

**The relationship between alliance, adherence, and
attendance when using a contingency management
intervention in opiate substitution therapy**

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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

This volume consists of three parts.

Part 1, the literature review, examines 20 papers to describe the current understanding of the relationship between therapist alliance, therapist adherence and outcome in individual psychotherapy.

Part 2, the empirical paper, uses data from participants in the Positive Reinforcement targeting Abstinence In Substance misuse (PRAISe) randomised control trial being conducted in south east England. This trial investigates the effectiveness of contingency management (CM) interventions in opiate substitution therapy to improve attendance and abstinence of heroin. The paper explores the impact of CM interventions on levels of attendance in opiate substitution therapy and investigates the relationship between client factors, therapeutic alliance, therapist adherence to the CM and levels of attendance.

Part 3, the critical appraisal, is in two sections. The first section explores the debate between research that attributes therapeutic outcome to factors that are common across different types of psychotherapy such as the therapeutic alliance, and research that highlights the importance of the contribution of theory specific interventions, measured by therapist adherence. The second section considers some of the moral and ethical concerns about using incentives in health care and some of the implications for future research and clinical practice.

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Part 1: Literature Review

Is there a relationship between therapeutic alliance, therapist adherence, and outcome in individual psychological therapy?

Abstract

Aims Therapeutic alliance has been found to have an association with outcome in psychotherapy, and concern has been expressed that therapist adherence to manualised treatment can impact negatively on the therapeutic alliance. The purpose of this review is to report on the current understanding of the relationship between therapeutic alliance, therapist adherence and outcome in individual psychotherapy.

Methods A literature search aimed at identifying studies that included quantitative measures of therapeutic alliance and therapist adherence in individual psychotherapy was conducted.

Results 20 papers were identified to be included in the review reflecting the limited amount of literature that considers the relationship between adherence and alliance. Included papers focused on a range of therapies and clinical presentations.

Conclusion This review suggests that adherence does not have a detrimental effect on alliance. Furthermore, most studies do not find an interaction between adherence and alliance in predicting outcome. Some studies report a relationship between curvilinear adherence and alliance in predicting outcome. The few studies that consider this relationship indicate that in the context of low alliance, moderate adherence is best for outcome. It is suggested that this reflects therapists using intervention to support the therapeutic alliance whilst remaining largely consistent with the therapeutic model. Therapy models should therefore include strategies to help foster the therapeutic alliance. It is noted that the conclusions made in this review are limited by the small number of studies that consider the relationship between adherence, alliance and outcome and the individual study limitations.

Introduction

The aim of this review is to describe the existing understanding of the relationship between therapist adherence, therapeutic alliance and outcome. The rationale for this is based on findings of a relationship between alliance and outcome, (e.g. Horvath, Del Re, Fluckiger, & Symonds, 2011) and concern that therapist adherence can have a negative effect on alliance (e.g. Addis, Wade, & Hatgis, 1999). This introduction considers psychotherapy process research that fuels the interest into ‘common factors’ and the therapeutic alliance. The current understanding of the relationships between alliance and outcome, and adherence and outcome are summarised. Studies that have specifically considered the relationship between adherence, alliance and outcome are highlighted.

Equivalent outcomes across psychotherapies

Investigations into the effect of factors such as the therapeutic alliance and therapist adherence stem from studies that find equivalent outcomes when comparing psychotherapies (e.g. Luborsky Rosenthal, Diguier, Andrusyna, Bermin Levitt et al., 2002; Luborky, Singer & Luborsky, 1975), raising the question of what is the mechanism of change in psychotherapy. Messer and Wampold (2002) states that ‘study after study, meta-analysis after meta-analysis have produced small or non-existent differences among therapies’ (pp.22) which indicates that there are pervasive common factors across psychotherapies that result in the equivalence of outcome when comparing psychotherapies (Rosenzweig , 1936, as cited in Luborsky et al., 1975). Many supporters of this common factors perspective believe the therapeutic alliance is the mechanism of change in therapy (McCarthy, 2009).

Therapeutic alliance

One of the most frequently and extensively studied common factors is the therapeutic alliance (Castonguay, Constantino, & Holtforth, 2006) but there remains ambiguity in the definition of it (Horvath et al., 2011). A commonly cited definition of alliance is proposed by Bordin (1979). Bordin (1979) concept of alliance is based on achieving a collaborative stance in psychotherapy. This alliance is based on three components; *goals*, *tasks* and *bond*. *Goals* refer to the client and therapist agreeing on what the client hopes to gain from therapy. *Tasks* refers to agreement on what needs to be done to reach the client's goals. *Bond* refers to the trust and attachment that develops between a therapist and client.

Horvath et al. (2011) conducted a meta-analysis of studies that investigated the relationship between therapeutic alliance and the outcomes in individual psychotherapy. The authors report a small but significant aggregate effect size¹, with no indication of publication bias and no significant relationship with time of publication. This result is similar to previous analyses (Horvath & Symonds, 1991; Martin, Garske, & Davis, 2000; Horvath & Bedi, 2002).

Therapist Adherence

Critics of the common factors perspective argue that findings of equivalence do not imply that the same mechanisms produce the outcome (DeRubeis, Brotman, & Gibbons, 2005) and instead work through interventions specific to a theoretical orientation (McCarthy, 2009). There is therefore an interest in the extent to which a therapist is delivering theory specific techniques.

¹ Throughout this review interpretation of effect size is informed by Cohen (1998) .10 are considered small,.30 are moderate, and.50 are large.

Adherence is defined as the degree to which therapists are delivering the specified techniques of an intervention (Webb, DeRubeis & Barber, 2010).

Adherence measures are often employed in psychotherapy research to ensure a treatment is delivered as intended (Weck, Weigel, Richtberg, & Stangier, 2011) and to further understanding of which elements of an intervention contribute to outcome (Webb et al., 2010). Treatment research increasingly involves the use of manual based treatments (Godley, White, Diamond, & Passetti, 2001) which are strategic and technical guidelines for the therapist to follow in conducting therapy.

There is an interesting distinction here between adherence as a common factor across different types of therapy, and the ‘specific factors’ of a particular treatment that are being considered by the measure of adherence. Adherence may contribute to outcome not by virtue of the specific technique being measured, but as a variable regardless of which technique is being measured i.e. as a common factor. Therapists adhering strictly to a manual, having low adherence or using techniques flexibly may have differential effects on outcome regardless of the treatment type being employed. Indeed critics of manualised treatments arguing that rigid adherence can have a detrimental effect on the therapeutic alliance discuss adherence in general terms, as though it is a common factor.

Generally adherence-outcome studies have reported mixed findings (Webb et al., 2012a). A recent meta-analysis (Webb et al., 2010) reported non-significant effect sizes for adherence-outcome relationships. However the heterogeneity of effect sizes across studies, and therefore mean effect sizes should be interpreted with caution. It may be that adherence is related to outcome only in some contexts or treatment modalities (Webb et al. 2012a). Some studies have reported a curvilinear

relationship between adherence and outcome (Hogue et al., 2008a; Barber et al., 2006) indicating that modest levels of adherence are associated with best outcome.

The Adherence-Alliance relationship

Some authors report concern about a possibility of a negative effect of therapist adherence to manual based treatment on the therapeutic alliance (Wilson, 1998). Addis et al. (1999) state that it is a common concern that it is not possible to develop an effective alliance while using manualised treatments. Although, as Wilson (1996) emphasises, ‘far from undermining therapist’s personal expertise in conducting treatment, manual based therapies require specific skills in developing effective therapeutic alliances with patients’ (pp. 11).

There is little research focusing on the relationship between adherence, alliance and outcome. Some authors report a negative association between adherence and alliance (Henry, Strupp, Butler, Schacht, & Binder, 1993a; Henry, Strupp, Butler, Schacht, & Binder, 1993b). Other research suggests a more complicated relationship between adherence, alliance and outcome. For example Barber et al. (2006) found a moderating effect of alliance on the relationship between adherence and outcome. When alliance was high, adherence was largely irrelevant to outcome. However, when alliance was weaker, moderate levels of adherence were most beneficial for outcome.

Aims

Given the reported relationships between alliance, adherence and outcome, and concerns about a negative effect of adherence on alliance this review endeavours to capture the existing understanding of the relationship between these variables. Specifically, whether alliance and adherence have a negative association and whether the interaction between adherence and alliance impacts on outcome.

Method

Literature search strategy

A systematic search of the literature was conducted using PsycINFO, MEDLINE and PUBMED computerised databases. A slightly different search strategy was used for each database due to their different organisation, features, thesaurus and subject headings.

Scoping searches indicated little literature specifically researching the relationship between adherence or competence and alliance. Indeed, conducting a meta-analysis on 36 papers investigating the relationship between adherence and outcome Webb et al. (2010) identified only 11 papers that controlled for therapeutic alliance. Therefore a deliberately broad search strategy was employed in order to capture as many relevant papers as possible.

Searching PsycInfo used combinations of the keywords; *Alliance, fidelity, competence*² and *adherence*. In addition the following terms mapped to subject headings were used: *manual based therapy*³, *competence*, and *therapist competence*. The following terms were exploded; *therapeutic alliance, competence, professional competence*.

Searching MEDLINE used combinations of the following words mapped to subject headings; *professional-patient relations, alliance, guideline adherence, adherence, therapist competence, professional competence, manual based therapy*.

Searching PUBMED used combinations of the following words: *alliance, adherence, fidelity, therapist competence, and manual based therapy*.

² Competence was included in the search term as there was an indication that the terms may be used interchangeably in the literature.

³ The following search terms were used to identify papers relevant to manual based therapy in all databases: manual based therap*. manual guided therap* manuali?ed therap*.

These searches identified 4689 studies for consideration for the review. 11 additional studies were found through hand searching and reference lists. From these studies 20 were included in the review (meeting the criteria below). Figure 1 shows the results from the search and study selection.

Paper inclusion criteria

Informed by previous reviews of studies investigating alliance-outcome (Martin et al., 2000; Horvath et al., 2011) and adherence outcome relationships (Webb et al. 2010), the following criteria were used.

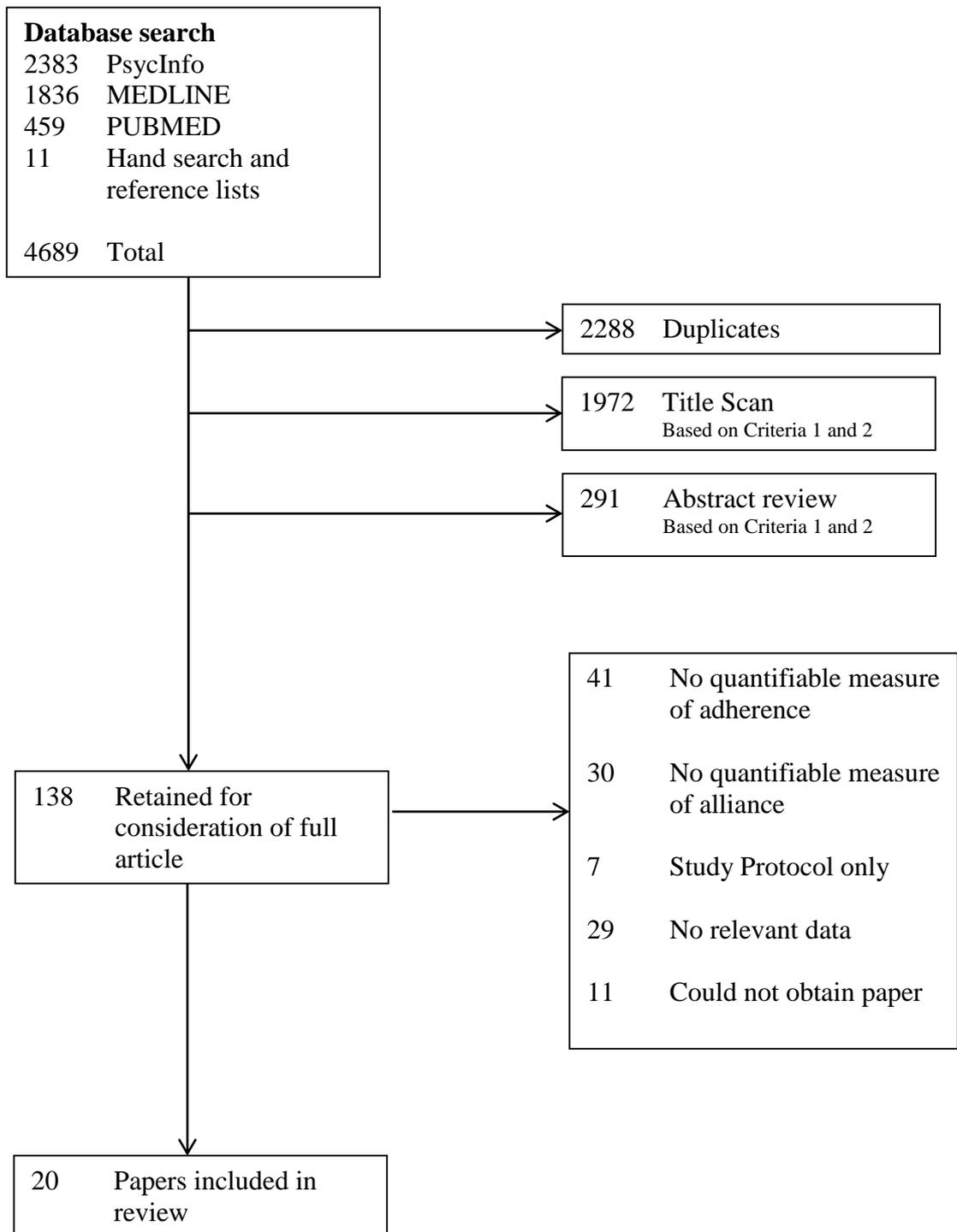
- 1) Clinical population
- 2) An investigation of individual psychological treatment
- 3) Quantifiable measures of alliance and adherence
- 4) Data relevant to the research question. Specifically:
 - i. Correlational data of adherence- alliance, or
 - ii. Analyses predicting alliance from adherence or vice versa, or
 - iii. Analyses predicting outcome from adherence and alliance, presenting interaction data.

Quality assessment

No formal measure of quality was used. The Cochrane collaboration (Higgins & Green, 2011) warns against using scales or checklists instead recommending a domain based evaluation. The Cochrane collaboration's tool for assessing risk of bias is better suited to assessing the quality of randomised clinical control trials. This review is focused on the particular relationship between alliance, adherence and outcome, and involves extracting data from different study designs. As such particular attention is given to the sample size, the aspects of adherence and alliance

that are being measured, the expertise and independence of the raters assessing adherence and alliance, the inter-rater reliability where more than one rater is used, the timing of the assessment of adherence alliance and outcome in relation to each other, and the validity of diagnosis and outcome measurement.

Figure 1: Flow diagram of search and study selection



Results

In order to address the aims of the review the results of the identified studies are presented and summarised using narrative synthesis (Popay et al., 2006). Narrative synthesis takes a textual approach in synthesising the results to tell a story. First studies focussing on depression are considered followed by studies focused on substance use disorders and those considering other clinical presentations. A summary table of significant statistics can be found in Table 1.

Studies focusing on depression

Eight studies were identified that focused on depression (Table 2). Various criteria were used to assess depression and all appear valid. For example, using a structured clinical interview to establish a DSM diagnosis (Bambling, King, Raue, Schweitzer & Lambert, 2006) or meeting Research Diagnostic Criteria (e.g. Castonguay, Goldfried, Wisner, Raue and Haye, 1996), or identifying clinical caseness using a clinical cut off on a validated self-report instrument such as the Beck Depression Inventory (BDI) (Minonne, 2008). Where presented inter-rater reliability coefficients were adequate, ranging from moderate to perfect agreement (Appendix A).

Treatment of Depression Collaborative Research Program (TDCRP): Three studies used data from the TDCRP. Strunk, Brotman & DeRubeis (2010) considered the relationship between adherence to cognitive therapy and alliance within each of the first four sessions. The authors report several moderate correlations between different aspects of cognitive therapy and alliance and no interaction between adherence and alliance in predicting outcome.

Table 1

Results summary table

Study Title	Test	Result
Studies focusing on depression		
Strunk et al. (2010)	<i>Correlation (r) alliance and adherence</i> Alliance and Cognitive Methods Alliance and Negotiating/Structuring; Alliance and Behavioural Methods Homework <i>Adherence X Alliance interaction in predicting outcome</i>	$r = 0.36, p < .05$ $r = .48, p < .05$ $r = 0.29, p < .05$ no significant interaction
Webb et al. (2012b)	<i>Correlations (r) alliance and adherence</i> Alliance and Cognitive therapy (Concrete Factor) <i>Adherence X Alliance interaction in predicting outcome</i>	$r = .43, p < .01$ No significant interaction
Minonne (2008)	<i>Correlations (r) alliance and adherence</i> Alliance and CBT, Alliance and IPT <i>Adherence X Alliance interaction in predicting outcome</i>	No significant correlation $r = .36, p = 0.005$ No analysis
Castonguay et al. (1996)	<i>Correlations (r) alliance and adherence</i> Alliance and CT technique <i>Adherence X Alliance interaction in predicting outcome</i>	No significant correlation No analysis

Strunk et al. (2012)	<i>Correlations (r) alliance and adherence</i> Alliance and Cognitive Methods Alliance and Negotiating/Structuring Alliance and Behavioural Methods Homework: <i>Adherence X Alliance interaction in predicting outcome</i>	 $r = 0.21, p < .05$ $r = 0.24, p < .05$ No significant correlation No significant interaction
Gaston and Ring (1992)	<i>Correlations (r) alliance and adherence</i> Whole sample Improved patients: alliance and exploratory strategies Non-Improved patients: alliance and exploratory Strategies <i>Adherence X Alliance interaction in predicting outcome</i>	 No significant correlations $r = 0.65, p < 0.01$ $r = 0.30, p > 0.05$ No analysis
Gaston et al. (1998)	<i>Correlations (r) alliance and adherence</i> Patient working capacity and explorative strategies Patient working capacity and supportive strategies Other scales of CALPAS-R and adherence <i>Adherence X Alliance interaction in predicting outcome</i> BT Sample Patient working capacity and explorative strategies CT Sample Patient working capacity and explorative strategies BDT Sample Patient working capacity and explorative strategies	 $r = .36$ (stated to be ‘significant’) $r = -.29$ (stated to be ‘significant’) No significant Correlations $R^2 = 10, p < .05$ CT $R^2 = 15, p < .05$ No significant interaction
Bambling et al. (2006)	<i>Correlations (r) alliance and adherence</i> Alliance and problems Solving therapy <i>Adherence X Alliance interaction in predicting outcome</i>	 No significant correlations No analysis

Studies focusing on substance misuse

Carroll et al. (1997)	<i>Correlations (r) alliance and adherence</i> Alliance and CBT <i>Adherence X Alliance interaction in predicting outcome</i>	$r = .41, p < .01$ No analysis
Hogue et al. (2008b)	<i>Correlations (r) alliance and adherence</i> Alliance and:CBT Alliance and MDFT- <i>Adherence X Alliance interaction in predicting outcome</i>	$r = .28, p < 0.05$ no significant correlation No analysis
Gibbons et al.(2010)	<i>Correlations (r) alliance and adherence</i> <i>Adherence X Alliance interaction in predicting outcome</i> General Linear Model Linear adherence 2 session MET X alliance- Linear adherence 9 session MET/CBT/CM X alliance Curvilinear adherence 2 session MET X alliance Curvilinear adherence 9 session MET/CBT/CM X alliance	No analysis no significant interaction no significant interaction No significant interaction $t = 2.77, p = 0.01$
Barber et al. (2008)	<i>Correlations (r) alliance and adherence</i> <i>Adherence X Alliance interaction in predicting outcome</i> Mixed model ANOVA Curvilinear adherence SET X CALPAS at session 2 Curvilinear adherence SET X HAQ at session 2 Curvilinear adherence SET X CALPAS at session 5 Curvilinear adherence SET X HAQ at session 5 Curvilinear adherence Expressive subscale X CALPAS Session 2	No significant correlations no significant interaction. $F(1, 86) = 4.94, p < .03$ $F(1.60) = 4.49, p < .04;$ $F(1.69) = 4.79, p < .04$ $F(1,86)= 5.17, p <.03;$

	Curvilinear adherence Expressive subscale X HAQ Session 2	$F(1.86) = 7.73, p < .007$
	Curvilinear adherence Supportive subscale X CALPAS Session 2	No significant interaction
	Curvilinear adherence Supportive subscale X HAQ Session 2	No significant interaction
	Curvilinear adherence Expressive subscale X CALPAS Session 5	$F(1, 69) = 8.08, p < 0.006$
	Curvilinear adherence Expressive subscale X HAQ Session 5	$F(1.69) = 3.81, p < .06$
	Curvilinear adherence Supportive subscale X CALPAS Session 5	No significant interaction
	Curvilinear adherence Supportive subscale X HAQ Session 5	No significant interaction
Barber et al. (2006)	<i>Correlations (r) alliance and adherence</i>	No analysis
	<i>Adherence X Alliance interaction in predicting outcome</i>	
	Mixed model ANOVA	
	Linear adherence IDC X alliance- no significant interaction	no significant interaction
	Curvilinear adherence IDC X CALPAS at session 2:	$F(1, 82) = 5.06, p < 0.03$
	Curvilinear adherence IDC X HAQ at session 2:	$F(1, 82) = 3.98, p = .05.$
	Curvilinear adherence IDC X CALPAS at session 5:	$F(1, 53) = 4.04, p < .05$
	Curvilinear adherence IDC X HAQ at session 5:	$F(1, 53) = 5.90, p < .02$
Studies focusing on other clinical presentations		
Evans-Jones et al. (2009)	<i>Correlations (r) alliance and adherence</i>	
	Alliance and CBT	$r = .468, p = .02$ (a trend $p < .01$ used)
	<i>Adherence X Alliance interaction in predicting outcome</i>	NA
Goldman and Gregory (2009)	<i>Correlations (r) alliance and adherence</i>	
	Alliance and DDP	No significant correlation
	<i>Adherence X Alliance interaction in predicting outcome</i>	No analysis

Ogrodniczuk, and Piper (1999)	<i>Correlations (r) alliance and adherence</i> Alliance and interpretive therapy: Interpretive therapy sample Whole sample Alliance and supportive therapy Supportive therapy sample Whole sample	$r = 0.23, p < .05$ $r = 0.21, p < .05$ $r = 0.36, p < .05$ $r = 0.18, p < .05$
Gaston et al.(1994)	<i>Correlations (r) alliance and adherence</i> Patient working capacity and exploratory strategies Patient commitment Scale and exploratory strategies Patient working capacity and supportive strategies Patient Commitment and supportive strategies <i>Adherence X Alliance interaction in predicting outcome</i> Hierarchical multiple regression Long term psychotherapy sample Explorative Strategies X alliance predicting depression and anxiety Supportive Strategies X alliance predicting depression and anxiety Explorative Strategies X alliance predicting Interpersonal Behaviour Supportive Strategies X alliance predicting interpersonal behaviour	$r = 0.29$ $r = .11$ $r = .47, p < .01.$ $r = -.25$ $R^2 = .25, p < .05$ $R^2 = .16, p < .05$ $R^2 = .30, p < .05$ $R^2 = .17, p < .05$
Pavio et al. (2004)	<i>Correlations (r) alliance and adherence</i> Alliance and EFT <i>Adherence X Alliance interaction in predicting outcome</i>	$r = .35, p \leq .05$ No analysis
Liber et al.(2010)	<i>Correlations (r) alliance and adherence</i> Alliance and early CBT adherence Alliance and late CBT adherence.	$r = .44, p < .05$ $r = .45, p < .05$

	<i>Adherence X Alliance interaction in predicting outcome</i>	No analysis
Loeb et al. (2005)	<i>Correlations (r) alliance and adherence</i>	
	Patient factor and CBT at session 6	$r = .55, p < .01$
	Patient factor and CBT at session 12	$r = .51, p < .01$
	Patient factor and CBT at session 18	$r = .46, p < .01$
	Therapist factor and CBT at session 6	$r = .63, p < .01$
	Therapist factor and CBT at session 12	$r = .74, p < .01$
	Therapist factor and CBT at session 18	$r = .65, p < .01$
	Patient factor and IPT at session 6	$r = .58, p < .01$
	Patient factor and IPT at session 12	$r = .39, p < .01$
	Patient factor and IPT at session 18	$r = .43, p < .01$
	Therapist factor and IPT at session 6	$r = .65, p < .01$
	Therapist factor and IPT at session 12	$r = .56, p < .01$
	Therapist factor and IPT at session 18	$r = .64, p < .01$
	<i>Adherence X Alliance interaction in predicting outcome</i>	No analysis

CT= Cognitive Therapy, ADM= Anti-depressant Medication, CBT= Cognitive Behavioural Therapy, IPT= Interpersonal Therapy, BDT= Brief Dynamic Therapy, MDFT= Multi-Dimensional Family Therapy, MET= Motivational Enhancement Therapy, CM= Clinical Management, SET= Supportive Expressive Dynamic Therapy, EFT=Emotion Focused Therapy, DDP= Dynamic deconstructive psychotherapy, CALPAS= = California Psychotherapy Alliance Scales HAQ= Helping Alliance Questionnaire,

Table 2

Studies focusing on patients with depression

Study Title	Sample	Therapy	Primary Focus	Adherence Measure	Alliance measure	Outcome
Strunk et al. (2010)	N=60 adults from CT Arm of TDCRP	CT Sessions twice weekly for the first 4–12 weeks and weekly thereafter	Relationship between adherence and outcome	3 scales from the CSPRS; Cognitive methods subscale; Negotiating/Structuring subscale Behavioural; Methods Subscale.	Observer rated WAI	Session to Session change on BDI
Webb, et al. (2012b)	N= 105 Adults from CT arm TDCRP and University of Washington Trial	CT 16 weeks	Evaluating the relationship between adherence alliance and outcome	CSPRS: <i>CT-Concrete Factor-</i> active, symptom focused methods	Observer rated WAI	Post treatment BDI

Minonne (2008)	N= 120 adults taken from TDCRP CBT (n=59) and IPT (n=61) conditions	CBT IPT 16 weeks	Relationship between adherence, alliance and outcome	CSPRS: CBT and IPT scales	VTAS	Post treatment BDI
Castonguay et al.s (1996)	N=30 Adults from CT condition of Cognitive-Pharmacotherapy Project	CT Average 15.4 sessions	Relationship between unique aspects of CT, alliance , patient involvement and outcome	<i>The Coding System of Therapist Feedback.</i> Rating the cause and effect between two components of the patient's functioning.	Observer rated WAI	Post treatment BDI and HDRS
Strunk,et al. (2012)	N= 176 adults from combined CT and ADM condition of a three-site, randomized trial	CT + ADM	Relationship between adherence, alliance outcome	3 scales CSPRS: Cognitive methods subscale; Negotiating/Structuring subscale; Behavioural and Methods Subscale	Observer rated WAI	Session to session change on BDI
Gaston and Ring (1992)	N= 10 Older Adults from Brief Dynamic Therapy arm of.	Brief Dynamic Therapy. 16-20 session	Assessing the qualities of adherence measure	ITS	CALPAS: Total Score; Therapist Understanding and Involvement	Post BDI and HDRS scores

	larger controlled clinical trial				Scale	
Gaston et al. (1998)	N=91 Older adults from active treatment conditions of controlled clinical trial	Behaviour Therapy, CT, Brief Dynamic Therapy 16- 20 sessions	Relationship between alliance, therapy technique and outcome	ITS	CALPAS: Patient Working Capacity Scale; Patient Commitment Scale; Working Strategy Consensus and Therapist Understanding scale	Post treatment BDI and HDRS scores
Bambling, et al. (2006)	N=127 Adults	PST 8 session	Evaluating the impact of clinical supervision on working alliances and outcome	PST adherence Scale completed by therapists self report and observer rated.	Client rated WAI	NA

CT= Cognitive Therapy, TDCRP= Treatment of Depression Collaborative Research Program, ADM= Antidepressant Medication, CSPRS =Collaborative Study Psychotherapy Rating Scale, WAI=Working Alliance Inventory, BDI=Beck Depression Inventory, ITS= Inventory of Therapeutic Strategies, HDRS= Hamilton Depression Rating Scale, CALPAS=California Psychotherapy Alliance Scales, PST= Problem Solving Therapy, CBT= Cognitive Behavioural Therapy, IPT= Interpersonal Therapy, VTAS= Vanderbilt Therapeutic Alliance Scale, MAPE=Manualised Active Psycho-Education, HAQ= Helping Alliance Questionnaire⁴

⁴ Full references for adherence, alliance and outcome measures can be found in appendix B

Strunk et al. (2010) study benefits from using established measures of alliance and adherence. Alliance, adherence and outcome are collected at the same session, and therefore, any relationship between the variables is unlikely to be due to processes that occur between their measurements (Webb et al., 2010). However no analysis is offered investigating how alliance and adherence may be related across the course of therapy. Although raters were blind to outcome the same raters rated all process variables across all sessions. It is possible that raters' hypotheses about the relationship between variables and knowledge of symptom change could have biased ratings.

Webb, Dimidjian, Hollon, and Amsterdam (2012b) use data from the TDCRP and also from the University of Washington Study. This study reports a moderate relationship between symptom focused methods of cognitive therapy and alliance assessed at an early session of therapy. The authors found no interaction between adherence and alliance in predicting outcome.

Webb et al.(2012b) benefits from controlling for symptom change occurring before the measurement of adherence and alliance. Another strength is that authors present a power analysis demonstrating their sample size was sufficient. Adherence and alliance were used to predict outcome at the end of therapy. Therefore any relationship between the predictors and outcome could be overshadowed by other processes occurring between their measurements. The authors also note that, there may be a restriction in range of adherence and alliance limiting the ability to detect interactions.

The studies above are informative about the relationship between alliance and adherence when collected at the same session. A recent doctoral dissertation (Minonne, 2008) provides information about the relationship between alliance and

adherence measured at different points in therapy. Minonne (2008) used data from the CBT and Interpersonal Therapy (IPT) conditions of the TDCRP. In CBT, Minonne (2008) reports no significant relationships between alliance and adherence and a non-significant trend for early alliance to be associated with adherence. For IPT, early alliance was associated with later IPT adherence. These findings indicate that it may be important to consider the relationship between alliance and adherence across the course of therapy, and in relation to specific forms of therapy.

Minonne (2008) benefits from using two raters per tape and only one session per patient was rated for adherence by each rater. This limits the possibility of prior knowledge of a particular patient's, adherence, alliance, or symptomology from biasing ratings. However no information is provided as to inter rater reliability or rater expertise for alliance ratings.

Studies using data from other sources: Castonguay et al. (1996) reports a non-significant correlation between adherence to specific CBT strategies and alliance collected during a single session of cognitive therapy. Descriptive analyses suggest that therapists increased their adherence to correct problems with therapeutic alliance, which worsens alliance strains. It is emphasised that the correlation between adherence and alliance is statistically non-significant and there was no significant interaction between alliance and adherence in predicting outcome. These findings indicate that it may be necessary to consider the relationship between alliance and adherence over time, in this case over the course of a session to understand how the two variables may be associated and interact.

Castonguay et al. (1996) benefits from using multiple raters for each variable. This study also conducts analysis demonstrating that reported findings are not dependent on drop out pattern. Again adherence and alliance were measured at the

same session so little can be known about the relationship between them over the course of therapy . Outcome was measured at the end of therapy and therefore any relationship between, or absence thereof, could be attributed to processes that occur between measurement of the predictor and outcome variables. This study used adherence to a specific strategy and therefore findings may not be generalisable to other aspects of adherence.

With the exception of Minonne (2008), the studies above provide information on the relationship between adherence and alliance when they are assessed at the same sessions. Strunk, Cooper, Ryan, DeRubeis and Hollon (2012) differ from the previous studies in that a mean rating of adherence and alliance from across the sessions is used. The authors found significant small correlations between cognitive methods and alliance, and between Negotiating/Structuring and alliance but not between Methods/Homework and alliance. No interaction between alliance and adherence in predicting outcome was found. Again this indicates that the adherence-alliance relationship may differ depending on what aspect of adherence is measured.

Gaston and Ring (1992) use data from 10 patients in the brief dynamic therapy arm of a clinical trial using data collected at three sessions across the course of therapy. Gaston and Ring (1992) report no significant correlations between adherence and alliance.

Gaston and Ring (1992) conducted further analysis that found a large correlation between adherence to exploratory strategies (those which address a patient's reactions as problematic, and provoke anxiety) and alliance for the improved, but not for unimproved patients. The authors suggest this indicates that with improved patients therapists employed more exploratory strategies when

alliance was better and that this was not the case with unimproved patients. It is equally possible that the use of exploratory strategies influenced alliance, or that a better alliance set the context for the use of more exploratory strategies, or that a third unmeasured variable influenced the relationship. That said, it seems that there is a different relationship between adherence and alliance in patients that demonstrate clinical improvement compared to those that do not.

Gaston and Ring (1992) benefit from collecting a measure of adherence and alliance across therapy. However a mean of these measures is used and as such no inference can be made about how change in alliance and adherence scores across therapy may interact or influence outcome. Gaston and Ring (1992) use t tests and correlations which are less powerful than regression models in their ability to predict outcome and limit claims of causality. Gaston and Ring (1992) suffer from having a small sample size (n=10) and provide no information on how this sample was selected. The adherence measure used is not a measure of adherence to a particular therapy but to various different strategies. Any correlations between the adherence and alliance could reflect a relationship between a particular strategy and alliance as opposed to adherence to a therapeutic protocol. Given the context of a brief dynamic therapy, and the authors finding that dynamic therapists placed more emphasis on exploratory strategies than cognitive therapists, it seems fair to accept the ratings for exploratory strategies as adherence to an ingredient of brief dynamic therapy.

Gaston, Thompson, Gallagher, Cournoyer, and Gagnon (1998) draw on the same data set and methods as Gaston and Ring (1992) and considered participants from all active treatment arms of therapy in the trial; cognitive therapy, behavioural therapy, and brief dynamic therapy. Gaston et al. (1998) report that the patient's ability to form a working alliance with the therapist, termed 'Patient Working

Capacity' was significantly related to exploratory strategies, and had an inverse relationship with supportive strategies (supportive interventions are those which attempt to support or structure a patient's sense of self and reduce anxiety).

Correlations between adherence and other aspects of alliance were not significant.

The authors point out, that although not significant, more exploratory interventions in the context of good alliances predicted better outcome and less explorative interventions in the context of poor alliances predicted worse outcome.

Gaston et al. (1998) also looked at data from an individual session in the middle of therapy. The authors report that in behaviour therapy and cognitive therapy exploratory interventions interacted with patient working capacity to predict outcome; less exploratory interventions in the context of a better alliance predicted better outcomes. This relationship was not observed for brief dynamic therapy. Interestingly alliance was predictive of a reduction in depressive symptoms whilst explorative interventions were not. This indicates that considering adherence in isolation does not give a full picture. Alliance may be independently associated with outcome but may also interact with adherence to effect outcome.

Gaston et al. (1998) report the first negative correlation reported in this review. This finding indicates a negative correlation between therapists' use of supportive strategies and Patient Working Capacity. Interestingly this study reports the first significant interaction between alliance and adherence in predicting outcome, finding that in cognitive therapy and behaviour therapy less frequent use of exploratory strategies in the context of better alliances is beneficial for outcome. Interpretations of these findings are problematic as the measure of adherence used is designed to be used across therapeutic modalities and includes a number of different strategies. The authors note that as such further analysis is required of the types of

exploratory or supportive techniques that are being employed as to whether they represent cognitive, behavioural or dynamic techniques. These results do indicate that adherence to different strategies have a different relationship with alliance and outcome.

A final study reports no significant correlation between adherence to Problem Solving Therapy and alliance. Bambling et al. (2006) benefits from using both therapist rated adherence and observer rated adherence. However there is no information as to when adherence was measured, which measure (therapist or observer) was used in analysis, or the expertise of the raters. This limits interpretations that can be made about the association (or lack of) between adherence and alliance as it could be due to processes occurring between measurements.

Summary of studies focused on depression

This summary should be considered in the context of the limitations identified above. In CBT, two studies (Strunk, et al., 2010; Webb et al., 2012b) report significant correlations between alliance and adherence when measured within a single session. This pattern was also observed when using mean alliance and adherence ratings collected over the course of therapy (Strunk et al., 2012). None of these three studies found a significant interaction between adherence and alliance in predicting outcome. These findings indicate that in CBT for depression, adherence and alliance can have a significant positive association, but their interaction is not associated with clinical improvement.

Using mean levels of adherence from a single session or multiple sessions across the course of therapy cannot inform us of the relationship between the variables over time. One study (Minonne, 2008) indicates alliance early in therapy may be associated with adherence later in therapy. This could be interpreted as a

strong alliance setting the context for greater levels of adherence. That is, in conditions of a strong alliance, therapists are able to successfully implement and adhere to a therapeutic intervention. This relationship was statistically non-significant and was not found across both types of therapy being investigated (CBT and IPT), so this interpretation is made tentatively.

Another study highlights the importance of considering the relationship between adherence and alliance over time. Castonguay et al. (1996) claim that their descriptive analysis indicates that therapists increase adherence in an attempt to repair a disrupted alliance. This further weakens the alliance and has a detrimental effect on outcome. This association is not statistically significant making the assertion that adherence impacts negatively on alliance problematic. Although the results do indicate that alliance and adherence may be associated and interact in a way that will not be detected using analysis of means. Furthermore it indicates that flexibility in adhering to a model may be important.

Results from another study by Gaston et al. (1998) support the idea that therapists are flexible to the aspects of a model they adhere to, dependent on the context of the alliance. Gaston et al. (1998) found a positive association between explorative interventions and alliance and a negative association between supportive strategies and the alliance. Although using correlations it is not possible to infer causality, these results could be interpreted as therapists using more supportive strategies in conditions of a weak alliance, in an attempt to repair it. In conditions of strong alliance therapists are able to focus on explorative strategies focused on the patient's problematic reactions. Again it is of note that other correlations between adherence and alliance were not significant.

Results from these studies indicate that adherence and alliance often have an association with each other, and that the aspects of the model being adhered to may be affected by the quality of the therapeutic alliance. It appears that it is important to consider how adherence and alliance are associated and interact over time as opposed to using data from a single time point, or a mean from multiple time points. There does not seem to be significant evidence that adherence has a detrimental effect on alliance. As to the interaction between the variables impacting on outcome, the majority of studies found no interaction. This may be because no study assesses the impact on outcome of the interaction between adherence and alliance over time. One exception (Gaston et al., 1998) found that less use of exploratory interventions in CBT in the context of a better alliance predicted better outcomes. However, interpreting this finding is problematic as ‘explorative strategies’ may represent dynamically orientated interventions. It may be that when cognitive therapists employed less use of dynamically orientated interventions in the context of a good alliance patient outcome improved. This could reflect cognitive therapists using non-dynamic strategies not detected by the adherence measure. One other (Gaston & Ring, 1992) study indicates that adherence was associated with alliance, but only in patients that demonstrated clinical improvement. Not all associations were found to be significant which could represent adherence to different strategies having different relationships with alliance and outcome.

Studies focusing on substance disorders

Five studies (Table 3) focused on adherence and alliance with participants with substance disorders. All studies appeared to use valid assessment with participants meeting Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria for a substance use disorder. Studies varied about when in therapy adherence

and alliance were assessed. Where presented, inter-rater reliability coefficients were adequate, ranging from moderate to perfect agreement (Appendix A). Interestingly, three of the studies consider the relationship between curvilinear adherence and alliance.

Carroll, Nich, and Rounsaville (1997) assess adherence and alliance at an early session of CBT or Clinical Management for cocaine dependent patients and report a significant moderate correlation between adherence to CBT strategies and alliance. This study benefits from conducting analysis on CBT and a control condition therefore increasing the likelihood of variability in levels of adherence. Another strength is that raters were blind to the therapy condition. However, the study offers no information about the relationship between the variables over time or across therapy, and does not investigate how adherence and alliance interact over time to affect outcome.

Hogue, Dauber, Chinchilla, Fried, Henderson, Inclan, Reiner, & Liddle (2008b) used means from assessments of adherence across the course of therapy and alliance collected at two time points. A significant moderate correlation between adherence and alliance in Cognitive Behavioural Therapy (CBT) was found. In Multi-Dimensional-Family-Therapy (MDFT), adherence and alliance were not significantly correlated. This study benefits from using measures of adherence and alliance from multiple points in therapy. The sample used consisted of participants for whom there was available assessment data. No analysis was conducted to identify if this sub sample differed systematically from the larger sample. Furthermore, only 80% of the sample met criteria for substance use disorder. Alliance measures were not assessed for all participants, which could affect the pattern of results observed.

Table 3

Studies focusing on substance use disorders

Study Title	Sample	Therapy	Primary Focus	Adherence Measure	Alliance measure	Outcome
Carroll et al. (1997)	N=103 adults with cocaine dependence from a randomised control trial comparing CBT to a control condition	Condition 1: CBT Condition 2: CM	Relationship between alliance and outcome in active versus control conditions	CSPRS (adapted for treatment involved in this study)	VTAS-observer rated	NA
Hogue et al. (2008b)	N=136 substance abusing adolescents (DSM from a larger RCT comparing CBT (n= 62) MDFT (n=74)	CBT MDFT 16-24 weeks	Assessing the qualities of an adherence measure	Therapist Behaviour Rating Scale	VTAS observer rated	
Gibbons et al. (2010)	N=450 Adults with Marijuana Dependence from The Marijuana	Condition 1: MET 2 sessions	Relationship between alliance, adherence and outcome	Yale Adherence and Competence Rating Scale: Treatment Specific MET, CBT	Client and Therapist Self report WAI	Diagnosis assessed using SCID. ASI. Interview

	Treatment Project randomised to two therapy conditions	Condition 2: Integrated MET, CBT and CM 9 sessions		and CM scales; General Structure and Facilitative Scales.		assessing pattern frequency and pattern of drug use.
Barber et al. (2008)	N= 108 adult with dependence from Supportive Expressive dynamic therapy condition of NIDA Collaborative Cocaine Treatment Study	SET 24 weeks	Relationship between alliance adherence and outcome	Adherence/Competence Scale for SET for cocaine dependence Adherence/Competence Sale for Individual Drug Counselling	CALPAS self-report and HAQ self-report	ASI administered at baseline and then monthly (1-6 months)
Barber et al. (2006)	N=96 from IDC condition of NIDA Collaborative Cocaine Treatment Study	IDC 24 weeks	Relationship between adherence, competence, alliance and outcome.	Adherence/Competence Scale for IDC for cocaine dependence	CALPAS self-report and HAQ self-report	ASI and BDI administered at baseline and then monthly (1-6 months)

MET= Motivational Enhancement Therapy, CBT=Cognitive Behavioural Therapy, CM=Case Management, WAI=Working Alliance Inventory, SCID= Structured Clinical Interview for DSM, ASI= Addiction Severity Index, VTAS=Vanderbilt Therapeutic Alliance Scale, CSPRS =Collaborative Study Psychotherapy Rating Scale, NIDA= National Institute on Drug Abuse, IDC=Individual Drug Counselling, HAQ=Helping Alliance Questionnaire, BDI=Becks Depression Inventory, SET= Supportive Expressive Dynamic Therapy, CALPAS= California Psychotherapy Alliance Scales, MDFT= Multi Dimensional Family Therapy⁵

⁵ Full references for adherence, alliance and outcome measures can be found in appendix B

Gibbons et al. (2010) use adherence ratings gathered from assessments at each session and alliance assessed at session two of a two session Motivational enhancement intervention and a nine session, integrated MET, CBT and Clinical Management intervention. Gibbons et al. (2010) report no significant interaction between alliance and adherence in predicting outcome in either therapy. However a significant interaction was reported between curvilinear adherence and alliance in predicting outcome in the nine session intervention. This indicates that in the context of high alliance, adherence had less impact on outcome, but when alliance was weaker adherence was more influential.

Interestingly neither linear nor curvilinear adherence was significant in predicting outcome when considered individually. A significant relationship was reported between alliance and outcome. This indicates that whilst alliance may be associated with positive outcome when considered in isolation the same cannot be said of adherence. However, curvilinear adherence and alliance may interact to predict outcome.

This study benefits from assessing adherence at every session and conducting analysis considering curvilinear adherence. The majority of analysis presented in Gibbons et al. (2010) focus on adherence to MET (the adherence measure used includes CBT, Clinical Management, and general scales), however it is not clear whether analysis of the interaction between adherence and alliance uses MET adherence or a mean of all scales in the measure. Raters were blind to outcome. However, half the study sample were not assessed for adherence, and alliance was only rated at one time point. It is not clear how many raters routinely rated each tape, although inter rater reliability for a sample of nine tapes was excellent and the authors conduct a power analysis indicating the sample size is sufficient. Although

Gibbons et al. (2010) reports that in context of weaker alliance adherence was influential, there is no analysis conducted to inform how the level of adherence (e.g. low, moderate, high) is associated with better outcomes.

Two other studies provide information about the relationship between curvilinear adherence, alliance and outcome using data from a large randomized control trial investigating treatment for cocaine dependence. Barber et al. (2006) report a significant interaction between curvilinear adherence to Individual Drug Counselling (IDC) techniques and alliance in predicting outcome. This relationship was observed using alliance data collected at sessions two and five using two measures of alliance. These results indicated that a strong alliance negated the impact of adherence and a weaker alliance was associated with better outcomes when there were moderate levels of adherence. Interestingly in this study neither linear adherence nor alliance significantly predict outcome alone, however, curvilinear adherence did predict outcome. This indicates that only considering the contribution of linear adherence and alliance to outcome does not give a full picture. It is important to consider curvilinear adherence. Furthermore it is important to consider the interaction between curvilinear adherence and alliance in order to understand the role of these variables in predicting outcome.

Barber et al. (2008) reports data from the Supportive Expressive Dynamic Therapy (SET) condition of the trial. Using the same methods as the previous study the authors found an interaction between curvilinear adherence to SET and one of the measures of alliance at session two in predicting outcome. These results indicated that in the context of a poor alliance, moderate adherence was slightly better for outcome than low or high levels of adherence. In the context of a strong alliance, low

adherence was associated with better outcomes than when adherence was moderate or high.

Interestingly when considering the variables individually, greater adherence to SET predicted worse outcome whilst there was no significant relationship between curvilinear adherence and outcome. There was no significant relationship between alliance at session two and outcome, but one of the measures of alliance at session five was associated with better outcome. These findings indicate that considering the contributions of alliance and adherence in isolation do not give a full picture. It is important to consider their interaction, particularly using curvilinear adherence to understand their relationship with outcome.

Further analysis considered the subscales of the SET adherence measure. Although neither of the subscales were independently associated with outcome, a significant interaction was found between curvilinear adherence to interpretive and clarifying techniques and both measures of alliance in predicting outcome. No interaction was observed between supportive techniques and alliance in predicting outcome. Barber et al. (2008) also investigated the impact of the incidental use of IDC techniques. The authors found no significant interaction between curvilinear adherence to IDC and alliance in predicting outcome. It is of note that IDC was measured for a subsample of participants. These findings indicate that adherence to different types of strategy have different relationships with alliance and outcome.

These two studies benefit from using raters blind to outcome, using two measures of alliance collected at two time points and conducting analysis investigating curvilinear adherence. This study also controlled for a number of baseline characteristics as covariates.⁶

⁶ Site, (as it was a multi-site trial) baseline score of outcome variables, psychiatric severity and socialisation score of the California Personality were entered as covariates.

Summary of studies focussing on substance use disorders

Two studies report significant correlations between adherence and alliance in CBT (Carroll et al., 1997; Hogue et al., 2008b). One study fails to find a correlation between the variables in MDFT (Hogue et al., 2008b). Two other studies also indicate that adherence in different treatment conditions (Gibbons et al., 2010) or to different specific strategies (Barber et al., 2008) have different relationships with alliance and outcome. It is of note that none of these studies report a negative association between the variables, supporting the assertion that adherence does not have a negative effect on alliance.

Three studies report on the interaction between adherence and alliance in predicting outcome (Barber et al., 2006; Barber et al., 2008; Gibbons et al., 2010). The results indicate that whilst adherence and alliance may not predict outcome when considered in isolation, a different pattern of results emerges when considering the relationship between curvilinear adherence, alliance and outcome. Two of the studies found that in the context of high alliance, adherence had no impact on outcome (Barber et al., 2006; Gibbons et al., 2010). Whilst one study found that low adherence was more beneficial to outcome in conditions of high alliance (Barber et al., 2008). All three studies report a relationship between curvilinear adherence and outcome in the context of a low alliance. Two of the studies agree that in such conditions moderate adherence is associated with best outcome. It appears that there is a curvilinear relationship between adherence and alliance in predicting outcome which has clinical implications. It may be that in the context of a high alliance, adherence does not matter much, or possibly that low adherence is best. However in conditions of a low alliance it seems that moderate adherence is best. This may reflect therapists using a therapeutic model flexibly, using strategies to build the

alliance whilst remaining largely on model and adherent to theory specific interventions.

Studies focusing on other clinical presentations

Seven studies focused on other clinical presentations (Table 4). All included participants meeting criteria for a psychiatric diagnosis with the exception of Pavio, Holowaty, & Hall (2004) which included adult survivors of childhood abuse, although the authors note that 54% of the sample met criteria for post-traumatic stress disorder (PTSD) on the PTSD Symptom Severity Interview. Where presented inter-rater reliability coefficients for adherence and alliance were adequate, ranging from moderate to perfect agreement (Appendix A)

Evans-Jones, Peters and Barker (2009) used adherence and alliance data collected from a single session of CBT for psychosis. Due to the authors conducting multiple comparisons a value of $p < .01$ was used. The following correlations are considered trends. The authors report a moderate correlation between patient rated alliance and adherence. Alliance ratings were found to be higher when a CBT formulation had been presented than when it had not. There were no differences between therapist rated alliance when a formulation had been presented and when it had not. This study benefits from using a theory specific adherence measure and presents analysis that indicates that the alliance measure was measuring a construct that was independent of therapist and client characteristics. It is limited by its relatively small sample size ($n=24$).

Goldman and Gregory (2009) found no significant correlation between mean adherence and alliance in long term dynamic deconstructive psychotherapy for adults with a diagnosis of borderline personality disorder and alcohol use disorders. This study benefits from using a therapy specific measure of adherence and collecting

Table 4

Studies focusing on other clinical presentations

Study Title	Sample	Therapy	Primary Focus	Adherence Measure	Alliance measure	Outcome
Evans-Jones et al. (2009)	N=24 adults with schizophrenia spectrum diagnosis.	CBT for psychosis. Patients between session 2-9	Relationship between client and therapist factors and alliance.	Presentation of a Case Formulation Checklist Cognitive behaviour therapy for psychosis checklist	WAI client and therapist self report	NA
Goldman & Gregory (2009)	N=10 adults with BPD and Alcohol Misuse from DDP condition of RCT	DDP 12 months	Relationship between adherence and outcome	DDP adherence measure	Observer rated WAI	NA
Ogrodniczuk, & Piper (1999)	N=144 adults with Axis 1 (73%) and Axis 2 (60%) diagnoses from randomised Comparative trial	Condition1- Short term interpretive Therapy Condition 2: short term supportive therapy 20 sessions	The development of adherence measures	Interpretive and Supportive Techniques Scale: Interpretive and Supportive subscales.	Measure of 'working relationship'. Therapist self report	NA

Gaston, et al. (1994)	N=32 adults diagnosed with neurosis (66%) or personality disorder (33%) from short term (n=17) and long term (n=15) conditions of RCT	Short term analytic psychotherapy Average 22 weeks Long term analytic psychotherapy Average 76 weeks	Relationship between adherence, alliance and outcome	ITS: Explorative and Supportive subscales	Observer rated CALPAS: Patient Working Patient Commitment Subscales	Depression Anxiety Scale of the Psychiatric Status Schedule and the IBS
Pavio et al. (2004)	N= 37 adults recruited through newspaper advertisement. Adults who experienced childhood abuse suitable for short term insight orientated therapy	EFT Average 19 sessions	Evaluating the relationship between adherence, competence and outcome.	The EFT adherence checklist	WAI- client self report	NA
Liber, et al. (2010)	Data from children with diagnoses of various anxiety disorders taken from a larger Randomised trial comparing CBT with Group CBT. N=52, but analysis presented based only on children in CBT condition n=?	Individual CBT based on Australian FRIENDS manual 14 sessions	Relationship between alliance, adherence and outcome	Australian adherence protocol for Friends Treatment	Therapist Process Observational Coding System for Child Psychotherapy-alliance scale (TPOCS-A)	NA

Loeb et al. (2005)	N=81 women with diagnosis of Bulimia Nervosa from a larger RCT	CBT and IPT 19 sessions	Relationship between alliance, adherence and outcome	Measure derived from items from Minnesota Therapy Rating Scale and the Therapy Rating Scale producing individual measures for IPT and CBT.	VTAS- observer rated	NA
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BPD=Borderline Personality Disorder, DDP=Dynamic Deconstructive Psychotherapy, RCT=Randomised Control Trial, WAI-Working Alliance Inventory, ITS=Inventory of Therapeutic Strategies, CALPAS= California Psychotherapy Alliance Scales, IBS= Interpersonal Behaviour Scale, CBT=Cognitive Behaviour Therapy, IPT=Interpersonal Therapy, EFT=Emotion Focused Therapy⁷

⁷ Full references for adherence, alliance and outcome measures can be found in appendix B

adherence and alliance data from multiple time points, although using a mean score cannot inform us to the relationship between the variables over time. Raters were blind to study outcome. However it appears the same raters rated both alliance and adherence. Furthermore one of the raters was the second author of the paper. It is possible that raters hypothesis about the relationship between adherence, alliance and outcome may have biased ratings. This study is limited by a particularly small sample size (n=10).

Ogrodniczuk and Piper (1999) used average ratings of adherence and alliance taken from nine sessions across the course of 20 session interpretive therapy and supportive therapy treatment conditions for patients with axis I and axis II diagnosis. Small significant correlations between adherence and alliance across both conditions were found. A significant moderate correlation was found between adherence to interpretive techniques and alliance in interpretive therapy. A small significant correlation was found between adherence to supportive techniques and alliance across both conditions. This study benefits from using a large sample, multiple raters, and adherence and alliance data collected at multiple points across the course of therapy. Unfortunately, there is no information about the relationship between adherence and alliance in the supportive therapy condition as no correlations are presented. Finally a measure of ‘working relationship’ was for alliance which may not be comparable to other measures of alliance used in process-outcome research.

Gaston, Debbane, Bienvenu, and Grant (1994) also use alliance and adherence ratings taken from sessions across the course of short term and long term analytic therapy for patients with diagnoses of neurosis and personality disorder. Small and moderate correlations between exploratory strategies and alliance were found. The patient’s ability to form a working alliance, and the patient’s commitment

to treatment had negative correlations with adherence to supportive strategies. This indicated that when alliance is higher, adherence to supportive strategies was lower.

In short term analytic therapy the interaction between adherence and alliance was not significant in predicting outcome. In long term analytic therapy the authors report several significant interactions between aspects of adherence and alliance in predicting outcome. The authors report that the results indicate that when alliance was stronger there were better outcomes when there was more use of explorative strategies and less use of supportive strategies. For weaker alliances there were better outcomes when there was less use of explorative strategies and more use of supportive strategies. Interestingly when considered individually neither supportive strategies, explorative strategies, nor alliance were significantly associated with outcome. This is with the exception of the patient's ability to form a working alliance which significantly predicted interpersonal behaviour at outcome. This indicates that considering the contributions of these variables to outcome in isolation does not give a full picture and it is necessary to consider their interaction. These results also support the argument that adherence to different strategies have different relationships with alliance and outcome.

This study benefits from collecting data from time points across therapy but again uses a mean score, so no inference can be made about temporal relationships. The multiple regression analysis benefits from controlling for initial levels on outcome variables. The authors note the analysis is based on only five observations per predictor so results should be considered preliminary. Furthermore this study is limited by a small sample size ($n=10$).

Pavio et al. (2004) report a significant moderate correlation between alliance and adherence across the course of emotion focused therapy for adult survivors of

childhood abuse. This study benefits from collecting alliance data at each session and adherence data across the course of therapy. However, there is limited information on the rating of adherence with regard to the number of sessions rated or how many raters were used. Participants were recruited from newspaper advertisements offering free therapy. Those who met criteria for suitability for therapy based on motivation and capacity to form a therapeutic relationship were included. It is possible that individuals that seeks therapy via a newspaper advertisement with high levels of motivation and ability to form an alliance may have higher alliances and differ systematically from other groups of patients. This could limit the generalisability of these findings. This study uses a relatively small sample size (n=32) and presents multiple comparisons. The authors note that the study is exploratory so no Bonferonni corrections were made. The results should therefore be interpreted with caution.

Liber et al. (2010) assessed adherence to CBT and alliance at early and late sessions of treatment of childhood anxiety disorders. The authors report a significant moderate correlation between early adherence and early alliance, and between late adherence and late alliance. This study suffers a number of limitations. Children in the study are diagnosed with a variety of diagnoses. It is possible that children with different diagnoses differ systematically in ability to form working alliances or impact differently on a therapist's ability to adhere to treatment. The study considers children in group and individual CBT. It does not provide information as to how many are in each condition but it is likely to be a relatively small sample given the size of the entire sample (n=52). Whilst ratings of adherence and alliance were collected at the same session, only a sample of sessions were coded. Finally although authors describe a measure of adherence, the description states that raters judge

therapists on how well they meet the aims of the therapeutic activity which could be considered a measure of competence.

Using a sample of patients with a diagnosis of Bulimia Nervosa treated with CBT or IPT, Loeb et al. (2005) collected alliance and adherence data from an early, middle and late session of 19 session CBT and IPT interventions. Loeb et al. (2005) considers the relationship between adherence and the therapist factor (contribution the therapist makes to the alliance) and the patient factor (patients contribution to the alliance and mutual engagement of therapist and patient) of the alliance individually. The authors report many significant correlations between adherence and alliance across the course of therapy in both CBT and IPT. This study benefits from using random number tables to identify the sample used from the larger sample in the trial. The authors also report that the sample differed significantly from the larger sample on a number of baseline variables⁸. It is possible that these patient characteristics influence the therapeutic alliance, therapist adherence and the relationship between the variables.

This study collects adherence and alliance data at the same session therefore any relationship between the variables is unlikely to be due to processes that occur between their measurements. Only one judge rated each session although reported interclass coefficients based on a sample of tapes are adequate. Unfortunately none of the multiple regression analyses reported include an alliance and adherence interaction term.

Summary of studies focussing on other clinical presentations

All the studies focused on other clinical presentations report significant correlations between adherence and alliance with the exception of one study which

⁸ The current sample had lower scores on measures of shape concern, weight concern and eating concern and a longer history of purging.

had a particularly small sample size (Goldman & Gregory, 2009). Again measures of adherence were often to particular strategies indicating that adherence to different strategies have different relationships between alliance and outcome. Results from one study indicate that the positive relationship between alliance and adherence is stable over time, finding significant correlations at three sessions spread over the course of therapy (Loeb et al., 2005). The only negative correlation reported (Gaston et al., 1998) indicates that therapists employ more supportive strategies when the alliance is weak, in an attempt to strengthen it. The results from this study also indicate that in the context of a strong alliance greater use of strategies that address patients' problematic reactions and less use of supportive strategies is beneficial for outcome. Conversely in conditions of weak alliance, less use of strategies addressing problematic reactions and more supportive strategies are beneficial. These findings could be interpreted as therapists using strategies flexibly, to address alliance to produce the best outcome. When necessary therapists adhere to strategies within the model that address the therapeutic alliance. When alliance is strong therapists are able to focus on strategies that address problematic functioning directly.

These results indicate there is often an association between aspects of adherence and alliance. Importantly there is no significant evidence that adherence has a detrimental effect on alliance. With regard to predicting outcome the results indicate that flexible adherence is associated with best outcome.

Discussion

This review captures the developing understanding about the relationship between adherence, alliance and outcome in individual psychotherapy. The review includes studies focusing on a range of therapies, using a number of measures of

adherence and alliance with patients presenting with depression, substance use disorders, and a range of other clinical presentations. The findings from this review are summarised and synthesised below, followed by discussions of key considerations with regard to measurement of variables and limitations of this review.

The results indicate that adherence and alliance are often associated. Not all analysis report significant correlations. Whilst this may be due to methodological limitations it is likely that adherence to different strategies have different relationships with alliance and outcome. Importantly, this review suggests that adherence does not have a detrimental effect on alliance. The literature also indicates that it is important to consider the relationship between the variables over time and whether a good alliance sets the context for therapists to adhere to the therapeutic model. Most studies do not report an interaction between adherence and alliance in predicting outcome when using mean measurements. This review suggests that research should consider of curvilinear adherence. Results indicate that in conditions of low alliance, moderate adherence is best for outcome. Considering this finding alongside results indicating that therapists use a greater frequency of supportive strategies when alliance is strained (which is associated with better outcome) indicates that a flexible approach is best. When there is a strain on the alliance, patients benefit most when therapists engage in interventions to support the alliance but remain largely consistent with their model (i.e. moderate adherence). It is of course easier to remain adherent to an approach and support alliance if the therapeutic approach includes interventions to help to build the therapeutic alliance (i.e. supportive strategies). This has obvious clinical implications. Therapy models

should include strategies to help foster therapeutic alliance, and therapists should employ models flexibly addressing ruptures in the therapeutic alliance appropriately.

Issues of Measurement

Articles considering depressed patients include cognitive, behavioural, dynamic, problem solving, and psycho-education treatment. Therefore, although adherence can be considered a common factor, the measures of adherence will invariably be measuring different techniques across therapies. This makes generalisations about the relationship between adherence and alliance problematic. Secondly, often studies use a mean score for a particular part or scale of an adherence measure, or assess adherence to one particular technique. Therefore any reported relationships between adherence and alliance could be specific to the intervention measured and relationships between adherence to other aspects of a treatment and alliance will not be detected. It is unclear what exactly some measures of adherence are measuring. For example the Inventory of Therapeutic Strategies is described as a tool to measure specific ingredients across psychotherapies. Although the authors state that it is informed predominantly from a dynamic perspective, it is also informed by cognitive and behavioural perspectives. It is therefore not possible to know whether the adherence-alliance relationships observed reflect adherence to dynamic, cognitive or behavioural techniques.

With regard to alliance, four measures are used across the studies focusing on depression. Some studies employ the full measures, some studies use subscales from the measures. It has been shown that these measures' shared variance is less than 50% (Horvath et al, 2011). It is possible that studies could have produced different patterns of results had they used a different measure of alliance. This is highlighted in the Barber et al. (2006) study that reports different results using two different

measures of alliance in the same analysis. There also may be differing relationships with adherence when considering self report, patient rated, and therapist rated alliance. This is highlighted by Evans-Jones et al. (2009) who reported different relationships with adherence for therapist rated and patient rated alliance. Due to the diversity of the measures it is difficult to make generalisations about adherence-alliance relationships.

Limitations

In addition to individual study limitations a number of more general limitations should be noted. With regard to statistical analysis, no inference can be made about direction of causality and whether there is a third unmeasured variable that is affecting results when using correlational analysis. Studies that present regression analysis typically do not account for any variables other than alliance and adherence with the exception of one study controlling for site in a multi-site trial (Strunk et al., 2010), and two studies controlling for prior symptom change (Strunk et al., 2012; Webb et al., 2012b). Finally this review indicates that it is important to consider curvilinear adherence relationships, only three of the studies do this.

Another limitation is with regard to when measures of alliance and adherence are taken. Using adherence and alliance measures from a single session restricts the possibility of any observed relationship being due to processes occurring between their measurement but cannot inform us about the relationship between adherence and alliance during other sessions of therapy. Studies using mean measures of adherence and alliance taken from across the course of therapy are limited as they cannot inform us to the changing relationship or interaction between the variables across the course of therapy. This is highlighted by Gaston et al. (1998) which reports a different pattern of results when using a mean measure of alliance

compared to a measure of alliance from a single session. With regard to predicting outcome, many studies predict outcome post treatment using measures of adherence and alliance taken earlier in therapy. Therefore, any relationship between predictor variables could be due to processes occurring between the adherence/alliance measurement and the measurement of outcome.

Although many studies use similar measures and some studies draw on the same data set, there remains significant variability in the measures used. Studies also vary on the clinical presentation that is focused on and the type of therapy used. Beutler (1979) questioned the legitimacy of collapsing groups of patients and therapies when conducting a meta-analysis and the same concern is relevant here when considering these results together. Studies also vary on the sample size used, some of which are particularly small. As mentioned above studies also vary on the timing of measurement of the variables and on statistical analysis conducted. The heterogeneity of the literature limits generalisations that can be made about the patterns of relationships observed.

Future Research

The findings of this review indicate that the relationship between adherence and alliance, and their interaction in predicting outcome are worthy of further investigation. There is a relatively small amount of literature considering the interaction of these variables. More research involving different therapies and clinical presentations is required for replication and further investigation.

Future research should employ measures of adherence and alliance at multiple time points across the course of therapy. This will allow for the investigation of the relationship between these variables over time, without relying on means which has limitations identified above. Similarly outcome should be

collected at multiple time points across the course of therapy to limit the possibility of any observed relationship being due to undetected processes occurring in between measurements, and develop the understanding of the relationship between adherence and alliance in predicting outcome across the course of therapy. Collecting data at multiple time points in this way will also make it possible to assess if therapists are using flexible adherence. This review also indicates that future research should consider the interaction between curvilinear adherence and alliance in predicting outcome.

When considering measures of adherence it is important that adherence to specific interventions as well as a more general theoretical approach is assessed. This will allow for the identification of 'active ingredients' in therapy but also the consideration of adherence as a common factor. This will also reduce the possibility of adherence to theory specific interventions that may be related to alliance going undetected. With regard to measures of alliance, research should be mindful of the variation in the definition and diversity of measures and also consider any overlap between the measure of adherence and alliance in terms of what phenomena they are measuring.

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Part 2: Empirical Paper

**The relationship between alliance, adherence, and attendance when
using a contingency management intervention in opiate substitution
therapy**

Abstract

Aims This study investigates whether the use of a contingency management (CM) intervention improves attendance to Opiate Substitution Therapy (OST) compared to treatment as usual (TAU). The relationship between client factors, therapeutic alliance, therapist adherence and attendance is considered.

Methods: Data from 47 participants receiving a CM intervention and OST, and 30 participants receiving OST alone (TAU) who had reached session four in the PRAISE trial were used. The CM group and TAU group were compared on levels of attendance. The relationship between client variables (demographic information, social functioning, previous treatment experience, and motivation), therapeutic alliance, therapist adherence, and attendance was investigated. The effect of the interaction between therapeutic alliance and curvilinear adherence on levels of attendance was focused on.

Results Participants receiving the CM interventions had higher levels of attendance (77%) than the TAU (41%) group. High levels of alliance were observed in the CM group. Within the CM group higher levels of alliance were associated with higher levels of attendance. No relationship between client factors and therapeutic alliance, adherence or attendance was found. Alliance did not interact with adherence to impact on levels of attendance.

Conclusions CM interventions are effective in increasing attendance in OST. It is hypothesised that the provision of an incentive promotes the therapeutic alliance and is sufficiently rewarding to increase attendance. Failure to replicate previous findings of an association between client factors and attendance, and of an interaction between curvilinear adherence and alliance effecting outcome are thought to be a

result of the short period of therapy considered, a ceiling effect in alliance, and a small sample size.

Introduction

Drug misuse is a persistent problem for society. Of an estimated 330,000 problem drug users in the England, 280,000 are believed to be opiate users (Hay, Gannon, MacDougall, Millar, Eastwood & McKeganey, 2007). Amato, Davoli, Perucci, Ferri, Faggiano and Mattick (2005) describe how opiate dependence has huge economic and social costs due to crime, unemployment, relationship breakdown and cost of law enforcement. Class A drug use, the highest classification of controlled drugs considered to be the most harmful to the individual and society, was estimated to cost society £15.4 billion in 2003/2004 (Home Office, 2008). Furthermore opiate user's mortality rate is more than 10 times that of the general population (Cornish, MacLeod, Strang, Vickerman, Hickman , 2010) with mortality rates of untreated heroin dependence estimated at 1-3% a year, half of which is attributed to overdose (Darke & Hall, 2003; Sporer, 1999).

Opiate Substitution Therapy

Although abstinence is the long term goal of treatment for opiate addiction, detoxification is recognised as a key stage to reach this goal (NICE, 2007). Opiate Substitution Therapy (OST) is recommended as the first line treatment in opioid detoxification (NICE, 2007). OST has been shown to be effective in suppressing heroin use (Amato et al., 2005), has an extensive evidence base (NICE, 2006) and is shown to be cost effective (Godfrey, Stewart, & Gossop, 2004). OST is a maintenance approach that aims to provide stability by reducing craving, preventing withdrawal, eliminating the hazards of injecting, freeing the person from preoccupation with obtaining illicit opioids, and to enhance overall function. A

substitution opioid is prescribed (typically methadone or buprenorphine) to reduce and stop illicit use.

Retention and treatment duration have been repeatedly found to be associated with drug treatment outcomes (Zhang, Friedmann, & Gerstein, 2003). OST has high attrition, with reported drop-out rates of 40% within less than 3 months (Mattick, Breen, Kimber & Davoili, 2007; Gossop, Marsden, Steward & Treacy, 2001), rising to over 50% within 6 months (Mattick, et al., 2007) and over 60% at a year (Ball & Ross, 1991).

Contingency Management

Contingency Management (CM) interventions are based on operant conditioning and involve the systematic application of behavioural consequences to promote change in behaviour (Higgins, Silverman & Heil, 2008). CM interventions have been developed to provide positive reinforcement for attendance, medication compliance and abstinence of street drugs. Petry (2006) states that CM programs typically include 3 basic components. First is the identification of a target behaviour such as attendance at a drug program or abstinence from illicit drug use . Second is the provision of an incentive when the target behaviour is achieved. Finally the incentive is withheld when the target behaviour is not achieved. Evidence from randomised control trials suggests that CM reduces attrition and illicit drug use, and increases attainment and retention of abstinence (NICE 2007).

CM is identified as having the potential to increase and extend the benefit of OST and is recommended for UK implementation (NICE, 2007). However, there is a need to generate evidence about the feasibility, acceptability and clinical and cost effectiveness of CM interventions in the UK NHS drug treatment setting (NIHR, 2012). Furthermore NICE (2007) recommends that research should focus on specific

components of the program. This will develop the understanding of the process of change and ‘active ingredients’ of contingency management. The current study aims to address this question by considering the relationship between contingency management, attendance for treatment, client factors and therapy process variables. Specifically, therapeutic alliance and therapist adherence will be considered.

Therapeutic Alliance

Although various definitions exist, the term therapeutic alliance refers to the strength and quality of the relationship between the client and therapist (Horvath, 2001). Cahill et al, (2005) identify five dimensions; bond, partnership (agreement on tasks of therapy and shared goals), confident collaboration, openness to disclose and reveal personal material, and client initiative (the client taking responsibility for the direction of therapy).

Alliance has been found to be consistently associated with outcome in various types of psychotherapy (Loeb et al., 2005) and a number of meta-analyses report a significant association between alliance and outcome in individual psychotherapy (Horvath & Symonds, 1991; Horvath, Del Re, Fluckiger & Symonds, 2011; Martin, Garske, & Davis, 2000; Horvath & Bedi, 2002). Reviewing the substance misuse literature Meier, Barrowclough, and Donmall, (2005) report that alliance is a consistent predictor of engagement and retention. Meier et al. (2005) identify a number of client factors that predict a better therapeutic alliance in substance misuse treatment including; motivation, coping strategies for cravings, social support and a secure attachment style.

There is a lack of empirical data regarding the therapeutic alliance in contingency management interventions but Petry (2006) suggests that providing

reinforcement may help to strengthen the therapeutic alliance. However, McQuaid, Bowden-Jones and Weaver (2007) highlights concerns that the use of incentives has the potential to damage the relationship between staff and clients.

These findings indicate that it is important to consider the role of the therapeutic alliance when considering the efficacy of contingency management interventions reinforcing attendance.

Adherence

Adherence measures are used to assess the degree to which therapists are delivering the specified techniques of an intervention (Webb, DeRubeis & Barber, 2010). They are used to ensure that treatment is delivered as intended and to provide information on which aspects, or 'active ingredients' of a treatment contribute to outcome. Despite the increasing importance attributed to adherence in the therapeutic outcome literature, a recent meta-analysis reports no significant relationship between adherence and outcome (Webb et al., 2010) in individual psychological therapy. In the substance misuse field findings are also unclear, one study report a positive relationship between adherence and outcome (Hogue et al .2008), another reports a negative relationship (Barber et al., 2006) and some studies report no relationship (Barber et al.m 2008; Gibbons et al., 2010).

Adherence, alliance and outcome

While some studies have investigated the effects of adherence and alliance on outcome independently, there are few studies investigating the interaction between adherence and alliance and their relationship to outcome. Those that do indicate that it is important to consider curvilinear adherence (Kember, 2013). Investigating the interaction between curvilinear adherence and alliance allows for the consideration

of a non-linear relationship and how varying levels of adherence may interact with different levels of alliance.

Results from three studies in the substance misuse field suggest a relationship between curvilinear adherence and alliance, and outcome. These studies indicate that in the context of a high alliance, adherence had no impact on outcome (Barber et al., 2006; Gibbons et al., 2010), or that low adherence was most effective (Barber et al., 2008). Whilst in the context of low alliance, moderate adherence was best (Barber et al., 2008; Barber et al., 2006). This may reflect therapists using a therapeutic model flexibly, using strategies to build the alliance whilst remaining largely adherent to the theory specific interventions. These findings indicate that it is important to consider the interaction between adherence and alliance and their relationship with attendance in contingency management interventions.

Client factors

A number of client factors have been identified as predictors of retention in OST including social stability (being married, employed and having fewer prior arrests), previous treatment experience, and motivation for treatment (Simpson & Joe, 1993; Joe, Simpson, & Broome, 1998;). Frequency of drug use and age has also been found to be associated with outcome in OST. Simpson, Joe, and Rowan-Szal (1997) found that older patients had better outcomes with regard to drug use, alcohol use and criminal behaviour. The authors also reported that lower frequency of opiate use was associated with better outcomes. Similarly McLellan et al. (1994) report that severity of opiate use prior to treatment predicted substance use at follow up. Simpson et al. (1997) also suggest it is important to consider several other client factors including ethnicity and gender.

Aims of the current study

In order to enhance treatment outcomes in substance misuse, further research focusing on patient attributes and therapeutic process is needed (Simpson et al., 1997). This study aims to investigate the relationship between adherence and alliance, client factors and attendance in contingency management interventions in OST. This will begin to develop an understanding of the therapeutic processes in contingency management interventions in OST. It will also begin to address a more general gap in the literature as to how the interaction between adherence and alliance may be associated with outcome.

The current study uses data from the on-going Positive Reinforcement targeting Abstinence In Substance misuse (PRAISE) trial; a National Institute of Health Research (NIHR) funded trial which aims to develop the UK evidence base of Contingency Management (CM) in Opiate Substitution Therapy (OST). It aims to assess the acceptability, feasibility, clinical and cost effectiveness of CM to improve treatment attendance and abstinence from street heroin. It uses a cluster randomised design to compare 3 arms; Treatment As Usual (TAU) and two 12 week contingency management programmes targeting treatment attendance and abstinence of opiates respectively. Recruitment into the trial is on-going. The current study uses data from the first four treatment sessions to investigate the effect of CM interventions on attendance and explore the relationship between client factors and therapeutic process variables. During the first four sessions reinforcement is given for attendance in both treatment arms. Clients are not reinforced for abstinence until the fifth session (for further details of the interventions see NIHR, 2012).

The current study will investigate whether the use of contingency management interventions in the PRAISE trial is associated with increased

attendance. Client factors previously found to be associated with retention in OST including social functioning, previous treatment experiences and motivation for treatment will be investigated for an association with attendance. The current study will also: a) investigate whether the level of alliance is associated with increased attendance in contingency management interventions, and; b) will build on previous research cited above to investigate the relationship between adherence and alliance in predicting attendance in contingency management interventions.

Hypotheses

1. Attendance will be higher in contingency management arms than the TAU arms
2. Client factors including social functioning, number of previous OST treatments and motivation for treatment will be associated with level of attendance
3. Higher levels of alliance will be associated with higher levels of attendance.
4. In contingency management treatment the interaction between adherence and alliance will be associated with level of attendance. When alliance is high, the level of adherence will not have an effect, or low levels of adherence will be associated with increased attendance. When alliance is low moderate levels of adherence will be associated with increased attendance.

Method

Participants

Participants in PRAISe trial

All clients starting a new OST program at all sites are being screened for eligibility for the PRAISe trial. Inclusion criteria are:

- aged >18 seeking new episode of OST treatment (not transferring from prison or another drug service)
- regular user of street heroin in preceding one month (as evidenced by self report >15/30 days in preceding month (at least 3 days a week), and all urine drug screen (UDS) in previous month positive for opiates (must have at least 1 UDS result in last month), opiate dependent (meeting ICD-10 criteria), and
- at liberty to participate in the study for 24 weeks.
- willing and able to provide informed consent. This will exclude those patients who cannot read English AND require the service of an interpreter to understand a brief oral description of the study – these patients cannot be considered to have given informed consent and will NOT be entered in to the trial.
- Willing to receive 12 week CM intervention reinforcing abstinence

Exclusion criteria include:

- pregnant or breastfeeding
- active severe mental health illness or significant cognitive impairment
- A client who has entered the trial may not re-enter.

Participants in the current study

The current study draws on a sample of 76 participants who have reached week four of the study from six sites. 47 participants were identified from four contingency management sites and 30 from two treatment as usual sites. Participants who had been discharged (n=3) or transferred (n=1) before session four and those whose research file was missing (n=2) were not included in this sample. The majority of the sample were male (79%), White British (63%), with an average age of 38 (S.D =8.94).

Power Analysis

Power analysis was informed by the work of Barber et al. (2008). The authors investigated the interaction between curvilinear adherence to Supportive Expressive Therapy and alliance in predicting change in drug use. Barber et al. (2008) found a small effect size ($r = 0.24$). Power calculation was carried out using G*Power 3 computer program (Faul, Erdfelder, Lang and Buchner, 2007), specifying alpha = 5% and desired power = 80%. The required sample size is estimated at 143. This indicates that unless effect size in the current study is considerably larger then it is unlikely to be detected in the current sample.

Ethics

Ethical approval for the PRAISe trial was granted by the National Research Ethics Service South East Coast- Surrey (Appendix C).

Interventions

Treatment as usual

Treatment as usual consists of Opiate Substitution Therapy involving the prescription of either methadone or buprenorphine and 12 weekly key work sessions.

Key work sessions include harm reduction, care planning, reviewing progress, risk assessment, brief psycho-social interventions and help addressing social problems (NIHR, 2012).

Contingency management

CM interventions consist of TAU and a contingency management intervention. Timely attendance is the target behaviour which is reinforced using a £10 supermarket voucher as an incentive. The PRAISe protocol states that CM interventions should be delivered using an empathic and positive approach which rewards desired behaviours and is neutral to undesired behaviours (NIHR, 2012). During the intervention target behaviour and incentives should be clearly identified, and an explicit link made between the receiving the incentive and achieving the target behaviour. When a target behaviour is not achieved this should be explicitly linked to the absence of giving the incentive.

Process measures

Therapeutic alliance

Clients receiving the CM intervention are asked to rate the level of therapeutic alliance using the Agnew Relationship Measure-5 (Cahill et al, 2011). Participants are asked to indicate their level of agreement on 5 items pertaining to the therapeutic alliance on a Likert scale ranging from 1-7 yielding a total score out of 35.

Adherence to CM model

The Adherence Measure for PRAISe Contingency Management Program Attendance and Abstinence versions were used to assess therapist adherence

(Appendix D). These measures were developed by myself and Professor Steve Pilling, a principal investigator on the PRAISE trial.

The measure maps onto the PRAISE protocol which outlines a sequenced approach for the delivery of CM. This involves the therapist introducing themselves, reminding the client of the CM program and the incentive schedule and commenting explicitly on the target behaviour (timely attendance). The therapist is expected to make an explicit link between the target behaviour and receipt of the incentive and to make an appointment for next session, emphasising the importance of attendance and linking it with the incentive. For each item adherence is rated from 0-3, representing poor, adequate, good and excellent adherence. Scoring judgements are made using reference to a manual which I developed in conjunction with Steve Pilling (Appendix E). Adequate ratings are typically given when only the core aspect of the item is adhered to. Excellent ratings typically reflect all aspects of the model being adhered to including in a positive and empathic manner. Total scores are converted to a percentage. Adherence levels below 33% are considered poor, over 33% are adequate and over 66% are good.

Client factors

Socio-demographic and treatment history information

An interview schedule was administered at baseline. For the current research, age, gender, ethnicity and number of previous OST treatments is used.

Drug use

Section 2 of the Opiate Treatment Index (OTI) (Darke, Ward, Hall, Heather, Wodak, 1991) was used to assess drug use. The OTI consists of a comprehensive, standardized set of measures for the evaluation of opiate treatment. For the current

research the number of days the client used opiates in the last 30 days is used as an indication of severity of drug use. The OTI is designed to measure episodes of drug use rather than amount per occasion. This is because reports of ‘average’ use are known to under-report consumption (Gregson & Stacey, 1980) and reports based on weight and price are influenced by the current market value of the drug and purity (Darke, et al 1991).

Social functioning

Section 4 of the OTI was used to measure social functioning. This section addresses employment, residential stability, inter-personal conflict, social support and involvement in drug sub culture. There are 12 items covering these areas. Participants indicate the frequency of their difficulties on a scale of 0-4 yielding a total score out of 48 for social functioning. A higher score indicates greater impairment in social functioning. In addition, the number of times on remand, number of times sentenced to prison, and employment status was used as an indication of social functioning.

Motivation

Treatment Self-Regulation Questionnaire for Drug Abstinence was used to assess motivation. Versions of this measure have been validated in other areas of addiction and health behaviours (Levesque et al., 2007). For the current study 10 questions covering the individual’s readiness, confidence, commitment, and the importance of reducing and quitting heroin use are rated from 0-10, yielding a total score out of 40 for motivation to quit and 40 for motivation to reduce drug use. A higher score indicates a higher level of motivation.

Attendance

Attendance is defined as participants attending the scheduled session within 15 minute of the scheduled time. This is consistent with the definition of timely attendance reinforced in the contingency management intervention of the PRAISe trial. Total attendance is represented as a proportion of 1, with 1 representing 100% attendance of all available sessions.

Procedure

Client factor data was collected at baseline before the first treatment session. Participants receiving the contingency management intervention completed Agnew Relationship Measure-5 (ARM-5) at session four. In four cases the alliance measure was completed at a later session due to clinic error or non-attendance at session four. Alliance measured at session 5 was used in 3 cases. Alliance measured at session 6 was used in 1 case.

I received training in how to use the adherence measures from a principal investigator on the trial. I rated session four tapes for participants from the contingency management sites. Where session four tapes were not available, due to non-attendance or an absence of an audio recording, session 3 tapes were used. There were no tapes available for six cases.

Data analysis strategy

SPSS statistics package was used for data analysis. First descriptive statistics were examined for the independent variables for the whole sample (TAU and CM); drug use, treatment history, social functioning, and motivation. Non-parametric tests were then used to assess differences in variables between TAU and CM sites. Difference in levels of attendance between TAU and CM interventions was assessed using a Mann Whitney test to test hypothesis one.

Relationships between client factors, therapist alliance, adherence and attendance were then investigated in the sample receiving CM interventions. Multiple Imputation methods were used to aid this investigation. Multiple Imputation is a method used to handle missing data (von Hippel, 2013). Multiple imputation uses existing data values in the data set to predict values that are missing. These methods have been shown to produce unbiased estimates that are robust to violations of assumptions of normality. They have also been shown to be effective using small sample sizes and high rates of missing data (Wayman, 2003). SPSS automatic multiple imputation method was used. When using multiple imputation methods the process of imputation and analysis is run multiple times. This produces multiple databases, in this case five, and a pooled statistic.

Using the sample that received contingency management interventions descriptive statistics were examined for alliance, adherence and attendance. Spearman rho correlations were used to investigate relationships between the following continuous variables; client factors (age, previous treatment, social functioning, prison history, alcohol use, recent drug use, and motivation) alliance, adherence and attendance. Kruskal Willis and Mann Whitney tests were used to investigate the relationship between categorical client variables (employment, gender, ethnicity) and attendance. These tests were examined for a relationship between client factors and attendance to test hypothesis two. To test hypothesis three, the relationship between alliance and attendance was investigated using Spearman rho correlation and further investigated using a linear regression model.

Multiple regression analysis was used to investigate the interaction between adherence and alliance in predicting attendance. This included terms for linear and curvilinear adherence. Using curvilinear adherence allowed for the investigation of a

nonlinear relationship, and whether varying levels of adherence interacts with level of alliance to predict attendance.

Results

Descriptive statistics for whole sample (CM and TAU combined)

Means and standard deviations for client factors are presented in table 1. Participants reported a high frequency of recent opiate use in the last 30 days and 80% had received at least one OST treatment previously. Responses on the social functioning section of the OTI indicate variation in levels of dysfunction with scores ranging from four to 31. 53% of participants reported having been on remand before and 57% had received a prison sentence. 92% of the sample was unemployed. Average scores on the Motivation and Treatment Self-Regulation Questionnaire were high, indicating high levels of importance, readiness, confidence and commitment to stop and reduce drug use

Comparison of CM and TAU sites

Independent variables

Shapiro Wilk tests identified that all variables, with the exception of age and social functioning were not normally distributed. Mann Whitney and Chi Square tests indicated that the distributions of the variables across contingency management and TAU groups were not significantly different (Table 2). Due to conducting multiple correlations a more stringent significance value of $p < .01$ is used. Interpretations of correlations are guided by Cohen (1998), $r = .10$ are considered small, $r = .30$ are moderate, and $r = .50$ are large.

Table 1

Client factors for whole sample: means and standard deviations

	Mean	Standard Deviation
Previous Treatments	2.55	2.56
Remand	2.36	3.98
Prison Sentences	3.10	5.70
Last 30 days opiate use	25.36	6.07
OTI Social Functioning	17.68	6.34
Motivation to reduce drug use	34.68	6.16
Motivation to stop drug use	35.19	5.19

OTI=Opiate Treatment Index

Table 2

Comparison of variables across CM and TAU sites

Variable	Statistic
Age	$U=600.00, p=.38, r=.01$
Number of previous treatments	$U= 657.50, p=.80, r=.03$
Number of times on remand	$U=598.50, p=.59, r=.06$
Number of times prison sentenced	$U=653.00, p= .74, r=.04$
Recent drug use	$U=613.50, p=.45, r=.09$
Motivation to reduce drug use	$U= 719.00, p=.69, r=.05$
Motivation to stop drug use	$U=575.50, p=.24, p=.13$
Gender	$X^2(1, 76) = .27, p=.77$
Ethnicity	$X^2(12, 76) =11.11, p=.61$
Employment status	$X^2(3, 76)= 3.66, p=.28$

Attendance

In the CM group average attendance was 77%. In the TAU group average attendance was 48%. Mann Whitney test revealed that attendance across the four sessions was significantly higher in the contingency management group (mean rank 45.63), than the TAU group (26.95), $U= 346.50$, $p= .01$, $r=0.43$, supporting hypothesis 1.

Analysis of data from CM sample

The current study used SPSS automatic method to impute values for 13 missing alliance scores and 3 missing adherence scores. Correspondingly values were also imputed for 3 missing curvilinear adherence values, 13 missing values representing the interactions between linear adherence and alliance and 13 missing values representing the interaction between curvilinear adherence and alliance.

Attendance, alliance and adherence

On average participants receiving CM attended 77% of sessions (Mean=.77, S.D=.30). High levels of alliance were reported (M= 34, S.D. 2.01). This high level of alliance and small standard deviation suggests a ceiling effect. Average adherence was 41% indicating adequate levels of adherence (Mean= 0.41, S.D 0.15). These means and standard deviations are derived from the original sample. Multiple Imputation in SPSS methods does not produce a pooled standard deviation. Pooled mean levels of alliance were the same as those reported for the original sample to the nearest whole number. Pooled levels of adherence were the same as those reported for the whole sample to two decimal points.

Relationships between variables

Multiple Spearman rho correlations were used to investigate relationships between continuous variables (Table 3). Differences in levels of alliance, adherence

and attendance based on categorical variables were assessed using Mann Whitney and Kruskal Wallis tests (Table 4). There were no differences in alliance, adherence or attendance based on categorical variables. There were no significant associations between any of the client factors and alliance or adherence. There were no significant correlations between client factors and attendance; hypothesis two was not supported

Relationship between alliance and attendance

A large correlation was found indicating that higher levels of alliance were associated with increased attendance, $r(45)=.58, p<.0001$, supporting hypothesis three. As a precautionary measure 3 cases which had standard deviations higher or lower than 2.5 were then removed. A correlation for these selected cases produced essentially the same results $r(42)=.58, p < .0001$.

A linear regression model and standard diagnostic statistics⁹ were used to further investigate the relationships between alliance and attendance. Diagnostic tests demonstrated that the assumptions of the regression model had been met and that individual cases were not having excessive influence on the model. Although three cases had high centred leverage values, Cook's distance values were acceptable and so there was no need to remove these cases from the model (Field, 2009). Alliance scores explained a significant proportion of variance in attendance. Using the original data, $R^2=.32, F(1, 33) = 15.29, p<.001$. All imputed models produced $R^2 >.21, F > 12$ and $p <.001$. This indicates that alliance accounts for at least 20% of the variance in attendance. A pooled statistic demonstrated that alliance significantly predicted attendance $B = 0.08, t(46) = 3.60, p<0.001$. This indicates that as alliance increases by 1 point, attendance increases 8.3%.

⁹ Durbin-Watson, Cooks Distance, Centred Leverage and Mahalanobis Distance

Table 3

Correlations between continuous variables

	Age	Previous treatment	Remand	Prison	Drug use	Social Fx	Alliance	Adherence	Motivation-R	Motivation-S	Attendance
Age		-.00	.42**	.29	-.07	-.08	.03	.19	.28	.32*	.10
Previous treatment	-.00		.19	.30*	-.10	-.01	.04	.19	-.03	-.09	-.05
Remand	.42**	.19		.85**	-.16	.03	.16	.09	-.03	-.05	.22
Prison	.29	.30*	.85**		-.22	-.02	.15	.14	-.12	-.11	.11
Drug use	-.07	-.10	-.16	-.22		.33*	-.10	-.21	-.35*	-.27	.22
Social Fx	-.09	-.01	.03	-.02	.33*		-.23	-.14	-.33*	-.47**	-.09
Alliance	.03	.04	.16	.15	-.10	-.23		-.18	.22	.29	.58**
Adherence	.19	.19	.09	.14	-.21	-.14	-.18		.07	.01	-.27
Motivation-R	.28	-.03	-.03	-.12	-.35*	-.33*	.22	.07		.86**	.22
Motivation-S	.32*	-.09	-.05	-.11	-.27	-.47**	.29	.01	.86**		.22
Attendance	.10	-.05	.22	.11	.22	-.09	.58**	-.27	.22	.22	

Remand=Number of times on remand, Previous treatments=Number of previous treatments, Prison =Number of times sentenced to prison, Drug Use= Last 30 days opiate use, Social Fx=Social functioning section of Opiate Treatment Index, Alliance= Agnew Relationship Measure- 5 total, Adherence = The Adherence Measure for PRAISE Contingency Management Program, Attendance=proportion of sessions attended, Motivation R= Motivation to reduce opiate use total of Treatment Self-Regulation Questionnaire for Drug Abstinence, Motivation S= Motivation to stop opiate use total of Treatment Self-Regulation Questionnaire for Drug Abstinence, * $p < .05$, ** $p < .01$

Table 4

Differences in alliance, adherence, and attendance based on categorical variables

	Alliance	Adherence	Attendance
Ethnicity	$X^2(10, N= 34) = 7.60, p=.67$	$X^2(12, N= 44) = 15.78, p=.20$	$X^2(12, N= 47) = 6.14, p=.89$
Employment	$U= 44.00, p=.30, r=.017$	$U=41.5 p=.86, r=.03$	$U= 65.00, p=.24, r= 0.17$
Gender	$U= 56.00, p=.35, r= .16$	$U=127.5, p=.61, r=.07$	$U=94, p=.037, r=0.34.$

Relationship between alliance, adherence and attendance

A multiple linear regression was used to investigate the interaction of alliance with both linear and curvilinear adherence predicting attendance. The model was not significant for the original data, $R^2=.05$, $F(2,31) = .82$, $p = .45$. This indicates that neither the interaction between linear adherence and alliance ($B = -.03$, $t(2, 46) = -.65$, $p = .53$) or the interaction between curvilinear adherence and alliance ($B = .02$, $t(2, 46) = .46$, $p = .65$) is associated with attendance. Similarly, none of the imputed models were found to be significant. Hypothesis 4 has not been supported.

Discussion

This study aimed to investigate the relationship between client factors, alliance, adherence and attendance in the first four sessions of a contingency management intervention using data from the on-going PRAISE RCT. Participants in the current sample reported frequent drug use over the last 30 days, and also indicated varying levels of social dysfunction and high levels of motivation to reduce and quit illicit opiate use. Variables were equally distributed across CM and TAU groups indicating that randomisation was effective and significant findings are unlikely to be due to systematic differences between CM and TAU samples.

Levels of attendance were significantly higher in contingency management interventions compared to treatment as usual. This indicates that the contingency management interventions are effective in increasing level of attendance to OST. CM has previously been found to improve retention in OST (Dutra, Stathopoulou, Basden, Leyro, Powers, & Otto, 2008) which is particularly important as retention has been shown to be associated with improved outcomes (Zhang et al., 2003).

This study did not replicate previous findings of an association between alliance and client variables such as social support and motivation. This may be due to the ceiling effect found in the measurement of alliance in this trial. Similarly this study did not replicate findings of an association between attendance and client factors such as social stability, previous treatment and motivation. This may be due to the number of sessions observed. Investigating the relationships between client background variables and retention Simpson and Joe (1993) used a sample of patients who had completed 2 months treatment. It is possible that an association between client factors and attendance may not become apparent until further into therapy.

High levels of alliance were observed in contingency management interventions which supports the theoretical position that providing reinforcement helps to strengthen the therapeutic alliance. This is particularly important given that this client group is considered difficult to engage and that the position of a drug therapist may be somewhat different to in other types of therapy. Specifically, the educational aspect of a drug therapist's job, for example highlighting the unwanted side effects of continued illicit drug use (Millman, 1986) and sometimes being in the position of restricting access to drugs (Carroll, 2005), can be problematic for the therapeutic alliance.

Further investigation revealed that higher levels of alliance were associated with increased attendance. This indicates that that having a strong therapeutic alliance can further improve attendance in addition to providing an incentive. It could be that the alliance has a direct impact on attendance, that alliance itself is a positive reinforcer and increases attendance. However, individuals who have attended more sessions will also have received more contingency management

incentives. It may be that being given more supermarket vouchers by the therapist results in a more positive view of the relationship.

Average levels of adherence were found to be adequate and were not associated with any other variables including attendance. This indicates that the level of adherence to the CM model does not have an impact on levels of attendance. It is of note that even in cases of poor adherence the incentive was appropriately given or withheld. It may be that the incentive itself is sufficiently high and rewarding. The incentive may constitute the ‘active ingredient’ of the intervention whilst other aspects, such as commenting on the date and using explicit verbal praise are less important.

No association was found between adherence and alliance supporting previous findings that adherence to a model does not negatively impact on the therapeutic alliance (Kember, 2013). There was no interaction between adherence and alliance to predict attendance. This is likely to be due, in part, to a ceiling effect in alliance. Investigating curvilinear interactions allows explorations of how varying levels of adherence may have different relationships with outcome depending on the level of alliance. When alliance is uniformly high there is unlikely to be an interaction. Previous research suggests that when alliance is high, the level of adherence does not impact on outcome (Barber et al., 2006; Gibbons et al., 2010) which could be being reflected in the results of this study.

Limitations

The current study is limited by a small sample size. Power analysis indicated that the sample size was not sufficient to detect the expected effect size regarding the interaction between curvilinear adherence and alliance predicting attendance.

Relationships between the variables of interest may be detected using a larger sample. The current study is also limited as it only uses data from the first four sessions of an intervention. The findings reported may not generalise or be applicable later in therapy. Furthermore relationships between the variables of interest may not become apparent until later in therapy.

As alliance and adherence were measured at session four and attendance measured across therapy no inferences about causal relationships can be made. Furthermore adherence and alliance is measured at a single time point which may not be representative of the level of these variables across the course of therapy.

There is also the question of what exactly is being measured with regard to alliance and adherence. Although frequently cited, the term alliance can be understood in different ways and commonly used measures of alliance are reported to have less than 50% shared variance (Horvath, et al., 2011). Furthermore the uniformly high levels of alliance indicate a ceiling effect which restricts the exploration of its relationship with other variables. With regard to the ‘active ingredients’ and adherence to the CM intervention, there may also be other unmeasured therapeutic techniques involved in the key work session that are impacting on outcome. It is also important to consider the relevance of attendance as an outcome. Although it is important to address the high attrition and lack of attendance in OST, the key outcome in any therapy for substance use disorders is reduced illicit drug use which has not been addressed in the current study.

Future research

Future research should address the issue of power using a greater number of participants. Using a longer period of therapy with multiple measures of alliance and

adherence will provide an opportunity to see if a relationship between client factors, adherence, alliance and outcome develop over the course of therapy. This will also provide information on the temporal relationship between variables and allow inferences about causality to be made.

Future research should investigate the relationship between attendance and a reduction in illicit drug use in contingency management interventions. Furthermore research should investigate the relationship between the variables of interest in the current study with reduced illicit drug use as the primary outcome measure. It is of note that when completed, the full PRAISE dataset will be able to address these limitations.

Finally although the ARM 5 has acceptable psychometric properties and converges with the full ARM (Cahill et al., 2011), future research should consider using the full arm in order to maximise the opportunity to detect variability in levels of alliance and avoid a ceiling effect. A further alternative would be to use an observer measure of the alliance, although this is of course more labour intensive.

Conclusion

This study demonstrates that contingency management interventions are efficient in increasing attendance in OST over the first four sessions of therapy. Previous findings of an association between client factors and attendance were not replicated in the current study. It is suggested that this is due to differences in measurement and the length of treatment being considered. Alliance was found to have a significant association with increased attendance. It is suggested that observed high levels of alliance are a result of increased attendance and receipt of incentives. The previous finding of an interaction between adherence and alliance predicting

outcome was not replicated in the current study. It is suggested that this is due to sample size and a ceiling effect in alliance. It could also be that levels of adherence do not impact on outcome in conditions of high alliance as has been demonstrated in previous research. It is argued that the results indicate the basic fundamental part of the CM intervention- the incentive- promotes the therapeutic alliance and is sufficiently high and rewarding to increase attendance. Future research should aim to address the identified limitations, and in particular investigate the relationship between alliance, adherence and attendance over a longer period of therapy using measurements at multiple time points and reduction in illicit drug use as an outcome.

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Part 3: Critical Appraisal

**Limitations of common and specific factors research and
the ethical and moral considerations of using incentives in
healthcare**

Introduction

The literature review and empirical paper focus on the relationship between common factors such as the therapeutic alliance, and specific factors such as adherence, in relation to therapeutic outcome. Despite this focus there has been little opportunity to explore the debate between common and specific factors in the psychotherapy literature (DeRubeis, Brotman & Gibbons, 2005; Messer & Wampold, 2002). The first section of this critical appraisal highlights some of the key limitations of the research into alliance as a common factor, and specific factors as measured by adherence.

Another area relevant to the empirical paper is the ethical and moral considerations of using incentives in health care. The second section of this critical appraisal offers a brief description of some of the concerns about contingency management (CM) and some of the implications for research and clinical practice are discussed.

Section 1: Common and specific factors

Section 1 will first consider some of the limitations of the ‘common factors’ research. Common factors are those variables that are present in more than one form of therapy (Castonguay, 1993) for example the therapeutic alliance, a healing setting and education. This section will focus in particular on the therapeutic alliance. The way in which study design can affect results will be highlighted. It is stressed that caution should be exercised when making generalisations about the relationship

between common factors and outcome from one type of therapy or patient group to another.

Next, research into 'specific factors' will be considered. Specific factors are those variables that represent techniques used by a therapist (Castonguay, 1993). Castonguay and Holtforth (2005) explain further that the term specific factors refer to theory specific techniques prescribed for a particular therapy. The limitations in the literature and difficulty with implementing research into this area are highlighted, which it is argued could account for the lack of consistent findings regarding the relationship between specific factors and outcome.

Common factors

DeRubeis et al. (2005) describe how numerous findings have been used to support the claim that benefits of psychotherapies can be attributed to common factors. In particular, Luborsky's (2002) meta-analysis finding equivalent outcomes from different psychotherapies has led to the conclusion that common factors are responsible for clinical improvement. Considering common factors such as placebo effects, working alliance, and therapist allegiance, Messer and Wampold (2002) conclude that such factors account for a much larger proportion of variance in outcome than specific factors.

DeRubeis et al. (2005) argue that the specific effects of psychotherapies may be substantially stronger than is widely believed. The authors go on to suggest that it is entirely possible that two treatments each work by specific and different means to effect outcome, resulting in equivalent benefit. Findings of equivalence may also be due to studies comparing active treatments to control groups using small samples, and therefore being underpowered (Jensen, Weersing, Hoagwood, & Goldman,

2005). There are methodological criticisms of studies that report findings of equivalence, such as problems associated with using meta-analyses, and issues of measurement, which call into question the conclusions that are made about common factors.

Beutler (2002) criticises Luborsky's (2002) analysis, which is based on collapsing 100 different types of patient into one group and 400 types of psychotherapy into six groups. Beutler (1979) questions the legitimacy of collapsing groups in this way as it assumes uniformity of patients and therapies. Such analysis does not allow for consideration that personality and pathology characteristics may determine response to treatment. Beutler (2002) identifies that patients with different diagnoses respond differently to different treatments. For example, particular therapies are associated with positive outcome for specific anxiety disorders whilst patients with depression respond similarly to many different treatments. Beutler (2002) notes that the Luborsky analysis is heavily loaded with depression studies which could have affected the results. Similarly Beutler (2002) criticises the assumption that theoretically similar therapies (on which Luborsky's categorisation is based) are functionally similar and that this assumption does not allow for consideration of differential effects of functionally different therapies.

Beutler (1979) presents an analysis that divided patients by personality, problem complexity and severity, and divided treatments into groups of procedures. This analysis found a number of differential effects of treatment. For example, Beutler (1979) found insight therapy to be more effective than behavioural therapy for patients who were highly 'reactive'. The term 'reactive' describes patients who are likely to resist external influences to their autonomy. Behavioural therapy was found to be more effective than insight therapy in patients who were less 'reactive'.

Beutler's (1979; 2002) comments illustrate the difficulties with interpreting the results from meta-analyses on which the evidence for common factors, particularly the alliance, is largely based on. Horvath and colleagues (Horvath & Bedi, 2002; Horvath, Del Re, Fluckiger, & Symonds 2011; Horvath & Symonds, 1991) meta-analyses are frequently cited as demonstrating the impact of alliance across psychotherapies. However, meta-analyses can over simplify matters relying on arbitrary decisions about categories. These decisions about categories and study selection procedures can introduce bias (Ehlers et al., 2010) which Beutler (2002) has demonstrated can significantly affect the results and conclusions made.

There are further methodological considerations when interpreting results from meta-analyses. In particular, concluding equivalence from different comparison studies reporting no difference can be misleading. Comparisons of two effective therapies may find a null result. Similarly comparisons of two ineffective therapies may find a null result. This of course does not mean that the findings of no difference in both such comparison studies indicate that all therapies are equivalently effective (Ehlers et al., 2010).

DeRubeis et al. (2005) highlight further difficulties when using meta-analyses, criticising the Horvath et al. (2011) meta-analysis stating that because it included studies that involved interventions from a variety of orientations, the relationship between alliance and outcome in specific types of therapy had not been addressed. Consistent with this criticism, studies that focus on the alliance-outcome relationship in a specific therapy have yielded inconsistent results. This inconsistency has led to the argument that the influence of alliance on outcome may in fact be different across different types of therapy (Gaston, Thompson, Gallagher,

Cournoyer, & Gagnon, 1998; Safran & Wallner, 1991 as cited in DeRubeis et al., 2005).

In addition to the problems identified when using meta-analysis (i.e. problems with defining categories, comparison studies of effective therapies producing null results, and relationships between alliance and specific types of therapy being neglected) it is of note that the correlations reported by meta-analyses investigating the relationship between alliance and outcome are small (DeRubeis et al. 2005). This not only raises questions about the strength of the association between alliance and outcome but also the question of what else is responsible for therapeutic improvement.

There are also general limitations in the alliance-outcome research literature which meta-analyses draw on. Alliance is usually assessed during treatment and then correlated with pre-treatment and post treatment scores. Therefore, alliance-outcome correlations could be due to the influence of prior symptom change on the quality of alliance (Webb, Auerbach, & DeRubeis. 2012). Furthermore as Horvath et al. (2011) notes, the ambiguity of the definition of alliance has consequences for the tools developed to measure it. The Horvath et al. (2011) meta-analysis is based on studies that use over 30 different measures of alliance. Although two thirds of the papers use '4 core measures', as mentioned in the literature review, even these have a shared variance of less than 50% indicating that they are measuring somewhat different constructs. Horvath et al. (2011) emphasises that what is known of the relationship between alliance and outcome is based on the diverse instruments used to measure it. Given these limitations it is suggested that one should be cautious when interpreting results from studies into common factors such as the alliance

Specific factors

The degree to which therapists are delivering theory specific techniques in the manner that they were intended is referred to as therapist adherence. Research investigating the impact of specific factors considers correlations between levels of adherence and outcome in psychotherapy. Webb, DeRubeis and Barber (2010) conducted a meta-analysis and conclude that adherence has little impact on outcome. However there are a number of factors that should be considered with regard to such findings.

Firstly, the Webb et al. (2010) meta-analysis included studies that involved a variety of interventions in numerous contexts. It is possible that adherence is related to outcome in some contexts, but not others. Therefore it may not be sensible to conduct a meta-analysis which aggregates effect sizes of these different studies. Similar to the criticism of common factors research, one should exercise caution when making generalisation about the relationship between theory specific interventions and outcomes from one type of therapy or patient group to another.

There are a number of limitations in the research that Webb et al. (2010) draws on that should be considered when making conclusions about the results. Ratings of adherence are usually collected early in treatment and correlated with outcomes collected a considerable amount of time later. Therefore, any relationship between adherence and outcome may be overshadowed by processes that occur between measurement of adherence and measurement of outcome (Webb et al., 2010).

Another issue is that often analysis investigating the relationship between adherence and outcome is based on mean scores. It may be that particular

interventions captured by the measures are associated with improved outcome, whilst others are not. Such associations would not be detected by using a mean score (Webb et al., 2012). This is extremely important. Measures of adherence often include a number of items reflecting a variety of interventions within a therapeutic modality. Not only will a mean score fail to detect associations between a specific intervention and outcome, there are also likely to be other theory specific interventions being used that are not being measured but are having an impact on outcome. Therefore making conclusions about the relationship between a particular type of therapy and outcome based on adherence scores may be misleading and should be restricted to only the particular theory specific technique being measured. This is particularly relevant given that several techniques have been identified as common to many approaches (Castonguay & Holtforth, 2005), for example goal setting and providing a formulation.

It is emphasised that there is a relative lack of research into the impact of specific factors and the adherence-outcome relationship. For example, Webb et al (2010) found no previous meta-analyses investigating the adherence outcome relationship whilst there are many meta-analyses focusing on the alliance-outcome relationship cited above. The lack of research investigating adherence-outcome relationships may be partly attributable to the focus on investigations into common factors, rather than specific interventions, fuelled by the dodo bird verdict (Webb et al., 2010). In addition, techniques required to gather adherence data, such as rating tapes of therapy sessions, are more labour intensive than self-report techniques employed to collect data on therapeutic alliance.

Another factor that is important to consider is that studies that collect adherence data also often take care to train therapists in the intervention being

investigated resulting in high levels of adherence with little variability. This high level and restricted range would result in smaller effect sizes than would be expected to be observed from a broader population of therapists.

It is suggested that one should be cautious when making generalisations about the association between specific factors and outcome based on adherence-outcome studies. This suggestion is based on the limitations in the research and the fact that measures of adherence will fail to measure all specific factors that may be associated with outcome

Conclusion and recommendations

Section 1 of this critical appraisal suggests that the limitations regarding the use of meta-analyses, the methodological limitations of studies investigating common factors, and issues of measurement mean caution should be exercised when considering research findings regarding common factors such as alliance. It is likely that alliance has a different relationship with outcome in different types of therapy with different types of patients. This has implications for future research. It is important that effectiveness studies continue to incorporate measures of alliance into study design. This will help to develop the understanding of the relationship between alliance and outcome using different types of therapy with different groups of patients. However, this appraisal also indicates that there is significant variation in how alliance is conceptualised and measured. Horvath (2006) states that there is a need for clarification on the elements that make up the therapeutic alliance. Until such clarification is achieved it is difficult to give recommendations, guidance or training to a therapist with regard to the therapeutic alliance (Horvath, 2004 as cited in Horvath, 2006). Therefore whilst the debate continues as to what constitutes the therapeutic alliance, researchers may wish to examine the measure of alliance used

more closely to consider what aspects of the ‘alliance’ are being assessed, and how these specific aspects relate to outcome.

With regard to specific factors this critical appraisal argues that although research does not consistently report an association between adherence and outcome there are a number of methodological limitations that should be considered when interpreting such findings. A particular limitation is that in any given therapy there are likely to be unmeasured specific factors that could be contributing to outcome that are not detected by the measure of adherence. Future research should therefore continue to incorporate measures of adherence to advance the understanding of how theory specific interventions contribute to outcome in different therapies and different patient groups. Finally given the ambiguity in the definition of alliance and limitations of the measures of adherence, researchers should be cautious when making generalisations from their findings about ‘adherence’ and ‘alliance’. It is also noted that delineating the active components of treatment, whether they be common or specific factors, is a complicated process. As Horvath (2006) suggests, it may be that “the concept of treatment is too high a level of aggregation to serve as a discriminatory notion to determine what is effective in therapy” (pp. 261).

Section 2: Ethical and Moral Considerations of Contingency Management

This section focuses on some of the moral and ethical concerns about the use of health incentives and contingency management (CM) interventions. How these concerns impact on clinician’s views and the adoption of CM into clinical practice is

considered. It is suggested that it is important to consider these factors when designing a clinical trial and attempting to implement CM interventions.

CM interventions in substance use are typically implemented to retain service users in treatment and to foster drug abstinence. CM interventions involve identification of a target behaviour such as abstinence which is reinforced with an incentive when it occurs, and the incentive is withheld when the target behaviour does not occur (Petry, 2006). Often a voucher such as that used in the PRAISE trial detailed in the empirical paper, is used as an incentive.

A commonly cited concern regarding the use of incentives in health care is that it is coercive, paternalistic and infringes on an individual's autonomy (Halpern, Madison & Volpp, 2009). Such an argument has ramifications for the ethics of implementing CM in a health care setting such as the NHS. These arguments may also affect a clinician's attitudes to CM and its incorporation into clinical practice.

Concerns are also expressed that CM interventions discriminate against the poorest and most vulnerable in society. Interestingly, high rates of taxation on cigarettes, which can be considered as a disincentive and punitive, and arguably disproportionately affect the poorest, have been accepted by society. Halpern et al. (2009) emphasise that incentive programs differ from disincentive interventions in that they offer more support to the disadvantaged and promote wellbeing.

Halpern et al. (2009) argues that the use of incentives rather than being coercive can in fact be considered an example of libertarian paternalism. This is the idea that private and public institutions encourage people to make decisions that will improve their lives without restricting freedom of choice. Thaler and Sunstein (2003) state that it is inevitable that organisations make decisions and take action that will

impact on people's choices. Examples of such decisions range from implementing an opt out organ donor scheme, to removing unhealthy food and snacks from school cafeterias. Thaler and Sunstein (2003) suggest that taking actions that impact on people's choices does not necessarily equate to coercion. Individuals will often make choices that they would not make if they had full information, no restriction on their cognitive abilities and sufficient will power (Thaler & Sunstein, 2003). Libertarian paternalism and providing an incentive does not limit the choices or options available to the individual. Instead it helps guide them towards making better choices, as judged as better by themselves (Halpern et al., 2009). Halpern et al. (2009) develops this argument explaining that people possess varying degrees of ability to change their behaviours that impact on their health. These abilities are affected by environmental, economic and genetic factors, and society has a responsibility to help people who encounter such barriers.

In other areas where libertarian paternalism is exercised, involving a change of the 'default' position, for example changing an organ donation system from opt in to opt out (as will be implemented in Wales in 2015) one could argue that an individual's freedom of choice is being restricted as decisions are not consciously thought through (Rajan, 2012). This critical appraisal suggests that the same argument is not as applicable in the case of CM for opiate users in the PRAISE trial. Participants in the PRAISE trial are voluntarily attending an Opiate Substitution Treatment (OST), which has an explicit aim of reducing illicit drug use. Therefore, the accepted goal of reducing illicit opiate use has been consciously considered by the individual and CM supports them in reaching this goal, rather than being coercive.

Clinicians can hold ethical concerns and negative views about CM which can effect the uptake of CM (Sinclair, Burton, Ashcroft & Priebe, 2011). Kirby, Benishek, Dugosh and Kerwin, (2006) identifies a concern amongst clinicians that CM does not address the underlying issues that lead to drug addiction. Rash, Petry, Kirby, Martino, Roll, and Stitzer, (2012) conducted a web based study to develop a measure assessing beliefs about CM and to examine the relation of these beliefs to clinician characteristics. The authors identified a number of other commonly held negative beliefs about CM that could affect its uptake. These included the cost of the intervention and a concern about what happens after the withdrawal of the incentive. Rash et al. (2012) also highlight an attitude that the empirical basis of CM is not relevant to everyday clinical populations. Attitudes toward treatment manuals, evidence based practice (Henggeler et al., 2008) and traditional views about treatment can be barriers to the adoption of a new treatment like CM (McCarty et al. 2007). Another concern held by clinicians is that patients will use the incentive gained to obtain more drugs (Petry, 2006), although research suggests that when participants receive incentives during drug abuse research they are able to use these payments in a responsible and safe manner (Festinger et al. 2005).

Rash et al. (2012) states that the sorts of negative beliefs described above reflect a limited understanding of CM. Cameron and Ritter (2007) surveyed drug practitioners and found that their attitudes were based on a cursory understanding of CM. Practitioners often used an over-inclusive definition of CM that involved providing positive reinforcement on an ad hoc basis as opposed to on a structured contractual basis.

Roll, Madden, Rawson, and Petry, (2009) identified that a lack of familiarity with CM and its empirical support may affect its uptake . Cameron and Ritter (2007)

found that practitioners in their study changed their ideas about CM over the course of the study as a result of being provided with written information. Similarly Rash et al. (2012) identified that having received training in CM was associated with less endorsement of barriers to the uptake of CM. These findings indicate that providing information and training is vital to address clinician's understanding of CM which can affect their attitudes and perspectives and likelihood of using CM.

Conclusions and recommendations

It is argued in section 2 of this critical appraisal that the use of CM interventions in substance misuse can be considered libertarian paternalism as opposed to coercion. These interventions serve to offer more support to the disadvantaged and to promote their wellbeing, and help people to reach their own goals.

The literature reviewed above identified that clinicians may have concerns regarding CM; e.g. what will happen when the incentive is withdrawn, what the incentive may be used for, that it may not address the underlying issues causing drug addiction and that it is coercive. The literature suggests that negative views held by clinicians may be due to a cursory understanding and that providing information and training can effect clinicians attitudes and their likelihood of using CM. This has implications for clinical research investigating the use of incentives. It may be important to survey therapists involved in a clinical trial on their attitudes towards CM. Negative attitudes could have an impact on their adherence to the CM model and could also influence the therapeutic alliance. As the research shows that a cursory understanding of CM can lead to negative views of CM, it is important that therapists receive sufficient training, information and on-going supervision to address the perceived barriers to using CM. It is likely that participants may also

hold negative views about CM. Providing therapists with a comprehensive understanding of the principles of CM may empower them to communicate this understanding to participants as necessary, and increase participants' motivation to engage with the program.

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Appendix A: Inter rater reliability information

Inter Rater Information

Study	Inter- rate reliability information
Strunk et al. (2010)	2 trained raters rated all sessions. *
Webb, et al. (2012b)	3 rd session randomly assigned to 5 trained raters. Each tape rated independently by 2 raters. *
Minonne (2008)	8 trained raters were used to rate adherence. 4 videotapes per patient were rated, 2 from sessions early in treatment and 2 from sessions late in treatment. 2 raters rated each tape. ***
Castonguay et al.s (1996)	4 Trained raters. A random tape was selected from first half of therapy and rated by 3 raters. *
Strunk,et al. (2012)	50 Trained raters. First 3 sessions rated by 4 independent raters. *
Gaston and Ring (1992)	Sessions 5, 10, and 15 independently rated by two raters.*
Gaston et al. (1998)	Sessions 5, 10, and 15 independently rated by two raters. * Therapist Understanding Subscale rater agreement ranged from fair to moderate.
Bambling et al. (2006)	2 raters rated tapes for PST adherence. ***
Carroll et al. (1997)	5 experienced and trained clinicians blind to therapy condition rated an early session rated *

Hogue et al. (2008b)	7 trained raters for CBT, and 8 for MDFT were used. 2 judges rated each tape. First two sessions of therapy and 3 consecutive tapes from session 6. *** 1 random early session and one late session was coded for alliance. For CBT 71 sessions across 47 cases were coded. For MDFT 73 sessions across 67 cases were coded.
Gibbons et al. (2010)	8 trained raters rated all available sessions from 163 patients for adherence. 9 randomly selected sessions rated by all 8 raters indicated almost perfect agreement between raters
Barber et al. (2008)	For SET adherence 2 raters, expert in SET rated one randomly selected session between sessions 2-10, for each patient. ** For IDC adherence two experts rated a sample of 54 tapes from 37 patients. *
Barber et al. (2006)	2 raters, expert in IDC rated a random session between 2-10, for each patient**
Evans-Jones et al. (2009)	Adherence measures completed by therapist, typically rated at session 6.
Goldman and Gregory	1 trained rater and 1 expert independently rated adherence *** and alliance** assessed at 5 time points across therapy

Ogrodniczuk, & Piper (1999)	10 trained raters were used. 9 sessions for each patient rated for Interpretive * & Supportive*** adherence by all raters.
Gaston et al. (1994)	Trained Experienced psychotherapists Data on alliance and adherence from 3 sessions across the course of therapy was collected by two teams of 3 raters. ***
Pavio et al. (1994)	Trained raters assessed adherence in a random sample of segments from randomly selected early, middle and late sessions. Authors report 'good' rater reliability based random sample. Alliance data collected at end of each session
Liber et al. (2010)	8 trained raters used. 104 randomly selected sessions sampled from early and late sessions were coded for alliance*** and adherence*
Loeb et al. (2005)	Doctoral level Clinical Psychology Students rated sessions 6, 12, and 18 for adherence and alliance. One rater per tape. Rater reliability based on sample of 24 tapes ***

* Interclass coefficient indicate moderate to strong agreement between raters. ** Inter class coefficient indicate strong agreement between raters.*** Inter class coefficient indicate almost perfect agreement between raters.

Appendix B: Adherence, alliance and outcome measures

Alliance Measures

California Psychotherapy Alliance Scales

Marmar, C.R., Weiss, D.S., Gaston, L. (1989). Towards the validation of the California Therapeutic Alliance Rating System. *Journal of Consulting and Clinical Psychology, 1*, 46-52.

Helping Alliance Questionnaire

Luborsky, L., Barber, J. P., Siqueland, L., Johnson, S., Najavits, L. M., Frank, A. (1996). The revised helping alliance questionnaire (HAQ-II): Psychometric properties. *Journal of Psychotherapy. Practice and Research* , 5, 260-271.

The Therapy Process Observational Coding System for Child Psychotherapy—Alliance scale

McLeod, B. D. (2005). *Therapy process observational coding system for child psychotherapy – alliance scale*. Unpublished coding manual prepared at Virginia Commonwealth University.

Vanderbilt Therapeutic Alliance Scale

Hartley, D.E., & Strupp, H.H. (1983). The therapeutic alliance: Its relationship to outcome in brief psychotherapy. In J. Masling (Ed.), *Empirical studies of psychoanalytical theories* (Vol. 1). Hillsdale, NJ: Erlbaum.

Working Alliance Inventory

Horvath, A.O., & Greenberg, L.S. (1989). Development and validation of the working alliance inventory. *Journal of Counselling Psychology, 2*, 223-233.

Adherence Measures

Adherence/Competence Scale for Supportive Expressive Therapy for cocaine dependence

Barber, J. P., & Crits-Christoph, P. (1996). Development of an adherence/competence scale for dynamic therapy: Preliminary findings. *Psychotherapy Research*, 6, 81-94.

Adherence/Competence Scale for Individual Drug Counselling

Barber, J. P., Mercer, D., Krakauer, I., & Calvo, N. (1996). Development of an adherence/Competence Rating Scale for individual drug counselling. *Drug and Alcohol Dependence*, 43, 125-132.

The Australian treatment adherence protocol for the FRIENDS treatment

Barrett, P. M. (1999). *FRIENDS Support Material*. Unpublished manuscript. Australia: Queensland.

Collaborative Study Psychotherapy Rating Scale

Hill, C.E., O'Grady, K.E., Elkin, I. (1992). Applying the Collaborative Study Psychotherapy Rating Scale to rate therapist adherence in cognitive-behavior therapy, interpersonal therapy and clinical management. *Journal of Consulting and Clinical Psychology*, 60, 73-79.

The Coding System of Therapist Feedback

Goldfried, M. R., Newman, C. N., & Hayes, A. M. (1989). *The coding system of therapeutic focus*. Unpublished training manual, State University of New York at Stony Brook.

Emotion Focused Therapy Adherence Checklist

Paivio, S. C., & Nieuwenhuis, J. A. (2001). Efficacy of emotion focused therapy for adult survivors of childhood abuse: A preliminary study. *Journal of Traumatic Stress, 14*, 115–134.

Interpretive and Supportive Techniques Scale

Ogrodniczuk, J.S., & Piper, W.E. (1999). Measuring therapist technique in psychodynamic psychotherapies. *Journal of Psychotherapy Practice and Research, 8*, 142-154.

Inventory of Therapeutic Strategies

Gaston, L., & Ring, J. M. (1992). Preliminary results on the Inventory of Therapeutic Strategies (ITS). *Journal of Psychotherapy Research and Practice, 1*, 1-13.

Measure of 'working relationship'. Therapist self report.

Ogrodniczuk, J.S., & Piper, W.E. (1999). Measuring therapist technique in psychodynamic psychotherapies. *Journal of Psychotherapy Practice and Research, 8*, 142-154.

The Minnesota Therapy Rating Scale

DeRubeis, R. J., Hollon, S. D., Evans, S. D., Evans, M. D., & Bemis, K. M. (1982). Can psychotherapies for depression be discriminated? A systematic investigation of cognitive therapy and interpersonal therapy. *Journal of Consulting and Clinical Psychology, 50*, 744–756.

Problem Solving Therapy Adherence Scale

Bambling, M., King, R., Raue, P., Schweitzer, R., & Lambert, W. (2006). Clinical supervision: its influence on client-rated working alliance and client symptom

reduction in the brief treatment of major depression. *Psychotherapy Research, 16*, 317-331.

Therapist Behaviour Rating Scale

Diamond, G. S., & Diamond, G. M. (2002). Studying a matrix of change mechanisms: An agenda for family-based process research. In H. A. Liddle, D. A. Santisteban, R. F. Levant, & J. H. Bray (Eds.), *Family psychology: Science-based interventions*. Washington, DC: American Psychological Association.

The Therapy Rating Scale

Wagner, E. F., Frank, E., & Steiner, S. C. (1992). Discriminating maintenance treatments for recurrent depression: Development and implementation of a rating scale. *Journal of Psychotherapy Practice and Research, 1*, 280–290.

Yale Adherence and Competence Rating Scale

Carroll K. M., Nich C., Sifry R., Frankforter T., Nuro K. F., Ball S. A. (2007). A general system for evaluating therapist adherence and competence in psychotherapy research in the addictions. *Drug Alcohol Dependence, 57*, 225–38.

Outcome Measures

Addiction Severity Index

McLellan A. T., Kushner H., Metzger D., Peters R., Smith I., & Grissom G (1992). The fifth edition of the Addiction Severity Index. *Journal of Substance Abuse Treatment, 9*, 199–213.

Becks Depression Inventory

Beck, A. T., Steer, R. A. and Brown, G. K. (1996). *Beck depression inventory-II: Manual*. San Antonio: The Psychological Corporation.

Hamilton Depression Rating Scale

Hamilton, M. (1960). A rating scale for depression. *Journal of Neurological and Neurosurgical Psychiatry*, 23, 56-61.

Interpersonal Behaviour Scale

Piper, W. E., Debbane, E. G., & Garant, J. (1977). An outcome study of group psychotherapy. *Archives of General Psychiatry*, 34, 264-274.

Psychiatric Status Schedule

Spitzer, R. L., Endicott, J. E., & Cohen, G. M. (1967). *Psychiatric status schedule*. New York: New York State Department of Mental Hygiene.

Structured Clinical Interview for DSM

First M. B., Spitzer R. L., Gibbon M., Williams J. B.W. (1995). *Structured Clinical Interview for DSM-IV, Patient Edition*. Washington, DC: American Psychiatric Press;

Appendix C: Letter of ethical approval



Health Research Authority

NRES Committee South East Coast - Surrey

Room 12, 4th Floor West
Charing Cross Hospital,
Fulham Palace Road,
London, W6 8RF

Telephone: 020 3311 7282

27 June 2012

Prof John Strang
Professor in the Psychiatry of Addictions
South London & Maudsley NHS Trust/ Institute of Psychiatry
National Addiction Centre
12th Floor West

Dear Prof Strang

Study title: Cluster randomised controlled trial of two Contingency Management schedules targeting a) treatment attendance or b) abstinence from street heroin use in people treated for heroin dependence

REC reference: 12/LO/0910

The Research Ethics Committee reviewed the above application at the meeting held on 12 June 2012.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

1. The confidentiality there seems to be a blanket assurance and it needs to be qualified that in some cases if necessary some information will be disclosed. The committee felt that this should also be in the Participant Information Sheet and consent form.
2. The whole of the group records can not be destroyed based on one participant
3. Breakdown of group vouchers should be clarified in the Participant Information Sheet.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		18 May 2012
Investigator CV		09 March 2012
Other: CV for supervisor (Dr Weaver)		24 February 2012
Other: CV for student (Ms Poovendran)		18 May 2012
Other: Letter from funder - NIHR Letter		12 November 2008
Other: Screening Form	1	14 May 2012
Other: Attendance Form	1	14 May 2012
Other: Abstinence Form	1	14 May 2012
Other: TAU Form	1	14 May 2012
Other: Programme grant Proposal	1	29 August 2008
Participant Consent Form: SU Consent Form	1	14 May 2012
Participant Consent Form: SU Consent Form Focus Group	1	14 May 2012
Participant Consent Form: SU Consent Form Followup locator	1	14 May 2012

Participant Consent Form: Staff Consent Form Focus Group	1	14 May 2012
Participant Information Sheet: SU Information Sheet	1	14 May 2012
Participant Information Sheet: SU Information Sheet Focus Group	1	14 May 2012
Participant Information Sheet: Staff Information Sheet	1	14 May 2012
Participant Information Sheet: Staff Information Sheet Focus Group	1	14 May 2012
Protocol	1.0	16 May 2012
Questionnaire: OTI drug use (validated)		
Questionnaire: OTI social functioning (validated)		
Questionnaire: EQ-5D (validated)		
Questionnaire: SF-36 (validated)		
Questionnaire: AD-SUS (validated)		
Questionnaire: AUDIT (validated)		
Questionnaire: demographics (non-validated)	1	14 May 2012
Questionnaire: Delay discounting (non-validated)	1	14 May 2012
Questionnaire: Treatment Self-regulation (non-validated)	1	14 May 2012
Questionnaire: OTI Crime (non-validated)	1	14 May 2012
REC application	IRAS 3.4	22 May 2012
Referees or other scientific critique report		11 April 2008

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/LO/0910	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project

Yours sincerely


Prof David Russell-Jones
Chair
Email: dr.d.russell-jones@imperial.ac.uk

*Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers" [SL-AR2]*

*Copy to: Dr Timothy Weaver, Imperial College Faculty of Medicine
Ms Jenny Liebscher, South London & Maudsley NHS Foundation Trust*

NRES Committee South East Coast - Surrey

Attendance at Committee meeting on 12 June 2012

Committee Members:

Name	Profession	Present	Notes
Miss M Ayton	Infection Control Adviser	No	
Dr Julia Boyle	Director Surrey CRC/Pharmacologist	No	
Miss Elizabeth Cheshire	Consultant in Emergency Medicine	Yes	
Dr Matthew Dickinson	Consultant Anaesthetist	No	
Mrs Margaret Handyside	Lay Member	Yes	
Rev D Hobden	Senior Chaplain	No	
Dr Stephen Houston	Consultant Medical Oncologist	Yes	
Ms Wendy Jay	Lay Member	Yes	
Mrs Chrissie Lawson	Nurse Specialist	Yes	
Dr Charles Li	Consultant Physician	No	
Ms Georgina Marshall	Coordinator	Yes	
Mr Michael Morris	Lay Member	Yes	
Dr JHP Powell	Consultant Physician	No	
Prof David Russell-Jones	Professor of Diabetes and Endocrinology	Yes	
Mrs Ann Sayer	Lay Member	Yes	
Dr L Selby	General Practitioner	No	
Dr Jane Stuart	Public Health Researcher	No	

**Appendix D: Adherence Measure for PRAISE contingency
management program: abstinence and attendance versions.**

DRAFT

Adherence Measure for PRAISE Contingency Management Programme- ATTENDANCE

Rating to be made on basis of an audio recording

Please place an X in the box that best describes the nature of the interaction

	Poor 0	Adequate 1	Good 2	Excellent 3
1. Introduced self and put client at ease	No introduction and no general inquiry	Limited introduction and limited general inquiry	Clear introduction and general inquiry	Full and clear Introduction and general inquiry
2. Described the purpose of the CM intervention	No description of the intervention	Limited description of the intervention	Full description of the intervention and few, if any, elements missing	Full and positive description of the intervention, no element missing
3. Checked service users understanding and answered any questions	No attempt to check service users understanding or answer questions	Attempt to check service users understanding but no/limited answer to questions	Good check of understanding and questions fully addressed	Excellent check of understanding and questions fully addressed in a very positive manner
4. Relevant incentive schedule clearly specified:	No schedule set out	Schedule set out but limited link between incentive and attending at the agreed date and time	Schedule clearly set out and clear explicit link made between incentive and attending at the agreed date and time	Positive and encouraging manner. Schedule clearly set out and clear explicit link made between incentive and attending at the agreed date & time

ITEMS 5 and 6 to be completed when Incentive HAS been given				
<p>5. Comments positively on clients attendance at correct time</p> <p><i>Score this item double</i></p>	No comment on attendance at correct time- date or time	Limited comment on attendance at correct time-specifying time or date	Clear comment on attendance at correct time AND date	Clear and positive comment on attendance at correct time AND date
<p>6. Gives the incentive and clearly states in positive manner it is for attending on time</p>	Incentive not given	Gives Incentive with limited comment on link to attendance	Gives incentive with clear comment on link to attendance	Gives incentive and offers praise with clear comment in a positive tone on attendance.
ITEMS 7 and 8 to be completed when Incentive HAS NOT been given				
<p>7. Commented in a neutral manner on service user's attendance at incorrect time</p>	Punitive tone with or without comment on service user attendance at incorrect time	Limited comment on service user attendance at incorrect time	Neutral tone. Clear comment on service user attendance at incorrect time	Neutral tone. Clear comment on service user attendance at incorrect time. Comment to shape future behaviour.
<p>8. Withholds the incentive and clearly states this is due to the client not attending at the correct time</p>	<p>Incentive given</p> <p><i>Or</i></p> <p>Punitive Tone. Incentive not given and no link to attendance at incorrect time</p>	Incentive not given with limited link to attendance at incorrect time	Incentive not given with clear comment on link to attendance at incorrect time	Incentive not given with clear comment on link to attendance at incorrect time. Praise attendance although at incorrect time.

9. Agrees the day/date of the next test session	No time given	Time given and clearly specified	Time given and clearly specified – importance of attendance emphasized	Time given and clearly specified – importance of attendance and incentive emphasised in a positive manner
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DRAFT

Adherence Measure for PRAISe Contingency Management Programme- ABSTINENCE

Rating to be made on basis of an audio recording.

Please place an X in the box that best describes the nature of the interaction

	Poor 0	Adequate 1	Good 2	Excellent 3
1. Introduced self and put client at ease	No introduction and no general inquiry	Limited introduction and limited general inquiry	Clear introduction and general inquiry	Full and clear Introduction and general inquiry
2. Described the purpose of the CM intervention	No description of the intervention	Limited description of the intervention	Full description of the intervention and few, if any, elements missing	Full and positive description of the intervention, no element missing
3. Checked service users understanding and answered any questions	No attempt to check service users understanding or answer questions	Attempt to check service users understanding but no/limited answer to questions	Good check of understanding and questions fully addressed	Excellent check of understanding and questions fully addressed in a very positive manner

<p>4. Relevant incentive schedule clearly specified:</p> <p><i>a) Sessions 1-4: attendance and provision of a urine sample</i></p>	<p>No schedule set out</p>	<p>Schedule set out but limited link between incentive and</p> <p>attendance and provision of a urine sample</p>	<p>Schedule clearly set out and clear explicit link made between incentive and</p> <p>attendance and provision of a urine sample</p>	<p>Positive and encouraging manner. Schedule clearly set out and clear explicit link made between incentive and</p> <p>attendance and provision of a urine sample</p>
<p><i>b) Sessions 5-12: attendance and provision of a negative urine sample</i></p>		<p>attendance and provision of a negative urine sample</p>	<p>attendance and provision of a negative urine sample</p>	<p>attendance and provision of a negative urine sample</p>

Items 5, 6 and 7 to be completed when Incentive HAS been given				
5. Comments positively on clients attendance at correct time	No comment on attendance at correct time- date or time	Limited comment on attendance at correct time-specifying time or date	Clear comment on attendance at correct time AND date	Clear and positive comment on attendance at correct time AND date
6. Comments positively on clients <i>a) Sessions 1-4 providing a urine sample</i>	No comment on providing a urine sample	Limited comment on provision of required urine sample	Clear comment on provision of required urine sample. Offers praise.	Clear and positive comment on provision of urine sample. Offers praise and encouragement
<i>b) Sessions 5-12 providing a negative drug screening.</i>	No comment on providing a negative urine sample	Limited comment on provision of a negative urine sample	Clear comment on provision of a negative urine sample. Offers Praise	Clear and positive comment on provision of a negative urine sample. Offers praise and encouragement
7.Gives the incentive and clearly states in positive manner it is for attending on time and <i>a) Sessions 1-4:provision of a urine</i>	Incentive not given	Gives Incentive with limited comment on link to attendance or provision of Urine sample	Gives incentive with clear comment on link to both attendance and Urine sample	Gives incentive and offers praise with clear comment in a positive tone on link to both attendance and Urine sample

sample				
<i>b) Sessions 5-12: provision of a negative urine sample.</i>		Negative urine sample	Negative urine sample	Negative urine sample
<i>Items 8 and 9 to be completed when incentive HAS NOT been given</i>				
8. Commented in a neutral manner on service user's attendance at incorrect time and	Punitive tone with or without comment on service user attendance or	Limited comment on service user attendance or	Neutral tone. Clear comment on service user attendance AND	Neutral tone. Comment to shape future behaviour. Clear comment on both service user attendance AND
<i>a) Sessions 1-4: failure to provide a urine sample</i>	failure to provide a urine sample	failure to provide a urine sample	failure to provide a urine sample	failure to provide a urine sample
<i>b) providing a positive urine sample</i>	providing +ve urine	providing +ve urine	providing +ve urine	providing +ve urine

<p>9) Withholds the incentive and clearly states this is due to the client not attending at the correct time or</p> <p>a) Sessions 1-4: failure to provide a urine sample</p>	<p>Incentive given</p> <p><i>Or</i></p> <p>Punitive Tone. Incentive not given and no link to attendance or</p> <p>Failure to provide a urine sample</p>	<p>Incentive not given with limited link to attendance OR</p> <p>Failure to provide a urine sample</p>	<p>Incentive not given with clear comment on link to attendance AND</p> <p>Failure to provide a urine sample</p>	<p>Incentive not given. Comment to shape future behaviour. Clear comment on link to attendance AND</p> <p>Failure to provide a urine sample</p>
<p>b) Sessions 5-12: providing a positive urine sample.</p>	<p>providing a +ve urine</p>	<p>providing a +ve urine</p>	<p>providing a +ve urine</p>	<p>providing a +ve urine</p>
<p>10. Agrees the day/date of the next test session</p>	<p>No time given</p>	<p>Time given and clearly specified</p>	<p>Time given and clearly specified – importance of attendance emphasized</p>	<p>Time given and clearly specified – importance of attendance and incentive emphasised in a positive manner</p>

Appendix E: Handbook for adherence measure for PRAISe
contingency management program: Attendance and Abstinence
versions

DRAFT

**Handbook for Adherence Measure for PRAISE contingency management
program-Attendance**

In addition to individual training and supervision please use the descriptions below to aid judgments on adherence ratings.

Item 1-Introduced self and put client at ease

Poor –Key worker does not introduce themselves by name, does not mention clients name, or make general enquiry e.g. about wellbeing or recent activity in attempt to establish rapport and put client at ease

Adequate- Therapist greets client offers some general inquiry to establish some rapport and put client at ease

Good-Therapist clearly introduces themselves by name, specifies clients name. Makes some general enquiry to establish rapport or put client at ease.

Excellent-Therapist clearly introduces themselves by name, specifies clients name. Makes explicit general enquiry in attempt to establish rapport and out client at ease, appropriate follow up questions. Positive tone.

Item 2- Described the purpose of the CM intervention

Poor – No description of current session offered, no agenda set, no reference to contingency management or trial, or general aim to reduce illicit drug use

Adequate- Comments that appointment involves using an incentive aiming to help reduce illicit drug use.

Good-Comments that appointment is in addition to on-going OST treatment which involves providing incentive aiming to help reduce illicit drug use.

Excellent- Comments that appointment is in addition to on-going OST treatment which involves providing incentive aiming to help reduce illicit drug use as part of a research trial.

Item 3- Checked Service User Understanding

Poor- No attempt to check understanding of CM intervention

Adequate- Enquires about understanding and provided information but fails to address all questions fully

Good- Enquire about understanding, provides relevant information and answers all questions

Excellent- Enquires about understanding, provided relevant information, answers all questions and checks if questions have been answered satisfactorily. Positive and empathic stance.

Item 4- relevant incentive schedule clearly specified

Poor- No reference to incentive schedule.

Adequate- Comments that an incentive is given for attendance.

Good- Explains that incentive will be given for attending at agreed time. Describes incentive schedule i.e. £10 supermarket voucher for 12 weeks.

Excellent- Explains incentive will be given for attending at agreed time (or within 15 minute window immediately following agreed time). Describes incentive schedule i.e. £10 supermarket voucher for 12 weeks. Describe purposes voucher can be put to. Make clear it will be given at beginning of session

Item 5- Comments positively on clients' attendance at correct time

Poor- No comment

Adequate- Offers some comment on timely attendance. Specifies time or date. No explicit praise.

Good- Clear comment on attendance at correct time, offers some praise. Specifies time and date.

Excellent- Clear comment on attendance at correct time. Offers Praise and encouragement. Specified time and date

Item 6- Give incentive and clearly states in a positive manner it is for attending on time

Poor- Incentive not given

Adequate- Gives incentive. Makes reference to timely attendance but does not make clear explicit link.

Good- Gives incentive and makes a clear and explicit link to timely attendance. Offers some praise.

Excellent- Give incentive and makes clear explicit link to timely attendance. Offers Praise and encouragement in a positive tone.

Item 7- Commented in a neutral manner on service user's attendance at incorrect time

Poor- Talks in a punitive tone. Irrespective of whether therapist comments on attendance using a punitive tone scores 0.

Adequate- Makes some comment on client attending at incorrect time . Is not punitive.

*Good.-*Makes clear explicit comment on attending at incorrect time in a neutral tone.

*Excellent-*Makes clear explicit comment on attending at incorrect time in a neutral tone. Praises attendance and encourages future attendance to be on time in effort to shape future behaviour.

Item 9- Withholds incentive and clearly states this is due to the client not attending at correct time

Poor- Therapist mistakenly gives incentive OR Uses a punitive tone OR Incentive is not given but no link is made to attendance

Adequate.- Incentive is not given. Makes reference to attendance but does not make clear explicit link

*Good-*Incentive not given, makes clear explicit link between lack of incentive and attendance

Excellent- Incentive not given, clear explicit link between lack of incentive and attendance . Praises attendance and encourage future attendance to be on time in effort to shape future behaviour.

Item 10-Agress time and date of next session. See measure, nothing to elaborate on.

DRAFT

Handbook for Adherence Measure for PRAISE contingency management
program Abstinence

In addition to individual training and supervision please use the descriptions below to aid judgments on adherence ratings.

Item 1-Introduced self and put client at ease

Poor –Key worker does not introduce themselves by name, does not mention clients name, or comment enquire about wellbeing or recent activity in attempt to establish rapport and put client at ease

Adequate- Therapist greets client offers some general inquiry to establish some rapport and put client at ease

Good-Therapist clearly introduces themselves by name, specifies clients name. Makes some general enquiry to establish rapport or put client at ease.

Excellent-Therapist clearly introduces themselves by name, specifies clients name. Makes explicit general enquiry in attempt to establish rapport and out client at ease, appropriate follow up questions. Positive tone

Item 2- Described the purpose of the CM intervention

Poor – No description of current session offered, no agenda set, no reference to contingency management or trial or general aim to reduce illicit drug use

Adequate- - Comments that appointment involves using an incentive aiming to help reduce illicit drug use.

Good-Comments that appointment is in addition of on-going OST treatment which involves providing incentive aiming to help reduce illicit drug use.

Excellent- Comments that appointment is in addition to on-going OST treatment which involves providing incentive aiming to help reduce illicit drug use as part of a research trial.

Item 3- Checked Service User Understanding

Poor- No attempt to check understanding

Adequate- Enquires about understanding and provided information but fails to address all questions fully

Good- Enquire about understanding, provides relevant information and answers all questions

Excellent- Enquires about understanding, provided relevant information, answers all questions and checks if questions have been answered satisfactorily. Positive and empathic stance

Item 4- relevant incentive schedule clearly specified

Poor- No reference to incentive schedule.

Adequate- Comments that an incentive is given for attendance/provision of urine.

Good- Explains that incentive will be given for attending at agreed time AND providing urine (makes distinction about first 4 weeks and subsequent weeks i.e.

incentive is not contingent on a negative urine sample in first 4 weeks). Describes incentive schedule i.e. £10 supermarket voucher for 12 weeks.

Excellent- Explains incentive will be given for attending at agreed time and provision of urine (or within 15 minute window immediately following agreed time). Makes distinction about first 4 weeks and subsequent weeks. Describes incentive schedule i.e. £10 supermarket voucher for 12 weeks. Describe purposes voucher can be put to. Make clear it will be given at beginning of session

Item 5- Comments positively on clients' attendance at correct time

Poor- No comment

Adequate- Offers some comment on timely attendance. Specifies time or date. No explicit praise.

Good- Clear comment on attendance at correct time, offers some praise. Specifies time and date.

Excellent- Clear comment on attendance at correct time. Offers Praise and encouragement. Specified time and date

Item 6- Comments positively on:

Sessions 1-4; clients provision of a urine test

Sessions 5-12; client's provision of –ve urine test

Poor- No comment

Adequate- Offers some comment on provision of urine sample but does not explicitly praise.

Good- Clear comment on provision of urine sample, offers some praise

Excellent- Clear comment on provision of urine sample. Offers praise and encouragement in a positive tone.

Item 7- Give incentive and clearly states in a positive manner it is for attending on time and urine sample

Poor- Incentive not given

Adequate- Gives incentive. Makes reference to timely attendance or urine test but does not make clear explicit link.

Good- Gives incentive and makes a clear and explicit link to timely attendance and urine sample. Offers some praise.

Excellent- Give incentive and makes clear explicit link to timely attendance and urine sample. Offers praise and encouragement in a positive tone.

Item 8- Commented in a neutral manner on service user's attendance at incorrect time and urine sample

Poor- Talks in a punitive tone. Irrespective of whether therapist comments on attendance or urine sample, using a punitive tone scores 0

Adequate- Makes some comment on client attending at incorrect time or urine sample. Is not punitive but does not explicitly mention both.

Good.-Makes clear explicit comment about attendance and urine sample in a neutral tone.

Excellent-makes clear explicit comment on both attendance and urine sample in a neutral tone. Praises target behaviour met, or attendance at incorrect time, and encourage future target behaviours in an effort to shape behaviour.

Item 9- Withholds incentive and clearly states this is due to the client not attending at correct time or urine sample

Poor- Therapist mistakenly gives incentive OR Uses a punitive tone OR Incentive is not given but no link is made to attendance or urine sample.

Adequate.- Incentive is not given. Makes reference to attendance or urine sample but does not make clear explicit link

Good-Incentive not given, makes clear explicit link between lack of incentive and relevant target behaviour (or both).

Excellent- Incentive not given, clear explicit link between lack of incentive and target behaviour. Comments on target behaviour that was successful if appropriate and emphasises importance of target behaviours and link to future incentive.

Item 10-Agress time and date of next session. See measure, nothing to elaborate on

