., 2004; Frovenholt et al., 2007; Sandell et al., 2011).

Research Design for Identification of Patient Treatment Preference Effects

Rosen (1967) was one of the first to address the knowledge gaps in the research regarding patient treatment preferences, and the need to test the effect of such preferences on outcomes with the use of an experimental design. Twenty-two years later, Brewin and Bradley (1989) argued that randomised controlled trials (RCTs) comparing two or more treatments may give misleading results if the patient's preferences for the offered treatment alternatives were not controlled for. Thus, to the extent that patient's treatment preference influences the outcome for a specific type of psychotherapy, the treatment that is preferred by the majority of the patient population will appear superior, even if the preferred and non-preferred treatments are equally effective "in themselves". So in a trial where patients can select their preferred treatment from two or more evidence-based treatments, it is possible that there will be little or no differences in outcomes for patients in the different treatment groups. According to Brewin and Bradley (1989), it also possible that the treatments that are patient-selected may be, on a group level, more effective than treatments that are randomly assigned. It has also been noted that the external validity of standard RCT's may be called into question because patients with strong treatment preferences may refuse to be randomised and thus are excluded from the trial (Swift & Callahan, 2009). A recent meta-analysis by Wasmann et al. (2019) found that in nearly half of the identified trials where participants could refuse randomization and still participate, more than 50% of participants did refuse randomization. The authors found that older patients, more often female, with higher levels of education and more severe symptoms were more likely to do so.

Different study designs have been employed to assess how patient treatment preferences influence outcomes (including satisfaction with treatment), often in a secondary way as a part of a trial that was originally designed to test the efficacy of two distinct therapies (e.g., medication versus CBT) or two versions of the same therapy (e.g., group versus individual CBT). In conventional RCT studies, patient preferences for the treatment(s) offered in the trial may be assessed either before or after randomization, with the relationship of this stated preference to outcomes in the randomly assigned treatments evaluated when the trial is completed. However, as patients are randomly allocated to treatment conditions, such a design provides no test of the effect of choosing one's preferred treatment. It also permits very limited inferences about the effects of patient treatment preferences on outcomes because the randomization process may lead to imbalances in the proportion of participants in the treatment groups who did or did not receive their preferred treatment (Swift & Callahan, 2009; Walter et al., 2017).

A number of alternatives exist to evaluating the influence of patient treatment preferences on outcomes in an RCT design. In match/no-match designs, also called fully randomised preference trials, the patient's treatment preferences are assessed before the participants are randomised to either their preferred or non-preferred treatment. However, while the preference effect can be assessed it cannot be separated from the treatment effect. In a partially randomised preference trial participants with a strong preference for one of the treatments under test, and who refuse randomization, are offered their preferred treatment, while the remaining participants are randomised to the different treatments under test. Again, the inferences that can be drawn about patient treatment preferences on outcomes are limited because: a) such designs compare participants with strong treatment preferences to those with weak preferences; and b) it is not possible to separate preference from treatment effects (Swift & Callahan, 2009; Walter et al., 2017). It is possible to separate the effects of patient treatment preferences and treatment effects in a doubly randomised preference trial (Long et al., 2008; Walter et al., 2017). In such a trial patients are randomised to either a self-selection or random allocation to treatment condition. As will be discussed below, no such hybrid design has been applied to compare two forms of psychological treatment for any condition.

Mechanisms of Preference Effects

A number of different hypotheses have been put forth in the literature to explain how improved outcomes are achieved by matching patients to their preferred treatment (Lindhiem et al., 2014). Aptitude-by-treatment interaction research suggests that patients may benefit from different treatments based on their personal characteristics

(Dance & Neufeld, 1988). However, to date few strong predictors of outcome have received empirical support and patient preferences have been suggested as a possible surrogate marker for other predictors of treatment response (Dunlop et al., 2012). This differential suitability for treatment options may be based on, for example, the patient's degree of psychological mindedness (Hardy et al., 1995), idiosyncratic coping behaviours (Dance & Neufeld, 1988), and/or beliefs about the causes of their illness (Johnson et al., 2000). It has also been suggested that the act of choosing a treatment may have positive effects on outcome that are separable from the effect of being matched to one's preferred treatment through an enhanced sense of responsibility for the chosen treatment (Calsyn et al., 2000; Delevry & Le, 2019; Lindhiem et al., 2014; Seligman, 1995). Some authors have suggested that when patients are matched to their preferred treatment, they feel more "active" in the treatment processes and methods and this in turn improves the working alliance with the therapist (Elkin et al., 1999; Iacoviello et al., 2007). Lindhiem et al. (2014) summarising the available evidence for why offering patient their preferred treatment may improve outcomes concluded that the most promising area of study is the broad construct of therapeutic alliance, including aspects such as treatment adherence, positive outcome expectancies, and enhanced patient/therapist communication. While there is a fairly substantial body of evidence suggesting that patient's ratings of the working alliance are related to outcomes in psychotherapy (Flückiger et al., 2018), there are few studies on the extent to which any variable relates directly to patient treatment preferences and then outcomes, and further studies are needed (Swift & Callahan, 2009).

Measurement of Patient Treatment Preferences

Before proceeding, it is important to state that there is no agreed upon standard for assessing patient treatment preferences, and that all of the available methods require further evaluation of their validity and reliability (Wensing & Elwyn, 2003).

Swift et al. (2018) describe five most common ways for assessing patient treatment preferences in the literature. First, the patients are asked which treatment they prefer based on some form of information (text, video demonstrations, etc.). The patient's treatment preference may then be assessed with a global measure (i.e., preference indication based on all aspects of the treatment) or attribute-based measure (i.e., preference indication based on the variety of treatment features) (Crits-Christoph et al., 2017). Second, the clinician discusses the various treatment options with the patient and the patient expresses a preference. Third, the patients are asked how much they are willing to sacrifice Y to achieve X, (e.g., sacrificing treatment efficacy for a good working

alliance with the therapist). This delay-discounting method has been criticised for not representing the manner in which patient treatment preferences and choice of treatment are dealt with in real-world settings (Kirk et al., 2016). Fourth, the patient is administered a questionnaire(s) that assess attitudes towards different treatment components (e.g. therapist and patient roles and treatment activities). Examples of such questionnaires include the Psychotherapy Experience Questionnaire (PEX; Sandell et al., 2011), Preferences for College Counselling Inventory (PCCI; Hatchett, 2015), and the Cooper-Norcross Inventory of Preferences (C-NIP; Cooper & Norcross, 2016). Fifth, the clinician uses standardized, structured discussion tools for assessing patient treatment preferences (Vollmer et al., 2009). This fifth approach more closely resembles what is described in the broader (medical) SDM literature, wherein the patient and clinician use detailed treatment/illness information sheets and written decision tools to arrive at a treatment decision.

The timing and context of the assessment of the patient's treatment preferences is also relevant. Although not always specified in the individual preference studies themselves, there is a common assumption in the literature that patient treatment preferences should be assessed in the context of a full, accurate, and transparent assessment of their presenting problems/diagnoses with the patient being provided as specific information as possible (Kirk et al., 2016). In addition, a common distinction made in the literature is between stated and exercised preferences. The stated preference refers to the treatment the person would have chosen if he or she had the possibility to choose; the exercised preference refers to the realisation of that treatment preference, i.e. the actual choice of treatment. The two may not be the same; it is possible that a client may state a preference for one treatment and then, if given a choice, actually choose another (Walter et al., 2017). Also, it has been suggested that being asked about one's preference and then not being allowed to exercise that preference may negatively impact outcomes in the received treatment (Walter et al., 2017). There are mixed evidence reported for if choice of treatment has any added value beyond receiving ones preferred treatment; one meta-analysis suggests that the effects are comparable (Lindhiem et al., 2014), another suggests a small but significant effect of choice ($d = 0.14$) (Delevry & Le, 2019). Regardless of the effects on outcome, letting the patient choose between evidence-based treatments is no doubt closer to clinical practice than having the patient state their preference and then (in some cases) giving them another treatment.

Delevry and Le (2019) point to four common limitations in the assessment of preferences in trials. Firstly, the assessment of preferences may require a high health literacy on the patient's part to adequately comprehend the treatment options. Secondly, preference strength has been identified as an important aspect of preference measurement (Johansson et al., 2013; Markowitz et al., 2016) but it is rarely reported

upon in the preference literature. Thirdly, preference is usually measured once prior to the start of treatment, which assumes that the patient's preference remains constant during the treatment phase whether they are receiving their preferred treatment or not. However, there is widespread recognition that a patient's preference for different treatments may change during the course of any specific treatment. Lastly, it may be that the reasons patients have for preferring a specific treatment option vary between individuals, and the reasons for the preference may influence the degree to which it affects treatment outcome. For example, preference due to the treatment methods may influence outcome more than preference due to practical arrangement of the treatment. However, the reasons for the expressed preference are rarely assessed.

Overview of the Evidence for Patient Preference Effects

Effects on Treatment Outcome, Satisfaction, Attrition and Alliance

Eight meta-analysis have assessed the effects on outcome of receiving versus not receiving one's preferred treatment in patients with various mental and physical complaints (Delevry & Le, 2019; King et al., 2005; Lindhiem et al., 2014; Swift & Callahan, 2009; Swift et al., 2018; Swift et al., 2011; Tillbrook, 2008; Windle et al., 2019). The reported mean effect sizes on treatment outcome of receiving one's preferred treatment, represented by Cohen's *d* (Cohen, 1988), ranged from $d = 0.01$ ($p = 0.91$) to $d = 0.31$ ($p = <0.001$) across the eight meta-analyses, suggesting that preference effects fall in the null to small range. However, the two meta-analyses reporting non-significant preference effects for treatment outcome differed from the other six in non-negligible ways. First, the meta-analysis by King et al. (2005) included only studies using partially randomised preference designs, which have been criticised for their ability to adequately assess preference effects and to separate preference from treatment effects on outcomes (Swift & Callahan, 2009; Walter et al., 2017). Second, the meta-analysis by Windle et al. (2019) differed from the others in that it only included studies involving mental health treatments, although half of the included studies overlapped with those included by Swift et al. (2011) in their earlier meta-analysis. Importantly, the non-significant preference effect reported in the Windle et al. (2019) meta-analysis may owe more to the inclusion of studies using the much-criticised partially randomised preference design, than limiting inclusions to preference studies involving mental health treatments. In partial support of this, the meta-analysis by Delevry and Le (2019) only included studies using full or doubly randomised preference designs and found larger effect sizes for preference studies involving

treatments for mental health (d = 0.23) than for pain and functional disorders (d = 0.09).

Five meta-analyses have reported a significant preference effect on attrition, with fewer drop outs from treatment (*OR* 1.37 to 1.79) (Lindhiem et al., 2014; Swift & Callahan, 2009; Swift et al., 2018; Swift et al., 2011; Windle et al., 2019). In addition, Windle et al. (2019) observed a significant beneficial effect of receiving one's preferred treatment on the therapeutic alliance (d = 0.48) but no effect on treatment satisfaction, while Lindhiem et al. (2014) found a relationship between treatment preference and satisfaction (d = 0.34).

It is important to point out that the majority of the preference trials involving mental health treatments included in the meta-analyses cited above involved patients undergoing treatment for depression and/or comparisons between medication and psychotherapy. In addition, several of the individual preference trials involved a choice between two versions of the same treatment (e.g., group versus individual format, outpatient versus inpatient treatment, face-to-face versus internet delivery), which may underestimate the preference effect when the choice is between two distinct forms of treatment (e.g., medication versus psychotherapy, CBT vs PDT) (Rokke et al., 1999).

To date, there have been four trials assessing preference effects on outcomes in CBT and psychodynamic therapy (PDT), and they have yielded mixed results. The first study (Hardy et al., 1995) was an RCT study comparing CBT and PDT in adults with depression (N = 117). Receiving one's preferred treatment, as measured by the Opinions about Psychological Problems Questionnaire (OPP; Pistrang & Barker, 1992), was associated with improved outcomes in PDT but not in CBT. In the second study (Kadish, 1999), a match/no match design comparing CBT and PDT in adults with social phobia (N = 22), receiving one's preferred treatment was not associated with improved outcomes. In the third study (Johansson et al., 2013), a preference trial comparing internet based versions of CBT and PDT in adults with depression (N = 44) who had originally been randomised to the wait-list control condition in a trial comparing the online CBT and PDT protocols. In this study, all participants received their preferred treatment (CBT or PDT, online) after completing the wait-list condition. Strength of preference predicted improved long-term outcome for those who chose CBT but not PDT. The fourth study (Leuzinger-Bohleber et al., 2019) was a partially randomised preference trial comparing long-term CBT and PDT in adults with depression (N = 252). Receiving ones preferred treatment was not associated with improved outcomes. In addition, there was a significant interaction between time and treatment group due to an increase of symptoms in the preference CBT arm and a further decrease of symptoms in the randomised CBT arm at the three-year follow-up. Further studies, employing larger samples and doubly randomised preference designs,

are needed before any firm conclusions can be drawn about the influence of patient preferences on outcomes in CBT and PDT.

Moderators of the Preference Effect on Treatment Outcomes

A number of candidate moderators of the preference effect on treatment outcome have been evaluated in the above cited meta-analyses, with few significant results reported. Swift and colleagues (Swift & Callahan, 2009; Swift et al., 2018; Swift et al., 2011) found preference effects to be moderated by study design. Specifically, studies with partially randomised preference designs together yielded significantly smaller effect sizes for treatment preferences than did RCTs and match/no match studies. Further, in the 2011 meta-analysis preference effects on outcome varied slightly depending upon the disorder being targeted in treatment (anxiety disorders (6 trials): d = 0.49; depression (12 trials): d = 0.35; substance abuse (8 trials): d = 0.34) (Swift et al., 2011). This finding was confirmed in the later meta-analysis by the same lead author (Swift et al., 2018); a larger preference effect was obtained for participants with anxiety and depression than those with substance abuse, psychoses, and behavioral health problems. Delevry and Le (2019) also found the preference effect on outcomes to be moderated by diagnosis, with larger effect sizes for treatments targeting mental conditions (d = 0.23) than for those targeting pain and functional disorders (d = 0.09). In contrast, Lindhiem et al. (2014) failed to find any significant moderators of preference effects, including study design and diagnosis (mental health versus other). However, it is important to note that there have not been enough well-designed preference trials, which attempt to address issues relating to physical and psychiatric comorbidity, to draw firm conclusions about whether diagnosis moderates preference effects. Combining or averaging effect sizes for patient treatment preferences across diverse patient groups with significant comorbidity, based on their primary diagnosis, may yield misleading results. For example, Delevry and Le (2019) found that individuals who received their preferred treatment for obesity (4 trials) accrued no benefit, or even had poorer outcomes, in terms of weight loss. However, it is widely known that individual's seeking treatment for obesity suffer from much higher rates of anxiety and depression, and other comorbid psychiatric conditions, than the general population (Simon et al., 2006). Thus, more well-designed preference trials are needed for different physical and mental conditions that are sufficiently large to allow for the effects of comorbidity on the relationship between preference and outcomes for the primary condition to be estimated.

Panic Disorder With or Without Agoraphobia

Description of the Condition

Panic Disorder (PD) first entered diagnostic classification systems in 1980 with the publication of DSM-III (Breilmann et al., 2019). The core features of PD have remained largely unchanged in subsequent editions of the DSM. According to the fourth, text-revised edition (DSM-IV-TR) (American Psychiatric Association, 2000), which was the latest version of the manual when this program of research started, the defining features of PD are recurrent unexpected panic attacks, i.e., discrete episodes of fear or anxiety with a peak within 10 minutes from onset, as well an intense fear of future attacks, both of which causing marked impairment in functioning. In DSM-IV-TR, patients with PD could be further categorized as either with or without Agoraphobia (PD/A); agoraphobia being an intense fear (and avoidance) of being in places or situations where panic attacks were more likely to occur and from which escape will either be difficult or embarrassing. In most recent edition of the DSM (DSM-5) (American Psychiatric Association, 2013), these subtypes were removed and Agoraphobia established as a separate disorder.

PD/A is common in the general population, with a lifetime prevalence of 1% to 3.5% (American Psychiatric Association, 2000). The prevalence for the Swedish population is likely comparable to the prevalence found in studies from Norway and USA (Statens Beredning för medicinsk utvärdering, 2005). Psychiatric comorbidity is common, with concurrent depression found in 10-65%, social anxiety and generalized anxiety disorder in 15-30%, specific phobia in 2-20%, obsessive compulsive disorder in 10%, and PTSD in 2-10% (American Psychiatric Association, 2000). In addition, between 25-60% of individuals with PD/A also meet criteria for a personality disorder (any), the most common being the personality disorders from the anxiety subtype (Cluster C), i.e. Avoidant, Dependent, and Obsessive-Compulsive personality disorders (Craske & Barlow, 2006; Navinés et al., 2016). PD with Agoraphobia is associated with increased PD severity and worse outcomes (Kessler et al., 2006). Adults with PD/A, and particularly those with Agoraphobia, are at increased risk of alcohol and drug use, health complaints and healthcare utilization, morbidity and mortality, diminished capacity for work and financial dependency, marital discord and social impairments, and a lower quality of life (Goodwin et al., 2005; Markowitz et al., 1989; Roest et al., 2019).

Etiological Models

The etiology of PD/A is not fully understood and it is likely that the causes are heterogeneous in nature (Breilmann et al., 2019). The best available evidence from epidemiological studies (both cross-sectional and longitudinal), as well as twin,

adoption, and genetic linkage studies suggest that multiple genes, trait-like dispositions (including anxiety, anxiety sensitivity, neuroticism, and perfectionism), exposure to ongoing stress (work, illness), and stressful life events (physical/sexual abuse, loss) are all associated with an increased risk of developing PD/A (Gorman et al., 2000; Kim & Kim, 2018; Roy-Byrne et al., 2006).

Within a CBT framework, two models have tended to dominate the literature. Clark´s (1986) cognitive model emphasizes the role played by panic-specific beliefs in the onset and maintenance of PD/A, specifically idiographic and dysfunctional beliefs about the nature of otherwise normal bodily sensations (and fluctuations in the same) and about how best to avoid, and/or minimize the consequences of, future panic attacks. Craske and Barlow (1988) acknowledges the importance of dysfunctional panic-specific beliefs but argues from a more traditional two-factor learning theory tradition, i.e. that the fear (panic) response can be acquired through classical conditioning and is then maintained by instrumental behaviors that are intended to reduce the intensity and frequency of panic attacks. The differences between the two models lessens (somewhat) in the application of the treatments that emanates from them; both approaches involve exposure to panic cues/situations and modification of panic-specific beliefs (Pompoli et al., 2016).

The etiological model that underpins the only panic-specific PDT treatment, Panic Focused Psychodynamic Therapy (PFPP; Milrod et al., 1997), asserts a central role for ambivalent attachments in the onset and maintenance of PD/A. The onset of PD/A is linked to developmental challenges, e.g. strivings toward independence, intimacy, and role related changes (e.g., marriage, pregnancy, work and education). For example, during childhood, a sense of fearful dependency on the parent may lead to the development of anger towards him or her. A vicious cycle may develop in which the child's anger threatens the emotional connection to the parent, and thereby increases fearful dependency, which promotes further frustration and rage at the parent. This cycle may then reoccur in adulthood at times when threats to attachment trigger intense feelings of abandonment, anger and anxiety, leading to the development of panic attacks and then the full disorder (Busch et al., 2012).

Overview of PD/A Treatment

Psychological Treatments for PD/A

Pompoli et al. (2016) conducted a Cochrane review comparing different types of psychological treatments for PD and included 54 RCTs in their analyses. The most

studied of the included psychological therapies was CBT (32 studies), followed by Behaviour Therapy (12 studies), Physiological Therapies (10 studies), Cognitive Therapy (3 studies), Supportive Psychotherapy (3 studies), and PDT (2 studies). Thus, in this meta-analysis, 47 of the 54 included RCTs (87%) involved some form of CBT. Irrespective of the type of psychotherapy evaluated, the authors conclude that there were considerable levels of heterogeneity in the evaluated studies as well as evidence of publication and researcher allegiance bias. While the results show that CBT was often superior to other therapies, effect size differences were small and clinically irrelevant. Overall, the authors conclude that no unequivocal evidence exists to support the superiority of one form of psychological treatment over another for the treatment of PD/A in adults, and further trials evaluating forms of psychotherapy other than CBT are needed.

Panic Control Treatment (PCT)

Panic Control Treatment (PCT; Craske & Barlow, 2006) is a manualized, individual form of CBT for adults with PD/A. As delivered, PCT typically involves weekly sessions lasting between 60-120 minutes, delivered over 12 weeks. PCT, or variants of this approach, is one of the most studied CBT protocols for PD/A, and has been shown to be effective at both acute and long-term follow-ups, and when delivered in a variety of settings (Fairholme et al., 2017; Furukawa et al., 2007; Pompoli et al., 2016).

Panic Focused Psychodynamic Psychotherapy (PFPP)

Panic Focused Psychodynamic Psychotherapy (PFPP; Milrod et al., 1997) is a manualized, individual psychodynamic treatment designed specifically for adults with PD/A. Treatment consists of 45 minute sessions, occurring twice weekly, for up to 12 weeks (19-24 sessions). To date PFPP is the only form of PDT having been evaluated specifically for adults identified because of a primary diagnosis of PD/A. PFPP has been shown to be effective at both acute (Milrod et al., 2016; Milrod et al., 2007) and long-term follow-ups (McCarthy et al., 2018), and when delivered in routine clinical practice (Beutel et al., 2013).

Medication Treatment

A Cochrane review from 2007 found evidence to support the use of combined therapy (antidepressants plus psychotherapy), or psychotherapy alone, but not medication alone, as a first-line treatment for PD/A (Furukawa et al., 2007). However, subsequent meta-analytic reviews have failed to find sufficient evidence for the superiority of combination treatments for PD/A, partly owing to significant heterogeneity across the available RCTs (Bighelli et al., 2016; Imai et al., 2016; Watanabe et al., 2009). As detailed in the first study from this dissertation, there is evidence from the literature

that a significant proportion of adults with PD/A refuse to take medications (or discontinue) prescribed medication for their PD/A because of concerns about side effects and dependency (Sandell et al., 2015).

In summary, CBT in general and PCT specifically are highly researched and effective treatments for PD/A, and across countries, are the forms of psychotherapy that are most often identified and recommended in treatment guidelines. While other forms of psychotherapy (and physical therapies) are less well researched for PD/A, the available evidence suggests that they yield effect sizes comparable to CBT. Indeed, the most recent Cochrane review concluded that there was insufficient evidence to conclude that any one form of psychotherapy was superior to another for PD/A (Pompoli et al., 2016). There is evidence for the efficacy of PDT for PD/A in the form of PFPP. While CBT is an effective treatment for PD/A, and the first-line recommended treatment in most national treatment guidelines, not all patients can tolerate this approach and approximately 30-40% fail to achieve a clinically meaningful reduction in symptoms (Pompoli et al., 2016). Additional large scale RCTs involving different forms of psychotherapy for PD/A, including PFPP, are needed.

Preferences Effects in the Treatment of PD/A

To date, three studies have assessed treatment preference effects for individuals with PD/A (Bakker et al., 2000; Perreault et al., 2014; Van Dyck & Spinhoven, 1997). The Van Dyck and Spinhoven (1997) study was a match/no-match study involving 64 adults treated with either in vivo exposure alone or in combination with hypnosis. There were no differences between the group that received their preferred treatment and the group that did not, nor was there any association between the severity of panic symptoms at post treatment and the strength of treatment preference as assessed prior to treatment. The Bakker et al. (2000) study was a partially randomised preference trial involving 66 adults who either had a strong preference for CBT (versus medical treatment) and refused randomization or agreed to be randomised to either CBT or medical treatment. No differences were observed between the randomised and preference group. The Perreault et al. (2014) study was a match/no match design in which all participants (N = 109) received group CBT. At pre-treatment participants completed a self-report measure of their preference for group versus individual CBT. Treatment completers had a significantly stronger preference for group CBT than participants who dropped out from treatment. The design of these trials, including a non-recommended treatment for PD/A (hypnosis) and two forms of CBT, significantly limits the inferences that can be drawn from about the role of patient preferences on

outcomes in psychotherapy for PD/A. In addition, little is known about the factors that are associated with patient preferences for different PD/A treatments. To date, one study (Perreault et al., 2014) assessed patient preferences for individual versus group therapy prior to their enrolment in group-based CBT for PD/A. No associations were observed between patient demographics, medication usage, treatment experience, or the severity of panic and agoraphobic symptoms and patient preferences for either group or individual CBT.

General and Specific Aims

In sum, treatment preferences have been studied in patients suffering from physical and mental health conditions, although in the latter group primarily in adults with depression. Patient treatment preferences have been found to be positively associated with treatment outcomes for the primary, targeted-condition, although the effects are in the small range and there is significant heterogeneity in the quality and methods of preference studies. The beneficial effects of patient preferences for psychotherapy have largely been evaluated in relation to the choice between psychotherapy (usually CBT) and pharmacotherapy or between formats/delivery methods for a single form of psychotherapy (again, usually CBT). Little is known about the effects of patient treatment preferences when the choice is between two distinct forms of psychotherapy, and this is true for any psychiatric disorder. With respect to PD/A, the three existing studies provide very limited information about preference effects owing to the choice of treatments and/or the use of a design that confounds or underestimates preference effects relative to treatment effects. Lastly, little is known about patient characteristics that may influence their actual choice of treatments, which is important to our understanding of the mechanisms through which matching patient preferences to treatment may influence outcomes.

The present thesis aimed to help address these gaps in the literature using the most methodologically rigorous preference design, the doubly randomised controlled preference trial (DRCPT), with two empirically-supported and distinct psychological treatments for PD/A. Specifically, the primary aims of this thesis were twofold. First, the thesis sought to evaluate the effects on outcomes for PD/A of patient preference for either Panic Control Treatment (PCT) or Panic Focused Psychodynamic Therapy (PFPP). Preference effects are evaluated for the primary outcomes (clinician-rated severity of PD, work status, and sick-leave absences) at post-treatment, 6-, 12-, and 24-month follow-ups. A preparatory study was undertaken to establish the validity of the Swedish-language versions of the Panic Disorder Severity Scale in the clinician- and

self-rated formats, as these were the primary and one of the secondary outcomes measures in this first of a kind DRCPT. Second, with quantitative and qualitative methods, the thesis aimed to better understand why patients allocated to the choice condition in this DRCPT chose either PCT or PFPP.

A parallel PhD conducted by Thomas Nilsson (Department of Psychology, Lund University) concerns itself with the second overarching aim of Project POSE, i.e., the relative efficacy of PCT and PFPP at post-treatment and follow-up and potential moderators of the primary and secondary outcomes. Therefore, the discussion section of this doctoral thesis does not address the comparison between PCT and PFPP.

Study I: This is the published protocol for the DRCPT (Project POSE). The article presents the theoretical and empirical justification for the DRCPT for two psychological treatments of PD/A, the study design, and aspects associated with the inclusion process.

Study II: This published study used baseline data from the DRCPT to assess the psychometric properties and validity, including the factor structure, of the Swedish translations of the PDSS in both the clinician-rated (primary psychiatric outcome measure in the DRCPT) self-report versions (secondary outcome in the DRCPT).

Study III: This published study used quantitative and qualitative data obtained just after randomisation from participants in the choice condition of the DRCPT to explore associations between their chosen treatment (PCT or PFPP) and their background characteristics, helpfulness-beliefs about the two treatments, and preferred learning styles.

Study IV: This published study describes the primary and secondary outcomes at post-treatment and all follow-ups for all participants in the DRCPT involving a comparison between random allocation to treatment (PCT or PFPP), choosing one's preferred treatment (PCT or PFPP), or a wait-list with subsequent re-randomization to the choice or random allocation conditions.

Method

Design and Settings

Project POSE was a multicentre DRCPT comparing PCT and PFPP for PD/A. Participants were randomly allocated to self-selection/choice of treatment (Choice), random assignment to treatment (Random), or to a wait-list control condition (Control). Participants allocated to Choice were provided written information about the two treatments and then asked to choose either PCT or PFPP. Participants allocated to Random were randomly allocated to PCT or PFPP. Participants allocated to Control were re-randomised to either the Choice or Random conditions at the end of the 3-month Control. The primary aim of the trial was to evaluate the relative efficacy of random assignment to two types of treatment type (Random) versus the patient choosing their preferred option from the same two treatment types (Choice). The wait-list condition was included to control for the possibility that both the randomly assigned and chosen treatments were equally ineffective in treating symptoms of PD/A. The trial was carried out in four regions in Sweden at outpatient psychiatry, primary health care, and youth guidance clinics. Martin Svensson and Thomas Nilsson were responsible for running the sites and all assessments from pre-treatment to 24 month follow up.

Participants

Participants in the three empirical studies were adults with PD/A recruited to Project POSE between November 2011 and May 2017. Study II used all pre-treatment data (N = 221) collected between 2011 and 2017. Study III used pre-treatment data from the Choice arm (N = 109) collected between 2011 and 2017. Study IV used all available data from participants randomised to the Choice or Random condition (N = 217) from the five assessment points (pre-treatment, post-treatment, 6-, 12-, and 24 month follow-up) collected between 2011 and 2019.

Inclusion and Exclusion Criteria

Inclusion criteria were: 1) aged 18 to 70 years; 2) current principal DSM-IV diagnosis of PD/A, including at least one panic attack per week during the three weeks preceding trial assessment; 3) if medicated, staying on a stable dose for at least one month prior to trial inclusion; 4) willing to keep medication dosage stable throughout the trial treatment phase; 5) not currently engaged in psychotherapy and willing to refrain from starting new treatments during the treatment phase; 6) ability to complete the treatment phase within 16 weeks; and 7) if participants actively avoided situations that caused them panic, they had to: 1) score ≥ 5 on an apprehension question about having a panic attack from the Anxiety Disorder Interview Schedule for DSM-IV (Brown, 2004) and: 2) score ≥ 4 on at least one question from the Avoidance-Alone Subscale of the Mobility Inventory for Agoraphobia (Chambless et al., 1985). Exclusion criteria were: 1) a current substance abuse/dependence disorder (or in remission for >12 months prior to trial inclusion); 2) current psychosis, delusions, mania, or Autism diagnosis; 3) acutely suicidal; 4) a history and current presentation of at least one clinically significant medical condition sufficient to cause cognitive or physical impairments that might prevent full participation in treatment; and 5) active involvement in a legal dispute related to their mental health.

Interventions

Panic Control Treatment (PCT)

PCT is a manualized, individual cognitive-behavioural treatment for adults with PD/A (Craske & Barlow, 2006). In the POSE trial, PCT involved 12-14 sessions completed within 10-16 weeks; week 1 and 2 includes two sessions and subsequent weeks one session each. Each session is 60 minutes in duration, extended to 90-120 minutes for those including therapist-assisted exposure. Between two and five sessions includes therapist-assisted exposure. Total treatment duration is 780 - 1140 minutes. Session 1 and 2: psycho-education about the nature of PD and agoraphobia and the patient learns how to self-monitor their anxiety/panic, session 3: building a hierarchy of agoraphobic situations, sessions 4-6: cognitive restructuring techniques and breathing retraining, sessions 6-13: in vivo/situational- and interceptive exposure. Session 14: relapse prevention. Between-sessions: homework assignments, done throughout treatment, involving symptom self-monitoring and after the first session with therapist-led exposure, planned patient-led exposures.

Panic Focused Psychodynamic Psychotherapy (PFPP)

PFPP is a manualized, individual psychodynamic treatment for adults with PD/A (Milrod et al., 1997). PFPP delivered in POSE comprised of 19-24 sessions completed within 10-16 weeks; in principle two sessions per week, 45 minutes each. Total treatment duration is 855-1080 minutes. PFPP proceeds in three phases. In Phase I, the therapist works to identify the specific content and meanings of the panic episodes and to help the patient examine the stressors and feelings surrounding the onset and persistence of panic. The patient is aided in bringing forth fantasies and feelings that may have been unconscious or difficult to tolerate, such as vengeful wishes or abandonment fears, and to identify intra-psychic conflicts surrounding anger, separation, and sexuality. Phase II seeks to address the dynamics that maintain vulnerability to panic and the persistence of panic symptoms (e.g., difficulties with anger recognition and management, separation, and fears of loss or abandonment). Improved understanding of these conflicts helps to prevent the development of a vicious cycle of PD recurrence. In Phase III, the therapist and patient work with the patient's conflicts with anger and separation as they emerge in the context of termination. Increased assertiveness and the capacity to communicate about conflicts in relationships should improve quality of life and reduce panic vulnerability.

Wait-List Control

Control participants were contacted by phone by a trial assessor every second week for a brief conversation about their general wellbeing and panic symptoms during the past week. No advice/intervention was provided during the conversations; the purpose was to provide a minimal level of support that would help the participant remain in the condition/trial until re-randomisation.

Power-calculation

Power calculations were performed using Power IN Two-level designs (PINT v. 2.12, September 2007) (Bosker et al., 2003) for change scores on the PDSS. Based on previous research on preference effects on the severity of psychiatric symptoms (Swift & Callahan, 2009; Swift et al., 2011), we assumed that the effect of allocation (choice vs. randomisation) would have a Standardized Mean Difference (SMD) = 0.40 on the PDSS post-treatment and during follow-up. Therefore, at alpha = 0.05, power = 0.80, and SMD = 0.40, 200 participants were required, with a planned recruitment of 221 to allow for attrition. In addition, a power calculation was performed to assess the number of participants needed to test the interaction between assignment and

treatment type. In the absence of a priori information about the size of the interaction effect between allocation and these two specific treatments, we assumed that the interaction effect size would be equal in size to the hypothesized main effect of allocation. At alpha = 0.05, power = 0.80, and SMD = 0.40, the same number of participants were required for the test of the interaction effect as for the main effect of choice.

Randomisation

The allocation ratio to the Choice, Random, and Control conditions was 4:4:1. At the end of the three-month Control condition, the re-allocation ratio to the Choice and Random conditions was 1:1. Participants were allocated to the Choice, Random, and Control conditions at each clinic. For the Random condition, a stratification procedure was used so that equal numbers of participants were allocated to PFPP and PCT at each clinic. Randomisation was done using the software Research Randomizer (Urbaniak & Plous, 2013).

Measures

At each time point; intake assessment, post-treatment, 6-, 12- and 24-month follow-up participants were interviewed and asked to complete the self-report measurements.

Table 1. Measurements across time points

Instrument	Intake	Week 1-11	Week 12	Month 6	Month 12	Month 24
SCID-I	X		X	X	X	X
SCID-II	X		X	X	X	X
PDSS	X		X	X	X	X
PDSS-SR	X	X	X	X	X	X
MI	X		X	X	X	X
BSQ	X		X	X	X	X
IIP	X		X	X	X	X
CORE-OM	X		X	X	X	X
MADRS-S	X		X	X	X	X
LSI-2	X					
PEX	X		X			
SDS	X		X	X	X	X

Specifically; sociodemographic information was assessed at intake; a full assessment with SCID I and II was completed at intake and 6 months follow up, at 12 and 24 month follow up the SCID diagnostic assessment was limited to PD/A. The PDSS, PDSS-SR, CORE-OM, MADRAS-S, SDS, BSQ, MI, IIP was assessed at all follow-up points. LSI-II was assessed at intake only, PEX at intake and treatment termination. In addition, the PDSS-SR was used in weekly assessments during treatment. However, the data on PEX at treatment termination is not part of this thesis.

Structured Clinical Interview for DSM-IV (SCID-I & SCID II)

The Structured Clinical Interview for DSM-IV (SCID-I and SCID-II; (First et al., 1996; First, 1997) was used in study II-IV to establish a PD/A diagnosis and possible psychiatric comorbidities. The SCID-I and II have been found have good psychometric properties and to be valid measures of psychiatric disorders, including personality disorders (Lobbestael et al., 2011).

Panic Disorder Severity Scale (PDSS)

The PDSS is a 7-item measure of the severity of the core features of PD over the past month (Shear et al., 1997) and was used to assess severity of PD/A in study II-IV. The 7 scales assesses the frequency of panic attacks, distress during panic attacks, anticipatory anxiety, agoraphobic fear and avoidance, body-sensation fear and avoidance, and impairment in work and social functioning. Items are rated on five-point scales (0 to 4) with higher scores indicating greater severity. In study II, the psychometric properties of the Swedish translations of PDSS and the PDSS-SR were assessed.

Panic Disorder Severity Scale – Self Report (PDSS-SR)

The PDSS-SR is the self-report version of PDSS (Houck et al., 2002), it contains the same 7 items and scoring system as the PDSS and possesses excellent psychometric properties (Furukawa et al., 2009). The items are identical but the time frame for the ratings is different (past month for the interview and past week for the self-report). The scale was used to assess self-reported severity of PD/A in studies II-IV.

Clinical Outcome in Routine Evaluation—Outcome Measure (CORE-OM)

The CORE—OM (Elfstrom et al., 2013; Evans, 2000) is a 34-item self-rating scale used in studies II-IV to assess the subjective well-being of participants (4 items), symptoms (12 items), functioning (12 items), and risk/harm behaviours (6 items). Each item is rated on a five-point frequency scale for the past week (0 = Not at all; 4 = Most of the time). A mean score for all items is computed; higher scores indicate greater levels of distress/dysfunction.

Montgomery Åsberg Depression Rating Scale (MADRAS-S)

The MADRAS-S (Montgomery & Asberg, 1979) is 9-item questionnaire used in studies II-IV to assess the severity of depressive symptoms over the past three days. Each item is rated on a seven-point (0-6) severity scale; higher scores indicate higher levels of depression. A total score is calculated with scores above 11 indicating mild to severe depression.

Sheehan Disability Scale (SDS)

The SDS (Sheehan, 1983) is a 3-item self-report measure used in studies II and IV to assess the extent of functional impairment in work, social life, and family life over the past week. Each item is rated on an 11-point scale (0 = Not at all; 10 = Extremely). A total score is computed with higher scores indicating higher levels of dysfunction.

Bodily Sensations Questionnaire (BSQ)

The BSQ (Chambless et al., 1984)) is a 17-item self-report measure used in study II to assess catastrophic interpretations of bodily sensations. Respondents rate the degree to which each bodily sensation causes them fear on a 5-point scale (1 = Not frightened; 5 = Extremely frightened).

Mobility Inventory for Agoraphobia (MI)

The MI (Chambless et al., 1985) is a self-report instrument used in studies II and IV to assess degree of agoraphobic avoidance. Respondents rate their level of avoidance (1 = Never avoid, 5 = Always avoid) in 24 places/situations when accompanied (Avoidance Accompanied) and when alone (Avoidance Alone). A mean is computed for the items on the Avoidance Alone and Avoidance Accompanied subscales (separately), and these are the scores used for research purposes.

Inventory of Interpersonal Problems (IIP)

The IIP (Horowitz et al., 2000) is a 64-item a self-rating scale used in study III to assess relational problems. The questionnaire has eight subscales (Domineering, Vindictive, Cold, Socially avoidant, Non-assertive, Exploitable, Overly Nurturant, and Intrusive) that identify a person's most salient interpersonal difficulties. Each item is rated on a five point scale (0-4), with higher scores indicating more relational problems.

Psychotherapy Experience Questionnaire (PEX)

The PEX (Sandell et al., 2011) is a 50-item self-report instrument used in study III to assess participant's beliefs about particular types of interventions and styles of doing psychotherapy. The questionnaire has five subscales (Externalization, Internalization,

Catharsis, Support, and Defensiveness). Each item is rated on a 6-point scale (1-6), higher scores indicating stronger helpfulness beliefs.

The Learning Style Inventory-II (LSI-II)

The LSI-II (Smith & Kolb, 1986) is a 13-item self-report questionnaire used in study III to assess participants' individual learning style. Each item asks the respondent to rank-order (1-4) four statements in a way that best describes his or her typical way of approaching a learning task, higher scores indicating more typical way of learning. It has four subscales (Concrete Experience, Reflective Observation, Abstract Conceptualization, and Active Experimentation).

Self-Selection Material

In the Choice condition, participants were provided separate, 500-word written descriptions of the two treatments. The treatment descriptions were written with the aim to be specific, well balanced, and easy-to-read presentations of PCT and PFPP. Each treatment description was comprised of three headed sections: 1) How is panic disorder viewed in treatment; 2) How do you work in treatment; and 3) What results can I expect. Six questions followed each of the text descriptions; the first two questions asked about the perceived credibility of each kind of therapy, followed by two questions about how challenging they perceived the two treatments to be. After choosing a treatment, the participants were asked about how certain they felt about their treatment choice. The participants were then asked to rate how important it was for them to have the opportunity to choose a treatment. Finally, the participants were asked two open-ended questions, "What do you find most appealing with the treatment you have selected?" and "Why did you choose that treatment?" and asked to provide their answers in writing. The full text descriptions, and the preference questions, are included in the appendix.

A decision was made during the writing of the text descriptions of PCT and PFPP not to address the level of empirical evidence for the two treatments, the time structure of treatment, nor the names (as CBT or PDT) of the treatments. The idea was to focus on the technical and theoretical differences between the treatments. The underlying assumption was that this information would be central for the participants making their choice of treatment with relevance for their engagement and the outcome of therapy. Focus was on the match between treatment and how the participant would like to address his or her problems in treatment. The left-out information was considered less vital for the choice, or possibly confounding the choice with other aspects with less relevance for outcome (e.g. the number of sessions per week).

Ethics

Ethical approval was obtained from the Regional Ethical Review Board in Lund (Ref: DNR-2010/88). Informed consent was obtained from every participant in the trial at intake assessment.

Data Analysis

Quantitative Methods

Study I presents an overview of the all the planned analyses for Project POSE as a whole, also including studies beyond this thesis.

Study II assessed internal consistency with Cronbach's alpha, test-retest reliability with product-moment correlations, and aspects of validity were evaluated with product-moment correlations between the PDSS or PDSS-SR and the different measures administered (MADRAS, CORE-OM, SDS, BSQ, & MIA). The inter-rater reliability of the PDSS was assessed by the intra-class correlation (ICC) between the internal and external assessors, sensitivity to change by the differences between intake and termination using paired samples *t*-tests. The factor structure was analysed using confirmatory factor analysis (CFA) and exploratory factor analysis (EFA). Data were analysed with the SPSS software for Windows, version 24, and Mplus (version 7.1; Muthén & Muthén, 1998-2010).

Study III assessed differences between Choice groups (PCT or PFPP) with chi-square and independent samples *t*-tests. SMDs were calculated according to Cohen's *d*, with pooled standard deviations as denominators (Cohen, 1988). Associations between continuous variables and treatment choice were examined using point-biserial correlations r_{pbis}. Logistic regression was used to assess the contribution of each variable to the choice. All data was analyzed using SPSS for Windows (Version 25).

Study IV reported outcomes following the intention-to-treat (ITT) principle. Post-treatment differences on the PDSS for participants in each treatment arm versus Control were compared using one-way ANOVAs. Trajectory differences between the treatments in the Random and Choice conditions were examined using segmented multilevel linear growth modelling. Change in medication and additional treatment during follow-up were added as time-dependent covariates. SMDs were calculated according to Feingold (2015) as the difference between treatments in model-estimated change from baseline, divided by the observed standard deviation at baseline across all

groups. Chi-square tests assessed responder status and the two work-related variables. Data were analysed with SPSS (Version 26) and Stata (Version 16).

Qualitative Methods

Study III carried out qualitative analysis on the written answers to the two open-ended questions about therapy type that were asked immediately after participants chose PCT or PFPP. The written responses (generally brief, 1-2 sentences per question) were coded according to the principles of text interpretation developed by Strauss and Corbin (1998). During coding, a deliberate effort was made to produce codes that were as close to participant's formulations as possible and were not specific for, or otherwise linked to, any particular theory.

Research Studies

Study I - The POSE study - panic control treatment versus panic-focused psychodynamic psychotherapy under randomised and self-selection conditions: Study protocol for a randomised controlled trial.

Introduction

This study outlines the protocol for the DRCPT (Project POSE). PD/A is a major health care problem that affects 2-3% of the population in Sweden (Statens Beredning för medicinsk utvärdering, 2005). Allowing patients to choose among evidence-based approaches to panic disorder may improve outcomes and reduce overall health costs. Preference trials comparing evidence-based psychotherapies on outcome in the longer-term are needed. The primary aim of the project is to investigate the extent to which patient's preferences for treatment influence a broad range of primary and secondary outcomes.

Method

A DRCPT carried out in routine care for adults (aged 18-70 years) with a primary diagnosis of PD/A treated with PCT (Craske & Barlow, 2006) or PFPP (Milrod et al., 1997). Within each clinic, patients are randomised to choice or random assignment of treatment (PCT or PFPP), or a wait-list control. Primary outcomes are changes in panic symptom severity as measured by the PDSS scale (Shear et al., 1997), occupational status, and sickness-related absences from work at 6, 12 and 24 months post-treatment. Secondary outcomes include changes in agoraphobic avoidance, psychiatric comorbidity, disability, and healthcare utilization. The assessors are not blind to treatment condition. However, all post-treatment and follow-up interviews are recorded and a proportion of these interviews will be evaluated by independent raters who are blinded to treatment condition.

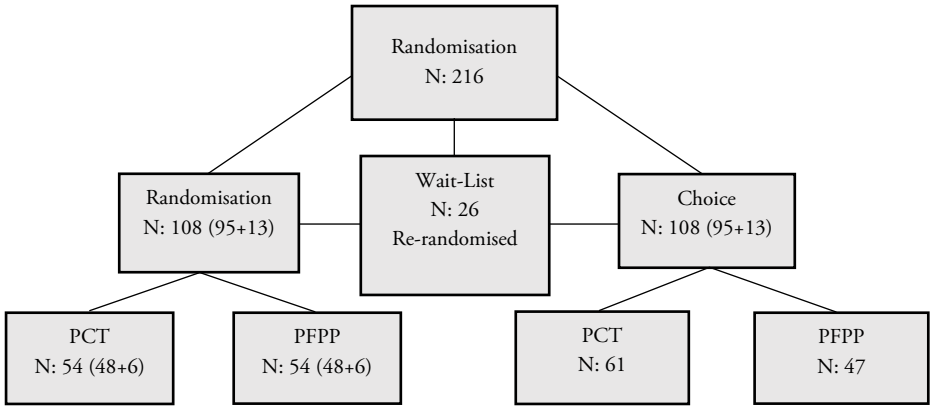

Figure 1. Participant flowchart
The estimated number of patients in each form of treatment in the choice condition in the flow chart is an estimation based on previous studies.

Discussion

Project POSE addresses the important but understudied issue of whether patient preference for a particular psychotherapeutic approach moderates outcome. In addition, little is known about the relative effectiveness of PCT and PFPP on symptoms of PD/A, work-related disability and healthcare utilization over the longer-term.

Study II - Psychometric analysis of the Swedish panic disorder severity scale and its self-report version.

Introduction

The Panic Disorder Severity Scale (PDSS; Shear et al., 1997) is the most widely used interview-based instrument for assessing disorder severity. There is also a self-report version of the instrument (PDSS-SR; Houck et al., 2002); both exist in a Swedish translation but their psychometric properties remain untested. In addition, the factor structure of the PDSS and PDSS-SR remains somewhat unclear in the international literature. The study evaluates the psychometric properties, including the factor structure of the PDSS and PDSS-SR.

Method

In addition to PDSS and PDSS-SR the participants completed self-reports including the CORE-OM, MADRAS-S, SDS, BSQ, and the MI (presented in Table 1). For both PDSS and PDSS-SR we analysed the mean across all items. The first two authors (M.S. and T.N.) administered assessments with all patients. To assess the inter-rater reliability of PDSS three additional assessors were trained to rate videotaped PDSS interviews. A sample of 264 videotaped interviews was randomly selected for the external rating of PDSS. The inter-rater reliability was calculated with intra-class correlation (ICC) between the interviewers (M.S and T.N.) and ratings of the external assessors. Internal consistency was assessed using Cronbach's alpha, and test-retest reliability was calculated using product-moment correlations. Validity was evaluated with product-moment correlations between the PDSS or PDSS-SR (total scores) and the different measures administered (MADRAS, CORE-OM, SDS, BSQ, & MI). Sensitivity to change was assessed by testing the differences between pre- and post-treatment using paired samples *t*-tests. Cohen's *d* (Cohen, 1988) criterion was used to measure the within-group effect size. The factor structure was analysed using confirmatory factor analysis and exploratory factor analysis. Data were analysed with the SPSS software for Windows, version 24, and Mplus (version 7.1; Muthén & Muthén, 1998-2010).

Table 2. Sample Baseline Characteristics

	Total (*n*=221)
Demographics	
Age at entry, yrs, *M, SD*	35 (12.6)
Female, *n*, %	165 (74.7)
Education, highest level, *n*, %	
Basic level education	23 (10.4)
High school	116 (52.5)
University education	82 (37.1)
Employment, *n*, %	
Employed	124 (56.1)
Self-employed	10 (4.5)
Student	51 (23.1)
Retired	2 (0.9)
Unemployed	19 (8.6)
Long term sick leave	7 (3.2)
Other	8 (3.6)
Current Psychiatric Conditions, *n*, %	
PD with agoraphobia	184 (83.3)
PD without agoraphobia	37 (16.7)
Any Axis I diagnosis besides PD/PDA	156 (7.6)
Any Axis II diagnosis (personality disorder)	52 (23.5)
No. Axis I diagnoses besides PD/PDA, *M, SD*	1.7 (1.7)
Clinical characteristics	
Panic history, months, *Md, IQR*	72 (144)
Panic episode, months, *Md, IQR*	10 (29)
PDSS, *M, SD*	15.6 (4.1)
Previous psychotherapy, *n*, %	136 (61.5)
Psychotropic use, *n*, %	117 (53.4)

Results

PDSS and PDSS-SR both possessed excellent psychometric properties (internal consistency, test-retest reliability) and convergent validity. In terms of clinical utility, the PDSS had very high inter-rater reliability (ICC(2, 1) = .98 for the total score) and correspondence with PD assessed via structured diagnostic interview. A single-factor structure for both versions was not confirmed. Table 3 presents the pairwise correlations (and their 95% confidence intervals) between the PDSS and PDSS-SR (separately) and the chosen self-report measures. As can be seen, all correlations were highly significant and in the moderate to large range.

Table 3. Total score correlations with 95% confidence intervals

Measure	PDSS	PDSS-SR
PDSS-SR	.728** (.655-.790)	-
CORE-OM	.487** (.379-.585)	.492** (.373-.588)
MADRAS-S	.492** (.387-.589)	.532** (.437-.623)
BSQ	.322** (.196-.447)	.325** (.201-.449)
MI	.572** (.483-.651)	.485** (.369-.586)
SDS	.644** (.557-.718)	.628** (.530-.712)

** p <.01 (2-tailed).

PDSS = Panic Disorder Severity Scale; PDSS-SR = Panic Disorder Severity Scale-Self-Report; CORE-OM = Clinical Outcome in Routine Evaluation—Outcome Measure; MADRAS-S = Self-rating version of the Montgomery Åsberg Depression Rating Scale; BSQ = Bodily Sensations Questionnaire; MI = Mobility Inventory; SDS = The Sheehan Disability Scale

Discussion

We conclude that the PDSS-SR in its Swedish version, like the PDSS, is an efficient, useful, and convenient way to evaluate treatment of PD. As reported in the original validation study of the PDSS-SR (Houck et al., 2002) the PDSS-SR ratings tended to be lower than PDSS. Our impressions from the intake-assessments were that patients tend to underestimate or deny the severity of their symptoms, and this is reflected more in the self-ratings than the interview ratings. An interviewer may help elicit a more forthright rating of the severity and consequences of the patient's panic attacks. Another interesting finding was that neither the PDSS nor the PDSS-SR conformed to a single-factor structure in this sample. The factor issue was obviously not settled by this study and requires additional research.

Study III - Preferences for panic control treatment and panic focused psychodynamic psychotherapy for panic disorder - Who chooses which and why?

Introduction

The primary aim of the study is to explore variables influencing the choice between PCT (Craske & Barlow, 2006) and PFPP (Milrod et al., 1997). Specifically, we test if the treatment choice is associated with: sociodemographic characteristics (gender, age, education, employment); clinical characteristics (symptom severity, comorbidity, prior treatment, and relational problems); participant's beliefs about the specific treatments; the relative helpfulness of various treatment components as measured by the PEX (Sandell et al., 2011); and participant learning style as measured by the LSI-II (Kolb, 1984). In addition, to further understand the reasons for participant´s treatment choice, we analyse their free-format answers to a question about what appealed to them with the chosen therapy and why they chose that therapy.

Method

Both quantitative and qualitative analyses were applied to data obtained from adults diagnosed with PD/A (N=109) who were randomised to the choice condition in the DRCPT from which this data were drawn. Differences between participants who chose either PCT or PFPP were examined using chi-square and independent samples t-tests. Variables that significantly differentiated between the PCT and PFPP choice groups were entered into a logistic regression as independent variables, with the choice of therapy type as the dependent variable. In addition, qualitative analysis was carried out on the written answers to the two questions about therapy type that were asked immediately after participants chose either PCT or PFPP.

Results

Of the 109 participants who were randomised to the Choice condition, 49 (45%) chose PCT and 60 (55%) chose PFPP ($\chi^2(1, 109) = 1.11$, $p = .29$). Participants in the PCT group had a longer duration of the current panic episode, and participants in the PFPP group had higher scores on the Trauma subscale of the CORE-OM and the Cold subscale of the IIP. Participants gave high credibility ratings to their chosen therapy and lower credibility ratings to the non-chosen therapy. Participants who chose PCT rated PCT as significantly more challenging than PFPP and vice versa (see Table 4). Table 5 presents the variables included in each block and the summary statistics for the variables in the final logistic regression model (including all three blocks). Only the

participants' ratings of the credibility of PCT and PFPP, and the challenging nature of PFPP, remained as significant predictors in the multivariate model. Qualitative analysis revealed that participants in the two groups gave contrasting reasons for their treatment choice, either a focus on the present: symptom reduction and problem-solving in sessions (PCT), or a focus on the past: understanding of symptom, and reflection (PFPP). The codes are summarized in Table 6.

Table 4. Means, standard deviations, and proportions for questions about treatment, helpfulness beliefs (PEX) and learning style (LSI) by chosen treatment group

	PCT	PFPP	Between Groups Comparison	
	(*n*=49)	(*n*=60)	*p*	SMDs (r_{pbis})
Beliefs about PCT/PFPP				
Credibility PCT, *M (SD)*	**8.00 (1.08)**	**6.45 (1.85)**	**.00**	**-1.00 (-.45)**
Credibility PFPP, *M (SD)*	**6.16 (1.98)**	**8.12 (0.94)**	**.00**	**1.31 (.55)**
Challenging PCT, *M, SD*	**6.47 (2.35)**	**5.33 (1.87)**	**.01**	**-0.54 (-.26)**
Challenging PFPP, *M, SD*	**5.14 (1.96)**	**6.58 (1.96)**	**.00**	**0.74 (.35)**
Certain about one's choice, *n, %*	31 (63.3)	46 (76.7)	.13	
Importance of choice, *M, SD*	6.06 (2.46)	6.47 (2.50)	.39	
PEX				
Externalization	**4.86 (0.73)**	**4.51 (0.76)**	**.02**	**-0.47 (-.23)**
Internalization	**3.56 (0.86)**	**3.90 (0.87)**	**.04**	**0.39 (.19)**
Catharsis	3.48 (0.83)	3.64 (0.81)	.32	
Support	4.12 (0.90)	4.24 (0.81)	.47	
Defensiveness	2.51 (1.10)	2.48 (0.88)	.86	
LSI				
Concrete Experience	2.37 (0.43)	2.34 (0.52)	.76	
Reflective Observation	**2.26 (0.44)**	**2.48 (0.52)**	**.02**	**0.45 (.22)**
Abstract Conceptualization,	2.52 (0.48)	2.55 (0.48)	.78	
Active Experimentation	**2.90 (0.51)**	**2.68 (0.54)**	**.04**	**-0.42 (-.20)**

Notes: Summaries are in bold when the between-group test is significant $p < 0.05$

Abbreviations: PCT = Panic Control Treatment; PFPP = Panic-Focused Psychodynamic Psychotherapy; SMD = Standardized Mean Difference; r_{pbis} = point-biserial correlation

Discussion

We found some limited evidence of an association between participant's sociodemographic and clinical characteristics and their choice of either PCT or PFPP for PD/A. While our findings point to the overarching importance of treatment credibility to the choice of treatment, future studies are needed to assess the factors influencing treatment credibility. Further, due to limitations in sample size, no cross validation of the logistic regression was performed. Lastly, the associations of choice found in this study could be viable candidates to be tested in moderator analysis of treatment outcome in the four treatment arms (randomised to PCT, randomised to PFPP, self-selected PCT, and self-selected PFPP).

Table 5. Logistic regression predicting participants' choice of treatment

	B	S.E.	Wald	Df	*P*	Odds Ratio	95.0 % C.I. for Odds Ratio	Percentage correctly classified
Block 1								
Episode	.00	.01	.00	1	.97	1.00	.99 to 1.01	
Trauma, CORE-OM	.60	.39	2.34	1	.13	1.82	.85 to 3.93	
Cold, IIP	-.05	.07	.38	1	.54	.96	.83 to 1.11	69.7
Block 2								
Internalization	.41	.48	.73	1	.39	1.51	.59 to 3.88	
Externalization	-.99	.68	2.13	1	.14	.37	.10 to 1.40	
Reflective Observation	1.63	.97	2.85	1	.09	5.10	.77 to 33.85	
Active Experimentation	-.13	.82	.025	1	.88	.88	.18 to 4.35	75.2
Block 3								
Credibility PCT	-.91	.34	7.18	1	.01	.40	.21 to .78	
Credibility PFPP	1.46	.42	12.40	1	.00	4.32	1.91 to 9.76	
Challenging PCT	-.34	.21	2.58	1	.11	.72	.47 to 1.08	
Challenging PFPP	.57	.23	5.91	1	.02	1.76	1.12 to 2.77	89.9
Constant	-6.64	5.44	1.49	1	.22	0.00		

Abbreviations: PCT = Panic Control Treatment; PFPP = Panic-Focused Psychodynamic Psychotherapy

Table 6. Participants' Reasons for Choosing Treatment

Code	PCT (N=49) *n* (%)	PFPP (N=60) *n* (%)
1. I want exercises / concrete / practical work with panic	28 (57)	0 (0)
2. I want to face my fears	18 (37)	4 (7)
3. Focus on the external situation	14 (29)	1 (2)
4. I want to be able to handle panic in a better way	13 (27)	2 (3)
5. Focus on my own activity and work in therapy	13 (27)	8 (13)
6. Just talking doesn't help	6 (12)	0 (0)
7. I do not want to go in the other treatment	9 (18)	6 (10)
8. Focus on the present	4 (8)	1 (2)
9. The treatment is in line with my own theory of the causes of panic	10 (20)	11 (18)
10. The treatment means something new to me	3 (6)	3 (5)
11. Focus on working with relationships	0 (0)	1 (2)
12. I want to avoid homework	0 (0)	2 (3)
13. Focus on unconscious feelings	0 (0)	2 (3)
14. Overall positive / fits me well	21 (43)	29 (48)
15. I've tested the other one already, want something different	1 (2)	4 (7)
16. Focus on the therapist as an expert (and not my own activity)	3 (6)	8 (13)
17. Focus on inner experiences	0 (0)	9 (15)
18. I want to understand my emotional reactions	0 (0)	9 (15)
19. I want to reflect / talk in therapy	0 (0)	15 (25)
20. Focus on the background / past	0 (0)	16 (27)
21. Patterns, how panic is connected to my life and background	0 (0)	18 (30)
22. I want to understand causal reasons for the panic	4 (8)	32 (53)

Abbreviations: PCT = Panic Control Treatment; PFPP = Panic-Focused Psychodynamic Psychotherapy

Study IV - The effect of patient´s choice of either cognitive behavioural or psychodynamic therapy on outcomes for panic disorder: A doubly randomised controlled preference trial.

Introduction

The primary aim of the present study is to evaluate short- and long-term change for participants with PD/A treated under self-selected versus randomised allocation to treatment conditions with PCT (Craske & Barlow, 2006) or PFPP (Milrod et al., 1997). Our hypotheses are that for clinician-rated PD/A severity: 1) outcomes in the treatment groups are superior to control at post-treatment; 2) outcomes for participants who chose their treatment, irrespective of treatment type, are superior to those of participants randomly assigned to treatment; and 3) PCT yields superior outcomes to PFPP. Additional primary (occupational status and absences from work) and secondary outcomes (mobility, depression and functional impairment) are assessed but no a priori hypotheses tested. Finally, and in an exploratory way, we test whether there is an interaction effect between treatment allocation and treatment types on outcome.

Method

In a DRCPT, 221 adults with PD/A were randomly assigned to: choosing PFPP or PCT; random assignment to PFPP or PCT; or Control. Outcomes were assessed at post-treatment, 6-, 12- and 24-month follow-ups. The primary outcome measure was the PDSS scale. Occupational status (Work) and the number of self-reported absences due to sickness (Absences) were included as additional primary outcomes. Secondary outcome measures were PDSS-SR, MI, SDS, and the MADRAS-S.

Results

As shown in Figure 2, 178 of the 217 participants (82%) randomised to the Choice and Random conditions completed treatment in accordance with the protocol. Irrespective of choice versus random assignment to treatment or treatment type, steep decreases for the estimated scores on the PDSS occurred during treatment. There was no significant effect of allocation (Choice vs. Random) during treatment or follow-up. Consistent with expectation, significantly larger reductions on the PDSS occurred for those receiving PCT than PFPP during treatment, but during follow-up the pattern was significantly reversed so that from baseline to the 24-month follow-up, the two treatments yielded similar outcomes. The allocation by therapy by time interaction was not significant during treatment or follow-up. All comparisons for Work or Absences

were non-significant during treatment and follow-up. The secondary outcomes showed the same pattern of effects as the clinician-rated PDSS.

Table 7. Effect Sizes (Standardized Mean Differences; SMDs) of Differential Change, by Treatment Contrasts and Time Segments (Confidence Intervals in Parentheses)

Outcome Measure	Segment/Months	C-R	PFPP- PCT	(RPFPP - CPFPP) - (RPCT - CPCT)	RPFPP - RPCT
PDSS	Baseline to Post-treatment	0.03 (-0.26 to 0.33)	-0.64 (-1.02 to -0.25)	-0.29 (-0.88 to 0.30)	-0.78 (-1.27 to -0.30)
	Post-treatment to 24 mos	0.08 (-0.26 to 0.42)	0.62 (0.27 to 0.98)	-0.28 (-0.96 to 0.41)	0.48 (-0.02 to 0.98)
	Baseline to 24 mos	0.11 (-0.26 to 0.48)	-0.01 (-0.47 to 0.44)	-0.57 (-1.31 to 0.17)	-0.30 (-0.89 to 0.29)
PDSS-SR	Baseline to Post-treatment	0.00 (-0.32 to 0.32)	-0.56 (-0.89 to -0.22)	-0.22 (-0.86 to 0.42)	-0.67 (-1.13 to -0.20)
	Post-treatment to 24 mos	0.04 (-0.25 to 0.33)	0.40 (0.11 to 0.69)	-0.12 (-0.70 to 0.46)	0.34 (-0.07 to 0.76)
	Baseline to 24 mos	0.04 (-0.27 to 0.34)	-0.15 (-0.48 to 0.17)	-0.34 (-0.95 to 0.27)	-0.32 (-0.77 to 0.13)
SDS	Baseline to Post-treatment	0.08 (-0.19 to 0.36)	-0.53 (-0.80 to -0.25)	-0.01 (-0.56 to 0.54)	-0.54 (-0.93 to -0.14)
	Post-treatment to 24 mos	-0.09 (-0.37 to 0.19)	0.37 (0.09 to 0.65)	-0.36 (-0.92 to 0.20)	0.19 (-0.22 to 0.59)
	Baseline to 24 mos	-0.01 (-0.29 to 0.27)	-0.16 (-0.44 to 0.11)	-0.37 (-0.93 to 0.18)	-0.35 (-0.75 to 0.05)
MI	Baseline to Post-treatment	0.03 (-0.27 to 0.22)	-0.49 (-0.73 to -0.25)	0.24 (-0.24 to 0.72)	-0.37 (-0.71 to -0.03)
	Post-treatment to 24 mos	0.11 (-0.12 to 0.33)	0.27 (0.02 to 0.51)	-0.24 (-0.68 to 0.20)	0.15 (-0.18 to 0.48)
	Baseline to 24 mos	0.08 (-0.21 to 0.37)	-0.22 (-0.53 to 0.09)	-0.00 (-0.59 to 0.58)	-0.22 (-0.65 to 0.21)
MADRS-S	Baseline to Post-treatment	0.11 (-0.18 to 0.40)	-0.26 (-0.55 to 0.02)	-0.19 (-0.77 to 0.38)	-0.36 (-0.77 to 0.05)
	Post-treatment to 24 mos	-0.14 (-0.44 to 0.15)	0.29 (-0.01 to 0.58)	-0.33 (-0.92 to 0.26)	0.13 (-0.30 to 0.55)
	Baseline to 24 mos	-0.03 (-0.32 to 0.25)	0.03 (-0.26 to 0.31)	-0.52 (-1.10 to 0.05)	-0.24 (-0.65 to 0.18)

Note. R = Randomised condition; C = Choice condition; PFPP = Panic-Focused Psychodynamic Psychotherapy; PCT = Panic Control Treatment; PDSS = Panic Disorder Severity Scale; PDSS-SR = Panic Disorder Severity Scale, Self-Rating; MI = Mobility Inventory for Agoraphobia; SDS = Sheehan Disability Scale; MADRS-S = Montgomery Asberg Depression Rating Scale; 24 mos = 24 month follow-up

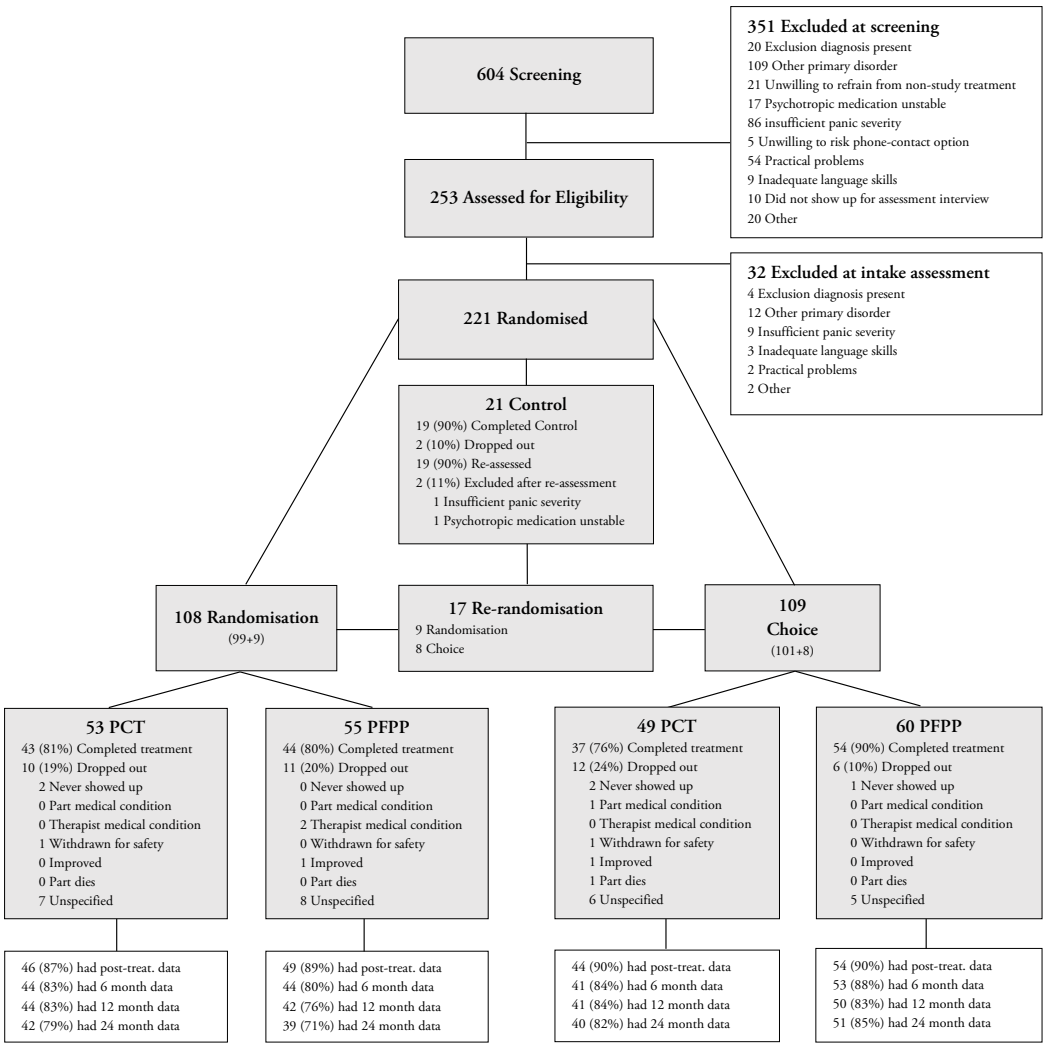

Figure 2. Participant Flowchart.

Abbreviations: PCT = Panic Control Treatment; PFPP = Panic-Focused Psychodynamic Psychotherapy; Control = Control condition; Part = Participants

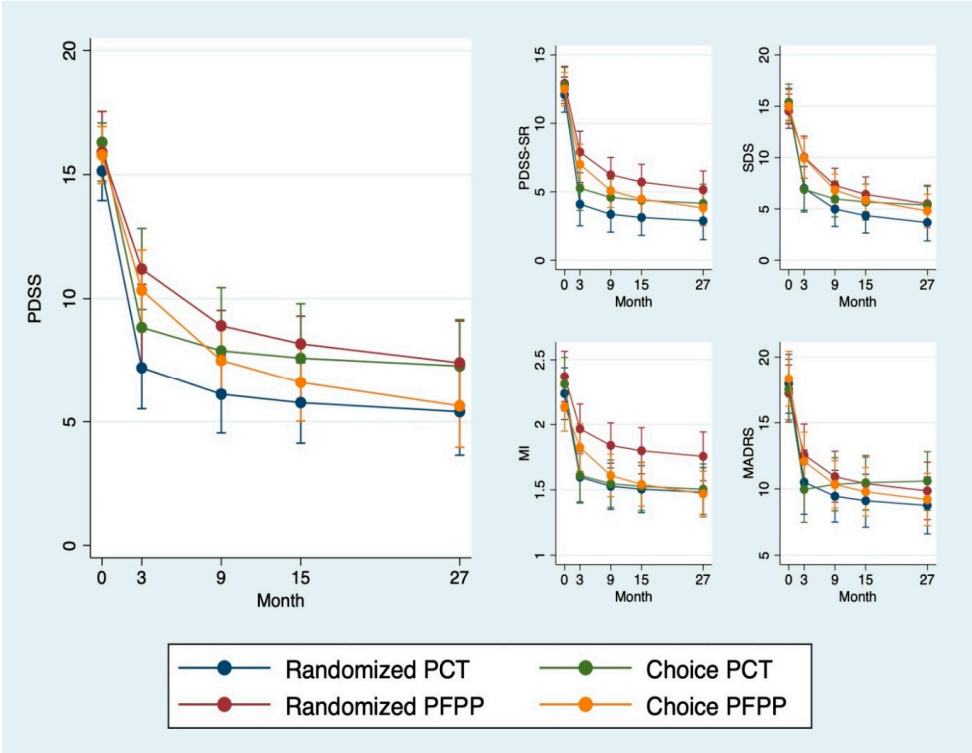

Figure 3. Modelled trajectories, with 95% confidence intervals, on the PDSS and the secondary outcome measures for the therapy types within the Choice and Random conditions

Abbreviations: 0 = Baseline; 3 = Post-treatment; 9 = 6 months follow-up; 15 = 12 months follow-up; 27 = 24 months follow-up.

Discussion

The main outcome suggests that treatment preference effects may be limited when the choice is between two evidenced-based psychotherapies when compared to psychotherapy versus medication. However, it is possible that our failure to find any beneficial effect of choice versus random allocation to treatment lies in the unexpected disordinal interaction between allocation and treatment type, suggesting that the effect of choice on PDSS is moderated by treatment type. Further, the finding that PCT was superior to PFPP during treatment, and PFPP superior to PCT during follow up, provides a demonstration of the importance of long-term follow-ups in PD/A trials. Further DRCPTs, employing larger sample sizes, different treatments, and similarly long-term follow-ups are warranted.

Discussion

The primary aim of this thesis was to help fill an important gap in the literature as regards the role of patient treatment preferences in long-term outcomes in adults with Panic Disorder with or without Agoraphobia (PD/A). Data for Studies II-IV were drawn from participants recruited to the first doubly randomised controlled preference trial (DRCPT) of two empirically-supported and distinct psychological treatments for PD/A: Panic Control Treatment (PCT) and Panic Focused Psychodynamic Therapy (PFPP). Study I summarised the preference literature, giving the theoretical and empirical justification for Project POSE, and described the protocol for the DRCPT. Study II demonstrated that the Swedish version of the Panic Disorder Severity Scale (PDSS), the primary outcome measure in the DRCPT, had excellent psychometric properties and good construct validity; as did the self-report version that was used as a secondary outcome measure. Study III, a quantitative and qualitative investigation of the participant's choice of treatments, suggested that credibility ratings, helpfulness beliefs about the two treatments, and learning style were more strongly associated with their choice of treatment than illness severity, prior treatment history and other participant characteristics. Study IV presented the results of the DRCPT, and contrary to expectation, offering patients a choice between PCT and PFPP did not yield a clear clinical benefit in relation to the primary or secondary outcomes assessed at post-treatment or follow-up.

General Discussion

Previous preference studies, across a wide range of conditions/disorders, suggest that there are additional benefits to patients, over and above the effects of treatment, of being offered a choice of treatments and receiving one´s preferred treatment. Overall, the findings from the DRCPT trial described in Study IV suggest that while treatment-seeking adults with PD/A appreciated a chance to choose their psychological treatment, the act of choosing was not associated with improved outcomes over and above the effect of the treatment itself. In this sense, these results are consistent with the findings from the preference literature overall, i.e. that preference effects exert benefits that fall

in the null to small range. However, as addressed in detail in the introduction, study design has been found to moderate the preference effect. This moderator effect is most likely due to the different types of treatment group comparisons performed in the various study designs. Firstly, the Partially Randomised Preference Trials (PRPT) compares participants *without* strong preferences to participants with strong preferences *all of whom* receive the preferred treatment. Secondly, the Fully Randomised Preference Trial (FRPT), also called Match/No Match design (M/NM), compares a group of participants *all of whom* receive their preferred treatment to a group in which *none of the participants* receives their preferred treatment. Lastly, in the DRPCT design used in the current trial, the comparison is between a group of participants *all of whom* receive their preferred treatment (Choice) and a group of participants in which the preference match is *mixed* (Random), including some participants that by chance receive the treatment they would have chosen had they been given a choice and others being randomised to the treatment they would not have chosen.

The above designs assess very different questions. PRPT designs provide information about preference effects under the very narrow set of conditions where participants have very strong treatment preferences and can act on those preferences by refusing randomisation. Such designs may not fully reflect 'real-world' conditions where patients may not have particularly "strong" preferences for one treatment over another, but at the same time the act of choosing a treatment may yield improvements in outcomes. By way of contrast, FRPT and M/NM designs provide information specifically about the effects on outcome of receiving versus not receiving one's preferred treatment. If the study objective is preference effects, they tend to be underestimated in the PRPT design, maximised (or possibly overestimated due to negative expectations/reactions for those who receives their non-preferred treatment) in the FRPT and M/NM designs, with the DRPCT somewhere in between. In DRCPT designs, including the current study, the primary aim is to separate and compare the treatment effect for participants given a free choice of treatment, to treatment effects in a randomised condition (the standard design for evaluating treatment effects), not to maximise the potential effect of preference per se. Because of this design choice, preference effects for PD/A in the present study may appear smaller than they would have in a FRPT design.

As is evident from the discussion above, a key factor in the choice of design relates to the timing of the assessment of the participant's treatment preferences. As described in the introduction, a common distinction is between stated and exercised preferences. The stated preference refers to the treatment the person would have chosen if he or she had the possibility to choose; the exercised preference refers to the actual choice of treatment. One possible strength of the DRCPT design is that, to the extent that

preferences are measured for all participants, the effect of choice can be separated from the effect of preference (Walter et al., 2017). However, there is mixed evidence as to whether choosing one's preferred treatment exerts any additional benefit over and above receiving one's preferred treatment as in the M/NM design (Delevry & Le, 2019; Lindhiem et al., 2014). In this DRPCT, we did not assess treatment preference for all randomised participants, only those randomised to the choice condition, who made their choice directly after the randomisation and reading the two 500-word treatment descriptions. Participants randomised to the random allocation to treatment condition only received information about the actual treatment to which they were randomised and no attempt was made to assess their preferences for the two treatments (PCT and PFPP). Asking the participants in the random allocation to treatment condition about their treatment preferences would have yielded information that may have helped us to further separate the effects of the treatment from preference effects. However, soliciting treatment preferences from participants about to be (or just) randomly allocated to treatment would possibly have introduced negative expectancies biases that could influence outcomes in unexpected ways, making the interpretation of the preference effect less clear (Walter et al., 2017). Consequently, we could only report on the effects of the "exercised" preference (Choice) in comparison to random allocation to treatment (Random), not on the preference effect separately (received preferred treatment versus did not receive preferred treatment). However, one alternative to the analysis performed in Study IV would be to estimate the preferences in the randomised arm. Long et al. (2008) present a model to estimate preferences in the randomised arm in DRCPTs from the distribution of treatment choices in the Choice arm. This solution offers as a possible way out of the negative consequences of randomly assigning some participants to their non-preferred treatment option.

Overall, it would be premature to conclude that preference effects are necessarily null or small when the choice is between CBT and PDT for PD/A. The present trial yielded a moderately sized (d = 0.57) but non-significant interaction between treatment type and allocation (choice versus random assignment). Specifically, participants who chose PFPP tended to do better than those randomly allocated to this same treatment, and participants who chose PCT tended to do worse than those randomly allocated to PCT. Thus, our failure to find any beneficial effect of choice over random allocation to PCT and PFPP is at least partly owing to this disordinal interaction, the presence of which mitigates any main effect of treatment preference.

Although this interaction was unexpected in the present study, this is not the first trial to report differing effects of preference for CBT and PDT (Hardy et al., 1995; Johansson et al., 2013; Leuzinger-Bohleber et al., 2019; Watzke et al., 2010). Watzke et al. (2010) reported differing effects of Systematic Treatment Selection (STS), a

mixture of clinician judgement (primarily) and patient preference (secondarily), on outcomes for inpatients with multiple psychiatric problems receiving either CBT or PDT. The PDT group had larger effects under STS condition than randomised condition, and vice versa for the CBT group. The authors argued that the differences in outcomes might be explained by the fact that a greater proportion of patients with more negative prognostic factors were assigned CBT than PDT in the systematic treatment selection procedure. Another trial reporting differing preference effects by treatment type was an RCT study comparing CBT and PDT for adults with depression (Hardy et al., 1995). In this study receiving the preferred treatment, as indicated by the Opinions about Psychological Problems Questionnaire (OPP; Pistrang & Barker, 1992), was associated with improved outcomes for PDT but not CBT participants. The authors argued that the OPP scale may assess a level of 'psychological mindedness' that may be more important to recovery in PDT than CBT approaches. Leuzinger-Bohleber et al. (2019) reported a significant interaction between time and treatment group due to an increase of symptoms in the preference CBT arm and a further decrease of symptoms in the randomised CBT arm at the three-year follow-up in their partially randomised preference trial on depression. The authors offers no explanation specific to this result. Lastly, in a non-randomised study where all participants received their preferred treatment for depression (internet delivered CBT or PDT) strength of preference predicted improved long-term outcome for those who chose CBT but not PDT (Johansson, et al., 2013). The authors offers no explanation to the result but to conclude that the research on the relationship between preference strength and outcome present mixed results. In sum, four out of six trials (the current included) investigating preference effects for CBT and PDT find differing effects of preference for CBT and PDT. However, these studies employ very different designs with different patient groups and the possible inferences that can be made are limited by this heterogeneity. In the absence of a priori knowledge about the likely size of a genuine interaction effect, the present trial was underpowered to detect a significant treatment type by allocation effect, even one of the observed magnitude. It is possible that future similarly designed trials, employing larger sample sizes, may find a similarly-sized but statistically significant interaction between treatment type and allocation for adults with PD/A.

The question remains, however, what does a treatment type by allocation (choice versus random assignment) interaction mean and why might it matter? In reference to the first question, the present results suggest, at least for PD/A, the potential benefits of offering patients a choice of psychological treatments may be dependent upon the treatments on offer. In this trial the benefit appeared to accrue only to those who chose the psychodynamic form of treatment (PFPP). It is possible that the long-term benefits of

choosing PFPP, albeit small, may be related to more psychologically minded participants reading the written descriptions about PCT and PFPP and choosing the latter, assuming that this patient characteristic is of particular importance in PDT treatment (Hardy et al., 1995; Valbak, 2004; Watzke et al., 2010).

As Delevry and Le (2019) point out, the reasons for preferring a specific treatment option may differ between patients. As presented in Study IV, such individual variation was evident in this trial, and the different reasons offered by the participants why they chose PCT or PFPP may have influenced the effect of treatment choice on outcomes in choice condition and relative to random allocation in the trial. It may be that some reasons for choosing one treatment over another exert a greater or lesser influence on one's response to the chosen treatment. Irrespective of the reasons why patients have preferences for specific treatments, and following Brewin and Bradley (1989), participants who chose PFPP in this trial may have had a stronger (and perhaps more accurate) sense of their own 'suitability' for psychodynamic therapy than patients who chose the cognitive behavioural approach. However, the treatment type by allocation interaction may be somewhat confounded by the fact that the two treatments on offer were chosen by the investigators to begin with. Thus, the absence of a main effect of choice versus random allocation, and the statistically insignificant treatment by allocation interaction, may reflect the fact that a significant number of participants in the choice condition did not find either PCT or PFPP to be particularly suitable to them, thereby washing out the effects of choice and treatment by choice on outcomes. Other psychological treatments, for which there is a limited evidence base in respect of PD/A exist, including interpersonal therapy and relaxation training. Had these (or other) treatments been offered alongside PCT and PFPP in a DRCPT trial, it is possible that there would have been a greater likelihood of matching patients to their most suitable treatment, the suitability indicated by their choice of treatment, and the effect of treatment choice been more evident. This seems like a reasonable hypothesis upon which to base the design of future DRCPT trials, given the consensus emerging in the literature that further improvements in outcomes for existing treatments for the most common mental health problems (including anxiety and depression) are likely to result from the clinician and patient working to better match the patient to the most "suitable" of the available treatments (Cohen & DeRubeis, 2018).

Study III identifies a few variables that may warrant further investigation in development and testing of any future patient-treatment matching algorithms for adults with PD/A. Before proceeding to a discussion of these variables, it is important to point out that in the assessment of the primary and secondary outcomes from the trial (Study IV), and the role of patient characteristics and beliefs in the choice of PCT or PFPP (Study III), there were very few significant differences between participants

who chose PCT versus PFFP. Nevertheless, in comparison to patients who chose PCT, those who chose PFPP had a shorter duration of their current PD/A episode, a higher incidence of traumatic exposure, and scored higher on a measure of interpersonal coldness.

It is difficult to draw meaningful inferences about how these few, rather modestly sized differences may have influenced the choice of either PCT of PFPP for PD/A, these may be chance findings. It is also possible that a trauma history and interpersonal coldness interact with other variables, particularly beliefs about the causes of the patients' own PD/A symptoms and/or their suitability for either PCT of PFPP. Treatments which were described as having either a pragmatic, skill-learning, present-moment focus on panic symptoms (PCT) versus a focus on emotional functioning more broadly and its links to historical antecedents, underlying psychological mechanisms, and interpersonal difficulties (PFPP). While participants who chose PFPP had a significantly shorter length of the current PD/A episode, we do not know whether the length of the current episode of PD/A is in any way related to the age-at-onset, number of previous episodes or their duration or severity, or to prior treatment history. However, longer duration of PD/A has been found linked to beliefs about PD/A having biological causes (El Amiri et al., 2018) and it has been suggested that such beliefs in turn may be linked to prognostic pessimism (Lebowitz et al., 2014). Further studies are needed that investigate whether treatment preferences vary as a function of the patient's panic history in a more detailed way.

It has been suggested that the patient's beliefs about the credibility of the treatments on offer should be accounted for in any attempt to match the patient and treatment; the implication being that such beliefs have an influence, potentially indirect, on outcomes (Cohen et al., 2015). Neither Study III nor IV tested this hypothesis. However, the results of Study III found that the participant's credibility ratings for the non-chosen treatment were comparable to their credibility ratings for the treatment they did ultimately choose; both being high. As we did not find a main effect of preference, and the interaction between treatment type and allocation (choice versus random) was non-significant, it would be difficult to conclude from the current trial that treatment credibility beliefs, which did not differ between the two offered treatments, exerted much of an effect on outcome. This does not mean that treatment credibility beliefs were not important in this DRCPT trial, rather that any influence on outcomes is likely to be through or in interaction with other variables.

In considering the findings for both Study III and IV, it is worth briefly revisiting the manner in which patient preferences for PCT and PFPP, and thus their resulting choice of, PCT or PFPP were elicited. Participants allocated to the choice condition were provided with two 500-word written statements that described the two approaches.

Participants were asked to read the descriptions straight away and to indicate their choice of treatments. These descriptions were designed to be accurate in terms of the theory and style of the two treatments, as well as balanced in their level of detail. For both treatments the descriptions asserted a positive outcome was possible but without reference to actual proportions, effect sizes, the number of trials etc. This was a similar method for eliciting patient treatment preference as used in previous preference trials. It is possible that the relatively weak preference effect observed in this and previous preference trials is due to a potential weakness in this commonly used method of eliciting treatment preferences.

Perhaps for some patients (not all) this method does not elicit a clear "preference" based on an understanding of the chosen treatment's credibility or personal suitability but rather a "rough guess" as to which treatment appears less threatening, easier or more likely to succeed etc. One might expect that a genuine preference would exert a greater influence on outcomes than a rough guess, particularly when the rough guess turns out to be wrong or based on a poor understanding of the treatment. As a method of eliciting patient preferences, both in this and other preference trials, it does diverge from recommendations in the Shared Decision Making (SDM) literature on how to best involve patients in treatment decisions, including psychotherapy (American Psychological Association, 2006; Kunneman et al., 2016; Stacey et al., 2017). In this literature, the use of written descriptions of the treatment are recommended but these are meant to include information about relative risks and outcomes, with opportunities for follow-up questions for the clinician, and time for the patient to digest this material and come back with further questions. Before firm conclusions about the role of patient preferences on psychotherapy outcomes can be drawn, further DRCPTs are needed that involve different methods for eliciting preference, including the use of patient decision making tools advocated in the SDM literature.

The PDSS in the clinician-rated or self-report versions is the most frequently used measure of PD severity in treatment trials (Santacana et al., 2014). Thus, it was important to the overall programme of research that the Swedish-language versions of the PDSS and PDSS-SR possessed similar psychometric properties and levels of construct validity as the English language originals. Using data from the DRCPT, Study II concluded that the clinician-rated and self-report versions the PDSS had excellent psychometric properties and good construct validity, similar to the English-language originals. Factor structure is also an important consideration when evaluating the validity of translated measures. Previous studies using different language versions of the PDSS/SR (but not in Swedish) have found both one and two-factor structures. Although the factor structure remains unsettled, the recommendation is to use a single total score for evaluating treatment outcomes (Furukawa et al., 2009; Shear et al.,

1997). Using data from our DRCPT sample, Study II found that the PDSS and PDSS-SR conformed to a two-factor structure. Previous studies that found two factors reported item 1 and 2 in one factor, and 3 through 7 in another in one factor. The factor structure presented in Study II for PDSS-SR were similar to these previous studies. Whereas for PDSS we found item 4 in one factor and the other six items in another factor. Although not addressed in this study, Iacobucci (2010) has noted that the Chi-Square test used to evaluate model fit tends to be overly conservative in large samples (N = 221 in the present study) and has suggested that a model demonstrates reasonable fit if the Chi-Square statistic adjusted by its degrees of freedom does not exceed 3.0 [$(\chi^2/df) \leq 3$]. When applied to the factor analyses in Study II, Iacobucci's modified Chi-Square test suggests that the PDSS had a one factor structure (22.94/13 = 1.76) and the PDSS-SR had not (112.62/14 = 8.04) but a two-factor one. Again, the observed one- and two-factor item loadings were comparable to those reported in previous studies.

Practice Implications

Irrespective of whether a significant preference effect was found in the DRCPT (Study IV), it is generally recommended that clinicians involve patients in decision making about their treatment as this is associated with patients making greater efforts to understand the nature of their difficulties, an increased sense of patient responsibility for change, and greater patient satisfaction with their healthcare (Stacey et al., 2017). These recommendations about shared decision making (SDM), including making an informed choice between available treatments, present mental healthcare providers in Sweden with big challenges. Long waiting lists and limited capacity mean that in practice, adults with anxiety and depression who are offered psychotherapy in primary and specialist care receive the type of psychotherapy that the first available therapist has been trained to provide. So shared decision making about treatment type is unlikely unless the therapist is capable of providing more than one form of treatment, or can quickly transfer the patient to a colleague who is trained in the patient's preferred form of treatment.

What Study III and IV suggest is that: a) patients appreciate being provided with written information about the type of treatments on offer and the opportunity to choose their preferred treatment; and b) being offered a choice of treatments was no less effective than random allocation to these treatments and may have possible benefits dependent upon the offered treatments. These results suggest that, at the very least, greater efforts are needed to implement shared decision making, including discussion

and decision-making tools for the patient and clinicians, into the Swedish mental healthcare system. However, to the extent that the non-significant interaction is a valid finding, it opens up a clinical practice complication. If we let patients choose their preferred treatment it may be that those who choose PFPP will be better off in terms of treatment outcome, and that those who choose PCT will be worse off than they would have been if they were not given a free choice of treatment. The Watzke et al. (2010) study described above, with a similar disordinal interaction is a related example of this possible dilemma but in regards to the clinical implications of a primarily clinician-led choice of either CBT or PDT for psychiatric inpatients with mixed disorders. To the extent that the differing effect of choice by treatment type is dependent on the assessment of preferences via the written descriptions of PCT and PFPP, this material needs to be rewritten and/or the procedure in which it is used changed. As noted in the introduction, there is no agreed upon standard for assessing patient preference, and that all of the available methods require further evaluation of their validity and reliability (Wensing & Elwyn, 2003). Of overarching importance in this endeavour is to ensure that the materials used for eliciting preference/choice guides the patient to the most suitable treatment.

This trial has many qualities of an effectiveness trial. After a brief, three-day training course in PCT or PFPP, the therapists in this trial treated project patients as a part of their service within routine health care. The therapists were selected based on their availability and interest in participating in the trial, not because of any particular level of competence over and above what is specified by law in Sweden to deliver psychotherapy. These factors, together with the overall positive treatment outcome from the trial, are evidence for the beneficial effects of PCT and PFPP in the real world clinical setting, and are an example of successful implementation of manualized evidence based treatments in the Swedish health care system.

Limitations

This trial is not the definitive preference trial. Although no main effect of choice was found in this trial, there may be other treatments or conditions for which preference may be an important predictor of the treatment outcome. In addition, preferences have been assessed in many different ways in research, and the way preferences were assessed in this trial could be improved upon and may have contributed to the null results.

The preparation material used for the informed choice of treatment may have biased the participant's choice in some unforeseen ways. In an early draft version of the treatment descriptions, we more strongly emphasized the differences between the

treatments, with the unwanted consequence that the descriptions gave a stereotyped image of the two treatments. Therefore, we decided to present the two treatments in a more equal and comparable way, which may have had the unintended consequence of the two treatments appearing more alike than they actually are. As noted above, another possible limitation may be that these written treatment descriptions simply did not provide the participants with enough information to make a fully informed decision, leaving some of the patient's choice of treatment to chance (guessing) and thereby possibly limiting the effects of choice on outcome. Nevertheless, the majority of participants appreciated being given a choice of treatments, and during the assessments there were only minor complaints about the descriptions from participants.

From an SDM perspective, it is important that the clinician makes the treatment decision together with the patient so that the patient does not feel abandoned in the decision making process (Kunneman et al., 2016). However, and consistent with the preference literature, the patients were not in any way aided in their choice of treatments in the current DRCPT. As in previous preference trials, the reason for this is to try make the actual choice process as uniform as possible across participants. Adding more individual information and/or support during the decision would make the choice process less standardized and potentially introduce variance into the choice process that would confound any observed findings for preference effects on outcomes. However, if the choice process was not sufficiently informative for some patients, as suggested above, it may not have been a sufficiently rigorous test of a genuine preference effect, assuming the latter involves some minimal threshold of patient understanding about the types of treatment on offer.

It is important to restate that preference in this DRCPT was assessed in a dichotomized fashion, the choice being either PCT or PFPP. This way of measuring preference can be considered ecologically valid to the extent that patients in routine care are offered distinctive treatment packages, e.g. pharmacotherapy, psychodynamic therapy, family therapy, cognitive therapy, CBT, dialectical behaviour therapy, interpersonal therapy, etc. However, recent research suggests that patient treatment preferences may be more "integrative" and less focused on a choice between these broad schools or modes of therapy, when patient preferences for separate methodological aspects or interventions from different psychotherapeutic schools are assessed (Glock et al., 2018). It may be that some of the participants in this trial actually had an integrative preference and that they would have had better outcomes given an integrative treatment approach better matched to their preference for particular treatment components rather than PCT versus PFPP.

As noted above, this DRCPT was underpowered to detect the unexpected disordinal interaction between allocation (choice versus random assignment) and treatment type

(PCT vs PFPP). The reasons for this were that at the time of trial planning, there was not a previous DRCPT in which randomisation was compared to the choice between two forms of psychotherapies to guide us, nor frequent reporting of similar interaction effects in the existing preference trials. Indeed, there was significant ambiguity in the literature about how to power for interaction effects and the utility of widely available software designed to provide researchers with the sample size needed to detect significant interaction effects (Brookes et al., 2004; Giner-Sorolla, 2018). However, the trial was primarily powered to detect the main effect of choice versus random allocation to treatment, not interaction effects.

Implications for Future Research

Although we did not see any significant main effect of choice in this trial, there may be subgroups of patients that benefit more than others do from a choice of treatment. A differential effect of choice may be related some psychological variable, demographics, comorbidity, etc. Mixture models may be applied to the sample as a whole, and separately for the choice and random condition in order to detect such subpopulations. Further, we plan to test the associations of choice found in study III in moderator analysis of treatment outcome in the four treatment arms (randomised to PCT, randomised to PFPP, self-selected PCT, and self-selected PFPP). In addition, in future studies we will address if the choice of treatment had any effect on other secondary outcomes such as work ability and health economics, or indeed attachment and relational problems.

The Contextual model of change (Wampold, 2015) suggests that common factors rather than specific therapeutic ingredients for specific disorders are the main vehicle for therapeutic change. The therapeutic alliance is the most researched common factor and relates to the change processes stipulated by the Contextual model. The broad construct of therapeutic alliance, including positive outcome expectancies, enhanced patient/therapist communication, and improved treatment adherence have also been suggested as a mechanism to help explain preference effects (Lindhiem et al., 2014). In partial support of this assertion, Study III found that patient's treatment credibility beliefs were related to their choice of treatment. Credibility beliefs may be a proxy for positive expectations by the match of the patient's personal beliefs about what specific ingredients will be helpful in therapy to a treatment. We have collected data on the therapeutic alliance and treatment adherence during the treatment phase and in future studies we plan to explore the relationship between alliance ratings, adherence, patient preferences, and treatment outcome.

There is a need to explore the circumstances under which patients can make treatment choices that have a positive influence on their outcome. One research option would be to experimentally test the effect of different assessment procedures and treatment information, on preference effects, by randomising participants into different preference assessment groups. In addition, at the six month follow up we conducted qualitative interviews (about 40 minutes in length) based on an adaption of the Psychotherapeutic Outcome Interview Schedule (POISE; Nilsson et al., 2007). This material can be used in several ways in future studies to deepen the understanding of the experience of the treatment choice, the treatment outcome, the appreciation of different methodological aspects, etc. In sum, there is a need for more DRCPT studies on psychotherapy, involving other diagnostic categories, and other treatment alternatives, including internet delivered treatment. In addition, preference measures may benefit from adding more information to the choice material, and possibly some form of structured support in the decision process.

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Appendix: Self-selection material in Project POSE

DITT VAL AV BEHANDLING

Du kommer nu att få välja vilken av de två behandlingarna, som utvärderas i studien, som du ska gå i. Innan du gör ditt val kommer du att få läsa beskrivningar av behandlingsformerna. De är båda utvecklade för behandling av panikångest och är 12 veckor långa.

De båda terapiformerna ser på panikångest på olika sätt, och arbetar också med problemen på olika sätt. Båda har emellertid utvärderats i flera vetenskapliga studier och funnits vara mycket bra behandlingsformer för personer med panikångest. Efter beskrivningarna följer några frågor, som vi vill att du svarar på.

Läs igenom noggrant och gör sedan ditt val!

Behandling 1

Hur ser man på panikångest i behandlingen?

Utgångspunkten för behandlingen är att panikångesten hänger samman med andra svårigheter i ditt liv. Personer med panikångest upplever ofta att panikattackerna kommer helt oväntat. Man ser ingen tydlig orsak men i själva verket finns det ofta bakomliggande orsaker till att man får panikångest. Panikattackerna kommer inte slumpmässigt. Många får panikångest när något händer eller förändras i livet. Det kan vara att man skiljer sig, byter skola, förändringar på arbetet, att man hamnar i en konflikt eller att något annat förändras i ens liv. Panikångesten har ofta sina rötter i erfarenheter du har med dig sedan din uppväxt och som gör det svårt för dig att klara av nuvarande påfrestningar. En del av problemen är man medveten om, medan andra aspekter är omedvetna. Problemen leder ofta till att det kan bli svårt i relationer till andra, samtidigt som de också kan hindra dig från att leva ditt liv så fritt som du vill.

Hur arbetar man i behandlingen?

Arbetet i behandlingen går till så att du och din terapeut genom samtal försöker förstå vad det är som orsakar dina panikattacker. Fokus är på hur attackerna upplevs av dig och vad de kan komma av. Vilka tankar, känslor och idéer du har om dem. Panikångesten kan bero på att vissa känslor är svåra att kännas vid och att uttrycka. Med hjälp av terapeuten är behandlingen ett utforskande av ditt liv, hur du mår, tänker och känner och hur det har bidragit till din nuvarande situation. När du blir medveten om bakgrunden till panikångesten samt förstår dig själv och dina omständigheter bättre, så kan du också utveckla ett annat förhållningssätt till din situation och då minskar panikångesten. Arbetet i behandlingen handlar om din panikångest, din livshistoria och hur du har det här och nu i dina relationer.

Terapeutens uppgift är att hjälpa dig att lägga märke till och förstå hur dina panikattacker hänger samman med ditt övriga liv. Hur dina relationer, din uppväxt och dina känslor påverkat och påverkar dig och bidrar till panikattackerna. En del av detta är du kanske inte medveten om själv. Terapeuten visar också på mönster och sammanhang i det som du berättar.

Din uppgift i behandlingen är att berätta om dig själv och att tillsammans med terapeuten utforska dina svårigheter på djupet; att berätta om dina panikattacker, känslor, tankar och relationer så öppet som du kan. Det underlättar om du är öppen för att prata om och reflektera kring dig själv.

Vad kan jag förvänta mig för resultat?

Att gå i denna behandling innebär att förstå hur panikångesten hänger samman med dina känslor, ditt nuvarande liv och din bakgrund. När du bättre förstår hur du fungerar känslomässigt blir du inte längre överrumplad av dina känslor såsom du blir vid en panikattack. Att förstå dig själv och din livshistoria bättre gör dig mindre sårbar. Målet är att du ska kunna leva ett fritt och självständigt liv utan panikångest.

Behandling 2

Hur ser man på panikångest i behandlingen?

Utgångspunkten för behandlingen är att dina reaktioner vid en panikattack egentligen är naturliga känslomässiga och kroppsliga reaktioner. Människan är nämligen skapad för att snabbt kunna höja puls och andning vid fara. Går man till exempel ut framför en bil är det viktigt att snabbt få energi för att kunna fly undan. Personer med panikångest upplever ofta att panikattackerna kommer helt oväntat och när man drabbas blir man ofta väldigt rädd och orolig för att man ska få en hjärtattack, svimma, tappa kontrollen eller något liknande. Oron för nya panikattacker gör en extra uppmärksam på kroppsliga reaktioner, såsom ökad puls, andfåddhet eller yrsel. När dessa kroppsliga reaktioner sedan kommer reagerar man med rädsla och panik på dem, oftast utan att själv se sambandet. Många börjar undvika situationer där man är rädd att få nya panikattacker. Problemen leder ibland till att det kan bli svårt i relationer till andra, samtidigt som de också kan hindra dig från att leva ditt liv så fritt som du vill.

Hur arbetar man i behandlingen?

Arbetet i behandlingen går till så att du och din terapeut genom samtal försöker förstå vad det är som orsakar dina panikattacker. En del av arbetet innebär att du får observera dina reaktioner på egen hand mellan sessionerna. Med hjälp av olika övningar arbetar ni med de tankar, känslor och beteenden som hör ihop med panikångesten. När du känner dig redo så kommer du att få möta de vardagliga situationer som väcker just din panikångest, till en början tillsammans med terapeuten och därefter alltmer på egen hand. Du får också lära dig andningsövningar som hjälper dig att klara svåra situationer. Steg för steg så minskar din panikångest. Arbetet i behandlingen handlar om din panikångest och hur du har det här och nu.

Terapeutens uppgift är att hjälpa dig att utforska och förstå hur dina panikattacker uppstår, samt hjälpa dig att utveckla ett nytt sätt att tänka och handla på när du får ångest. Steg för steg hjälper och stöttar terapeuten dig att utmana din rädsla för panikångesten bland annat med hjälp av olika övningar. Övningarna tränar du på tillsammans med terapeuten men du får också uppgifter att göra hemma mellan sessionerna.

Din uppgift i behandlingen är att berätta om din panikångest och att tillsammans med terapeuten utforska dina problem. Du får arbeta med dina tankar, känslor och din panikångest enligt en plan som du och din terapeut kommer överens om. Det underlättar om du är öppen för att prova nya sätt att bemöta din ångest.

Vad kan jag förvänta mig för resultat?

Att gå i denna behandling innebär att förstå hur panikångesten hänger samman med dina känslor, tankar och beteenden. När du bättre förstår sambandet mellan dessa och dina kroppsliga reaktioner blir du inte längre överrumplad av panikångest. När du ser sambanden kan du hantera dina rädslor på ett nytt sätt och blir mindre sårbar för panikångest. Målet är att du ska kunna leva ett fritt och självständigt liv utan panikångest.

Frågor om Ditt val

1. Hur trovärdig som behandling för panikångest tycker du att Behandling 1 är? Kryssa för den siffra du tycker stämmer bäst.

1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐
Inte alls trovärdig				Ganska trovärdig				Mycket trovärdig

2. Hur trovärdig som behandling för panikångest tycker du att Behandling 2 är? Kryssa för den siffra du tycker stämmer bäst.

1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐
Inte alls trovärdig				Ganska trovärdig				Mycket trovärdig

3. Hur jobbig tycker du att Behandling 1 verkar vara att gå i? Kryssa för den siffra du tycker stämmer bäst.

1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐
Inte alls jobbig				Ganska jobbig				Mycket jobbig

4. Hur jobbig tycker du att Behandling 2 verkar vara att gå i? Kryssa för den siffra du tycker stämmer bäst.

1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐
Inte alls jobbig				Ganska jobbig				Mycket jobbig

5. Vilken av de två Behandlingarna vill du gå i? Kryssa för ditt svar.

☐	Behandling 1
☐	Behandling 2
☐	Osäker, men jag väljer Behandling 1
☐	Osäker, men jag väljer Behandling 2

6. Nu när du själv har fått välja behandling, hur viktigt känner du att det var att själv få välja vilken behandling du ska gå i? Kryssa för den siffra du tycker stämmer bäst.

1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐
Inte alls viktigt				Ganska viktigt				Mycket viktigt

7. Vad tycker du är mest tilltalande med den behandling du valt?

…...……
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……...……
……...……
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8. Varför valde du denna behandling?

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