

Understanding the Role of Therapeutic Alliance in
Treatment for Heroin Dependence: An Exploratory
Analysis

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DClinPsy Thesis (Volume 1), 2021

University College London

UCL Doctorate in Clinical Psychology

Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Overview

Part one of the thesis describes a systematic review focused on implementing shared decision-making interventions in adult mental health services. It considers the barriers and facilitators to implementing different interventions at individual and service levels.

Part two explores the role of the therapeutic alliance in the treatment of heroin dependence. Secondary analysis of the Positive Reinforcement Targeting Abstinence in Substance Misuse (PRAISe) cluster randomised trial data is used to investigate whether the therapeutic alliance between keyworkers and patients changes over the course of 12-weeks of treatment. The study further explores whether the therapeutic alliance mediates the relationship between pre-treatment motivation and both treatment attendance and outcomes.

Part three is a critical appraisal of the process of completing the research. It includes reflection on how the researcher's values and experiences shaped the project and further discussion of the limitations and learning from the process.

Impact Statement

The systematic review of shared decision-making interventions suggests several areas for clinical services to focus on when developing implementation plans. Current conceptualisations of shared decision-making focus on individual decisions at one time point. However, the systematic review highlighted the importance of long-term relationships in facilitating, or creating barriers to, shared decision-making in mental health services. How services and professionals build and maintain relationships with patients should be considered as fundamental to implementing shared decision-making interventions if they are to be successful.

For clinicians and researchers, developing interventions that can be easily adapted or tailored to existing service processes should be a focus. Where this is successful, the present study suggests shared decision-making can facilitate improved relationships between staff and patients, which may have an impact on outcomes.

The findings of the systematic review therefore also have implications for future research into the effectiveness of shared decision-making. The high number of barriers found, and inconsistent or incomplete implementation of interventions, suggests that until effectiveness research also ensures implementation is consistent, it will not be possible to understand the true potential of these interventions.

The findings of the empirical paper point to a need to further consider mechanisms of change in psychosocial treatments for heroin dependence. The therapeutic alliance has long been thought of as important, but the present study suggests that there may be changes to the alliance over the course of treatment that may benefit from closer attention.

While research has previously linked therapeutic alliance with attendance, the findings suggest that services may benefit from considering how pre-treatment factors, such as motivation, affect the alliance. The study also demonstrates the

need for further research into how the complexity of patient's mental health and heroin use before treatment may affect their motivation, development of alliances, and success in treatment.

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Acknowledgements

Firstly, thank you to my research supervisors, Steve Pilling and Rob Saunders, for your support and guidance throughout the process, particularly when the pandemic was wreaking havoc on my carefully laid plans. Particular thanks to Rob for your calm reassurance and responding to all of my questions and worries about statistics with patience. Thank you also to Nicola Metrebian and all the PRAISe research team for allowing me to access and analyse the data you collected and managed from the trial.

Thank you to my course tutor Marc, for your kindness and support throughout the three years, particularly at times when life, health, and the pandemic loomed large over training.

To Jan, Holly, Lauren, and Grace, thank you for bringing so much laughter, friendship, and well-timed sweet treats to training, even when we could only see each other over zoom.

Thank you to Richard for your humour, support, and advice, whether in jest or in all seriousness.

Thank you to Lynzy, I can't imagine getting through many things without your friendship and this has been no exception.

Thank you to my dad, brothers, and close family for your humour, love, and encouragement over many years. A particular thank you to my nan, following your advice to "just do your best and leave the rest" has kept me going when things have been tough.

Finally, thank you to Andy, for your love, for feeding me, and for believing in me more than I ever could myself. I'm looking forward to returning the support as you begin your own journey on training.

Part 1: Literature Review

Implementing Shared Decision-Making Interventions in Adult Mental Health Services: A Systematic Review

Abstract

Aims: To understand barriers and facilitators to implementing shared decision-making (SDM) interventions in adult mental health services. To consider these within the context of the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009) to allow for increased generalisability and use of findings in clinical settings.

Methods: A systematic search of the Medline, PsycInfo, CINAHL and Web of Science databases was undertaken to identify relevant articles published up to September 2020. Barriers and facilitators were mapped using the constructs of the CFIR and thematic synthesis was conducted to provide necessary context.

Results: More barriers than facilitators were noted by identified studies. Eleven themes were identified across the five domains of the CFIR that highlighted the adaptability and complexity of SDM interventions, the influence of traditional service cultures, resources, and leadership on implementation in addition to the relational complexity of SDM and challenges in engaging staff and service users.

Conclusions: There is limited research of varying methodological quality focused on understanding implementation of SDM interventions in adult mental health services. When implementing interventions, it may be helpful to consider the existing relationships, resources, and systems within services at the planning stage to facilitate adaptation of interventions to specific contexts. Future research is needed to increase our understanding of how SDM interventions may be implemented across different settings.

Introduction

Shared decision-making (SDM) emphasises the roles of both professionals and service users in facilitating decision-making. Fundamentally, it involves the sharing of information, values, and preferences, between them with a final decision that is agreed on by both parties (Charles et al., 1997). Several systematic reviews in the area have identified that patients express a preference for SDM, placing importance on being respected, listened to, and having their viewpoint valued by professionals (Castillo & Ramon, 2017; Huang et al., 2020; Kaminskiy et al., 2017). Reviews have also found a consensus that SDM is generally a preferred style among mental healthcare professionals (Huang et al., 2020; Kaminskiy et al., 2017) with increased service user participation in care seen as connected to improved progress towards recovery and self-efficacy (Jørgensen & Dahl Rendtorff, 2018). These preferences have been reflected in national policies in the UK (Coulter et al., 2011; Coulter & Collins, 2011). Given this increase in both awareness and preferences for SDM, research attention has started to focus on possible interventions to increase its use and what the effects of these might be.

There are a range of differing interventions that purport to facilitate SDM in mental health services. These include decision aids (e.g., Deegan, 2010; Finnerty et al., 2018; Perestelo - Perez et al., 2017), staff training (e.g., Brooks et al., 2019; Farrelly et al., 2015), patient training (e.g., Hamann et al., 2017; Treichler et al., 2020), and programmes that combine multiple approaches (e.g., Aoki et al., 2019; Loh et al., 2007; Zisman-ilani et al., 2019). A review of interventions available recognised several different components of SDM often present in interventions (Zisman-Ilani et al., 2017). These components centred on the provision of information about different decision options, spending time eliciting patient preferences about the decision, alongside their values. Further components related

to enhancing patient's communication skills, and increasing patient motivation to participate in decisions, goal-setting, and care (Zisman-Ilani et al., 2017).

Multiple systematic reviews have focused on the impact of interventions in different mental health diagnoses, however the results of these are mixed. One review found evidence for positive impacts on service user outcomes in psychosis, such as increased empowerment and reduced hospitalisation (Stovell et al., 2016) and another found improved quality of life and decreases in symptoms of depression (van der Voort et al., 2011). However, most positive impacts found to date relate to areas such as engagement, knowledge about treatment, and medication adherence (Fisher et al., 2016; Samalin et al., 2018) or direct decision-related outcomes, such as reducing decisional conflict (Fisher et al., 2020), rather than wider clinical outcomes. The latest Cochrane review concluded that the current evidence for the use and impact of SDM interventions contains very low certainty (Legare et al., 2018).

There may be a consensus that SDM is an ethically important practice (Slade, 2017), but the limited understanding of whether it has an impact on outcomes may be affected by challenges in implementing it, particularly in mental health services. The process itself may be more important than who makes the final decision (Edwards & Elwyn, 2006) and the relational nature of this requires multiple interpersonal skills that both professionals and service users may need support to develop (Elwyn et al., 2000; Légaré et al., 2013). System level factors and relationships are also implicated, with discourses around SDM emphasising its potential to rebalance power between professionals and service users (Drake et al., 2010). However, ongoing power asymmetry and the challenge of balancing SDM and risk management are possible barriers to its implementation (Kaminskiy, 2015; Slade, 2017). There are also limitations in the understanding of how different backgrounds and identities impact this process, aside from several papers that have

considered possible effects of age (Burns et al., 2020) and educational attainment (Hamann et al., 2011). Most research has taken place in a small number of Western countries (James & Quirk, 2017), with only a few studies considering the impact of culture (Gao et al., 2019; Huang et al., 2020). It is arguable that unless research and practice consider how to ensure its implementation is culturally competent, the potential of SDM may be missed (Whitley, 2009).

Some of these wider issues have been reflected in research into the perceptions and attitudes of professionals and service users. Although professionals are found to support SDM in theory, concerns about the capacity of service users to participate in this process, particularly when in a crisis or when a diagnosis of psychosis is present, have been raised (Ali et al., 2015; Chong et al., 2013). Professionals may also view service users more negatively if they actively participate in their care by doubting professionals or insisting on their own preferences (Hamann et al., 2012). This is consistent with service user's reports of holding back due to fears about the repercussions of disagreeing with professionals and the impact of stigma on their confidence in taking part and being heard, alongside implied interactional roles where service users are passive and professionals active (Joseph-Williams et al., 2014; Kaminskiy et al., 2017).

The only identified review that focused on implementation of SDM was undertaken by Ramon, Brooks, et al., (2017). They used a purposive search strategy to identify relevant papers and synthesised these papers using normalisation process theory (NPT) (May et al., 2007). This highlighted several barriers to implementation; the lack of a coherent definition of SDM across settings, sustaining the relationships between service users and professionals necessary for SDM, and limited understanding of de-implementing previous practices to enable change. Based on this review they recommended clear communication of the advantages of SDM, training that facilitates favourable attitudes at each level, and

simple, mandated, SDM strategies or tools for staff and service users. This review was based largely on studies that examined attitudes and beliefs about SDM, alongside in depth consideration of one intervention, CommonGround (Deegan et al., 2008), rather than studies that had attempted to implement differing interventions in services.

Consequently, a question remains around what barriers and facilitators arise on the ground in services during the implementation process. This review aims to consider this question, focusing on interventions designed to introduce or improve SDM in adult mental health services. Given the limited nature of the existing evidence-base, this review has adopted a broad definition of SDM interventions and methods for considering implementation, to allow for all relevant papers at the present time to be included. The consolidated framework for implementation research (CFIR) is used as a guiding framework to allow future research and services looking to implement SDM interventions to easily draw on the findings and compare with their own contexts. The review was registered on PROSPERO, registration number CRD42021227227.

Methods

Search Strategy

The following databases were searched for articles published up to 11th September 2020: Medline, PsychInfo, CINAHL, Web of Science. Searches were conducted using the keywords “shared decision making”, “mental health”, “mental illness”, “mental disorder” psychiatr*, psycholog* (where asterisks represent the relevant truncation symbol per database). Subject headings for the search terms were also used in databases that had this function and this search was combined with the keyword search. The keywords and subject headings were searched separately and then combined with “shared decision making” using the operative

“and”. No restrictions were used in the searches to maximise the likelihood that all relevant papers were included. Search strategies from the databases can be found in Appendix A. Due to the time and resource limitations in the conduction of the present review, grey literature searches were limited to PsycExtra.

Inclusion and Exclusion Criteria

Papers were initially screened by title and abstract, before full text screening to identify the final papers for synthesis. Papers therefore were required to be available in English and in their full text through the UCL library, where requests for access to papers not available initially were made if necessary. Further criteria for inclusion fell under the following areas.

Design

Qualitative, quantitative, and mixed methods studies of any design were included as the focus of the review is on implementation. Papers that were not strictly empirical, such as narrative reports were also included in the study if they met the remainder of inclusion criteria.

Participants

Adult populations using mental healthcare services for any mental health condition were included in the study. Exclusion criteria were papers relating solely to child or adolescent participants up to the age of 18, participants aged over 65, participants using services for primary substance or alcohol misuse. Participants with dual diagnoses being treated within a mental health service setting were included.

Setting

Only settings that were classed as mental health services were included in the review. These could be community or inpatient settings. Due to the scope of the review, general primary care settings (e.g., GP practices) were excluded, alongside

studies using actors, or where implementation was conducted outside of the mental health service, for example in an academic setting.

Interventions

Inclusion criteria were any intervention aimed at introducing or improving SDM. These could be service user targeted, professional targeted, or those targeting service users and professionals. Exclusion criteria were interventions that primarily aimed to influence any other factor in mental health care.

Implementation

Studies were excluded if they did not provide information on implementation. This information was classed as any qualitative or quantitative indicators of barriers or facilitators in the process of carrying out the intervention in the service. A flow diagram showing the process of screening and exclusion, including the numbers of papers retrieved and reasons for exclusion is presented in Figure 1.

Data Quality

The quality of included studies was assessed using the Mixed Methods Appraisal Tool, version 2018 (MMAT) (Hong et al., 2018). This tool was chosen due to the heterogeneity of studies to be included in the review as it is explicitly designed for this purpose within systematic reviews in health research (Pluye et al., 2009). The original tool was developed through a critical review of existing methods and criteria used in reviews of mixed study designs (Pluye et al., 2009) and tested with regards to reliability (Pace et al., 2012). The 2018 version used in this review was further revised using e-Delphi methods to improve content validity (Hong et al., 2019). It was decided not to give papers overall scores, as it is recommended that the tool is used to provide context and considered appraisal (Hong et al., 2018). As a result, the methodological quality is reported descriptively alongside indications of the number of possible criteria met. The results of the MMAT quality appraisal were used to inform the weighting given to conclusions about the existing evidence base and implications of the review, rather than to exclude papers. The MMAT was used

alongside descriptive summaries of the aims and length of attempted implementation to provide further context to the present state of the evidence base.

Data Synthesis

The comprehensive framework for implementation research (CFIR) (Damschroder et al., 2009) was used to map factors affecting implementation that were reported by the studies in terms of barriers and facilitators. The CFIR is a structure composed of five domains: 'intervention characteristics', 'outer setting', 'inner setting', 'characteristics of individuals', and 'process'. It was designed to synthesise multiple similar approaches to implementation research and allow for understanding and consideration of the complex network of factors that affect the implementation of interventions in health settings.

The CFIR has multiple constructs within each of the five domains and a detailed overview of these is provided in Damschroder et al., (2009). Broadly, the 'intervention characteristics' domain includes the complexity, adaptability, and design quality of the intervention, alongside the cost and perceived evidence for and advantages of using it. The 'outer setting' focuses on the organisation and wider external context, such as quality standards, connections with other organisations, and the extent to which patient needs and resources are understood at organisational level. In the 'inner setting' the focus is within an organisation, service, or team, concerning the climate, resources, and structural elements present. 'Characteristics of individuals' concerns the beliefs, efficacy, and capacity for change of individuals, and how far they do or do not identify with their organisation. Finally, the 'process' domain relates to the planning, execution, and evaluation of the implementation itself. The CFIR has an established use within systematic reviews in health contexts to understand the implementation of interventions (Aref-Adib et al., 2019; Holmes et al., 2020; Louie et al., 2021; Ross et al., 2016; Weir et al., 2019). It was chosen as a guiding framework for the current review due to the

wide remit of contexts and interventions considered for inclusion and the CFIR's ability to understand commonality and difference across these.

The CFIR guided the data synthesis in two ways. Firstly, it provided a context for initial descriptive coding of the data, which were coded broadly as barriers or facilitators where relevant to each of the CFIR constructs, in the manner used by Holmes et al., (2020). All data within the results sections of papers were included in the synthesis, including both direct quotes from study participants and the analysis and description of the original authors. A thematic synthesis of the implementation data in the papers was then conducted following the process described by Thomas and Harden (2008) and was carried out in NVivo software. Data were line-by-line coded inductively and new codes added as data from each paper was reviewed. Initial descriptive themes were generated which closely represented the data and codes. These themes were refined and considered in relation to domains of the CFIR. Attention was paid to whether there were themes that did not fit within existing CFIR concepts; however, all codes and themes generated were related to constructs within this framework.

While it is impossible to fully separate or account for the subjectivity of the researcher within qualitative analysis, procedures were taken to increase reflexivity and minimise this bias (Spencer & Ritchie, 2012). Bracketing of preconceptions held by the researcher was undertaken through the use of a journal throughout the research (Tufford & Newman, 2012). To minimise the impact of any bias or preconceptions, secondary coding of a subsection of papers was undertaken by another doctoral researcher and coding frames were found to be largely consistent, with discrepancies discussed and reflected on. Themes and codes were also repeatedly checked against their prevalence across papers to ensure they were representative of the data. Additionally, exceptions or contradictory examples were actively sought to fully understand the dataset. The final codebook from NVivo is included in Appendix B.

Results

Characteristics of included papers

After full text screening 17 studies were included for synthesis. Two of the included studies were overview papers describing implementation, rather than clear empirical papers, and one further paper was a systematic review that contained two reflective narratives within it. Four papers were quantitative in design, two with randomised methods. A further five papers used qualitative methods and the remaining five studies were mixed methods in design. Most papers report on community mental health settings in the USA (8) with remaining studies set in community mental health in the UK (5), Sweden (1), Holland (1), inpatient services in the UK (1), and inpatient and community settings in Denmark (1). Most of the studies included participants with a broad range of serious mental illness diagnoses, with this specified as inclusion criteria in nine studies. In the six papers that did not specifically report diagnostic information, there were also no exclusion criteria included and all these interventions took place in community mental health services. One paper focused on participants with psychosis and one further paper specified those with non-affective psychosis as inclusion criteria. Further participant characteristics varied widely between papers and were not consistently reported. The full characteristics of included papers are summarised in Table 1.

SDM Interventions

Most of the papers included reported on decision aids in varying formats. Six papers (APA Gold Achievement Award, 2013; Bonfils et al., 2018; Deegan, 2010; Deegan et al., 2008; Finnerty et al., 2019; Goscha & Rapp, 2015) focused on the implementation of the CommonGround programme designed by Patricia Deegan and colleagues (Deegan, 2010). One of these papers (APA Gold Achievement Award, 2013) provides an overview of the implementation of CommonGround across routine mental health services in the USA, where the remaining papers

reported on more specific sites where this has been trialled. CommonGround is a web-based decision support tool that provides information about treatment options, videos of recovery stories, and spaces for individuals to record the effectiveness or side-effects of treatment to date alongside their goals (Deegan, 2010). A print-out from the programme is then produced to be used in consultation with a professional. All of the studies using CommonGround were based in community mental health settings in the USA and one of the studies had adapted CommonGround to be used within a computerised tool already being used in their services (Finnerty et al., 2019).

Figure 1.

Flow Chart of Paper Selection Process

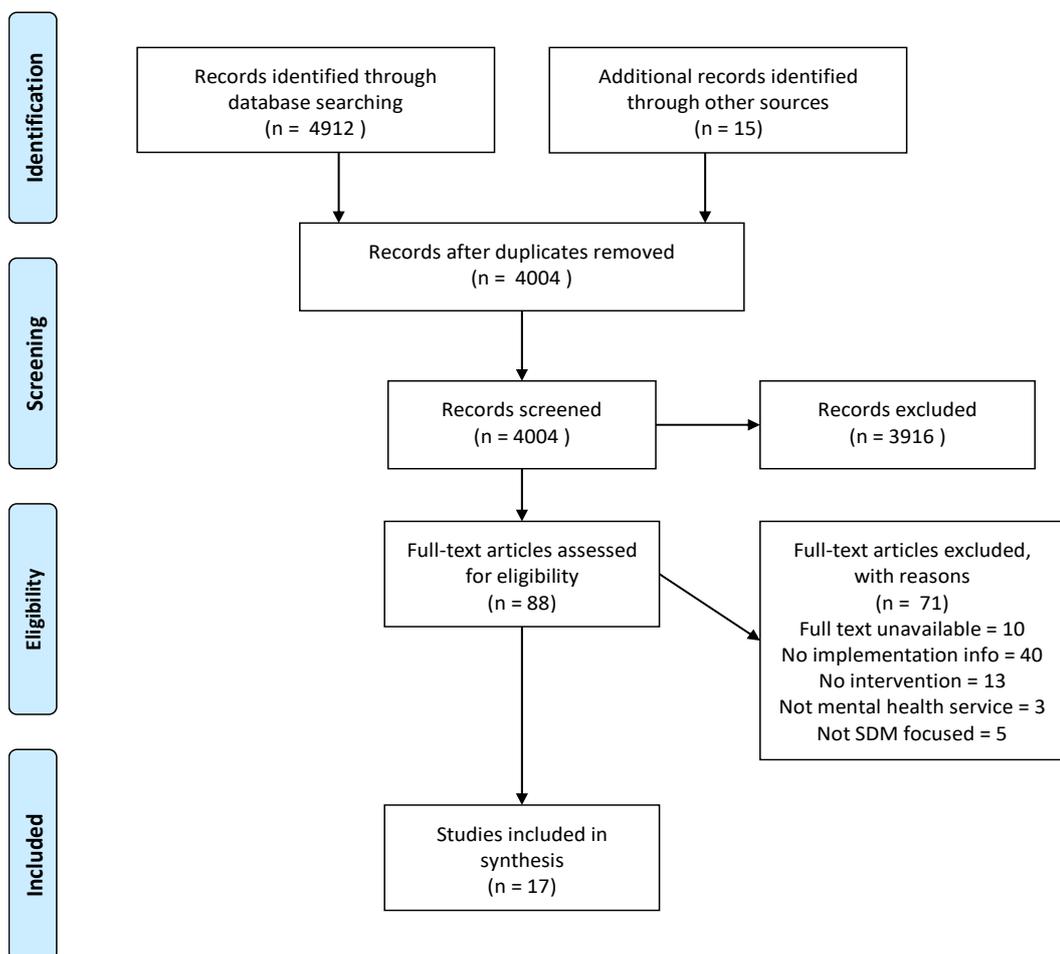


Table 1.

Characteristics of Included Papers and Quality Ratings

Study ID	Aims	Design	Setting	Intervention Participants	Implementation Participants	SDM intervention type	Duration	Follow up	MMAT criteria	MMAT comments	
Overview of CommonGround intervention, implementation and aims						Computerised decision support tool - CommonGround	2009	paper date	MMAT criteria	MMAT comments	
Bonfils et al 2018	To explore the CommonGround implementation process and identify strategies to enhance the program's impact at future sites	Qualitative (focus group and interviews)	Community mental health services USA	569 service users and their care professionals	50 Service user, 28 Care coordinator interviewed	Computerised decision support tool - CommonGround	3 years	None	12 of 15	All qualitative criteria met. Large data sample and insufficient details about detailed descriptions of target population and non response bias in quantitative element	
Farrelly et al 2015	barriers to it's implementation	(semi-structured interviews)	Community mental health services UK	107 service users	47 participants (21 professionals, 29 service users and 4 carers)	Structured meeting	2 meetings + 6hr follow up.	18month	5 of 5	procedures around bias and reporting of findings	
Brooks et al 2019	To report on the parallel process evaluation of implementation within a cluster randomised trial	(semi-structured interviews)	Community mental health services UK	604 Service users 90 carers, 36 CMHTs	29 service users and 4 carers)	Staff training in conversation aid	Programme ran for 14months	6 and 12 month	5 of 5	AQ Quantitative criteria met. descriptive analysis met. All qualitative criteria met.	
Finnerty et al 2019	To understand how able participants are to participate in the implementation process in clinics piloting the intervention	Mixed methods	Community mental health USA	543 service users	N/A implementation notes/plans/assessment visits used	Computerised decision support tool - MyCHOIS	One off interview within 1st week of admission. Avg 29min. No details on duration of	18month	None	11 of 15	Small pilot study. Insufficient detail about target population information on procedures to minimise bias
Burn et al 2019	users experienced by staff and service	Mixed methods	Inpatient wards	5 clinicians All service users and staff at mental health centre (no. not specified)	12service user interviewed. All 14professionals, 4 mental health treatment team interviewed	SDM Interview protocol	study	None	12 of 15	discussed	
Goscha & Rapp Deegan et al 2008 2015	To understand how staff and service users experienced the intervention in a 12 month pilot	Qualitative (focus groups)	Community mental health services USA	189 service users	16 service users interviewed	Computerised Decision support tool - CommonGround	12 months	None	3 of 5	Details of qualitative methods were reported with sufficient detail but examples from data.	
Deegan 2010	To summarise CommonGround and lessons learned	N/A	Community mental health services USA	8 sites with 4783 service users	N/A	Computerised Decision support tool - CommonGround	2006-paper date	None	N/A	Procedures for minimising bias discussed, but exact method of qualitative analysis unclear. Results themes are the research questions, so difficult to understand level of interpretation taken	
Korsbek & Tonder 2016	To understand how the intervention is experienced and if it influences participation in and quality of treatment consultations	Qualitative (focus groups)	Inpatient and community mental health Denmark	78 service users, 116 providers	7 Service users, 19 staff	Smartphone app decision support tool - Momentum	4 months	none	3 of 5		

Study ID	Aims	Design	Setting	Intervention Participants	Implementation Participants	SDM intervention type	Duration	Follow up	MMAT criteria	MMAT comments
Lovell et al 2018	To test practicality and feasibility of an intervention in routine community mental health services to embed shared decision-making	Cluster randomised trial	Community mental health teams UK	604 service users, 90 carers, 36 CMHTs (18 in each arm)	604 (497 after loss to follow up)	Staff training in conversation aid	2 day training +6hr follow up	6 months	4 of 5	Most criteria for randomised design met, but possible fidelity issues that are not detailed in the published paper.
Paudel et al 2018	To measure the effectiveness of the intervention. Commentary on implementation.	Nonrandomised pre-post design	Community mental health USA	14 service users	14 (22 consented, 8 drop out)	Programme: staff training, SDM group, 1:1 meetings with peer workers, nurses and psychiatrists	12 weeks	None	3 of 5	Limited detail on population and setting reported outside of age of participants possibly being unrepresentative. Drop out rates of 1/3 but reasons or characteristics not reported
Polo et al 2012	To describe the benefits and challenges of adopting an intervention to increase involvement in mental health care in relation to Latino service users	Learning from a nonrandomised controlled pre-post design	Community mental health USA	231 service users 141 in intervention group	Intervention:141 Control:90	Patient training - Right Question Project-Mental Health	3 sessions per person, ran for 2 years	None reported	N/A	All qualitative criteria met. Incomplete data for quantitative element, although this is considered as part of the analysis. Minimal information about target population for comparison
Ramon et al 2017b	To develop and evaluate a training programme for SDM in medication management in mental health services	Mixed methods (semi-structured interviews)	Community mental health UK	47 Service User 12 psychiatrists 35 care co/staff	interviews: 12 service users, 6 psychiatrists, 11 care coordinators	Patient and staff training groups (ShiMME)	CareCo: 3, 1.5hr sessions	12 month	12 of 15	

Study ID	Aims	Design	Setting	Intervention Participants	Implementation Participants	SDM intervention type	Duration	Follow up	MMAT criteria	MMAT comments
Ramon et al 2017a	To provide experiential context of implementation to systematic review findings	Reflective narrative from implementation programme. Details of experimental aspect Ramon Morant 2017	Community mental health UK	Not reported	2 mental health nurse and service user trainer	Staff training groups (ShiMME)	2 yr implementation post 12 week pilot	No	N/A	All criteria across all domains met. Quantitative outcomes of poor data quality excluded and reason outlined clearly. Remaining quantitative data used to triangulate qualitative elements
Schon et al 2018	To evaluate the implementation of the intervention and understand barriers and facilitators	Mixed methods pre-post intervention	Community mental health services Sweden	95 staff and all service users at 6 participating	29 staff in focus groups 73 completed follow up	Web-based Decision Support Tool	6month	None	15 of 15	Large drop out rates and process evaluation highlighted poor implementation of intervention
van der Krieke et al 2013	To investigate the intervention in a naturalistic setting	RCT with process evaluation	Community psychosis services Holland	250 service users across 2 trial arms	measures. 15 service users interviewed	Web-based Decision Support Tool	Once in 6 weeks. Trial ran for 12months	6 weeks	2 of 5	

Of the remaining studies using decision aids, three were also web-based (Korsbek & Tønder, 2016; Schön et al., 2018; van der Krieke et al., 2013). The remaining two were encounter-based tools designed to be used during interviews with service users and included staff training as part of the programme (Burn et al., 2019; Farrelly et al., 2015). Similar topics to those covered in CommonGround were included in the remaining decision aids, with space for service users to explore treatment options, prioritise conversation topics, and in the Burn et al., (2019) intervention, explicit steps were included around negotiating and not deciding unless agreed by both parties.

Alternatives to decision aids focused on either staff or patient training, or a combination of multiple approaches. Interventions focused on staff training included Ramon, Brooks, et al., (2017), Brooks et al., (2019) and Lovell et al., (2018), with each of these including introducing a conversation or decision aid as part of the training. Lovell et al., (2018) and Brooks et al., (2019) both relate to the same intervention, the EQUIP training for staff in SDM conversations, with the studies providing complementary information about the same research. The EQUIP training was delivered through 'train the trainer' models by service users and carers alongside mental health professionals and aimed to counter negative attitudes towards patient involvement while providing skills that could be used in short clinical encounters. The paper by Ramon, Brooks, et al., (2017) is a systematic review that included two reflective narratives from a senior nurse and a service user who led implementation of the Shared Involvement in Medication Management Education (ShIMME) programme. This intervention was also reported on by Ramon, Morant, et al., (2017) and the ShIMME programme included training sessions separately for service users, care coordinators and psychiatrists. This training included the process of SDM, facilitators and barriers, and decision-aids. One study had service user training in SDM as the focus of their intervention, (Polo, Alegri, & Sirkin, 2012) using

coaching for case managers who then provided individual training sessions for service users. This programme, the Right Question Project – Mental Health (RQP-MH), aimed to increase participation in and opportunities for SDM through training service users in how formulate and ask questions in interactions with mental health professionals. The final study considered a programme of staff and service user group training sessions alongside individual meetings between service users and members of their care team to put this training into practice (Paudel et al., 2018). The training itself was described as covering SDM principles and components from a recovery model perspective and included psychoeducation around treatment options for service users.

Quality of Evidence

While the present review was not examining outcomes, the quality of papers was considered to contextualise any findings. Pertinent in the present review is the balance between the types of information reported on by the papers regarding implementation. Seven of the papers explicitly focused on evaluating implementation as part of their study aims (Bonfils et al., 2018; Brooks et al., 2019; Farrelly et al., 2015; Finnerty et al., 2019; Polo et al., 2012; Ramon, Brooks et al., 2017; Schön et al., 2018), with three further papers providing overviews of lessons learned from implementation of one intervention, CommonGround, in differing sites (APA Gold Achievement Award, 2013; Deegan, 2010; Deegan et al., 2008). The remaining seven papers reported implementation information as part of understanding the feasibility or impact on outcomes of the SDM interventions (Burn et al., 2019; Goscha & Rapp, 2015; Korsbek & Tønder, 2016; Lovell et al., 2018; Paudel et al., 2018; Ramon, Morant et al., 2017; van der Krieke et al., 2013). This highlights that there are very few studies in the current literature that focus on the process of implementing SDM interventions in mental health services.

Fourteen papers reported on interventions that were implemented in services for longer than six months, with eleven of these including interventions that were followed for up to twelve months or more from onset (APA Gold Achievement Award, 2013; Bonfils et al., 2018; Brooks et al., 2019; Deegan, 2010; Deegan et al., 2008; Farrelly et al., 2015; Finnerty et al., 2019; Polo et al., 2012; Ramon, Brooks, et al., 2017; Ramon, Morant, et al., 2017; van der Krieke et al., 2013). This suggests that the papers included are in a large part able to speak to implementation of SDM interventions over at least six months. However, all the studies included were based in the USA or Western Europe, with the vast majority of these taking place in community mental health services (15 of 17 papers). There was some variation in the community mental health settings included, such as an early intervention in psychosis service (van der Krieke et al., 2013) and assertive community treatment teams (Bonfils et al., 2018), but overall there was a lack of diversity in the services and geographical and cultural locations of studies.

Further assessment of the quality of evidence was undertaken using the MMAT (Hong et al., 2018). Considering the papers that reported on empirical studies, on the whole quality was mixed, with some studies meeting all criteria required for the study design and others lacking clarity around key elements. Within quantitative or mixed methods papers a common difficulty was found in assessing the relevance of the sample to the target population, as this data was infrequently reported. Exceptions to this were two papers where all service users or professionals in a service were included in the study (Finnerty et al., 2019; Schön et al., 2018). There were also quality issues in several of the qualitative parts of papers in terms of limited reporting of qualitative methodology and analysis, rendering it difficult to clearly assess the risk of bias or procedures taken to mitigate this (Deegan et al., 2008; Finnerty et al., 2019; Korsbek & Tønder, 2016).

These issues were not unexpected due to the broad nature of papers included in the review to allow for inclusion of all relevant information about implementation. As a result, no papers were excluded on the basis of quality, however the weighting given to conclusions and the implications for future research were considered in light of these issues.

Mapping Barriers and Facilitators to CFIR Constructs

Information about the implementation of the SDM interventions was mapped to the constructs within the five domains of the CFIR and coded as either a barrier or a facilitator. For some papers, barriers and facilitators were reported within the same construct. There was a total of 128 barriers, facilitators, or both, identified within the papers. There were more barriers (68) than facilitators (27) with 33 instances of both barriers and facilitators being identified in a construct. The 'inner setting' was the domain where most barriers or facilitators were reported, with the majority being barriers. The only construct where every paper included reported either barriers, facilitators, or both, was the 'engaging' construct, within the 'process' domain. This relates to how stakeholders are engaged at every level throughout implementation of an intervention. The 'outer setting' had notably fewer barriers or facilitators reported than the other domains. The spread of these barriers and facilitators was reflected in and expanded across the themes identified through thematic synthesis. A summary showing this mapping across each construct and domain of the CFIR is displayed in Table 3.

Thematic Synthesis

Following analysis, themes were grouped by the constructs they related to and the domain of the CFIR that they fall within. A total of eleven themes across the five domains of the CFIR were identified and these are summarised in Table 3.

Table 3.

Summary of Themes for Each CFIR Domain

CFIR domain	Theme
Intervention Characteristics	Adaptability and complexity in specific service settings
Outer Setting	Understanding patient needs and resources
Inner Setting	Traditional service cultures can be challenged by SDM Service pressures create an inhospitable implementation climate The importance of organisational commitment in readying services for implementation
Characteristics of Individuals	Persistent beliefs that SDM is not for everyone Confidence, competence, and self-efficacy SDM interventions are valued
Process	Engaging staff and service users: the role of relationships Engaging staff: leadership at all levels Incomplete or slow execution of implementation

Intervention Characteristics

Adaptability and Complexity in Specific Service Settings.

Barriers and facilitators in the complexity and adaptability of interventions were noticed across nine papers. In terms of complexity, the most frequent barrier raised was that interventions needed separate systems and created extra

information, therefore requiring staff or service users to undertake multiple steps or go outside of their usual processes. Notably this was raised as a barrier in five of the CommonGround-based papers alongside another electronic decision aid, suggesting this may be more challenging with these kinds of interventions (APA Gold Achievement Award, 2013; Bonfils et al., 2018; Deegan, 2010; Deegan et al., 2008; Finnerty et al., 2019; Korsbek & Tønder, 2016). Being able to adapt interventions to fit more closely into existing processes, IT, and paper systems, was suggested as a useful facilitator to implementation. This kind of adaptation was able to be made across three papers (Bonfils et al., 2018; Brooks et al., 2019; Finnerty et al., 2019), for example finding ways to use electronic-based interventions in the community or increasing the visibility of the intervention within existing systems.

In attempting to overcome barriers of using CommonGround outside the CMHC, several staff mentioned printing handouts so they were easily accessible and could be taken into the community. (Bonfils et al., 2018)

Further examples were evident in three papers that highlighted the adaptability of interventions to service user capabilities and stage of change. Polo et al., (2012), gave multiple examples of adapting service user training sessions to different literacy levels and language needs. Burn et al., (2019) shared reflections from staff and service users on the need to flexibly adapt the timing of intervention delivery in inpatient settings, for example to work around being given heavily sedating medication. Schön et al., (2018) reported on the benefits of service users being able to use the decision aid at home in enabling them to write their thoughts down as they occur in a more relaxed setting.

Outer Setting

Understanding Patient Needs and Resources.

By far the most common area of barriers and facilitators reported in the outer setting was in understanding patient needs and resources, noted by seven papers (Bonfils et al., 2018; Brooks et al., 2019; Burn et al., 2019; Farrelly et al., 2015; Polo et al., 2012; Schön et al., 2018; van der Krieke et al., 2013). In two of the papers SDM interventions were seen as meeting a need that was understood by services for service users to have their voices heard (Bonfils et al., 2018; Burn et al., 2019). A more general sense in five of the papers was that the interventions were perceived as relevant to patient and service needs (Bonfils et al., 2018; Goscha & Rapp, 2015; Korsbek & Tønder, 2016; Paudel et al., 2018; Schön et al., 2018), although one paper highlighted where the intervention listed options that were not relevant (van der Krieke et al., 2013). There were also barriers in the understanding of service user needs and resources noted.

Clinicians were concerned that as the available care pathways may be quite limited and the JCP process was in fact providing false hope for service users. For example, “You see this is the problem. We’re doing the Joint Crisis Plan, but then we’re dictating the patient what we can offer. [...] He doesn’t really have a choice, if he deteriorates then the only help he will get is through the pathways that is currently being commissioned. If for instance [the SU says] ‘if I deteriorate I would like to, err... see the care coordinator straight away’, that’s not an option. The option is to see the crisis team practitioner, doctor straight away, [...] So in my opinion what were the patients choosing?” (Male, Psychiatrist, Interview) (Farrelly et al., 2015)

The gap between what service users themselves might want and feel they need and what services at a higher level were able to provide were seen as significant barriers to implementing SDM interventions. This was across commissioned service pathways (Farrelly et al., 2015), availability of interpreters or accessible resources (Polo et al., 2012), and in the relational gap in the

understanding of mental health difficulties felt by service users in interactions with their providers (Brooks et al., 2019).

Inner Setting

Traditional Service Cultures Can Be Challenged By SDM.

Six papers spoke to the theme of traditional service cultures and the ways in which these create barriers to implementing SDM interventions (Brooks et al., 2019; Burn et al., 2019; Farrelly et al., 2015; Polo et al., 2012; Ramon, Morant, et al., 2017; Schön et al., 2018). In these papers, ideas of SDM interventions conflicting with principles of beneficence and risk were raised, alongside the paternalism that was perceived within existing service cultures. Even when consciously implementing the interventions, Farrelly et al., (2015) noted a tendency in some staff to use communication styles that undermined the collaboration involved in SDM, such as “imploring”.

And also, there are things that the service user will want and request and you know it's not really what they need. You have to find a way, to actually communicate that, get them to understand without actually hurting them or without actually sending a message that you don't want them to get that, or you don't want to do it. (Female, Nurse, Focus Group 2)(Farrelly et al., 2015)

Traditional divisions between the roles of different professionals were also encountered as a barrier. Six papers reported a lack of buy in to SDM interventions by psychiatrists or prescribers, whether through choosing not to attend training sessions (Brooks et al., 2019; Lovell et al., 2018; Ramon, Morant, et al., 2017), lower usage of decision aids (Bonfils et al., 2018; Korsbek & Tønder, 2016; Ramon, Brooks, et al., 2017), or explicit statements (Ramon, Morant, et al., 2017). This was not universal, as the influence of psychiatrists who engaged with and valued SDM interventions was reported as facilitating implementation in other domains of the

CFIR. Nevertheless, that it was reported across different intervention types (decision aids, staff training and encounter-based tools) suggests that the influence of traditional medical models on the way different professionals may engage could hamper attempts to embed SDM interventions across disciplines.

Service Pressures Create an Inhospitable Implementation Climate.

Barriers and facilitators in the inner setting were concentrated across the constructs of structural characteristics, implementation climate, and readiness for implementation. In terms of the barriers in these domains, an interaction was noted in how challenges at a structural level, such as a lack of allocated resources or staff turnover, fed into pressures on the time and capacity of staff in individual services.

Applying SDM through the DST was perceived as something “over and above” their regular work load and something that required extra time in already stressful situations and in understaffed services. The following quote illustrates the participant’s experience: “There is so much, all of the time. There are a thousand things and constant crisis . . . We always have patients in acute crisis and that makes it very hard to focus” (p. 16). (Schön et al., 2018)

Attempting to introduce any new interventions in this context would be difficult, but SDM interventions were reported as seeming like extra work in eight papers (APA Gold Achievement Award, 2013; Bonfils et al., 2018; Brooks et al., 2019; Deegan, 2010; Deegan et al., 2008; Korsbek & Tønder, 2016; Ramon, Brooks, et al., 2017; Schön et al., 2018). This was seemingly exacerbated when there were difficulties integrating interventions with inflexible systems or standardised procedures, such as IT systems, clinic bookings, or training and development programmes. This led to SDM being viewed as an added pressure on an already stretched workload.

However it was also noted that five papers reported contrasting views from some participants that SDM was “already done” by staff in their everyday practice (Brooks et al., 2019; Farrelly et al., 2015; Finnerty et al., 2019; Ramon, Brooks, et al., 2017; Schön et al., 2018).

“I think we all thought it was a pain in the arse to be honest because... ..I think we all, have far too much work to do and the thought of giving up two full days, I think we all thought that, sort of, care management was our bread and butter.” 5002, professional (Brooks et al., 2019)

There were multiple suggested reasons for this, such as interventions being closely integrated with usual practice (e.g. care planning in Brooks et al., 2019), misperceptions about what is involved in SDM (Farrelly et al., 2015) or staff feeling too under pressure or criticised to have the capacity to learn (Ramon, Brooks, et al., 2017). Regardless of the reason, this perception impacted on the tension for change and relative priority of implementing SDM interventions, creating barriers in the implementation climate.

The Importance of Organisational Commitment in Readyng Services for Implementation.

While there were significant barriers reported in the inner setting, key facilitators were often linked to leadership and organisational support. The influence of commitment to the intervention by organisations was highlighted by 9 papers (APA Gold Achievement Award, 2013; Brooks et al., 2019; Deegan, 2010; Farrelly et al., 2015; Finnerty et al., 2019; Lovell et al., 2018; Polo et al., 2012; Ramon, Brooks, et al., 2017; Schön et al., 2018). Value and commitment could be shown by integrating the intervention into local policy and procedures, alongside sufficient allocation of resources and funding. Where SDM interventions were valued by organisations, this facilitated value to be placed on them through individual teams

and gave managers the necessary backing to push for change. However, no matter how much emphasis was placed on interventions by leadership, if resources and the funding required for these was not in place implementation was hampered.

A clear example of the differential impacts of organisation and leadership commitment was given by Finnerty et al., 2019 in their study understanding the different implementation of CommonGround at two community mental health clinics. In one clinic leadership was fully committed from the start, considering time, space, and staffing needs.

The clinic director at Clinic 2 had the autonomy to make the implementation decision and was committed to the program's success. For example, the Clinic 2 director gave up her office near the waiting room for MyCHOIS-CommonGround computer kiosks and peer staff and communicated an expectation for full integration into clinic workflows to all staff and clinic patients.

The contrast at the other clinic also highlights the role that organisation size and staff turnover can play in affecting leadership.

At Clinic 1, the hospital Executive Director made the implementation decision, and both the hospital Executive Director and the Clinic Director retired prior to program launch. The new Clinic 1 director took a more cautious implementation approach and protected clinic staff time and resources by starting with just one physician in the clinic, asking the TA team to find additional staff to support the program rather than dedicating their existing peer staff, and diverting tasks to the TA team and TA team-funded peer staff.

At the smaller clinic the director could have a large influence over resource allocation, service procedures and policies, which ultimately led to higher rates of

implementation being achieved. However, the clinic that was part of a larger organisation struggled to achieve the same commitment of resource and value. This ultimately contributed to lower implementation of CommonGround (Finnerty et al., 2019).

Characteristics of Individuals

Persistent Beliefs SDM is Not for Everyone.

Beliefs about who could participate in SDM interventions were raised as barriers by nine studies (Brooks et al., 2019; Burn et al., 2019; Farrelly et al., 2015; Korsbek & Tønder, 2016; Paudel et al., 2018; Ramon, Brooks, et al., 2017; Ramon, Morant, et al., 2017; Schön et al., 2018; van der Krieke et al., 2013). Beliefs raised centred around the insight and decision-making or cognitive capacity of service users, with the implication explicitly or implicitly stated that those who had lower insight about their mental health as judged by professionals would not be able to participate in SDM interventions in a way that was acceptable. These beliefs were sometimes noted as not being shared by all professionals (Ramon, Brooks, et al., 2017), or as being challenged once the professionals had used the intervention and had space to reflect on the capacity needed to participate (Korsbek & Tønder, 2016).

Confidence, Competence, and Self-Efficacy.

In relation to the nine papers that reported barriers or facilitators in the individual stage of change or self-efficacy of staff or service users (Brooks et al., 2019; Deegan et al., 2008; Farrelly et al., 2015; Finnerty et al., 2019; Goscha & Rapp, 2015; Korsbek & Tønder, 2016; Ramon, Brooks, et al., 2017; Ramon, Morant, et al., 2017; Schön et al., 2018), confidence and competency were often relevant. For some, the interventions seemed to increase confidence and competence over time, and this could lead to increased use.

“The more meaning we attach to it and the more familiar we are with the app... it’s something that our clients are responsive to. If we say that here is something we think can be a really good thing for you, they listen to it.”

(Korsbek & Tønder, 2016)

For others, a lack of self-efficacy and confidence remained a barrier. This was sometimes perceived as a self-fulfilling prophecy, where low confidence in their ability to use the intervention led to decreased engagement and use (e.g. Brooks et al., 2019).

Alongside reports of a lack of self-efficacy for staff, the experience of mental health difficulties and the impact on service users sense of their own confidence and competence were highlighted by three papers (Farrelly et al., 2015; Korsbek & Tønder, 2016; Polo et al., 2012). While SDM interventions were able to facilitate increased confidence and self-efficacy in some cases, where this is lacking barriers to implementation can be found.

SDM Interventions Are Valued.

Across thirteen studies the sense that SDM interventions were valued by staff was reported (APA Gold Achievement Award, 2013; Brooks et al., 2019; Burn et al., 2019; Deegan, 2010; Finnerty et al., 2019; Goscha & Rapp, 2015; Korsbek & Tønder, 2016; Lovell et al., 2018; Paudel et al., 2018; Ramon, Morant, et al., 2017; Ramon, Brooks, et al., 2017; Schön et al., 2018; van der Krieke et al., 2013). Only four studies reported that some did not see the value in these interventions (Bonfils et al., 2018; Brooks et al., 2019; Farrelly et al., 2015; Schön et al., 2018).

Such organisational constraints and a lack of consideration of the relational work required to undertake SDM in mental health services meant that despite ideological buy-in from professionals they were not able to routinely embed practices into local service provision. (Lovell et al., 2018)

However, the value placed on SDM as aligning with ethical or moral principles was often not seen as enough to overcome the contextual barriers or conflicting beliefs outlined in other CFIR constructs (Brooks et al., 2019; Farrelly et al., 2015; Korsbek & Tønder, 2016; Lovell et al., 2018; Ramon, Brooks, et al., 2017; Ramon, Morant, et al., 2017; Schön et al., 2018).

Process

Engagement in the implementation of interventions was the only construct with barriers and facilitators reported across all seventeen papers. Within this there were two key themes around engaging staff and service users.

Engaging Staff and Service Users: The Role of Relationships.

The importance of relationships in implementing SDM interventions were reported in twelve papers, both in terms of those between different professionals and between professionals and service users (Bonfils et al., 2018; Brooks et al., 2019; Deegan et al., 2008; Goscha & Rapp, 2015; Korsbek & Tønder, 2016; Lovell et al., 2018; Paudel et al., 2018; Polo et al., 2012; Ramon, Brooks, et al., 2017; Ramon, Morant, et al., 2017; Schön et al., 2018; van der Krieke et al., 2013). Relationships between professionals were affected by structural factors, such as staff turnover (Ramon, Brooks, et al., 2017) and perceived differences in workload (Brooks et al., 2019). Challenges in these inter-professional relationships could cause barriers to staff communication and engaging staff consistently across teams. In terms of relationships between staff and service users, these were reported in multiple papers to affect the uptake of interventions such as decision aids, or the trust placed in them (Brooks et al., 2019; Goscha & Rapp, 2015; Korsbek & Tønder, 2016).

Clients who had a positive working relationship with their prescriber tended to increase their involvement using CommonGround over the course of the

year to identify goals for using medications, share their concerns, and be more involved in the shared decision making process. Clients who were not highly involved in shared decision making often reported not feeling heard by their prescriber or being involved in decisions prior to CommonGround. The introduction of CommonGround did not change their level of involvement in decision making during the medication consultation. (Goscha & Rapp, 2015)

This suggests that while decision aids or training sessions for staff and patients are useful, unless how the already formed relationships will interact with the proposed intervention is considered, engagement in implementation is unlikely to be consistent. However, there was also evidence suggesting that the use of SDM interventions influenced improvements to therapeutic relationships between staff and service users. In particular, service user engagement in interventions was facilitated by a sense of empowerment and their voice being heard in ten papers (Bonfils et al., 2018; Burn et al., 2019; Deegan et al., 2008; Farrelly et al., 2015; Goscha & Rapp, 2015; Korsbek & Tønder, 2016; Polo et al., 2012; Ramon, Morant, et al., 2017; Schön et al., 2018; van der Krieke et al., 2013).

“To start with, you thereby have more control of what is important, right? Instead of you just show up completely unprepared.” Some of the consumers highlighted the fact that, as their strategies become an included part of the treatment preparation, it also becomes part of the treatment conversation, enabling staff and clients to work together during the consultation to further develop the strategies. (Korsbek & Tønder, 2016)

Feeling empowered and heard was noted as a distinct change and spoke to a shift in the dynamic of relationships between staff and service users. This shift then facilitated further engagement with the implementation of SDM interventions by both groups.

Engaging Staff: Leadership at All Levels.

While the role of leadership in facilitating implementation was raised at the inner setting, leadership was also highlighted in the process domain. This was in relation to engaging staff in the implementation and could be through informal or formal intervention champions (APA Gold Achievement Award, 2013; Deegan, 2010; Ramon, Brooks, et al., 2017; Schön et al., 2018), management reminders and support (Bonfils et al., 2018; Brooks et al., 2019; Finnerty et al., 2019; Paudel et al., 2018; Ramon, Brooks, et al., 2017), or influential figures from the same profession engaging in promotion efforts (APA Gold Achievement Award, 2013; Ramon, Brooks, et al., 2017).

However, the lack of engagement from psychiatrists and prescribers reported in six papers in particular (Bonfils et al., 2018; Brooks et al., 2019; Korsbek & Tønder, 2016; Lovell et al., 2018; Ramon, Brooks, et al., 2017; Ramon, Morant, et al., 2017) suggested barriers in engaging these professionals are a concern across the implementation of differing SDM interventions. Not all papers gave reasons for this, those that did suggested SDM wasn't seen as relevant (Korsbek & Tønder, 2016), the intervention was perceived as too time consuming (Ramon, Brooks, et al., 2017), and concerns were raised about the impact on adherence to medication (Ramon, Morant, et al., 2017).

Incomplete or Slow Execution of Implementation.

Unsurprisingly given the numerous barriers reported, eight studies specifically noted that they had not been able to fully execute the implementation plans they had made (APA Gold Achievement Award, 2013; Bonfils et al., 2018; Farrelly et al., 2015; Finnerty et al., 2019; Lovell et al., 2018; Ramon, Brooks, et al., 2017; Ramon, Morant, et al., 2017; Schön et al., 2018). These studies had all been able to implement some parts of the plan, but noted areas where this had been

either incomplete, delayed, or difficult to evaluate the true impact of. Involving stakeholders in the planning stage of implementation was reported as a facilitator, or as useful learning where this had been missed (APA Gold Achievement Award, 2013; Paudel et al., 2018; Ramon, Brooks, et al., 2017; Schön et al., 2018). How to ensure consistency between team members, services, and in sustaining implementation over time were also issues that the process raised across six papers (Bonfils et al., 2018; Brooks et al., 2019; Finnerty et al., 2019; Paudel et al., 2018; Ramon, Brooks, et al., 2017; Schön et al., 2018). The role of allowing for piloting and considering how learning and evaluation could guide implementation over time was seen as necessary in three papers (Polo et al., 2012; Ramon, Brooks, et al., 2017; Schön et al., 2018).

Discussion

This review aimed to understand the barriers and facilitators that occur when implementing SDM interventions in adult mental health services. Barriers and facilitators were identified within seventeen included papers and were mapped onto the constructs of the CFIR alongside a thematic synthesis. The 'inner setting' domain of the CFIR had the most barriers and facilitators identified in total. This is consistent with previous research that has suggested there are a lack of perceived facilitators for SDM at service and systemic levels (Brooks et al., 2017). The synthesis identified eleven themes that contextualise this mapping across the five CFIR domains.

The role of risk management and traditional models of mental health services, have previously been cited as being in conflict with increasing SDM (Kaminskiy, 2015; Slade, 2017). The findings of this review highlight some of the reasons this may be, for example through the role of individual beliefs about who can undertake SDM and when, alongside service level pressures and cultures. The themes across the 'inner setting' domain suggest the importance of understanding

the existing cultures present, the pressures faced by services, and the increase in resources that may be needed to ensure implementation of SDM is successful. Key in this was the role of leadership in readying services for implementation by undertaking this process, where this did not happen the significance of this as a barrier was prominent. Previous research has suggested a focus on how to “de-implement” existing practices alongside introducing SDM (Ramon, Brooks, et al., 2017) and this may be a useful concept to consider in future research.

The challenges in ensuring services have the resources needed and the capacity to undertake learning and change, is also reflected in the role of intervention complexity and adaptability. The synthesis highlighted the importance of how SDM interventions fit with existing service architecture and whether they complicate or can adapt to specific contexts. Previous reviews have suggested that specific SDM interventions are mandated in services to increase use (Ramon, Brooks, et al., 2017), but this review highlights the need to carefully consider how they will fit with the day-to-day running of a service. A particular example is how those that rely on technology can translate into existing record-keeping and community work (Bonfils et al., 2018), or the timing of conversational interventions in an inpatient setting (Burn et al., 2019).

Individual beliefs remained key in either preventing or facilitating the use of interventions throughout the implementation process. While the value of SDM from an ethical or moral standpoint and a preference for its use was often raised, beliefs that SDM cannot be done with everyone persist. These beliefs were often connected to the wider concepts of insight and capacity, which were repeatedly raised as barriers to consistently using interventions. This nuance, where the value placed on SDM is sometimes incompatible with beliefs about who is capable of participating, is consistent with previous research into perceptions of professionals (Ali et al., 2015; Chong et al., 2013; Kaminskiy et al., 2017). The impact of pervasive beliefs about

capacity and competence was also seen in how able service users felt to use the interventions. Interventions could play an important role in increasing people's confidence in their own recovery, but their experiences of mental health difficulties and services also led to examples of service users not fully engaging due to mistrust of their own abilities, or that of services to understand them. This is consistent with previous research regarding service user beliefs or experiences around SDM (Hamann et al., 2012; Kaminskiy et al., 2017). This review highlights how pre-existing perceptions of SDM investigated by previous research impact the implementation of interventions in practice.

SDM has traditionally been defined in terms of sharing of options, preferences, and values prior to agreeing a decision around a single issue (Charles et al., 1997). However, this review also raises the central role of ongoing and sustained relationships in this process. The role of interprofessional relationships within services was noted in being able to create change, challenge resistance, and facilitate consistent use of SDM interventions. The importance of relationships between service users and professionals was also key in successfully implementing interventions and engaging service users in them. Where engagement was facilitated, the interventions were often described in terms of their ability to empower service users and improve therapeutic relationships. This is in line with previous research that has sought to understand decision-making preferences among both groups (Castillo & Ramon, 2017; Clark, 1989; Huang et al., 2020; Jørgensen & Dahl Rendtorff, 2018; Kaminskiy et al., 2017). What may look like simple interventions can tap into a complexity of relationships that mean implementation requires time, resources, and commitment at multiple levels.

Given the complex findings of the present review, it is unsurprising that one of the themes was incomplete or inconsistent implementation. This may shed light on the mixed and limited evidence for the impact of SDM on outcomes in the current

literature (Slade, 2017). If the identified implementation barriers are not planned for and overcome, then the true ability of SDM to influence outcomes will remain challenging to assess.

Limitations

The findings of the review must be considered in the context of the mixed methodological quality of the studies included. Assessing quality in a review that includes papers with such heterogeneity of methods is challenging and therefore an appraisal tool was used alongside descriptive summaries to provide a contextualised understanding of the quality of studies available. Not all papers using qualitative methods reported these precisely or considered the role of the researcher. This may mean that some of the themes in the review have been unduly influenced by potential bias from the researchers in original studies. During the synthesis it became apparent that the more in-depth qualitative papers included in the review would have increased weight in the thematic synthesis (Bonfils et al., 2018; Brooks et al., 2019; Farrelly et al., 2015; Finnerty et al., 2019; Korsbek & Tønder, 2016; Ramon, Brooks, et al., 2017; Schön et al., 2018). While the papers that relate to each theme have been clearly cited throughout to increase clarity, this highlights the limited availability of evidence in this area and may further affect generalisability of the findings. Additionally, only a small number of studies explicitly focused on implementation, the remaining included studies may have missed key areas due this being a secondary aim.

Inconsistent reporting of demographic details for study populations leaves the full generalisability of the review difficult to assess. The studies included were concentrated in the USA and Western Europe, meaning generalisation to settings outside of these contexts is extremely limited. While there were largely broad inclusion criteria that allowed for SDM interventions to be used with a range of

mental health difficulties, most studies focused on community mental health settings, so the findings may also be less applicable to inpatient settings. Additionally, primary care was excluded from the review, which means findings may not be relevant to the treatment of mental health difficulties in these settings.

Implications

SDM is a complex interactional process that interventions can facilitate, but the relationships involved need to be carefully considered. A focus on achieving consistency in interprofessional relationships and the relationships between staff and service users may facilitate the conditions for interventions to be engaged with by all stakeholders.

The specific service context, including resources available and existing structural characteristics also need to be assessed in the planning stages of implementation. Leadership support in this, from organisational to within-service champions, is important in preparing services for the introduction of a SDM intervention. Interventions themselves need to be adaptable to these contexts, if they are too separate or complex, they are likely to be viewed as extra work and not prioritised. Together these aspects may help to facilitate implementation climates where staff have the time and capacity to develop confidence in using the intervention. This in turn may enable the creation of conditions that support service users to feel listened to and empowered to engage in SDM.

Further research is needed that focuses on understanding the implementation of different SDM interventions. This may assist services in choosing and adapting interventions to suit their context. The focus of research to date on community settings leaves a gap in understanding the use of SDM interventions in inpatient settings. This may reflect assumptions about where SDM is possible and who can participate, but without further research in these settings this remains

speculative. The limited reporting of demographic factors in the studies included in this review also leaves questions remaining about how differences between service providers and populations may intersect in relationships to affect SDM interventions. Whitley (2009) has argued for the necessity of SDM to be culturally competent and this review highlights that this is a remaining gap in understanding how current interventions are implemented.

The 'outer setting' was rarely mentioned by the papers included in this review. However, the role of cost may be implicit in some of the barriers cited in resources, time, and staffing. The variety of interventions, from conversation prompts to more complex computer-based interventions is likely to also mean a wide variety of financial costs. This is something that is likely to be important for future implementation research in the area to understand. Given the increase in external policy promoting SDM, particularly in the UK (Coulter et al., 2011; Coulter & Collins, 2011) understanding how, if at all, this does influence implementation of interventions in services will be important.

While a further focus is needed on implementation of SDM interventions, research into the efficacy of such interventions should not be forgotten. Understanding how the efficacy of interventions changes in the context of their implementation is likely to be important in continuing to improve SDM in mental health services.

Conclusion

There is currently limited research exploring the implementation of SDM interventions in adult mental health services. Research that exists is of varying methodological quality and carries significant limitations in generalisability to contexts wider than community mental health services in the USA and Western Europe. The findings of this review suggest that careful consideration of the

relational element of SDM is needed, regardless of the format or complexity of the intervention. Additionally, the existing service culture, pressures, and resources need to be planned for with leadership support and involvement of stakeholders to maximise the chances of interventions being implemented successfully. Future research is needed to further understand these processes and how to adapt interventions to specific service contexts.

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Part 2: Empirical Paper

Understanding the Role of Therapeutic Alliance in Treatment for Heroin Dependence: An Exploratory Analysis

Abstract

Aims: To explore the potential role of the therapeutic alliance as a mechanism of change in Opioid Substitution Treatment (OST) for heroin dependence using data from treatment services in England. Specifically, to investigate change to the alliance over the course of treatment and whether it mediates the impact of pre-treatment motivation on outcomes.

Methods: Secondary data analysis of the Positive Reinforcement Targeting Abstinence in Substance Misuse (PRAISe) cluster randomised trial was conducted. Mixed effects models were used to assess change to the alliance over time, and moderated mediation models were constructed to investigate the potential role of therapeutic alliance in affecting attendance and outcomes.

Results: Small decreases in ratings of the alliance were found over twelve weeks. Early therapeutic alliance had a direct effect on attendance and there was evidence that pre-treatment levels of heroin use predict heroin use at 12 weeks. There was no evidence in support of moderated mediation of pre-treatment motivation on attendance or outcomes in OST for heroin dependence. Inclusion of further pre-treatment factors suggested that pre-treatment motivation may influence the strength of the alliance.

Conclusions: The study provides preliminary evidence for changes to the therapeutic relationship over time in this patient group and adds to the evidence base for the role of therapeutic alliance as influencing attendance at treatment.. Further research is needed to understand these relationships and the potential effect of motivation on alliance, alongside investigations of how and when other pre-treatment factors may affect the process of change.

Introduction

How do therapies work? The role of common factors versus separate mechanisms of change in answering this question has long been debated (Mulder et al., 2017). In the treatment of substance misuse, building evidence for the effectiveness of psychosocial therapies has led to arguments for a shift towards understanding possible mechanisms of change (Simpson, 2004). Differing psychosocial approaches often have similar outcomes in substance misuse suggesting that common factors may be as important as their content in their effectiveness (Blonigen, Finney, Wilbourne, & Moos, 2015; Dutra et al., 2008; Petry, Alessi, Olmstead, Rash, & Zajac, 2017).

The alliance that is established between therapist and client is central to wider common factor explanations of therapeutic mechanisms (Wampold, 2015) and it has therefore also been a focus in substance misuse treatments. There are several key elements that are thought to comprise the therapeutic alliance; a bond that is trusting and can resolve difficulties or disagreements, agreement on the goals of therapy, agreement on the tasks of therapy, and the views of each person on the nature of the problem and the agreed therapeutic approach (Bordin, 1979; Dryden, 1989). However, measuring the concept of alliance brings with it challenges across contexts. In their systematic review of measures Elvins and Green (2008) noted that no measure of therapeutic alliance contained items that related to all of these theorised constructs within the concept. Additionally, when the structure of existing measures was analysed, their factor structures did not line up with those theoretically viewed as their basis. As a result, it can be difficult to know what changes on measures of alliance mean in practice, and how far they are able to measure what they claim to (Elvins & Green, 2008; Kazdin, 2006).

Further issues related to measurement have been raised in the substance misuse context. Research using early treatment ratings has found significant

differences between client and therapist ratings of alliance (Artkoski & Saarnio, 2012; Meier & Donmall, 2006). While some studies have found that client-ratings are predictive of outcomes where therapist ratings aren't (Cook, Heather, & McCambridge, 2015; Diamond et al., 2006; Prince et al., 2016), others have found therapist ratings are stronger predictors (Meier et al., 2006), or that therapist and client ratings are each associated with different elements of treatment (Knuuttila et al., 2012b, 2012a).

Therapeutic Alliance, Treatment Attendance, and Outcomes

Despite challenges in measurement, the therapeutic alliance has repeatedly been linked with increased attendance at and engagement in treatment for substance misuse, including heroin dependence (Broome, Simpson, & Joe, 1999; Meier, Barrowclough, & Donmall, 2005). Treatment retention itself is often cited as a common factor in improved outcomes (Gossop et al., 1999; Simpson et al., 1997), but how the two are related and whether there are additional varying factors that influence them is less clear (Simpson, 2004). The direct impact of alliance on outcomes has mixed evidence (Meier, Barrowclough, & Donmall, 2005). Therapeutic alliance predicted early gains in treatment across studies in a critical review of the literature, but was an inconsistent predictor of post-treatment or later outcomes (Meier, Barrowclough, et al., 2005).

In spite of assertions that it may be particularly challenging to develop and maintain relationships in substance misuse treatment, it has been noted that whether the alliance changes over time and the impact of this has received little attention in this area (Meier et al., 2005). The limited research to date has found session by session ratings can be linked to between-session drinking in alcohol dependence (Connors et al., 2016; Prince et al., 2016) and in the treatment of cannabis use some evidence has been found that varying alliance ratings throughout treatment differentially affect outcomes at three and six months (Tetzlaff

et al., 2005). In the wider literature patterns of alliance over time found have been mixed, with some researchers suggesting alliance varies linearly, with a period of building the relationship at the start (Kivlighan & Shaughnessy, 1995), where others have noted high-low-high patterns where challenges to the alliance occur in the middle of therapy, but can be resolved (Stiles et al., 2004).

Factors that Affect the Alliance

Therapeutic alliance may have an especially significant role in change for substance misuse treatment due to its potential to serve as a template for relationships that can be then generalised. This may be particularly important where individuals may have experienced difficulties in relationships outside therapy, with interpersonal difficulties both a risk factor for and a consequences of substance misuse (Von Braun et al., 2013). However existing interpersonal difficulties have also been associated with hostility towards professionals that can inhibit alliances forming (Joe et al., 1999). Interpersonal difficulties may be related to existing personality traits, attachment styles, and coping skills, which have also been associated with the strength of the therapeutic relationships that are built (Meier, Donmall, Barrowclough, McElduff, & Heller, 2005; Olesek et al., 2016; Urbanoski, Kelly, Hoepfner, & Slaymaker, 2012). Where people are under forms of coercion to attend treatment, such as legal requirements, or the treatment involves high educational or confrontational strategies by the therapist, the development of therapeutic alliances is also thought to be affected (Millman, 1986; Wolfe et al., 2013).

Qualitative research has highlighted several important therapist factors that aid the building of relationships: flexibility, negotiation, and skills in enhancing motivation (Allen & Olsen, 2016). Stronger alliances have also been linked to therapists who involve patients in decisions about treatment and facilitate open sharing in the relationship (Marchand et al., 2020).

Regarding patient factors, research suggests demographic variables are not associated with differences in the alliance (Meier, Barrowclough, et al., 2005). However, the severity of recent substance use has been linked to the strength of the therapeutic alliance built (Crits-Christoph et al., 2011). The age someone starts using substances has been linked with severity through the increased impact on wider functioning when substances are used earlier in life (Newcomb, 1997). In heroin use, the length of use and route of administration are often seen as important influences on the severity of dependence. However these have been found to interact early on to influence the rate of progress towards dependence, rather than maintaining effects on severity once a person is dependent on heroin (Barrio et al., 2001).

The frequent presence of mental health difficulties in those who use substances is well documented (Assanangkornchai & Edwards, 2012). There is some evidence that increased presence of mental health difficulties can increase negative perceptions of therapists in drug rehabilitation programmes (Cournoyer et al., 2007) which is likely to have a detrimental impact on the formation of therapeutic alliances. In their review of the literature on therapeutic alliance, Meier et al., (2005) argue that in those with psychiatric comorbidities, a strong alliance may be even more important for retention in treatment and outcomes.

This same review identified patient motivation for treatment as having one of the most consistent relationships with the strength of the therapeutic alliance (Meier et al., 2005). Motivation can include both the intrinsic readiness to change a person has, which may stem from negative personal experiences and consequences from substance use in this context, or external factors, such as relationship or legal pressures (Best et al., 2011; Joe et al., 1999) Other studies have also highlighted the role that pre-treatment motivation may have in affecting treatment retention and outcomes (Boyle et al., 2000; Joe et al., 1999; Wolfe et al., 2013). In particular

motivation has been linked with the perceived therapeutic bond and confidence in the therapist (Wolfe et al., 2013). While therapeutic alliance may be a key common element in the effectiveness of substance misuse treatments, there is still research needed to understand how it interacts with these additional factors to influence retention and outcomes.

Modelling the Process of Change in Substance Misuse

Literature to date on the mechanisms of change in substance misuse treatment has emanated predominantly from one group of researchers in the USA who have proposed an overall conceptual framework, the Texas Christian University (TCU) Treatment Process Model (Simpson, 2004). This model suggests sequential process links between patient and program attributes, early engagement, early recovery, stabilised recovery, and post-treatment outcomes (Simpson, 2004). The TCU model has since been used to target implementation and innovation efforts in addiction centres in the USA (Simpson et al., 2010).

Key in the first part of the TCU model is the person's existing motivation and readiness for treatment. These are suggested to influence the early therapeutic alliance that develops, which in turn affects attendance, participation in treatment, and treatment outcomes. This pathway was noted through research in opiate treatment centres in the USA and evidenced using data from the Drug Abuse Treatment Outcome Studies (DATOS) (Broome et al., 1999). Following this research, the therapeutic alliance was suggested as a mediator for the influence of patient motivation on retention and outcomes (Joe et al., 1999). Further patient attributes considered important in the TCU model are the severity of existing substance use and the presence of mental health difficulties. Consistent with wider research these are suggested to affect the strength of the alliance built, as well as retention in, and outcomes of treatment (Broome et al., 1999; Joe et al., 2001).

Gossop et al., (2003) have provided some preliminary evidence supporting some of the pathways in the TCU model for the treatment of heroin dependence with Opioid Substitution Treatment (OST) in the UK. OST involves the prescription of opioid substitutes for heroin, methadone or buprenorphine, in line with National Institute for Health and Care Excellence (NICE) guidelines (Pilling et al., 2007). They have questioned the impact of motivation on attendance at treatment but found motivation was related to outcomes in heroin use. However, they did not include the therapeutic alliance in their models, so this mediation pathway of the TCU process model remains untested in the context of UK services delivering OST for heroin dependence.

Aims

The present study aims to understand whether and how the therapeutic alliance affects treatment attendance and outcomes in OST for heroin dependence in treatment programmes in the UK. Firstly, this study aims to investigate whether the therapeutic alliance between participants and their keyworkers changes across three time points in treatment. The present study will also test the relationship between pre-treatment motivation and attendance at treatment, exploring the potential mediating role of the therapeutic alliance in this relationship. Finally, the study aims to test whether early therapeutic alliance also mediates the relationship between pre-treatment motivation and heroin use at the end of treatment. The study examines the TCU process model pathway in hypothesising that the relationships between pre-treatment motivation, alliance, and attendance or treatment outcomes will be moderated by severity of mental health difficulties and use of heroin on entry into treatment. A conceptual model of the relationships affecting treatment attendance can be found in Figure 1 and a conceptual model of the hypothesised pathways affecting end of treatment heroin use can be found in Figure 2.

Hypotheses

H₁: The therapeutic alliance between staff and heroin users in OST increases over time.

H₂: The early therapeutic alliance mediates the relationships between motivation for treatment and treatment attendance, moderated by pre-treatment mental health difficulties and severity of heroin use.

H₃: The early therapeutic alliance mediates the relationships between motivation for treatment and use of heroin at the end of treatment, moderated by pre-treatment mental health difficulties and severity of heroin use.

Figure 1.

Hypothesised Conceptual Model of the Effect of Pre-Treatment Motivation on Treatment Retention (H₂).

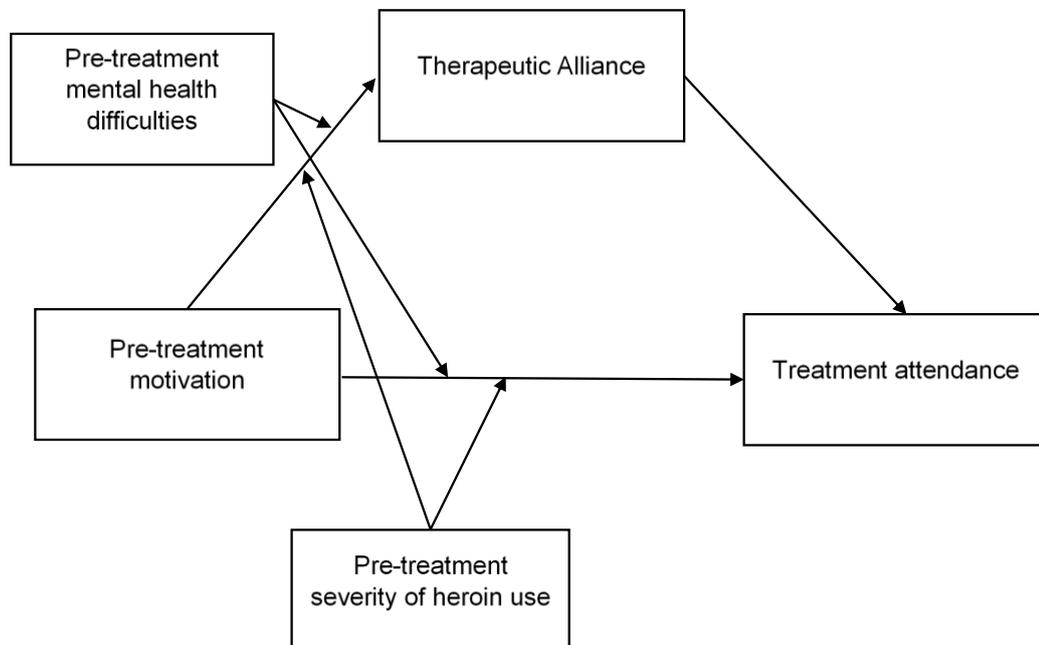
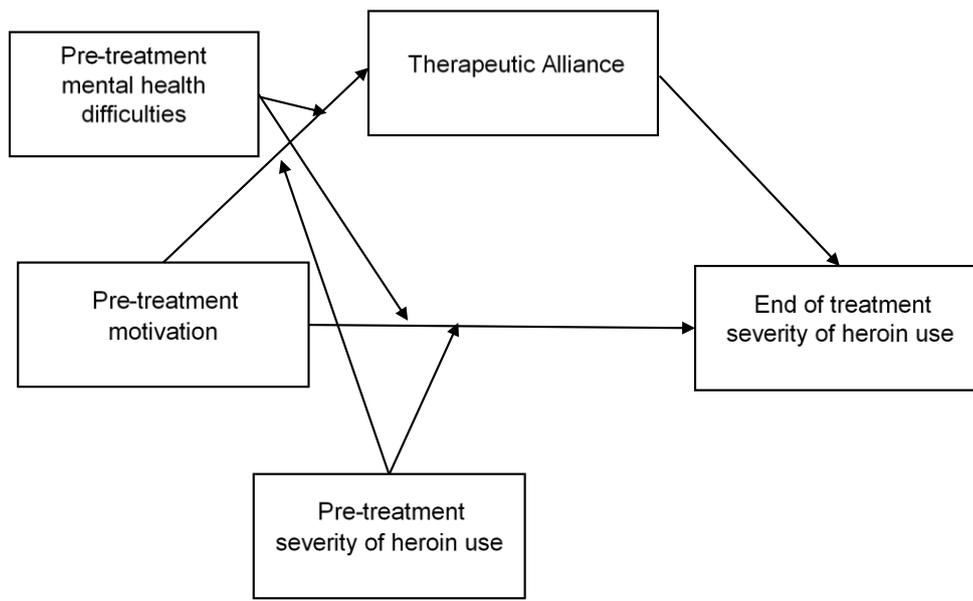


Figure 2.

Hypothesised Conceptual Model of the Effect of Pre-Treatment Motivation on Heroin Use at the End of Treatment (H₃).



Method

Participants and Setting

All data for the present study were collected from participants of the Positive Reinforcement Targeting Abstinence in Substance Misuse (PRAISE) cluster randomised controlled trial (Metrebian et al., 2018). The PRAISE trial aimed to investigate the effectiveness of contingency management (CM) in opioid substitution treatment (OST) for heroin use disorder in adults over the age of 18 in England. PRAISE contained three treatment arms to investigate whether positive reinforcement in the form of praise and financial incentives increased abstinence from street heroin. In all treatment conditions participants were offered weekly key-working sessions. The three treatment arms in PRAISE were as follows:

- 1) CM abstinence: CM targeting on time treatment attendance in a priming phase for the first 4 weeks, followed by reinforcement dependent on a negative urine drug screen for the remaining 8 weeks.
- 2) CM attendance: Reinforcement targeting on time attendance at treatment sessions only.
- 3) Treatment as Usual (TAU): No CM, OST alongside weekly keyworker meetings.

The PRAISE trial was conducted across 34 clinics that provide OST using either methadone or buprenorphine for heroin use in adults over the age of 18. The clinics were a mixture of NHS and non-NHS providers to reflect the current provision of addiction services in England. Clinics were recruited from London, Sussex, Hertfordshire, South Essex, Avon and Wiltshire, Birmingham, and Dudley and Walsall.

Those who approached the clinics for OST treatment were enrolled in the study if they were over the age of 18, met ICD-10 criteria for opiate dependence and had used street heroin for at least 15 of the past 30 days, at least 3 days per week. Participants were only recruited if they gave informed consent to participate in the study. Exclusion criteria were as follows: cannot read English and require an interpreter, being pregnant or breastfeeding, those referred through the criminal justice system, and having an existing ongoing drug treatment episode or one within the last month. In total 552 participants were recruited to the PRAISE trial and the majority of these were white (79%), male (73%), with a mean age of 38.2 (SD 8.8). Participant characteristics including previous treatment and use of opiates can be found in Table 1.

Table 1.*Participant Characteristics*

	N	%
Ethnicity		
White British	368	66.7%
White Irish	22	4.0%
Other white	45	8.2%
African	3	0.5%
Caribbean	18	3.3%
Other Black	12	2.2%
Indian	11	2.0%
Pakistani	10	1.8%
Bangladeshi	8	1.4%
Other Asian	13	2.4%
White and Black Caribbean	17	3.1%
White and Black African	5	0.9%
White and Asian	3	0.5%
Other Mixed	12	2.2%
Missing data	5	0.9%
Employment status		
Employed	62	11.2%
Unemployed/sickness benefit	481	87.1%
Student	1	0.2%
Housewife/husband	3	0.5%
Retired	2	0.4%
Other	3	0.5%
Housing status		
Owner/Occupier	43	7.8%
Rented private	111	20.1%
Rented (LA/HA)	223	40.4%
Living with parents/relatives	52	9.4%
B&B/hotel	7	1.3%
Hostel	50	9.1%
NFA	64	11.6%
Other	1	0.2%
Missing data	1	0.2%

	N	Mean (SD)
Opiate use		
Age at 1 st opiate use	542	23.5 (7.7)
Age starting regular opiate use	546	25.8 (8.0)
Age 1 st injected opiates*	322	26.2 (8.0)
Age 1 st received help/treatment	536	29.6 (8.7)
Previous treatment episodes	541	3.6 (6.7)

Note: LA/HA: Local authority/housing authority, NFA: No fixed abode.

*217 missing as injecting opiates not applicable.

Ethics

The PRAISE trial was granted ethical approval by NRES Committee South East Coast-Surrey 12/LO/0910 on 25/07/2012. Permission to use the data for the purposes stated in this paper was granted by the Chief Investigator in accordance with the data sharing protocol agreed for PRAISE. Data were shared in fully deidentified files to preserve anonymity and stored within the researcher's secure drive on the UCL server and only accessed through this server using the UCL VPN.

Measures

Predictor variables

Therapeutic alliance

Therapeutic alliance was measured at four, eight and 12 weeks and rated by participants using the Agnew Relationship Measure-5 (ARM-5) client scale. The ARM-5 was developed as a version of the full ARM 28 item scale that could be used to track core components of the alliance in busy, clinical settings (Cahill et al., 2012). It contains five items that aim to reflect the bond, partnership, and confidence within the alliance. The ARM-5 has demonstrated acceptable internal consistency, reliability, and convergent validity with the full ARM-28 scale on the core alliance indexes (Cahill et al., 2012). The mean of the five-item ratings at each time point was taken for the present study, with higher scores reflecting a stronger alliance.

Motivation for Treatment

The Treatment Self-Regulation Questionnaire for Drug Abstinence (TSRQ) was used to measure motivation to engage in treatment at baseline. The TRSQ is a measure that has been much adapted across health settings to assess motivation and reasons to change a variety of behaviours (Levesque et al., 2007). The exact number of items can vary and the measure often aims to measure introjected regulation, external regulation, and autonomous regulation as separate domains of motivation (Levesque et al., 2007). For the Praise trial, the TSRQ was adapted to assess motivation for drug abstinence using a 16-item measure. It consists of two restricted choice items asking participants whether they want to reduce or stop their drug use, each of which is followed by four Likert scales that ask participants to rate their readiness, confidence, commitment, and the importance of doing this from 1-10, where a higher score represents increased motivation for change. To calculate pre-treatment motivation each of the four Likert scale responses that assess motivation to stop and reduce heroin use in the TSRQ were averaged. The internal consistency of using these four responses as a scale was found to be high for both reducing (Cronbach's alpha = 0.83) and stopping heroin use (Cronbach's alpha = 0.84). The means for stopping and reducing heroin motivation were highly correlated with each other, $r(1) = 0.76$, $p < 0.01$, therefore the mean of the two scales was taken as a single composite measure of motivation to stop or reduce heroin use.

The TSRQ for Drug Abstinence also contained six further items relating to reasons for wanting to reduce or stop drug use that were rated on a scale from 1-5, where 1 is strongly disagree and 5 is strongly agree. These were adapted for use in this population, however their relation to the domains of motivation previously validated are not yet known. This process will be undertaken and reported elsewhere as part of the PRAISE analyses. Consequently, these items were not included in the analysis for the present study.

Mental health difficulties

Mental health difficulties were measured using the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). The HADS is a 14-item measure, with seven items that aim to measure depression and seven items that aim to measure anxiety. Each item is scored on a Likert scale from zero to three, with a higher score indicating higher levels of depression or anxiety. The extent to which the scale is able to measure depression and anxiety as separate constructs using these items has been debated more recently, with a systematic review examining the measure finding evidence for structures with one, two, three and four factor models (Cosco et al., 2012). In the present study the recommendations of this review have been followed and the HADS scores were taken as an overall summed total to indicate mental health difficulties.

Severity of heroin use

Section two of the Opiate Treatment Index (OTI; Darke et al., 1991) was administered at baseline, 12 and 24-weeks in the study to measure use of opiates. The OTI is an interview-based measure containing six outcome domains in relation to use of opiates, of which drug use is reported in section two. Within this section individuals are asked the last time they used heroin and how many times they used on this date, and then asked the same question for the date before that, and the date before that, if these dates are within the past 28 days. This provides a view of recent drug use from which a score can be calculated representing the severity of use over the past 28 days. This is calculated by adding the total of number of uses on each date (regardless of method of use) and dividing this by the summed total number of days between each episode of drug use, with a higher score representing more severe use and a score of zero meaning there was no use in the previous 28 days (Darke et al., 1991). This method of calculating severity of recent drug use in opiate users has been validated in clinical samples and this self-reported measure

found to have high agreement with urinalysis results and key-worker reports (Adelekan et al., 1996; Darke et al., 1991). The baseline ratings of this measure were used as an indicator of pre-treatment severity of heroin use.

Outcome variables

Severity of heroin use

Severity of heroin use as an outcome variable was calculated using the OTI in the same way as the predictor variable was derived but using the 12-week reports.

Treatment attendance

Data was collected each week on whether participants attended their key worker sessions. If they did not attend the originally booked appointment, it was recorded whether they attended a rescheduled appointment. If a participant attended either the original or the rescheduled key-worker appointment, this was counted as attending for the purposes of this study. The number of total key-worker sessions attended was used as a measure of attendance, regardless of whether there were missed weeks in-between. This decision was made as it has been found that the amount of sessions attended is of importance in heroin treatment in a dose-response relationship, rather than strictly the length of treatment (Fiorentine & Anglin, 1997; Simpson, 2004; Teesson et al., 2006).

Procedure

PRAISE used a pragmatic cluster randomised design, with each clinic acting as a cluster. The recruitment, randomisation procedure and full protocol for the study are reported elsewhere (Metrebian et al., 2018; Metrebian et al, in press). In each condition of the trial, participants received weekly sessions with their keyworker for 12 weeks alongside the OST and CM intervention, where relevant. To

be counted as attending each week participants had to attend the keyworker session, which lasted up to 50 minutes. These sessions comprised of assessment of risk, review of progress, harm reduction, psychosocial interventions in line with skills of the key worker and assistance with social problems, such as housing.

All measures apart from therapeutic alliance were taken during research interviews at baseline and 12 weeks. Therapeutic alliance between participants and their key worker was measured at 4, 8, and 12 weeks and completed forms were returned by participants independently of both their keyworker sessions and the research interviews. This aimed to increase honesty in the ratings as participants were not sharing these with their keyworkers.

Data linking the trial arm to participants or individual cluster sites were unavailable but the primary analysis from the trial (Metrebian et al., in press) did not find any significant differences between baseline measures or mean therapeutic alliance ratings in any of the trial conditions at any of the three time points this was taken.

Data Processing

Anonymised data were received in separate csv files for each measure with only unique participant identifier numbers remaining. Therefore, some data cleaning was required prior to analysis. Each separate file was formatted and merged into collective datafiles pre-analysis using the unique identifier numbers associated with each participant. Only the pre-processed ratings for each measurement scale were available. Therefore, total scores for each scale were generated from the individual items at each time point.

Analysis

Statistical analysis was undertaken in IBM Statistical Package for the Social Sciences v27 (SPSS). Descriptive statistics for each variable were calculated, including means and standard deviations.

Changes to the therapeutic alliance over time (H₁).

To investigate the first hypothesis that therapeutic alliance changes over time a mixed effects model was fitted initially as a linear fixed effects model of time on alliance ratings. This model was then compared to one allowing intercepts and slopes to vary for individual participants over time by specifying these as a random effect. The variance-covariance matrix can be specified with covariance structures that form the basis for calculation of model parameters, although, it is not usually possible to know in advance which will be best suited (Field, 2013). Therefore, several covariance structures that were judged as most appropriate based on the study design were tested and assessed as to whether they improved the model fit. The Diagonal structure was tested first as this is commonly used in repeated measures designs and assumes that while variances are independent of each other (i.e. covariances are limited to 0), they are heterogenous (Field, 2013). The Autoregressive First Order Heterogenous (ARH1) structure was also tested due to its relationship to measurements taken over equal time-points within participants. The structure assumes that observations that are closer together will be more closely related than those further apart, with variances allowed to be heterogenous along the main diagonal of the matrix (Wolfinger, 1996). These were compared to unstructured covariance (all variances and covariance can be heterogenous). The more highly specified covariance structures were tested prior to an unstructured model as they have advantages in increased parsimony and reduced number of model parameters (Wolfinger, 1996). Chi square critical values were used to assess change in the twice log linear information criteria (-2LL) between models and covariance structures tested. To accept a model, change in this criterion needed to

be significant; the model with the largest significant change from the fixed effects model was accepted. This was cross-checked by examining change in the Akaike Information Criterion (AIC) and the Bayesian Information Criterion (BIC) with the accepted model also minimising these criteria. Sensitivity testing was conducted using an ANOVA to investigate changes across the mean alliance ratings for cases with complete ARM-5 ratings at all three time points. This was conducted to understand whether any changes observed were consistent across those who had complete ratings at all time points.

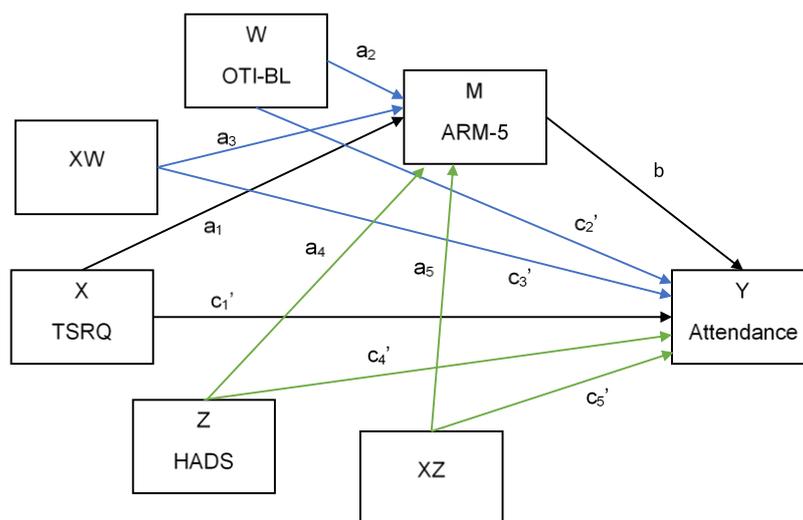
Moderated Mediation of Treatment Attendance and Treatment Outcomes (H_2 and H_3).

Moderated mediation analysis was undertaken using the PROCESS macro for SPSS (Hayes, 2018) to examine hypotheses 2 and 3 as conceptually modelled in Figures 1 and 2. This macro is a well-established addition to SPSS that performs a range of mediation and moderation models using ordinary least squares (OLS) and logistic regression methods. Moderated mediation analysis was used to examine both models of attendance at keyworker sessions (model 1 [H_2]: Treatment attendance) and level of heroin use at the end of treatment (model 2 [H_3]: Treatment outcome). In model 1 total keywork sessions attended was the main outcome variable, with self-reported levels of heroin use at treatment end entered as the outcome in model 2. In both models, pre-treatment motivation at baseline was the main predictor variable, with therapeutic alliance at four weeks entered as the mediator. Both direct and indirect effects were modelled as moderated by self-reported heroin use at baseline and mental health difficulties at baseline in both model one and two. Predictor variables in each model that did not already contain a meaningful zero (the HADS, TSRQ, and ARM-5) were mean-centered prior to analysis to aid interpretability of the models. As PROCESS does not automatically calculate standardised coefficients, z-scores were calculated and saved for each

variable prior to analysis using the descriptives function in SPSS. Analysis of each model was run separately with the standardised variables to obtain standardised coefficients for both moderated mediation models. While standardised coefficients are reported in the results, unstandardised coefficients and related data were used for the interpretation of tests and full standardised results are available in appendix C. Pathway models for the treatment attendance model (H_2) can be found in Figure 3 and for the treatment outcome model (H_3) in Figure 4.

Figure 3.

Pathway Model for Conditional Process Analysis of Treatment Attendance (Model 1, H_2).



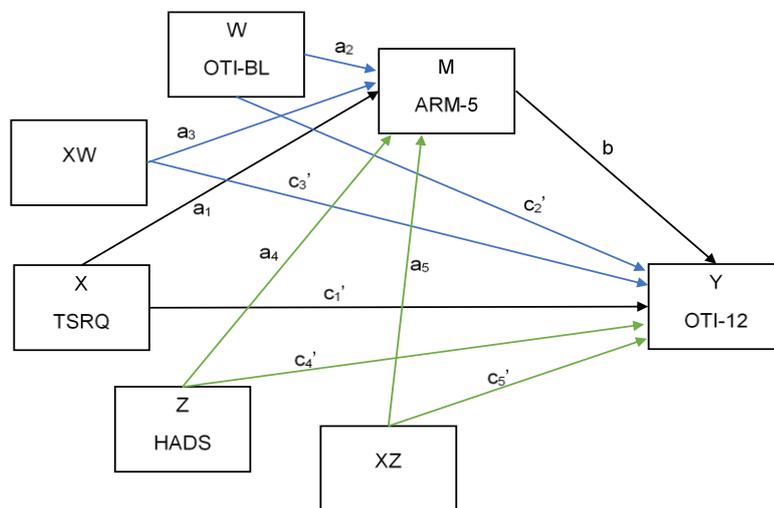
Note. *TSRQ* pre-treatment motivation levels, *ARM-5* therapeutic alliance rating at 4 weeks, *Attendance* number of keyworker sessions attended during treatment, *OTI-BL* levels of heroin use scored at baseline measurement, *HADS* scores on the HADS representing mental health difficulties at baseline measurement.

Percentile bootstrapped confidence intervals (5000 bootstrapped replications) were calculated to explore the robustness of the indirect and direct effects in the models. Conditional indirect and direct effects were probed using the “pick a point” method, with points at the 16th, 50th and 84th percentiles chosen to represent low, medium, and high values on each variable. These values were used

to construct plots to visualise the data. To further test the robustness and sensitivity of the models they were each run again with the age at first use of opiates and the number of previous treatment episodes included as covariates, given the potential influence of these patient attributes on treatment outcomes (Newcomb, 1997; Teesson et al., 2006). The results of this sensitivity testing are included alongside the presentation of results for each of model one and two.

Figure 4.

Pathway Model for Conditional Process Analysis of Treatment Outcome (Model 2, H_3).



Note. *TSRQ* pre-treatment motivation levels, *ARM-5* therapeutic alliance rating at 4 weeks, *OTI-12* levels of heroin use scored at the end of treatment (week 12), *OTI-BL* levels of heroin use scored at baseline measurement, *HADS* scores on the HADS representing mental health difficulties at baseline measurement.

Tests of model assumptions

Predictor variables for all models were examined in terms of distribution by visually inspecting histograms. Box plots were used to identify potential outliers, which were further examined to identify whether these were likely to be errors or to represent natural variation in the dataset. Inspection of the therapeutic alliance ratings strongly suggested the sample data was negatively skewed at all three time

points it was measured. While transformations were attempted on this data to normalise the distribution, these were ineffective (see appendix D for an example from the earliest time-point). Outliers were judged to be due to natural sample variation and retained in all analyses. Pre-treatment motivation also evidenced a negative skew but without notable outliers. Heroin use at baseline evidenced a positive skew, with four possible outliers that were each examined and viewed as consistent with natural sample variation. On inspection of the histogram the HADS scores at baseline approximated normal distribution and there were no notable outliers.

Pairwise correlations were conducted to understand the correlation of variables in each model, with Spearman's Rho used due to the concerns regarding the distribution of variables. Variable Inflation Factors (VIF) and tolerance were calculated for each of the models to assess the risk of multicollinearity (treatment attendance model: tolerance = .978 - .993, VIF= 1.007 – 1.023; treatment outcome model: tolerance = .996-.999, VIF= 1.001 – 1.004). These values are within widely accepted rules of thumb (Thompson et al., 2017) suggesting no evidence of multicollinearity.

Standardised residuals were examined using scatter plots and while there were no significant concerns regarding nonlinearity, possible heteroscedasticity was evidenced. Therefore, heteroscedasticity consistent standard error estimators were employed. The PROCESS macro provides four heteroscedasticity consistent (HC) error estimators. These estimators function by weighting the OLS residuals to counter bias that can be introduced in estimating standard errors when heteroscedasticity of an unknown form is present (Hayes & Cai, 2007). When this bias is present, there is a risk that the hypothesis tests that follow will have increased inaccuracy. The HC4 estimate was chosen as this has the most robust evidence for effectiveness in models including variables with heavy tails, as in the

therapeutic alliance data at week 4 (Cribari-Neto, 2004; Hayes & Cai, 2007). The standard errors and F values reported in all results were calculated using the HC4 estimate. Percentile bootstrapping of 95% confidence intervals (5000 bootstrap replications) was used to provide confidence intervals that were robust to these difficulties in meeting the assumptions in all moderated mediation models.

Missing data

Missing data at the level of each variable were examined. While there were missing data for all variables, there were very high levels of missing data within the ARM-5 measure at all three time points (see Table 2). Little's test of missing completely at random (MCAR) suggested that the pattern of missing data did not deviate significantly from the MCAR assumption, $X^2(117, N= 552) = 132.82, p = .151$.

Full information maximum likelihood procedures were used within the mixed effects models used to test H_1 . Multiple imputation for the moderated mediation models testing H_2 and H_3 was considered, however the PROCESS macro is unable to work with multiple imputed datasets. As missing data on the ARM-5 measure at the 4 week time point (the measure of alliance included in all moderated mediation models) was considerably greater than the 40% threshold for multiple imputation suggested by Jakobsen et al., (2017), it was considered most appropriate not to impute the data, as opposed to using alternative software. Therefore, only complete cases were included in the analyses for each model testing H_2 and H_3 . This did therefore affect the power of the models to detect smaller effect sizes. Percentile bootstrapping has been found to have increased power to detect effects in mediation models, and the sample size available for the present models is within those suggested to detect medium and large effects across model pathways using this method (Fritz & MacKinnon, 2007).

Table 2.*Missing Data and Descriptive Summary for All Variables*

	N valid	N missing	%	Mean	SD
Pre-treatment motivation (TSRQ)	550	2	.4	8.61	1.42
Therapeutic alliance week 4	212	340	61.6	6.54	.87
Therapeutic alliance week 8	161	391	70.7	6.52	.80
Therapeutic alliance week 12	341	209	37.9	6.23	1.19
Mental health difficulties (HADS)	551	1	.2	19.68	9.01
Heroin use at baseline (OTI)	523	29	5.3	2.22	2.13
Heroin use at week 12 (OTI)	279	273	49.5	.97	1.33
Total keywork sessions attended	552	0	.0	6.19	3.92

Note. Therapeutic alliance was measured by the ARM-5 at each time point.

Results

In total 552 participants were originally recruited to the PRAISe trial, with 8 subsequently withdrawing before the end of the 12-week intervention and 88 participants lost to follow-up at 12 weeks. Each of the variables at baseline had different levels of missing data and these are presented in Table 2. After examining each of the variables relevant for the present analysis there were complete data for 202 participants for the model of treatment attendance and 116 participants for the model of heroin use at 12 weeks. Descriptive statistics for the variables in each model prior to mean centering are displayed in Tables 3 and 4, including Spearman's Rho correlation coefficients which were run due to the non-normality of several variable distributions. Early therapeutic alliance refers to the ratings given at the 4-week time point in all models.

Table 3.*Descriptive Statistics and Pairwise Correlations for Model 1*

	r_s						
	M	SD	TSRQ	ARM-5	HADS	OTI	TA
Pre-treatment motivation (TSRQ)	8.68	1.43	--				
Early therapeutic alliance (ARM-5)	6.53	.88	.025	--			
Mental health difficulties (HADS)	19.42	8.84	-.102	.030	--		
Heroin use at baseline (OTI)	2.09	1.55	-.051	-.036	-.014	--	
Total keywork sessions attended	8.29	3.00	.038	.312**	.014	-.078	--

*p-value significant at .05

**p-value significant at .01

N = 202

Table 4.*Descriptive Statistics and Pairwise Correlations for Model 2.*

	r_s						
	M	SD	TSRQ	ARM-5	HADS	OTI	OTI-12
Pre-treatment motivation (TSRQ)	8.475	1.552	--				
Early therapeutic alliance (ARM-5)	6.522	.868	-.003	--			
Mental health difficulties (HADS)	19.922	8.672	-.034	.073	--		
Heroin use at baseline (OTI)	1.882	1.459	-.047	.071	-.015	--	
Heroin use at 12 weeks (OTI-12)	.826	1.170	-.214*	-.057	-.131	.235*	--

*p-value significant at .05

**p-value significant at .01

N = 116

The Therapeutic Alliance Over Time (Hypothesis 1)

Only 99 participants (18%) had complete ratings for ARM-5 data at all three time points (4, 8, and 12 weeks), with 395 participants (71.9%) rating the ARM-5 at least once over the course of treatment and 369 participants (67.2%) rating the ARM-5 at either 8 or 12 weeks. Mixed effect models were used to assess the effect of time on therapeutic alliance ratings on the ARM-5. Time was found to significantly affect ratings of the therapeutic alliance when modelled as a fixed effect across all participants, $F(1, 714) = 13.24, p < .001$. When the effects of individuals were allowed vary by both intercept and slope this effect remained significant, $F(1, 252.88) = 9.97, p = .002$. An unstructured model of the covariance was accepted as this most improved the model fit in comparison to the fixed effects only model with a chi squared statistic for the change in the -2LL information criteria of $X^2(3) = 120.35, p < .01$. Overall, therapeutic alliance was found to decrease over time with 95% confidence intervals remaining below zero, $b = -.03, t(252.88) = -3.16, p = .002, 95\% CI = -.05, -.01$. Covariance parameters for the random effects showed small amounts of variance in both intercepts (.88) and slopes (.01), across participants, with negative covariance between intercepts and slopes (-.08). This suggests that the higher the intercept, the flatter the slope, i.e., the higher early alliance ratings were, the less this rating changed over time.

However, sensitivity testing using an ANOVA of the 99 complete cases at all three time points failed to reject the null hypothesis that there is no change to the therapeutic alliance over time, $V = 0.015, F(2, 97) = 0.734, p = 0.483$. The assumption of sphericity was revealed to be violated by Mauchly's test ($p < 0.001$) therefore results reported are from multivariate tests.

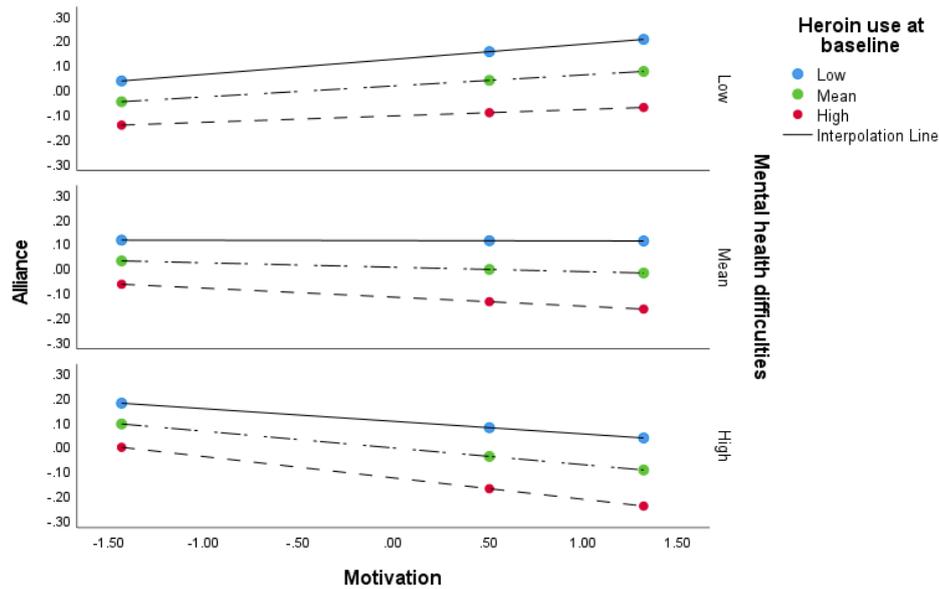
Moderated Mediation Analysis.

Model 1 (H₂): Direct and Indirect effects of Pre-Treatment Motivation on Treatment Retention

Findings for all pathways in the statistical model are presented in Table 6. The model summary for the conditional effect of pre-treatment motivation on therapeutic alliance showed that this was not significantly predictive $F(5, 196) = 1.01, p = .41$. A graph depicting the conditional effects of mental health difficulties and severity of heroin use pre-treatment on the relationship between pre-treatment motivation and therapeutic alliance is in Figure 5. On inspecting the graphs there are potential trends apparent and the coefficients for the conditional effects of both severity of heroin use at baseline (pathway a_2) and mental health difficulties (pathway a_4) are negative, indicating that both higher use of heroin and increased distress lead to lower ratings of therapeutic alliance at four weeks. However, the process analysis did not show any significant individual effects and the calculation of the additive effects of the proposed moderators on the relationship between pre-treatment motivation and therapeutic alliance did not find evidence that this relationship was significantly different from zero, $F(2, 195) = .873, p = .419$. The partial indices of moderated mediation supported this additive conclusion with percentile bootstrapped 95% confidence intervals that crossed zero for both mental health difficulties (pathway a_3 , CI = $-.016, .006$) and levels heroin use before treatment (pathway a_5 , CI = $-.073, .068$).

Figure 5.

The Conditional Effects of Pre-Treatment Motivation on Therapeutic Alliance.



Note. Low: 16th percentile, Mean: 50th percentile, High: 84th percentile.

The direct relationship between therapeutic alliance at four weeks and the total number of keyworker sessions attended (pathway b) was statistically significant and the bootstrapped confidence intervals did not cross zero ($B = .879$, $t(195) = 3.736$, $p < .001$, $CI = .553, 1.329$). This suggests that the stronger the therapeutic alliance at four weeks, the more keywork sessions are likely to be attended over the course of treatment.

Table 5.

Standardised (β) and Unstandardised (B) Coefficients for Model 1.

Predictors		M (Alliance)				Y (Attendance)				
		β	B	SE(B)	p	β	B	SE(B)	P	
X (TSRQ)	a_1	-.025	.011	.085	.899	c_1'	.031	.222	.307	.470
M (ARM-5)	--	--	--	--	--	b	.258	.879	.204	<.001
W (OTI)	a_2	-.143	-.081	.060	.173	c_2'	-.114	-.221	.161	.171
X*W	a_3	-.031	-.013	.043	.771	c_3'	-.055	-.075	.137	.584
Z (HADS)	a_4	-.011	-.001	.007	.881	c_4'	.022	.008	.023	.745

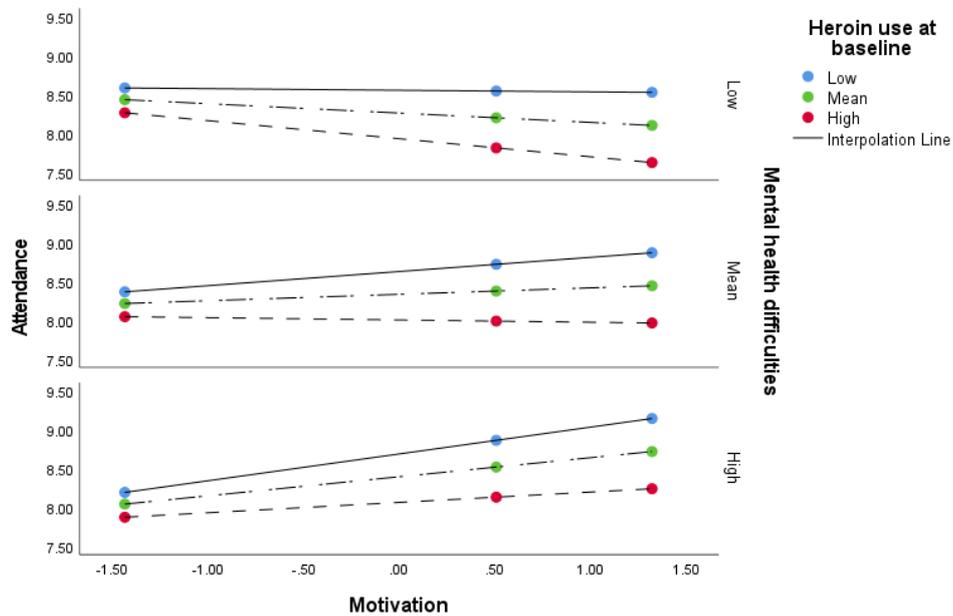
X*Z	a_5	-0.090	-.006	.006	.284	c_5'	.856	.020	.017	.224
Constant	i_m	-.008	.163	.113	.154	i_y	.006	.877	.383	<.001
$R^2 = .029$					$R^2 = .095$					
$F(5, 196) = 1.011, p = .412$					$F(6, 195) = 3.808, p = .001$					

The overall model was significantly able to predict attendance at keyworker sessions, $F(6,195)=3.808, p= .001$. However, on examining the coefficients and confidence intervals it is apparent that this overall effect is likely to be due to the direct effect of therapeutic alliance on attendance. This is in line with the correlations in Table 3. where only alliance was significantly correlated with attendance. All confidence intervals for the moderated effects crossed zero and a graph visualising these conditional direct effects can be found in Figure 6.

Sensitivity testing of the model was conducted through controlling for age at first use of heroin and the number of previous heroin treatment episodes by including them as covariates in the model. On inclusion of these variables the model summary of the conditional pathway from pre-treatment motivation to therapeutic alliance moved closer to significance, $F(7, 194)= 2.007, p= .056$. The observed direct effect of increased therapeutic alliance on treatment attendance was maintained, $B= .910, t(193)= 4.252, p< .001$, with a bootstrapped 95% confidence interval of .577 to 1.369. The overall indices of partially moderation mediation of the indirect pathway continued to indicate that this pathway is not a reliable predictor of treatment attendance with bootstrapped 95% confidence intervals crossing zero. The significant effect of the overall model was also maintained when these covariates were included in the model, $F(8, 193)= 3.159, p=.002$.

Figure 6.

The Conditional Effect of Pre-Treatment Motivation on Attendance



Note. Low: 16th percentile, Mean: 50th percentile, High: 84th percentile.

Model 2 (H₃): Direct and Indirect effects of Pre-Treatment Motivation on Heroin Use

Findings for all the pathways in the statistical model can be found in Table 7.

The model summary for the conditional effect of pre-treatment motivation on therapeutic alliance was non-significant, which is in line with this relationship in the model of treatment attendance ($F(5, 110) = .588, p = .709$). None of the indirect conditional effects evidenced significant predictive relationships and all bootstrapped confidence intervals crossed zero. Neither indices of the partial moderated mediation pathways (pathways a_3 and a_5) between pre-treatment motivation and levels of heroin use at 12 weeks, as mediated by therapeutic alliance, indicated a reliably predictive pathway (heroin use at baseline: 95% CI: $-.034, .016$; HADS scores: 95% CI: $-.044, .013$). A graph depicting the relationships modelled in the conditional indirect effect in the treatment outcome model is contained in Figure 7. In contrast to the model of treatment attendance, there was no evidence of a direct

effect of therapeutic alliance on levels of heroin use at 12 weeks (pathway b), with an unstandardised coefficient of $B = .098$, $t(109) = 1.115$, $p = .267$.

Table 6.

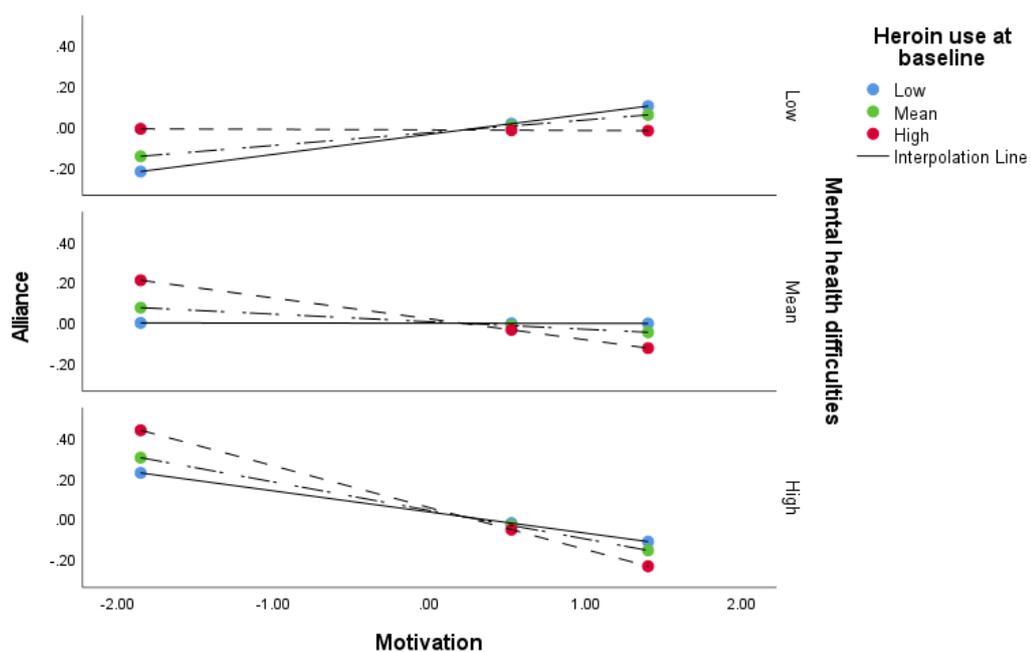
Standardised (β) and Unstandardised (B) Coefficients for Model 2.

Predictors		M (Alliance)				Y (Heroin use at 12 weeks)				
		B	B	SE(B)	P	β	B	SE(B)	P	
X (TSRQ)	a_1	-.096	.029	.112	.794	c_1'	-.108	.046	.150	.762
M (ARM-5)	--	--	--	--	--	b	.073	.098	.088	.267
W (OTI)	a_2	.016	.009	.073	.899	c_2'	.271	.218	.115	.062
X*W	a_3	-.115	-.044	.062	-.714	c_3'	-.130	-.067	.074	.366
Z (HADS)	a_4	.039	.004	.009	.674	c_4'	-.007	-.001	.013	.941
X*Z	a_5	-.173	-.011	.008	.159	c_5'	.098	.009	.010	.410
Constant	i_m	.004	-.014	.136	.917	i_y	-.004	.411	.206	.048
		$R^2 = .030$				$R^2 = .109$				
		$F(5, 110) = .588, p = .710$				$F(6, 109) = 1.248, p = .288$				

Figure 7.

The Conditional Effect of Pre-Treatment Motivation on Therapeutic Alliance in Model 2.

2.



Note. Low: 16th percentile, Mean: 50th percentile, High: 84th percentile.

In contrast to Model 1, the summary model of the conditional direct effect was not significant when examining the effect of pre-treatment motivation on severity of heroin use at the end of treatment, $F(6, 109) = 1.248, p = .288$. There were no reliably significant effects of pre-treatment motivation on end of treatment heroin use when the moderators were held constant (pathway c_1'). While most bootstrapped confidence intervals for the conditional direct effects crossed zero, that for baseline severity of heroin use did not, with the unstandardised coefficient suggesting a possible effect of higher pre-treatment heroin use on heroin use at the end of treatment when motivation and mental health difficulties are held at their means (pathway c_2'), $B = .218, t(109) = 1.887, p = .062, 95\% CI = .045, .416$. This possible effect was probed with the pick a point method at the 16th, 50th and 84th percentile for all predictor variables, however none of these interactions were significant and all confidence intervals crossed zero. A graph depicting the conditional direct effects in the model using these values at the 16th, 50th and 84th percentiles can be found in Figure 8. Overall, the results did not find any evidence supporting the pathways hypothesised as predicting end of treatment heroin use in Model 2.

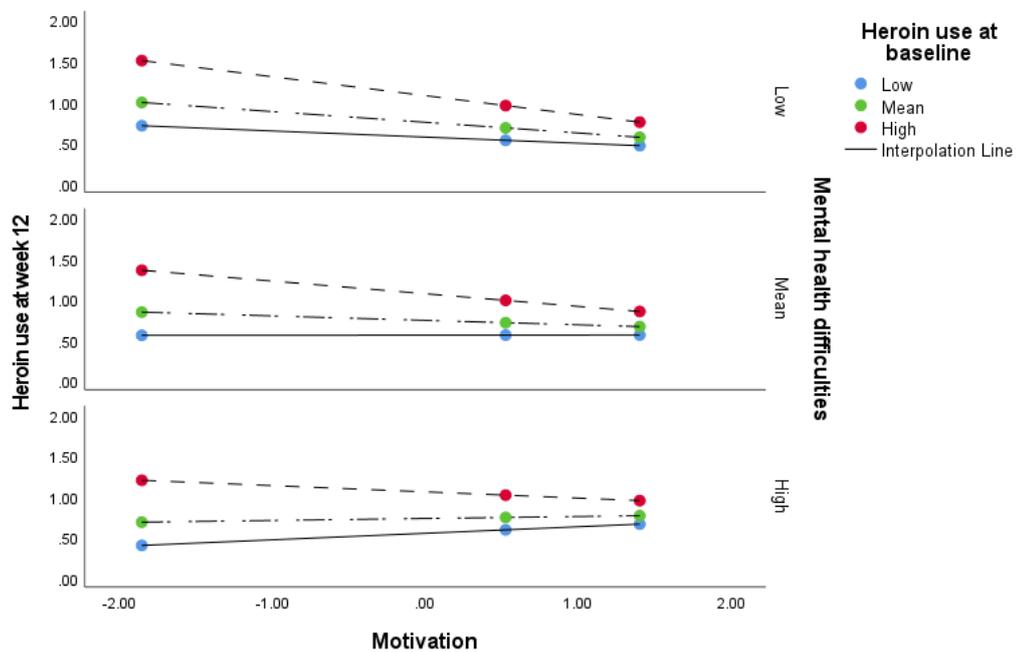
Sensitivity testing for the treatment outcome model was undertaken by including age at first use of opiates and the number of treatment episodes as covariates in the model. The inclusion of the covariates alongside the hypothesised moderators of heroin use and mental health difficulties at baseline seemingly improved the predictive ability of the model of the conditional effect of pre-treatment motivation on therapeutic alliance, $F(7, 108) = 2.493, p = .021$. This suggests that cumulatively the inclusion of these covariates improved the model of the relationship between pre-treatment motivation and therapeutic alliance, while individually the variables were not predictive. The overall non-significance of the conditional indirect

pathway between pre-treatment motivation and heroin use at the end of treatment, via therapeutic alliance as a mediator, was robust to the inclusion of the covariates.

In terms of the conditional direct effect of pre-treatment motivation on heroin use at the end of treatment, the original findings were robust to the inclusion of age of first use of opiates and previous treatment episodes as covariates. The possible individual effect of the severity of heroin use pre-treatment noted originally also held through the sensitivity testing, with this approaching significance in the model including the covariates and bootstrapped 95% confidence intervals remained above zero, $B = .215$, $t(107) = 1.922$, $p = .057$, $CI = .043, .410$.

Figure 8.

The Conditional Effect of Pre-Treatment Motivation on Use of Heroin at the End of Treatment.



Note. Low: 16th percentile, Mean: 50th percentile, High: 84th percentile.

Discussion

This study aimed to build on previous research into the process of change in the treatment of heroin dependence, focusing on the role of the therapeutic alliance

as a mediator in the relationship between pre-treatment factors and retention and outcomes of treatment. The therapeutic alliance with keyworkers in OST was found to decrease slightly over time in the mixed model analysis, however this was not supported by sensitivity testing using an ANOVA of complete cases only. While there were some findings in support for the conditional influence of pre-treatment motivation and the early therapeutic alliance on attendance, overall the hypothesised models were not supported.

The present study found evidence that the therapeutic alliance may decrease over time, with this decrease more pronounced at 12 weeks in those where the alliance is lower at the four week point in treatment. This is in contrast to wider research findings that suggest the alliance may improve over time, even where ruptures occur within the relationship (Kivlighan & Shaughnessy, 1995; Stiles et al., 2004). However, caution should be taken when interpreting this finding, particularly as the ANOVA of complete cases was not consistent with it. The challenge in finding measures that capture the range of concepts considered to be part of the alliance has been noted previously (Elvins & Green, 2008), alongside difficulties in understanding what small amounts of change on measures of latent concepts in psychology means (Kazdin, 2006). While the decrease noted in the mixed effects model may represent a genuine change over time due to the increased power in the increased sample size in comparison to the ANOVA, the shift in ratings was still very small, therefore it is particularly difficult to know what this may mean and if it would represent clinically significant change. While contingency management interventions are thought to work primarily through behavioural principles of reinforcement (Petry, 2000; Stitzer & Petry, 2006), there is the possibility that receiving financial rewards affected the ratings of therapeutic alliance given for those in these arms of the PRAISE trial. In contrast, if targets for reinforcement were missed (such as having negative urine drug screens) the refusal

to give financial incentives may have also affected the alliance. Interventions that require confrontational approaches from therapists have previously been suggested to adversely affect the alliance in substance misuse (Millman, 1986; Wolfe et al., 2013). This unknown should further add to the caution with which these findings are interpreted.

There was no reliable evidence found in support of the effect of pre-treatment motivation on attendance at keyworker sessions as mediated by therapeutic alliance and moderated by severity of heroin use or mental health difficulties before treatment. While previous research into the associations between motivation and therapeutic alliance on attendance suggested that this could be mediational in nature (Joe et al., 1999), this study has not found consistent evidence of alliance as a mediator in this way. However, there was an apparent direct effect of therapeutic alliance strength on attendance in treatment, with stronger alliance ratings predicting increased attendance at keyworker appointments. This is consistent with the established link between alliance and treatment retention noted in the literature (Meier, Barrowclough, et al., 2005). There was evidence that the overall model accounted for 11% of the variance in attendance at treatment, however this was likely due to this direct influence of alliance on attendance.

The individual interactions between pre-treatment motivation and the moderators did not reach significance. In prior research in the UK, the effect of pre-treatment motivation on participation in treatment has been queried and the present study was consistent with this in not finding any clear effects of motivation on attendance at treatment as moderated by mental health or severity of heroin use. This is in contrast to the pathways hypothesised by the TCU model (Simpson, 2004).

In the model of treatment outcome none of the pathways tested were significantly associated initially. This could be seen as consistent with previous

reviews that have suggested the evidence for the impact of therapeutic alliance on outcomes is mixed, while its' impact on treatment retention is more well established (Meier, Barrowclough, et al., 2005). However, when sensitivity tests were undertaken, the effect of pre-treatment motivation on alliance moved into significance, while there remained no evidence for the direct pathway in the model. A similar finding occurred in the model of treatment attendance, where inclusion of covariates moved the effect of pre-treatment motivation on alliance closer to significance. In both sensitivity tests age at first use of heroin was the only variable whose effect remained reliable when bootstrapped 95% confidence intervals were calculated.

While the TCU process model (Simpson, 2004) focuses on severity of substance use and mental health difficulties, these findings suggests that there may be other important patient factors on entering treatment that need to be examined. The younger someone is when they first begin using illicit drugs has been found to predict more significant difficulties in relationships, work, and psychological health as they move into adulthood (Newcomb, 1997) and being of a younger age has been associated with forming weaker therapeutic relationships in psychosocial interventions with adolescents (Garner et al., 2008; Urbanoski et al., 2012). It is possible that the age participants began using heroin represented differences between participants in these wider domains, which in turn had an impact on alliances formed and may have a further impact on outcomes.

Limitations

Overall findings of the present study were limited and represented small proportions of the variance in attendance at OST treatment and the impact of treatment on use of heroin after 12 weeks. There were multiple limitations noted in the data that may have impacted findings. Firstly, there were large amounts of missing data, mostly for the therapeutic alliance measures and ratings of heroin use

at 12 weeks. This will have naturally lowered the power of the present study to detect small effects, which may be seen through the unreliability of trends observed when robust methods such as bootstrapping were used to assess them. A statistical test suggested that missing data met the MCAR assumption, and the large amounts of missing data on the alliance measure may represent limitations in the capacity of the research teams at sites. This data was collected separately to the research interviews at the beginning and end of treatment and outside of keyworker sessions, so tracking and monitoring the amount of data collected on this measure may have been challenging throughout the trial.

Furthermore, there was a high negative skew to the alliance ratings and there were notably large numbers of maximum scores on this measure. This may indicate a “ceiling effect” of the measure. It is also possible that the consistently high ratings of alliance across all three time points represent an alternative latent construct, such as satisfaction with the sessions or treatment more widely. While the longer version of the ARM-5 measure (ARM-28) or an alternative, may have allowed for higher confidence that ratings represented the alliance and not another concept, a longer measure may have added to the burden of completion for participants, further affecting completion rates. The issues noted in this paper therefore reflect wider difficulties in balancing the collection of sufficient relevant data from the same participants to inform about the therapeutic alliance, whilst not over-burdening them or placing unrealistic demands on services taking part.

A further limitation of the present research is in the inability to include the presence or absence of contingency management interventions as factors in the models. While the original analysis found limited differences on the variables of interest in the present study, this may have been a factor in the variance that was unable to be accounted for in the present study.

Implications

The findings and limitations suggest several avenues for future research. Firstly, the present study provides preliminary indications that the therapeutic alliance may change over time, and that early alliance may mediate the impact of pre-treatment motivation on attendance and outcomes. However, the levels of missing data and concerns regarding how reflective ratings were of the actual alliance point to a need for further studies investigating the ways that therapeutic alliance may function as part of the mechanisms of change in OST. There were potential issues with ceiling effects on the ARM-5 so future research may consider whether this may be a specific limitation of the measure in substance misuse populations. The keyworker-participant alliance was the focus in this study, but to truly understand whether the effect of alliance on attendance is a common factor across treatments this should be replicated across differing psychosocial interventions for heroin dependence. The finding that pre-treatment motivation may influence alliance also warrants further exploration. The changes noted when age at first use of opiates and previous treatment episodes were included in the models suggests a need for further study of how different pre-treatment factors interact with the process of change in treatment for heroin dependence.

Conclusion

Prior research into how and when the therapeutic alliance effects change in the treatment of heroin dependence is limited. The present study found potential evidence that the therapeutic relationship between keyworkers and patients may decrease over time. Significant relationships were also found in support of the role of the early therapeutic alliance as influencing attendance at keyworker sessions, however there was no evidence that alliance mediated the effect of pre-treatment motivation on attendance or outcomes as moderated by mental health difficulties and severity of pre-treatment heroin use. The study was limited by missing data and

effects noted are small. Further research is needed to expand understanding of how the therapeutic alliance and pre-treatment factors affect the mechanisms of change in psychosocial treatments for heroin dependence.

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Part 3: Critical Appraisal

Overview

The following is a series of critical reflections on my experience of undertaking the research presented in my thesis. I initially explore how my background and values impacted the research I was drawn to. There were significant challenges and the project changed due to the impact of the coronavirus pandemic and I discuss reflections on the impact of this. This is followed by consideration of the systematic review. Finally, I share reflections on the methodology and limitations of my work, before concluding with the impact the project has had on me as a researcher.

Background

Prior to training I spent time as a student on a medium secure forensic ward and then worked for several years on a psychiatric rehabilitation ward. Through these settings I was at once introduced to the recovery movement and the conflict that occurs between this model and secure, restrictive, settings. I formed part of a small team of staff that led on achieving accreditation for the ward in rehabilitation principles. There were many challenges in implementing changes to the service provided as part of this work. However, I developed a passion for working to create change at a service level and found that this aligned with my personal values and beliefs in social justice.

Choosing a project

Given my experiences in inpatient services and prior beliefs that it is important to work for change within the system, as well as with individuals, I was naturally drawn to projects that worked at the service level. When I first approach my supervisor regarding the project that he was able to supervise, we had a conversation about the randomised controlled trial of Open Dialogue that was running in the NHS and the questions that remained around how, or if, it can be effective in mental health services outside of Finland. I began reading the work of the research team in Finland around this model which centres on shared conversations, understanding, and decision-making (Bergström et al., 2017; Olson et al., 2014; Seikkula et al.,

2003, 2011). Not only were their presented results promising, but ultimately the ethos and principles of trying to create truly collaborative services resonated with me and led me to move forward with the project.

The Impact of the Covid-19 Pandemic

Due to the pandemic the trial of Open Dialogue I was originally involved with moved to remote access only. This had the effect of preventing me from visiting sites to collect data. After several months of negotiating, there were too many concerns regarding unblinding my supervisor and jeopardising the results of the RCT for the project to continue via data extracts from the main database while the RCT was ongoing. This period coincided with local lockdowns, and I found it was hard to maintain focus through the combined uncertainty within my project, and more widely in the course, my placements, and the country. Overall, the effect of this change is that the systematic review and my empirical paper are largely unconnected as the systematic review was largely complete prior to the main research project changing.

The Systematic Review

I began considering the systematic review and conducting scoping searches of the literature in January 2020. I noticed that while there were several reviews that had asked questions about how effective shared decision-making is, there was a limited focus on how to translate shared decision-making into routine mental health services. The consideration of this was largely contained within conceptual overviews (Slade, 2017) and the practicalities were largely unexplored, despite varying interventions being developed. As I have experience in trying to introduce changes in practice in mental health settings and have found this experience to be complex and very challenging, I was curious as to how these interventions and the concept of SDM was translated into services. I had discussed some of the challenges in undertaking systematic reviews with my supervisor, but I think I underestimated how many small, yet important, decisions would need to be made through the process. The iterative narrowing of search terms and detail needed in

screening papers therefore took a lot longer than expected and I often spent time doubting and questioning decisions I had taken.

The nature of qualitative methods also led to frequent doubts and questioning of my own mind. I tried to maintain a sense of where my prior experiences and beliefs were having an influence throughout the process, as is recommended through bracketing principles (Tufford & Newman, 2012). I noticed that I was entering the review with pre-conceived ideas about where challenges in implementing the interventions might be from my own experiences. I found actively seeking exceptions during coding useful, and while I was previously unfamiliar with NVivo I found this to be a helpful tool in being able to compare the themes clearly and carefully with the coded data throughout the process. As I progressed through the analysis, I also recognised that elements highlighted in the included papers resonated with some of my prior experiences that had not been at the forefront of my mind initially, particularly around the impact of staff confidence levels on implementation. A fellow trainee and I agreed to undertake some second coding for each other and comparing our coding was a fascinating part of the project. We both noted how surprising it felt to have someone else pick out the same meaning and coding, despite not being familiar with each other's review topics. While I remained conscientious, this process allowed me to increase trust in my own work. The process also led me to reflect on how helpful it would have been to have started this exchange earlier in our reviews, at both the screening and data extraction phases. This is something that I would do differently if I had the opportunity to.

The findings of my systematic review have reinforced my commitment to working at the service level as part of my role as a psychologist in the NHS. It has led me to areas of theory and research, such as the work on the psychology of teams (Salas et al., 2018), that I had not previously come across. It has also reconnected me with previous areas of the literature that I had been interested in, such as the theory and debate around how we assess capacity in mental health

services (Dunn et al., 2007; Thornton, 2011; Williamson, 2011). This ended up being a further challenge in the review; how to retain a narrow focus when there were so many interesting, interconnected areas of theory involved. Ultimately, I chose to leave much of this out as it was context that felt perhaps too wide for the remit of a systematic review, but I have enjoyed both the discovery and re-discovery that was involved.

Ultimately, shared decision-making and the interventions that promote it tap into central ethical conflicts about what mental health care means and how it should look. Drake et al., (2010) have laid out the ways in which shared decision-making can fundamentally redistribute the power hierarchies in services and have criticised the focus on using SDM to increase forms of compliance, such as with medication. However, services retain a focus on risk and preventing harm that can seem incompatible with this at times. How do we walk alongside, empower, and flatten hierarchies, while preventing harm and managing risk through the use of legislation like the *Mental Health Act*, (1983)? I believe clinical psychology has a key role to play in developing services that can balance this dialectic. However, at the end of the systematic review, I am left with questions about how far shared decision-making interventions could ever truly support services in sustained change.

The Empirical Paper

One of the first challenges in this part of the research project was in developing an understanding of a new area of research and theory in a short space of time. I found myself initially searching for systematic reviews in the area and then working from the references of these in a snowball fashion. Prior to conducting my own systematic review, I may not have thought of looking for these as a starting point, but this was a helpful way in which the two parts of my thesis interacted and something I will take forward. Once I had discussed my reading with my supervisor and the key research questions had been narrowed down, I noticed that once again I was faced with a myriad of seemingly small, but important, decisions to make. This

is something I had not previously appreciated about quantitative methods. For example, I found myself reading many papers that would each say something slightly different about the best approach to take when an assumption is violated. I am aware that I can tend to want to do things perfectly and to get to the “right” answer. I think that when working in an area of research where I feel less confident, this tendency became more pronounced. However, I have gained confidence through the process in balancing different perspectives on analysis. I also found the advice from RS invaluable in weighing up options and taking decisions about which methods to use.

Prior to this I had no experience of large research projects that run across multiple sites. I have found the project has been a valuable insight into the challenges of this. As highlighted in my empirical paper, there were high levels of missing data at all three time points on the measure of therapeutic alliance. While the ARM-5 measure of therapeutic alliance is a short measure I wondered about the demands that collecting this at the three time points placed on the teams at the research sites. The measure was collected by someone other than the keyworker involved in the alliance, to increase the chances that they were rated honestly, however this requires coordination and extra resources. It is possible that this had an impact on how much data was collected at each time point. The ARM-5 is a short measure designed for collection in busy environments, but this also brings compromises. As noted in the limitations, there was a high number of maximum scores and this raises considerable questions about the validity of the ratings, or what they truly represent. Developing measures that can accurately reflect latent concepts, such as alliance, is a well-known challenge in psychology (Kazdin, 2006), and seems to have been particularly evident in the area of alliance (Elvins & Green, 2008). It is therefore possible that the measure has been completed in a way that was not originally intended, for example as a proxy for satisfaction with the keyworker. Given the questions regarding the reliability of the very small changes in

scores noted over time, this reinforces the need to interpret findings cautiously. It also raises an additional challenge in analysing secondary data that I had not originally considered. Without the hands-on experience of how the trial ran or involvement in the original decisions about which measure to use, trying to understand patterns of missing data or score distributions very quickly results in speculation that is difficult to resolve without designing and conducting further pieces of research.

As part of my initial project, I was able to work with an organisation of experts by experience associated with the RCT. I found this part of the project rewarding and had hoped to work further with this group as my project progressed. Co-production and collaboration are aspects of research I believe in, and I therefore feel a significant limitation of my present research is the lack of this. While a group of experts by experience were involved with the PRAISE trial, as I changed to this project at a very late stage, I did not have the space to seek out service user involvement. It is therefore very possible that I have asked questions of the data that miss key parts of people's experience. If I were to do the project again, this is something I would want to reconsider and find a way to do.

Finally, the eventual inability to link participants with the intervention arm of the PRAISE trial that they were in leaves unanswered questions in the project. Behavioural therapies such as contingency management (CM) have not traditionally been associated with a focus on the therapeutic alliance, but this has long been looked at as an important factor by some behavioural theorists (Sweet, 1984). The therapeutic alliance can be strengthened through the use of behavioural principles (Lejuez et al., 2005). A strong alliance can also act as a foundation that enables therapists and service users to develop a shared understanding of the factors that keep a behaviour going, and therefore to more effectively target behavioural strategies for change, such as reinforcement (Lejuez et al., 2005). It is therefore possible that the CM intervention arms had an unobserved impact on the

therapeutic alliance ratings or interacted with other factors in the moderated mediation models, which would also be an interesting avenue for future research.

Final Reflections

While reviewing my reflections throughout the project and putting together this critical appraisal, I noticed at how many points I either would have or did benefit from seeking advice or talking through challenges with supervisors and colleagues. I may not be able to say for sure whether I would have used increased collaborative working practices had the research not taken place in a pandemic, but this is a piece of learning I will take forward for the future. Broadly the topics of my systematic review and empirical paper may be different, but both relate to processes and interventions happening in everyday services. The importance of collaboration and working with others in these settings is often clear, but through the thesis I have learned the reflected importance of these in research.

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Appendices

Appendix A

Search Strategy

Medline and Psycinfo

The screenshot shows the Ovid database interface. At the top, there is a navigation bar with the Ovid logo on the left and user account information on the right, including "My Account", "Support & Training", "Help", "Feedback", and "Logged in as Rhiannon Storrie | Logoff". Below this is a secondary navigation bar with tabs for "Search", "Journals", "Books", "Multimedia", "My Workspace", "Links", and "What's New". Underneath, there are links for "My Projects", "My Searches & Alerts", and "My eTocs".

The main content area is titled "Permanent Searches" and includes buttons for "Run", "Delete", and "Copy". Below these are icons for "Rename", "Edit", "Display", and "Email Jumpstart".

There are two search strategy entries:

- SharedDecisionMaking Medline2**
 1. "shared decision making".mp. or Decision Making, Shared/
 2. ("mental health" or "mental illness" or "mental disorder" or psychiat* or psychologist*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
 3. exp Mental Health/
 4. exp Mental Health Services/
 5. Mental Disorders/
 6. exp Mental Disorders/
 7. 2 or 3 or 4 or 6
 8. 1 and 7
- SharedDecisionMaking Psycinfo3**
 1. "shared decision making".mp.
 2. ("Mental health" or "mental illness" or "mental disorder" or psychiatrist* or psychologist*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
 3. exp Mental Disorders/ or exp Mental Health Services/ or exp Mental Health/
 4. 2 or 3
 5. 1 and 4

CINAHL

Print Search History: EBSCOhost — Mozilla Firefox

web.a.ebscohost.com/ehost/searchhistory/PrintSearchHistory?vid=8&sid=74f71fee-5d49-4a27-b3b9-3b65f4a5d5d9%40sdc-v-sessmgr03&theSearchHistoryId=

EBSCOhost

Friday, July 02, 2021 1:05:28 PM

#	Query	Limiters/Expanders	Last Run Via	Results
S8	S6 AND S7	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus	Display
S7	S3 OR S4 OR S5	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus	Display
S6	S1 OR S2	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus	Display
S5	(MH "Mental Disorders+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus	Display
S4	(MH "Mental Health") OR (MH "Mental Health Services+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus	Display
S3	("mental health" OR "mental illness" OR "mental disorder") OR psychiatr* OR psycholog*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus	Display
S2	(MH "Decision Making, Shared")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus	Display
S1	"shared decision making"	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus	Display

Web of Science

Search History Web of Science Core Collection

Set	Results		Save History / Create Alert	Open Saved History	Edit Sets	Combine Sets <input type="radio"/> AND <input type="radio"/> OR	Delete Sets Select All
# 3	1,411	#2 AND #1 <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years</i>			Edit	<input type="checkbox"/>	<input type="checkbox"/>
# 2	1,037,518	TOPIC: ("mental health" OR "mental illness" OR "mental disorders" OR psychiat* OR psycholog*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years</i>			Edit	<input type="checkbox"/>	<input type="checkbox"/>
# 1	11,999	TOPIC: ("shared decision making") <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years</i>			Edit	<input type="checkbox"/>	<input type="checkbox"/>
						<input type="radio"/> AND <input type="radio"/> OR	Select All
						Combine	<input type="checkbox"/> Delete

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Appendix B

NVivo Codebook

Name	Description
Characteristics of individuals	Themes relating to this domain of CFIR
Belief not everyone can engage in SDM	Implicit or explicit reference to ability or service users to take part in SDM
Capacity and insight relevant to SDM	References to service user's capacity and insight relevant to SDM. Can include cognitive or decision-making capacity. Insight relates to mental health difficulties.
Competence and confidence	Collection parent code for staff/service users related codes
Staff competence and confidence	References to staff levels of competence and confidence using SDM or interventions
SU doubt own competence	Examples of service users doubts around their own ability to use/take part in SDM
Technology as a barrier	Confidence and competence in using technology related to interventions (staff or SU)
Value of SDM	Collection parent code for all value-related
SDM intervention not valued	Expressions from staff/service users SDM not valued
SDM not fully understood	Statements reflecting poor/incomplete understanding of SDM principles
SDM intervention seen as valuable	Expressions of value of SDM staff/service users
Fits with ethical and moral values	Suggestions/reports of SDM being consistent with staff moral or ethical values
Values vs practice	Value placed on SDM challenged by everyday practice/context barriers
Inner setting	Themes relating to this CFIR domain
Organisation resource and structures	Collection code for codes relating to organisational elements

Name	Description
Funding and resource	Any statement relating to funding and resource - sufficient or not
Integrating into policy and organisation structure	Any statements relating to how interventions are integrated, or not, into existing structures/policy
Organisational procedures	Any wider comments regarding organisational procedures and relevance to intervention
Organisational value and commitment	Any statements relating to how organisations show/don't show interventions are priority/valued and/or impact of this
Services are fragmented and under pressure	Broad references to pressure services are under
Already doing SDM	Any statements around concept of already doing SDM in usual practice
Crisis settings	Impact of crisis on implementation, either in service purpose or in day to day work in other settings
Intervention doesn't fit with existing systems	Any ways in which barriers were around a level of incompatibility of interventions with existing systems in services/teams
Intervention not integrated into treatment	Cases where interventions were seen as or practically used separately to treatment otherwise given
SDM intervention as extra work	Any reports of SDM feeling like/being extra to usual workload
Lack of staff resource to support intervention	Any statements relating to not having enough staffing levels to consistently implement intervention
Staff are overworked	
Staff turnover	
Time as a barrier to implementing	Any ways in which time is seen as a barrier
Intervention as a time-saver	Examples of the interventions saving time
Traditional service	Any references to the role of traditions in service culture,

Name	Description
cultures	e.g. "this is how it's always been"
Culture of paternalism	References to paternalism in relation to interventions, e.g. professionals having the expertise to make decisions for service users.
Best interests and risk	Any explicit references to role of risk and best interests in impacting implementation
Power hierarchies	Any references to power hierarchies between professionals or service users and professionals
Intervention characteristics	Themes relating to this CFIR domain
Adaptability of intervention	Any references to how interventions can/cannot be adapted
Complexity and integrating interventions with systems	References to interventions needing multiple steps or other aspects of complexity relating to a lack of fit between intervention and service systems
Intervention is normalising	Ways in which intervention normalises service user experiences
Outer setting	
Understanding patient needs	Any references relating to how services do or do not understand what patients need or how the intervention relates to this understanding
Relevance to the service	Any references to how relevant the interventions are perceived to be to what the service provides for service users
Process	Themes relating to this domain of CFIR
Engaging staff and teams	Any references to how/whether staff or teams were engaged in interventions/implementation
Lack of buy in from psychiatrists	Any reference to difference in engagement from psychiatrists or prescribers to other professionals
Role of leadership in engagement	Any references to how leadership (from people or organisationally) affected engagement of staff and teams
Intervention champions promote implementation	Any reference to how/whether intervention champions promote implementation
Role of peer	Ways in which peer workers supported staff and team

Name	Description
workers	engagement with interventions
Intervention never fully implemented	
Need to plan implementation over time	Any references to how implementation over time needs planning
Consistency needed to integrate into typical work	References to impact of planning on whether staff and teams use interventions with everyone and how affects integration.
Difficult to evaluate implementation	Any reference to challenges in evaluating SDM intervention progress
Necessary to pilot and adapt	References to how piloting or adapting did/would have facilitated implementation
Stakeholder involvement in implementation plan	Benefits or challenges of involving stakeholders in planning implementation
Role of relationships in engagement	Any references to how relationships impact engagement, either between staff or staff and service users.
Client empowerment	Any references to interventions interact with service users feeling empowered,
Client's voice and viewpoint supported	Any references to role of supporting client voices to be heard in engagement with intervention
Therapeutic conversations and relationship supported	Any references to how implementation of intervention affected therapeutic relationships between staff and service users.

Appendix C

Standardised results for moderated mediation models.

Model 1. Treatment Attendance

		Consequent					
		M (Alliance)					
Antecedent		β	SE	z	p	BootLLCI	BootULCI
X (TSRQ)	a_1	-.025	.069	-.360	.719	-.135	.104
M (ARM-5)		--	--	--	--	--	--
W (OTI)	a_2	-.143	.104	-1.368	.173	-.351	.039
X*W	a_3	-.031	.108	-.292	.771	-.175	.211
Z (HADS)	a_4	-.011	.072	-.150	.881	-.157	.104
X*Z	a_5	-.090	.084	-1.075	.284	-.221	.062
Constant	i_m	-.008	.073	-.105	.916	-.158	.124
		$R^2 = .029$					
		$F(5, 196) = 1.011, p = .412.$					
		Y (Attendance)					
		β	SE	z	p	BootLLCI	BootULCI
X(TSRQ)	c_1'	.031	.071	.437	.663	-.103	.161
M(ARM-5)	b	.258	.060	4.305	<.001	.163	.391
W(OTI)	c_2'	-.114	.083	-1.374	.171	-.248	.043
X*W	c_3'	-.055	.101	-.548	.584	-.217	.142
Z(HADS)	c_4'	.022	.069	.326	.745	-.113	.149
X*Z	c_5'	.856	.070	1.221	.224	-.058	.216
Constant	i_y	.006	.069	.084	.933	-.131	.137
		$R^2 = .095$					
		$F(6, 195) = 3.808, p = .001$					

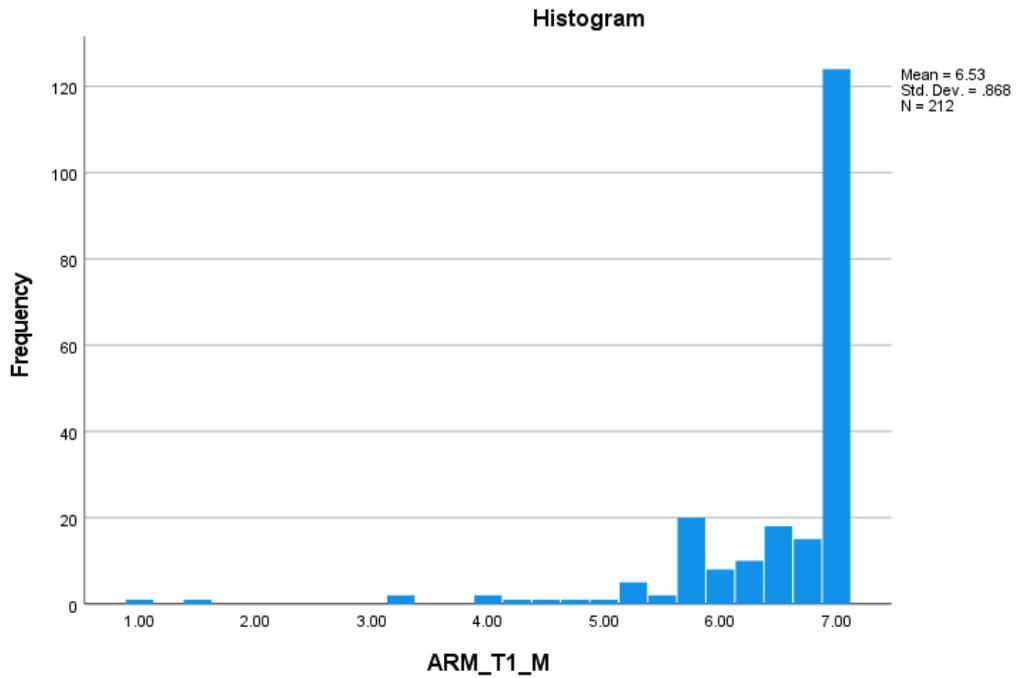
Model 2. Treatment Outcome

		Consequent					
		M (Alliance)					
Antecedent		β	SE	z	p	BootLLCI	BootULCI
X (TSRQ)	a_1	-.096	.094	-1.018	.311	-.271	.048
M (ARM-5)		--	--	--	--	--	--
W (OTI)	a_2	.016	.122	.127	.899	-.163	.183
X*W	a_3	-.115	.160	-.714	.477	-.268	.151
Z (HADS)	a_4	.039	.093	.422	.674	-.144	.183
X*Z	a_5	-.173	.122	-1.418	.159	-.378	.002
Constant	i_m	.004	.097	.038	.970	-.192	.178
		$R^2 = .030$					
		F (5, 110)= .588, $p =$					
		Y (Heroin use at 12 weeks)					
		β	SE	z	p	BootLLCI	BootULCI
X(TSRQ)	c_1'	-.108	.110	-.976	.331	-.337	.072
M(ARM-5)	b	.073	.065	1.115	.267	-.080	.192
W(OTI)	c_2'	.271	.144	1.887	.062	.057	.518.
X*W	c_3'	-.130	.143	-.908	.366	-.381	.078
Z(HADS)	c_4'	-.007	.099	-.075	.941	-.175	.195
X*Z	c_5'	.098	.118	.827	.410	-.150	.261
Constant	i_y	-.004	.093	-.045	.964	-.170	.191
		$R^2 = .109$					
		F (6, 109)= 1.248, $p = .288$					

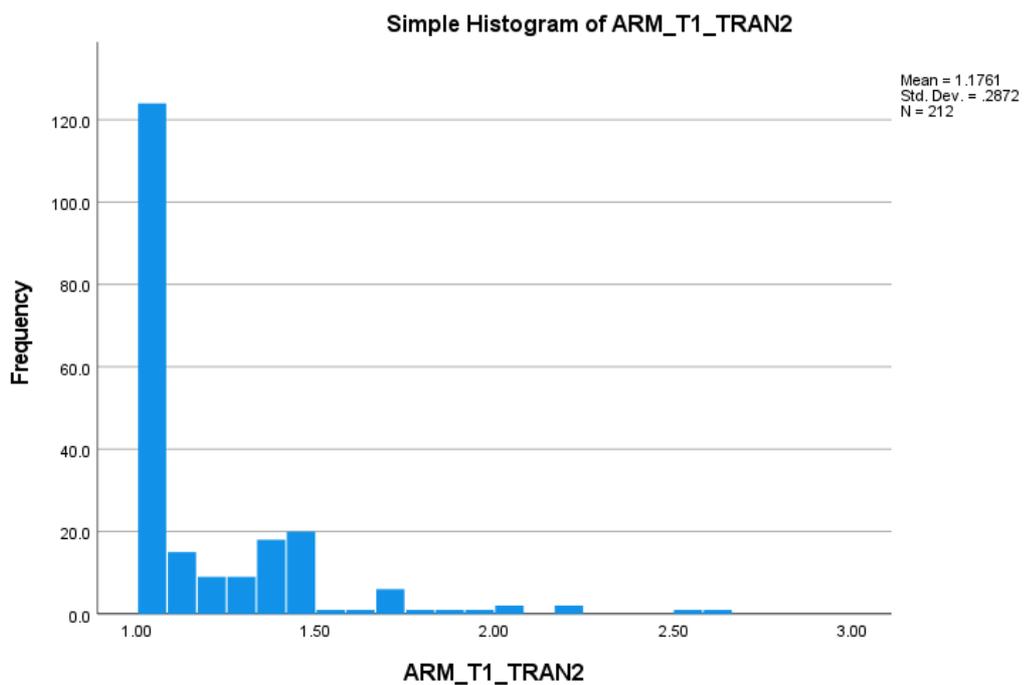
Appendix D.

Example Attempted Transformations of Therapeutic Alliance (ARM-5) Data for Ratings at Time 1.

Untransformed Histogram of ARM-5 means at 4 weeks



Square root transformation of ARM-5 means at 4 weeks



Log10 transformation of ARM-5 means at 4 weeks

