The Development of the Working Alliance in Self-Management Education (WASME) Scale

Thesis submitted to the University of Leicester
Centre for Medicine, School of Psychology
In the partial fulfilment for the degree of
Doctorate in Clinical Psychology

Lynsey Cobane
B.Sc. (Hons), M.Sc.
2016

Declaration

I confirm that the literature review, research report and critical appraisal contained within this thesis are my own work and have not been submitted for any other academic award.

Thesis Abstract

Chronic conditions present a growing challenge to healthcare systems due to increasing prevalence rates and the associated financial burden for the individuals, their family and the wider economy. Good self-management has been shown to reduce morbidity and mortality rates of those with chronic disease (Sabaté, 2003) and has led to the development of self-management education programs. Little is known about what factors improve individuals' adherence to treatment recommendations.

The current literature review sought to investigate the relationship between the patient-clinician working alliance and adherence in people with long-term physical health conditions. A synthesis of nine eligible studies revealed that eight of the nine studies identified significant positive correlations between working alliance and adherence across a variety of chronic conditions and settings. Investigation of the predictive power of working alliance on adherence in five studies elicited inconsistent results preventing generalisations. The review was limited by the paucity of research and the heterogeneity of measures used to assess working alliance and adherence.

The research report aimed to develop and examine the structure and psychometric properties of the Working Alliance in Self-Management Education (WASME) Scale. A collaborative and iterative process involving educators, self-management research staff and a clinical sample across five phases were used to develop the scale. Following the development and revision of initial items, 59 participants were recruited from a convenience sample of group self-management courses. A 15-item unidimensional scale was created which demonstrated excellent internal consistency. The WASME scale demonstrated good concurrent validity with the Consultations and Relational Empathy Measure (CARE) and was also moderately correlated to the Client Satisfaction Questionnaire (CSQ-8). Clinical implications and suggestions for future research were discussed.

The critical appraisal presents a reflective account of the development of the research and the trainees' decision making process to maximise transparency.

Word Count

Thesis Abstract   294

Part One: Literature Review

     Abstract   272

     Full text   6739

     References   1968

Part Two: Research Report

     Abstract   300

     Full text   11248

     References   3489

Part Three: Critical Appraisal

     Full text   3886

     References   159

Appendices

     Mandatory   2199

     Non-mandatory   3898

Total Word Count for Thesis*   **22445**

* excluding contents page, mandatory appendices, pictures and references.

Table of Contents

Part 3: Critical Appraisal

Appendices

Part 1: Literature Review

Examining the Relationship between Patient-Clinician Alliance and Treatment Adherence in Chronic Physical Health Conditions: A Systematic Review of the Evidence

Guidelines to authors for journal targeted for Literature Review can be found in

Appendix A

1. ABSTRACT

Objective: Adherence to treatment is a fundamental component in the management of chronic physical health conditions yet factors contributing to patient adherence remain poorly understood. One factor shown to impact patient adherence is the patient-clinician working alliance. This review aimed to examine the relationship between patient-clinician alliance and adherence in people with long-term physical health conditions.

Method: A systematic review of the literature was undertaken using electronic databases (PsychINFO, MEDLINE, Scopus and Web of Science) to elicit English peer-reviewed empirical research, with snowballing performed on relevant references and journals. Studies which assessed working alliance and adherence in adults with a chronic physical condition were identified and reviewed for eligibility and methodological quality.

Results: Nine studies met the eligibility criteria for review. Eight of the nine studies revealed significant positive relationships between working alliance and adherence across a variety of chronic conditions and settings. Investigation of the predictive power of working alliance for adherence conducted in five studies elicited inconsistent results preventing generalisations. Three different measures were used to assess working alliance with the majority of the studies using the Working Alliance Inventory (WAI; Horvath & Greenberg, 1989). The measurement of adherence occurred through questionnaires in all studies however only four studies utilised unmodified validated measures.

Conclusion: Despite the variable quality of papers, and the heterogeneity of populations, settings, measurement tools and relationships investigated, the review revealed consistently positive relationships between the patient-clinician alliance and adherence.

Clinical Implications: Routine assessment of working alliance, further training of clinicians and cultural change within the healthcare system are necessary to facilitate strong patient-clinician working alliance and improve patients with long-term conditions' adherence to treatment.

2. INTRODUCTION

Long-term physical health conditions are both common and costly, accounting for 70% of all deaths in the US (Centers for Disease Control and Prevention, 2013), and 70% of the total health and care budget in England (DOH, 2008). They often have no cure but may be managed through medication use, self-monitoring, dietary restrictions, attending regular healthcare appointments and lifestyle changes. Whilst potential adverse consequences of chronic conditions can be significantly reduced by following healthcare recommendations, adherence to these recommendations have been identified as a significant problem for patients (Dunbar-Jacob *et al*. 1995), across all elements of self-care behaviours, irrespective of the nature or severity of the chronic condition, or access to healthcare (WHO, 2003). With escalating incidence of chronic conditions, and the associated rise in the health and economic burden, there is impetus to improve the understanding of factors affecting patient adherence.

2.1 Adherence

Adherence, "the extent to which a person's behaviour - taking medications, following diets, and/or executing lifestyle changes corresponds with agreed recommendations from a health-care provider" (WHO, 2003) has been shown to predict the effectiveness and outcome of treatment for people across a range of chronic health conditions (DiMatteo *et al*. 2002). As many as 50% of patients with chronic diseases in developed countries do not adhere to recommended medical regimens and lifestyle changes (Haynes, 2001; Sabaté, 2003), risking increased morbidity and mortality, and creating financial repercussions for healthcare delivery and national economies (Kohler & Baghdadi-Sabeti, 2011). Additionally, those whose adherence is sub-optimal also report a lower quality of life and increased suffering when compared to those who follow treatment recommendations (Bosworth *et al*. 2006).

The operationalisation of adherence has proven to be complex. In a comprehensive meta-analysis, definitions of adherence appeared as varied as the disease processes, recommended regimes and patients investigated (DiMatteo, 2004). There is no "gold standard" measurement of the adherence (Vermeire *et al*. 2001), leading to numerous methods to capture the construct - notably self-report questionnaires, prescription renewal rates and biological markers (Lehmann *et al*. 2014; Rand, 2000). Efforts to assess adherence through indirect measures such as health outcomes have also been constrained

since even when patients adhere rigorously to recommendations, their health may deteriorate as a function of the progressive nature of chronic conditions (Vermeire *et al.* 2001). The majority of studies thus rely upon self-report measures as a valid method of adherence assessment (Goldstein *et al.* 2009; Ingersoll & Heckman, 2005).

Given that research reveals adherence to be markedly sub-optimal and that this has adverse health consequences, patient outcomes may be promoted more by increasing efficiency of adherence interventions than by enhancing specific medical treatments or innovations (Haynes *et al.* 2008). Indeed, interventions to improve adherence in patients with chronic disease have financial benefits, reducing utilisation of healthcare services (Holman *et al.* 1997). Yet it remains unclear which factors should be targeted to enhance adherence efficiently. One promising factor in understanding patients adherence to treatment is the patient-clinician relationship, underpinned by the theoretical model of working alliance.

2.2 Working Alliance

The concept of the alliance has its origins in psychoanalytic theories (Freud, 1958; Greenson, 1965) though has been operationalised from differing theoretical perspectives for more than thirty years (Brenner, 1979; Luborsky, 1976). Bordins' (1979) pan-theoretical model of working alliance has dominated research and conceptualises the alliance as "what makes it possible for the patient to accept and follow treatment faithfully" (1980, p2). Bordins' theory features three components: mutual agreement and collaboration on treatment goals; agreement on tasks needed to achieve these goals; and a positive, trusting and supportive bond between the patient and therapist dyad.

The concept of working alliance has been extensively researched in psychotherapy where it has been consistently shown to predict treatment outcomes across different models of psychological therapies and a range of mental health difficulties (Castonguay *et al.* 2006; Horvath & Symonds, 1991; Martin *et al.* 2000). These studies have focused on the role of the patient-therapist interaction typically through self-report of patients and/or therapists' perceptions of an emotional bond and agreement of goals and tasks. Working alliance has been assessed in a variety of ways, however despite the use of several measurement tools, different raters (client, therapist, observer) and measurement time-points, meta-analyses report a moderate and reliable alliance-outcome relationship (Horvath & Bedi, 2002; Martin *et al.* 2000).

The contributory role of working alliance for diverse treatment outcomes for mental health patients has been well documented (Horvath & Bedi, 2002), with a systematic review finding a positive association between the clinician-patient alliance and treatment adherence in mental health services (Thompson & McCabe, 2012). By contrast, the examination of the alliance-adherence relationship in chronic physical health appears to be less well-summarised. Some studies have investigated the patient-clinician relationship with specific foci such as communication (Stewart, 1995), trust (Hall *et al.* 2002), collaboration (Jahng *et al.* 2005) and empathy (Kim *et al.* 2004) and have shown positive relationships with outcomes such as satisfaction and adherence.

The relative absence of research examining the role of healthcare professional-related factors may reflect beliefs that adherence is nearly entirely a patient-driven problem (DiClemente *et al.* 2004). Greater interest in the patient-provider interaction is warranted given the shift in healthcare from a dominant biomedical perspective to a biopsychosocial construction characterised by a collaborative, patient-centred and multidimensional relationship (Borrell-Carrió *et al.* 2004). An investigation of non-specific factors such as the working alliance presents an opportunity to understand more about the impact of the clinician-patient relationship on patients' adherence, and may provide evidence to inform future targeted interventions.

2.3 Rationale & Aims of the Present Review

Numerous studies have identified working alliance to be a significant factor associated with adherence in mental health (Thompson & McCabe, 2012). Adherence appears to be a key component to successfully manage chronic physical health conditions, yet to date no review has sought to appraise and synthesise studies evaluating its relationship with working alliance. While there is possible parallels and transferability from alliance's role in mental health, differences in the context of treatment, frequency and nature of relationships with healthcare professionals for those with physical conditions is likely to alter the therapeutic relationship.

In this review, we identify and appraise published literature exploring the relationship between working alliance and adherence in chronic physical health conditions. A narrative synthesis of the empirical evidence is offered to meet a primary objective to examine any associations. The review affords a second objective - to ascertain methods used to measure alliance and adherence in chronic physical conditions.

3. METHOD

3.1 Search Strategy

An initial scoping exercise was conducted in July 2015 prior to the principal search, to ascertain both the quantity and range of literature available and any previous reviews conducted. This procedure identified no earlier reviews and a circumscribed number of studies. Thus, it was decided to include all papers investigating the relationship between working alliance and adherence across any chronic physical health condition. The identification of relevant search terms ocurred during the scoping exercise.

The combinations of search terms utilised, along with truncated terms can be seen in Table 1. Categorisation of search terms into three groups based on the review question took place. The search strategy focused on the 'alliance' or 'relationship' (Group 1) in patients with chronic physical conditions (Group 2) and its association with adherence (Group 3). No limits to databases were employed to avoid inadvertent exclusion of relevant papers.

Table 1. Search Terms with Truncation

Group terms combined by 'AND'		
Combined by 'OR' → group term 1	Combined by 'OR' → group term 2	Combined by 'OR' → group term 3
Group 1	Group 2	Group 3
alliance	chronic	adher*
relationship	long-term	complian*
	disease	concordan*
	cancer	nonadher*
	diabet*	noncomplian*
	cardiac failure	nonconcordan*
	hypertension	persistence
	stroke	attendance
	asthma	engag*
	chronic obstructive	DNA
	pulmonary disease	dropout
	athriti*	service use
	crohn*	
	multiple sclerosis	
	parkinson*	
	lupus	
	addison*	

A rigorous electronic search of the literature was performed in PsychINFO, MEDLINE, Scopus and Web of Science between August and September 2015 and repeated in March 2016. No time limit was applied due to a lack of previous reviews and the pausity of studies found during the scoping exercise. Further to the electronic search, bibliographies of all papers reviewed in full were cross-referenced to identify any additional studies, and then the resulting titles and abstracts from each database were imported to a reference managing programme (RefWorks). The identification and removal of all duplicate papers occurred before reviewing titles and abstracts of identified studies for suitability in relation to the research question and eligibility criteria. Categorisation of each paper's title and abstract as potentially relevant, not relevant, or of inadequate detail to make a judgement aided shortlisting. Where there was uncertainty about the eligibility of the study from the title and abstract, the paper was reviewed in full. Structured data extraction forms were used to capture data on study design, aims, participant characteristics, methods, measures used, and outcomes, of relevant papers (Appendix B).

3.2 Eligibility Criteria

Included studies were required to be published in peer reviewed journals and meet the following eligibility criteria:

3.2.1 Study Design

Studies that utilised a quantitative methodology were included in this review. All randomised controlled designs, interventional, prospective and cross-sectional studies available in English were eligible for review. Qualitative studies, case studies, and reviews were excluded in order to best meet the objectives of the review (to investigate the presence of relationships and examine how working alliance and adherence are measured), and to increase the feasibility and generalisability of the review.

3.2.2 Population

Studies were included if they included adults (over 18 years old) with one or more long-term physical health conditions but not chronic mental illness.

3.2.3 Outcomes

Studies were included if they assessed a relationship between working alliance and adherence or investigated differences in working alliance with those deemed adherent or non-adherent.

Working Alliance

Studies were included if they explicitly measured the working alliance between a patient and a healthcare professional as rated by either the patient, healthcare professional, or an observer. Healthcare professionals were defined as any clinician in contact with the participant regarding their physical health problem. The setting of this contact could be within inpatient, outpatient, community, rehabilitation or primary care setting. Studies that only examined one component of the patient-clinician relationship such as collaboration, communication or empathy were excluded.

Adherence

Studies were included if they assessed patient's adherence, defined as the extent to which participants' behaviour (taking medication, following advised diet, executing lifestyle changes, and attending medical appointments) was consistent with advice from a healthcare professional in contact with the patient regarding their chronic condition. Patient adherence could be assessed directly (through medical markers, prescription renewal, appointments attended) or indirectly, through self-report or clinician report.

3.3 Assessment of Study Quality

No 'gold standard' quality assessment tool was available and after exploring possibilities in a systematic review of available tools (Deeks *et al.* 2003), a modified version of the checklist developed by Downs and Black was selected (Downs & Black, 1998). This checklist is suitable for both randomised and non-randomised studies. As all papers in this review were non-randomised, questions relating to the randomisation process were removed. In addition to the 12 relevant questions taken from the Downs and Black (1998) quality appraisal tool, two further questions were used to assess the quality of the alliance and adherence measures utilised in the reviewed studies (See Appendix C).

4. RESULTS

A total of 1314 articles were obtained using the search strategy outlined in Table 1., following the removal of duplicates: Identification of 56 papers as potentially relevant by their titles and abstracts led to extraction and review of the full paper. Eight further papers were retrieved through the bibliography of the potentially relevant papers. Of these 64 papers; 26 were omitted as they did not include a measure of working alliance; 14 were excluded as they did not include patients with a chronic condition; 13 were removed as they did not measure the relationship between working alliance and adherence as an outcome, one study was excluded as it was conducted on an adolescent sample, and one study was removed as it was unavailable in English. A total of nine papers were eligible for review. The selection process is represented in Figure 1. A meta-analysis of the data could not be conducted due to the heterogeneity of study populations and measures of working alliance and adherence. Thus, the findings of the systematic review are provided as a narrative synthesis.

Figure 1. Flow diagram of study selection.
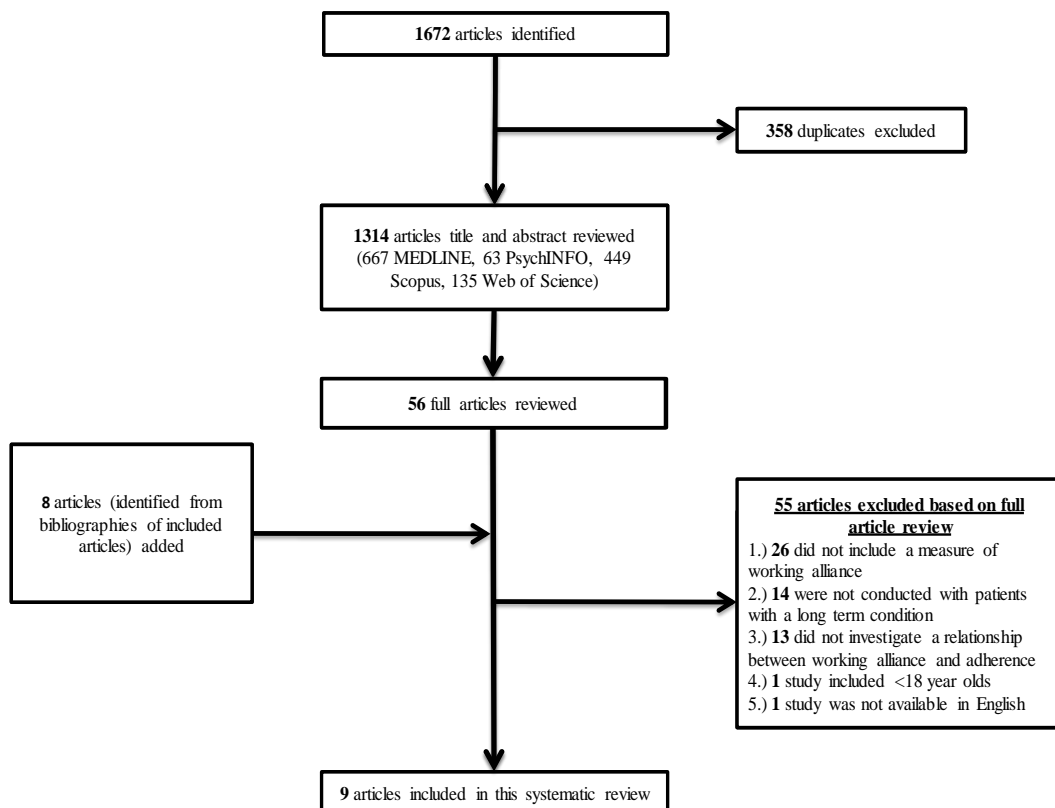
4.1 Characteristics of the Included Studies

Key characteristics of the studies are available in Appendix D. Studies were published between 2004 and 2015 suggesting an area of research in its infancy. All studies included in the review were observational in that the working alliance was correlated with adherence measures rather than experimentally manipulated. Six studies were conducted in the USA, one was carried out through disease-specific English language websites, and two studies were undertaken in Denmark. The review is limited in that it cannot investigate the impact that different health-care services and cultures may have on the role of working alliance and therefore findings are not globally representative.

Diverse long-term conditions were examined across the nine studies reviewed: two studies were conducted with cancer patients (one solely focused on patients with breast cancer (1), the other included patients with different cancer diagnoses (4)); two studies were conducted within rheumatology (one study with Systemic Lupus Erythematosus (SLE) patients (2) while one study did not detail the diagnosis of patients recruited from a rheumatology clinic (3)); two studies recruited patients from a brain injury rehabilitation program (8, 9); one study was conducted with neurology outpatients (6); one study involved patients enrolled in a cardiac rehabilitation program (7); and one study included a combination of patients with different chronic diseases including HIV+/AIDS, hypertension, and diabetes (5).

Recruitment took place in a number of settings. Three studies recruited patients from online websites (1, 2, 5), Three studies recruited patients from outpatient clinics (3, 4, 6), and three studies recruited from intensive rehabilitation programs (7, 8, 9). The sample size of the studies ranged from 80-1371 participants. Four studies had fewer than 100 participants; four studies recruited between 100 and 200 individuals, and 1371 people took part in one study.

4.1.1 Overview of the Methodological Quality of Studies

The overall study quality score was calculated out of a maximum total of 14 questions adapted from the Down and Black (1998) checklist to meet the needs of the review. Presentation of study quality calculations are presented with higher scores signifying higher quality studies (Appendix E). In brief; studies were of moderate quality. The range in quality of studies was 64% to 93%. Four studies obtained a rating of 64%; two studies

scored 79%; two studies were rated 86% for study quality; one study obtained a score of 93%. Five studies were cross-sectional in design (2, 3, 4, 5, & 6), three were prospective correlational (1, 7, & 9), and one study was retrospective correlational (8). The reporting in all the studies was high quality, although there were weaknesses in studies' power and ability to detect causality in five of the nine studies included in the review, given the preponderance of cross-sectional studies.

4.2 The Relationship between Alliance and Adherence

Eight of the nine studies reviewed identified significant positive associations between measures of the patient-clinician alliance and adherence (1, 2, 3, 4, 5, 6, 8, 9). The final study showed early self-efficacy predicted later working alliance in a cardiac rehabilitation program but not vice versa (7). The effect size of the working alliance–adherence relationship ranged from $r = .24$ to $.53$ suggesting a small to moderate effect in line with a previous meta-analysis of working alliance-outcome research in psychotherapy (Martin *et al.* 2000) and between clinicians and patients in mental health (Thompson & McCabe, 2012). Given the lack of homogeneity between included studies, results were grouped by study setting to reduce difficulties in comparison due to observed differences in the intensity and longevity of the patient-clinician relationship seen across settings. The three studies conducted via internet referred to patient-clinician relationship within an outpatient setting and therefore were grouped as such.

4.2.1 Outpatient Studies

Six of the studies investigated the relationship between working alliance and adherence with outpatients. These included two studies of patients with cancer, two studies of rheumatology outpatients, one study of neurology outpatients, and a final study which included patients with a variety of chronic conditions. Within the area of cancer, Stanton *et al.* (2014) found that women with breast cancer who stopped taking the recommended endocrine medication reported a significantly poorer quality patient-oncologist relationship compared to those who continued with their medication ($p < .001$). Women who were currently taking endocrine medication were also shown to be significantly less adherent to prescribed medication if they disclosed a poorer quality working alliance with their oncologist ($r = - .24$, $p < .01$). This finding appears consistent with Trevino's (2013) study in which young adults with advanced cancer showed significantly better adherence to cancer medication when they reported a stronger alliance ($\beta = .04$, $p < .005$) (4). However,

these latter findings were based on single-item self-report responses of adherence, and the same study found no relationship between patients' thoughts of stopping treatment and alliance when confounding variables were controlled. This finding suggests that a positive relationship with an oncologist does not prevent outpatients contemplating stopping treatment but may militate against them actually stopping.

In rheumatology, Bennet *et al.* (2011) studied participants with SLE who obtained higher scores on an adherence questionnaire when they reported a better working alliance with their physician ($r = .29$, $p < .001$). Similarly, Fuertes *et al.* (2015) identified a positive relationship between patient-physician working alliance and patient self-reported adherence self-efficacy ($r = .46$, $p < .01$) and physician rated adherence ($r = .25$, $p < .01$) with rheumatology outpatients. Likewise, Fuertes and colleagues' other studies (with neurology outpatients (6) and with patients with diverse chronic illnesses (5)) revealed positive patient-rated working alliance relationships with their physician was associated with greater treatment adherence self-efficacy ($r = .44$ and $r = .47$ respectively, $p < .001$) and patient self-reported adherence ($r = .35$, $r = .53$ respectively, $p < .001$). The three studies conducted by Fuertes and colleagues differed in their ability to detect a predictive relationship between working alliance and adherence. One study identified working alliance as a causal factor in patients with chronic disease (5). A second study found an indirect relationship between working alliance and adherence through patient satisfaction in rheumatology (3). The final study did not establish any predictive relationship between working alliance and adherence in neurology patient, although this may be due to limitations of its cross-sectional design (6).

4.2.2 Rehabilitation Studies

Three studies took place within rehabilitation programs. Two involved patients with a brain injury, while one study examined a rehabilitation program with cardiac patients. These programs ran over three to four months and involved three to four sessions per week. Schronberger and colleagues (2006a) found a positive association between dichotomised ratings of patients' working alliance and low, average, and high compliance scores both categorised by their neuropsychologist (Cramer's V = .79) and physiotherapist (Cramer's V = .76) in brain injury rehabilitation. These ratings were completed retrospectively between 18 months and four years after the patient completed the rehabilitation program which is likely to have affected the validity of the ratings due to

frailties in recall. Schronberger and colleagues (2006b) identified only a small positive relationship between the mid-treatment bond subscale of the patient rated working alliance and adherence score ($r = .30$, $p < .05$), despite measurement of both clients' and the primary therapists' working alliance and compliance at four points throughout a brain injury rehabilitation program. Therefore, out of a possible 24 correlations between the different subscales and the adherence measure only one positive correlation was found. No direct relationship between working alliance and compliance was identified however the relationship was mediated by patients' awareness of their brain injury. Therefore, patients' positive emotional bond with their therapist was associated with greater patient awareness of their injury which improved patients' adherence.

Patients' perceived alliance with all program staff was examined in cardiac rehabilitation with the only significant finding indicating that early changes in patients' exercise and diet self-efficacy were predictive of working alliance but not the reverse (7). This may suggest that patients' working alliance with a health-care professional is strengthened through patients' prompt initiation of lifestyle changes. These findings may be inconsistent with the other research in this area as a result of trying to capture the numerous complex relationships that patients may have with program staff using one measure.

4.3 Measurement of Working Alliance

Working alliance was assessed using patient self-report in eight of the nine studies reviewed (1, 2, 3, 4, 5, 6, 7, 9), and this was the only method used in seven of these studies. One study used both patient self-report and physician self-report measures of working alliance (9). In the final study working alliance was retrospectively rated by a neuropsychologist and a physiotherapist for each patient although the inter-rater agreement was low (8; Cohen's Kappa = .3, $p < .01$). The alliance was based on the relationship between a patient and one healthcare professional in all studies except one study which assessed the alliance between the patient and program staff (7). An overview of the measures used and their properties is shown in Table 2.

Three different measures were used to assess the patient-clinician working alliance in long-term physical health conditions. The most commonly used measure was the short form of the Working Alliance Inventory (WAI-S; Tracey & Kokotovic, 1989), a 12-item instrument which measures Bordin's (1979) concept of working alliance. Two other scales were also used in the reviewed studies: The Human Connection Scale (THC; Mack *et al.*

2009) was used in one study, specifically developed and validated for application in cancer settings (4); and one study modified the Prigatano Alliance Scale (PAS; Prigatano *et al.* 1994) which was not validated but had been utilised in previous research to assess working alliance (8).

Table 2. Properties of Working Alliance measures used.

Measure	Study	Conceptual model	Rating (R) and Scoring (S)	Psychometric properties
Working Alliance Inventory (WAI; Horvath and Greenberg, 1986, 1989)	1,2,3,5,6, 7,9	Based on the three factor model outlined by Bordin's (1979) consisting of the bond, agreement of goals, and agreement on task. Developed in psychotherapy	3 versions available depending on who is rating: client, therapist, and observer 36 items are rated on seven-point scale. The shorter version (WAI-S; Tracey & Kokotovic, 1989) contains 12 items. Studies using the PPWA remained the same as WAI-S except referred to the doctor-patient relationship and used a five-point scale	Strong support for the reliability of the WAI and good validity has also been shown. Predictive validity across of variety of treatments in psychotherapy (Klein *et al.* 2003; Howard *et al.* 2006) and in medical settings (Eveleigh *et al.* 2012) Adequate person and measure reliabilities ($\alpha = 88 - .92$)
The Human Connection Scale (THC; Mack *et al.* 2009)	4	Based on therapeutic alliance and psychiatric literature and specifically developed for palliative oncology. Items related to patients feeling listened to/understood, mutual caring and respect, understanding information, trust and working well together.	Rated by patient 16 items are rated on a four-point scale	High Internal consistency ($\alpha = .90$) Construct validity demonstrated for cancer patients
The Priganto Alliance Scale (PAS; Priganto *et al.* 1994)	8	Based on four items 1) Percentage of patient attendance 2) Quality of verbal agreement on course of action 3) Patient appreciation of accomplishments and services 4) Patient engagement	Scores for items categorised by clinician WA Score dichotomised as "good or excellent" or "poor or fair"	No psychometric analysis conducted. Moderate to good reliability in the reviewed study ($\alpha = .63 - .85$)

4.3 Measurement of Adherence

There was considerable variability in studies definitions of adherence and how it was evaluated (See Table 3). This variance highlights the difficulty in comparing the heterogeneous studies in this review. In total 12 measures were used to assess adherence of varying psychometric robustness; five were validated scales, two included items from a validated scale but did not use the whole scale, and five measures had not been psychometrically scrutinised. This is surprising as numerous well validated measures of adherence exist (Lehmann *et al.* 2014). The majority of the included studies assessed

patient's general adherence to behavioural aspects of their recommended treatment regime (2, 3, 5, 6, 8, 9). Three of these studies of general adherence also included a measure of adherence self-efficacy (3, 5, 6). Additionally, one study specifically investigated adherence self-efficacy to diet and exercise and participants' adherence to diet recommendations (7). Two studies examined adherence to medication (1, 4), with one of these including an additional measure of patient's willingness to adhere to treatment (4).

In six of the nine studies reviewed, adherence was assessed using only patient self-report (1, 2, 4, 5, 6, 7), consistent with previous reviews of adherence measures (DiMatteo, 2004). One study used both a patient and a clinician rating of adherence (3). Two studies relied solely on only the clinician to assess patient adherence (8, 9).

Table 3: Properties of adherence measures used

Construct	Study	Measure	Description	Strengths	Limitations
General adherence	2	The General Adherence Inventory (GAI; DiMatteo *et al.* 1993)	Patient self-report measure 15-items rated on a six-point Likert-type scale.	Internal Consistency reliability acceptable (Tarlov *et al.* 1989)	Not validated
	3	Five-item idiosyncratic scale	Physician rated items related to patients' adherence to treatment plan on a six-point Likert scale	Designed specifically for the study Excellent internal consistency reliability ($\alpha = .95$)	Not validated
	5, 6	Items from the Medical Outcomes Study (MOS; Hays *et al.* 1994)	Assessed patient adherence behaviours over the past 4 weeks through four/five items on a six-point Likert scale.	Validated questionnaire Questionable to good internal consistency reliability ($\alpha = .68$ and .88)	Patient self-report Unable to determine patients' long-term adherence
	8	Three-item idiosyncratic scale	Clinicians rating of patient engagement, acceptance of programme elements and objectives, and following the therapist's advice. Patients divided into groups of low, average or high compliance rating for analysis.	Two of the items were used in a previous study by Ezrachi *et al.* (1991) Excellent internal consistency reliability ($\alpha = .90$)	Not validated The division of patients into groups may underestimate the variation between groups
	9	Five-item idiosyncratic scale	Clinicians and patients rating of items related to patients' active participation, engagement, acceptance of programme elements and objective, and following advice taken at four time points.	Good internal consistency reliability ($\alpha = .87$) Prospective design	Not validated Eight adherence ratings were taken without clear rationale
Adherence self-efficacy	3	Treatment adherence self-efficacy	Patient rated scale regarding the extent to which participants think they can engage with the treatment and goals agreed with physician.	Strong psychometric properties and related to adherence to treatment Good internal consistency reliability ($\alpha = .88$)	Not a direct measure of adherence

	5,6	Adherence self-efficacy	Single item patient report. Patients asked to rate their agreement on how likely they feel able to engage in behaviours agreeable with the doctor's treatment plan.	Previously utilised measure (Catz et al. 2000). Excellent internal consistency reliability (α = .88-.89)	Only one general single item – low specificity
	7	Cardiac Exercise self-efficacy Instrument (ESE) and Cardiac Diet self-efficacy Instrument (DSE) (Mickey et al. 1992)	Assessed confidence about adhering to an exercise regime and low fat, low cholesterol diet using two 16-item scales.	Validated scale. Excellent internal consistency reliability for both ESE and DSE (Cronbach's α = .91 and .94 respectively). Scales predict subsequent diet and exercise behaviours (r = .62 and .53 respectively)	Self-report more susceptible to desirability and memory bias
Adherence to medication	1	Persisters vs. Non-persisters	Participants identified themselves as continuing with or discontinuing recommended medication	Allows to investigate between two groups	Desirability bias. Does not allow for identification of those who stopped and restarted
	1	Adapted Morisky Medication Adherence scale (Morisky et al. 1986)	Used three out of four questions from the MMAS and added two additional questions. Questions measured forgetfulness, stopping and altering doses.	Commonly used questionnaire with concurrent and predictive validity. Acceptable internal consistency reliability (α = .76)	Patient self-report. Adding questions may have impacted the validity of this measure
	4	Single item for the Cancer Therapy Satisfaction Questionnaire (CTSQ; Abetz et al. 2005)	A single item from CTSQ patient rated how often patient took their oral cancer medication in the last four weeks. Rated by patients on a five-point scale.	Part of a validated scale.	No opportunity to differentiate between adherence to different medications. Reliability not reported
Willingness to adhere	4	Two items for the Cancer Therapy Satisfaction Questionnaire (CTSQ; Abetz et al. 2005)	Patients rated agreement that cancer treatment was worth the adverse effects, and how often they had thought about stopping treatment in the last four weeks.	Items are part of a validated scale	The choice not to administer the wholes scale may impact the scales validity and reliability. Reliability not reported
Adherence to diet	7	Quick Check for Diet Progress (QCDP; Schaefer et al. 1992)	Progress on amount of calories and total fat consumes using a computer-assisted food analysis instrument measured at four points	Convergent validity and satisfactory test-re-test reliability (r = .78 for total fat)	Patient-self report measure

5. DISCUSSION

5.1 Summary of Findings

This systematic review sought to examine the relationship between patient-clinician working alliance and adherence in patients with chronic physical health conditions and, additionally, identify assessment tools used in this field. Nine studies, of moderate overall quality, met eligibility criteria for review. Despite heterogeneity of the studies, eight of the nine studies identified at least one statistically significant positive relationship between

measures of working alliance and adherence, consistent with existing empirical literature in the field of psychotherapy (Horvath & Bedi, 2002), and in clinical settings with mental health patients (Thompson & McCabe, 2012). Moderate effect sizes of the alliance-adherence association reported in this review were similar to a previous meta-analysis of studies investigating working-alliance and patient outcomes (Martin *et al*. 2000).

Results of the review indicate that a good patient-clinician working alliance appears to improve adherence to treatment in both outpatient and rehabilitation settings, with the exception of when working alliance is assessed in relation to all staff across a programme, rather than with a single clinician. This finding suggests that even relatively brief relationships marked by strong alliance may be powerful in promoting adherence. The absence of studies conducted in inpatient settings was notable and may reflect dynamics of care in which adherence is believed to be directed and assured by clinicians (e.g. administering drugs), by contrast to outpatients in which patient self-management is privileged. Studies identified were conducted in discrete areas; cancer, rheumatology, a combination of long-term diseases, cardiology, and neurology. Whilst chronic disease features in all these specialties it is surprising that diabetic care, respiratory diseases, and chronic pain have not been studied given the burden these conditions impose and patients noted sub-optimal adherence to treatment regimes (Bourbeau & Bartlett, 2008; Gonzalez *et al.* 2007; Rutten *et al.* 2010). The focus of the existing research base may be an artefact of specialties in which psychosocial factors impinging on care have been more widely considered.

While four of the studies used a cross-sectional design precluding assessment of causality, five studies design enabled exploration of the predictive relationship between working alliance and adherence (3, 5, 6, 7, 9). The findings were inconsistent as one study identified a causal relationship (5), one study found no predictive relationship (6), and two studies found an indirect relationship between working alliance and adherence mediated by patient satisfaction (3) and patients' awareness of the impact of their brain injury (9). However, this latter study only identified this predictive relationship when investigating only the bond subtest of the working alliance scale suggesting that patient's perception of an emotional bond between themselves and their clinician was more important than setting goals and agreeing on tasks. This may be specific to brain injury as difficulties of executive function following brain injury may compromise patients' ability to set goals (Arciniegas *et al*. 2002). This finding may also suggest that the role of clinician empathy is

central to predicitng adherence in brain injury although no research was found to support this hypothesis. Lastly, one study found that patients' early exercise and diet self-efficacy predicted a stronger working alliance later in a cardiac rehabilitation program but not the reverse (7). It could be that patients who had high diet and exercise self-efficacy elicited a more positive interaction from clinicians compared with those who doubted their ability to make dietary and exercise changes. This suggests that participants' initial engagement in rehabilitation programs predicts the strength of the relationships they build with the clinician.

A secondary aim of this review was to ascertain how working alliance and adherence were measured within chronic physical health conditions. Unsurprisingly, given its utility in psychological interventions, the WAI (Horvath & Greenberg, 1986, 1989) was the most frequently used scale. However, its derivation and validity are rooted in a psychotherapeutic relationship, arguably different to relationships in managing chronic physical disease where emotional expression and intensity of contact may substantially differ. It may be timely to develop more specific measures, such as the THC (Mack *et al.* 2009) - specifically developed to assess the patient-oncologist relationship. Attempts to measure the working alliance with the whole programme staff in one study appears flawed as this implies that patient's relationships with a whole team can be averaged and represented in a single measure thus ignoring the individual positive or negative relationships that might exist within this and risks oversimplifying complex relationship factors.

There was a great variability of adherence assessment tools seen in this area of research. All measures indirectly assessed adherence through patient self-report or clinician ratings rather than observational or absolute measures. The advantage of these measures is that they are easy to use and allow for patients and clinicians beliefs and attitudes to be captured which direct measures fail to do. Additionally, a meta-analysis has found no significant difference in adherence between studies that used and did not use an objective measure (DiMatteo, 2004).

5.2 Research Limitations

This review revealed several limitations within the published evidence base. Firstly, a paucity of adequate literature limits the robustness and generalisability of this review and the circumscribed number of studies eligible reveals a disparity in research examining the

alliance-outcome association in physical health contrasting with the extensive research undertaken in mental health research (Horvath & Bedi, 2002; Martin *et al.* 2000; Thompson & McCabe, 2012). Given that physical healthcare is increasingly constructed as a collaborative emotional engagement between clinician and patient, there is further opportunity to increase and refine the evidence base exploring factors that impinge this relationship such as the working alliance (Haynes *et al.* 2008; Holman *et al.* 1997).

A lack of homogeneity in eligible studies precluded direct comparisons of study findings and prevented causal inferences being drawn regarding the association between patient-clinician working alliance and adherence in patients with chronic health problems. Due to the diversity of conditions investigated it was not possible to explore differences in the relationship between working alliance and adherence across patient populations. It is conceivable that for some long-term health conditions the impact of the working alliance-adherence relationship may vary according to the related burden of treatment recommendations and the clinician's role.

All studies were of a cross-sectional correlational, retrospective or prospective design. Little mention was made of other factors such as disease process, stage of condition, and complexity of treatment regimen (Brown & Bussell, 2011; Dunbar-Jacob & Mortimer-Stephens, 2001) as potential confounds and mediators, particularly relevant given the diverse conditions and service context across studies. Included studies were also likely to have prevalence-incidence bias as patients whose health was poor were less likely to participate in this research. Furthermore, those studies recruiting online did not allow for a participation rate to be calculated in an effort to determine non-response bias. Future longitudinal studies could be conducted to broaden the base of biomedical and psychosocial indicators of adherence and capture adherence behaviours varying over time. Experimental designs could allow for further investigation into any causal role of working alliance on adherence of which inconsistent findings were identified in the present review.

Studies in the current review offered little insight into the mechanisms underlying the alliance-adherence relationship which may have been evident through qualitative research and is necessary to understand how it can be improved. This is not unexpected due to research in this area still focusing on demonstrating a relationship between alliance and adherence in long-term conditions before additional analysis on attributing factors can be undertaken. This review identified that diet and exercise self-efficacy predicted patients'

working alliance and this may indicate that clinicians invest more in building positive relationships with adherent patients (7). The role of patient factors were also recognised as patients' awareness of their health condition mediated the relationship between alliance and adherence (9). It may be that a good relationship allows for collaborative exploration of goals and tasks which may make patients more aware of their difficulties and encourage increased adherence. Other individual factors such as motivation, attitude, satisfaction, memory and impulsivity may explain part of this relationship however these were not investigated in the studies reviewed (Julius *et al.* 2009).

Adherence of course is not merely explained by working alliance, and health psychology has advanced theories to capture the complexity of what is a multidimensional process. The search strategy employed with a focus on quantitative literature and limited to those which explicitly measure working alliance is likely to have missed relevant literature that could provide a broader understanding of adherence. A multifactorial understanding has particular utility for physical health conditions when medical models have a propensity to present non-adherence as a unitary concept, with one cause, diagnosis and solution (Gillum & Barsky, 1974; Leventhal & Cameron, 1987). Patients' beliefs about the cost and benefits of treatment, subjective norms, efficacy expectations and attitudes toward treatment may play a significant role in patient adherence (Horne & Weinman, 1999, 2002), as may clinicians' behaviour towards patients in the shape of communication (Zolnierek & DiMatteo, 2009), collaboration (Arbuthnott & Sharpe, 2009), trust (Lee & Lin, 2009) and empathy (Kim *et al.* 2004). Since many of these processes may overlap with facets of working alliance it may be difficult to establish which are of fundamental importance in predicting adherence - a challenge to conducting research and developing interventions in the field.

Finally, the reviewed studies share the vulnerabilities of other studies examining working alliance and adherence, reliance on self-reports and thus vulnerable to desirability bias and memory recall difficulties. Given respondents may be reluctant to express antipathy to clinicians or disclose their sub-optimal adherence, alliance and adherence may be inflated. More diverse and robust tools of alliance and adherence (notably use of observers to rate working alliance and biomedical indices to assess adherence) should be pursued. Use of such measures would enhance the quality of the evidence base.

5.3 Limitations of the Review

This review is the first to examine the relationship of working alliance to adherence in patients with chronic physical health conditions, but has some limitations. The decision to only include published studies may have led to a publication bias and result in an overestimate of results (Rosenthal, 1979). Although an explicit, systematic search strategy and data extraction was undertaken to reduce any risk of bias, the search was conducted by only one researcher potentially biasing study selection. The exclusion of qualitative data potentially resulted in oversimplification of the relationship between working alliance and adherence and denied the possibility to obtaining unique individual experiences and perspectives which could have provided a more in depth understanding of how relationship factors may impact adherence. Furthermore, there may be discrete patient factors that affect patient's ability to form relationships and adhere to treatment, particularly mental health difficulties, social issues and financial problems not investigated in this review with may be potentially confounding.

5.4 Clinical Implications

Given rising prevalence rates of chronic illness, and benefits associated with enhancing adherence, greater understanding of factors associated with adherence in patients with chronic physical health problems appears warranted. The majority of studies in this review used measures constructed using Bordin's (1979) model of therapeutic alliance. Clinicians may consider routinely assessing the facets of patient working alliance to guide engagement and improve patients' adherence. Educating and training clinicians on the role of working alliance and techniques used to build upon their therapeutic skills as seen in psychotherapy may improve their patients' adherence to treatment. This is an important message given current fiscal austerity increasing time pressure on health professionals and potentially detracting from building a positive relationship with patients. A cultural change within healthcare organisations may be required to facilitate clinician's ability to build positive working alliances with patients as an essential part of their role.

5.5 Suggestions for Future Research

Despite extensive research exploring alliance within the context of psychotherapy, there is a dearth of similar evidence regarding patient-clinician alliance and adherence within chronic physical healthcare. The use of experimental designs in future research would

permit confounding variables to be controlled and to estimate how much variance of patient adherence can be explained by the patient-clinician alliance. It might also permit examination of alliance alongside other putative theories from health psychology to assess strongest predictors, as a basis to develop more tailored interventions. Additionally, longitudinal studies would offer opportunity to determine if a strong patient-physician alliance has a long-term impact, essential given the fluctuations and lifelong burden chronic conditions can impose. The repeated use of invalidated measures makes it necessary to recommended that further research in this area is conducted with a focus on the use of validated instruments, for both working alliance and adherence, in order to improve methodological rigor.

5.6 Conclusions

This review has examined the relationship between patient-clinician therapeutic alliance and patient adherence in long-term physical health conditions. Findings are consistent with the evidence that the patient-clinician working alliance plays an important role in patient's adherence to, and outcomes of, treatment in psychotherapy and clinical mental health settings (Martin *et al.* 2000, Thompson and McCabe, 2012). This review highlights the potential to enhance relationships with patients to potentially benefit adherence and make cost savings. However, to provide more definitive recommendations about the impact of improved alliance, a larger more sophisticated evidence base is needed, particularly examining what underpins improved alliance in more diverse chronic conditions. This requires robust longitudinal data, founded on well validated measures of working alliance and adherence.

6. REFERENCES

Abetz, L., Coombs, J.H., Keininger, D.L., Earle, C.C., Wade, C., Bury-Maynard, D., *et al.* (2005). Development of the cancer therapy satisfaction questionnaire: item generation and content validity testing. *Value in Health*, *8*, 41-53.

Arbuthnott, A., & Sharpe, D. (2009). The effect of physician–patient collaboration on patient adherence in non-psychiatric medicine. *Patient Education and Counseling*, *77*(1), 60-67.

Arciniegas, D.B., Held, K., & Wagner, P. (2002). Cognitive impairment following traumatic brain injury. *Current Treatment Options in Neurology*, *4*(1), 43-57.

* Bennett, J.K., Fuertes, J.N., Keitel, M., & Phillips, R. (2011). The role of patient attachment and working alliance on patient adherence, satisfaction, and health-related quality of life in lupus treatment. *Patient Education and Counseling*, *85*(1), 53-59.

Bordin, E.S. (1979). The generalizability of the psychoanalytic concept of the working alliance. *Psychotherapy: Theory, Research & Practice, 16*(3), 252.

Bordin, E.S. (1980). A psychodynamic view of counseling psychology. *The Counseling Psychologist*.

Borrell-Carrió, F., Suchman, A.L., & Epstein, R.M. (2004). The biopsychosocial model 25 years later: principles, practice, and scientific inquiry. *The Annals of Family Medicine*, *2*(6), 576-582.

Bourbeau, J., & Bartlett, S.J. (2008). Patient adherence in COPD. *Thorax*, *63*(9), 831-838.

Bosworth, H.B., Oddone, E.Z., & Weinberger, M. (Eds.). (2006). *Patient treatment adherence: Concepts, interventions, and measurement*. Psychology Press.

Brenner, C. (1979). Working alliance, therapeutic alliance, and transference. *Journal of the American Psychoanalytic Association*.

Brown, M.T., & Bussell, J.K. (2011). Medication adherence: WHO cares?. In *Mayo Clinic Proceedings* (Vol. 86, No. 4, pp. 304-314). Elsevier.

Castonguay, L.G., Constantino, M.J., & Holtforth, M.G. (2006). The working alliance: Where are we and where should we go?. *Psychotherapy: Theory, Research, Practice, Training*, *43*(3), 271.

Catz, S.L., Kelly, J.A., Bogart, L.M., Benotsch, E.G., & McAuliffe, T.L. (2000). Patterns, correlates, and barriers to medication adherence among persons prescribed new treatments for HIV disease. *Health Psychology*, *19*(2), 124.

Centers for Disease Control and Prevention. (2013). *Death and Mortality*. NCHS FastStats. Retrieved 10th July 2015 from: http://www.cdc.gov/nchs/fastats/deaths.htm.

Deeks, J.J., Dinnes, J., D'amico, R., Sowden, A.J., Sakarovitch, C., Song, F. *et al.* (2003). Evaluating non-randomised intervention studies. *Health Technology Assessment*, *7*(27), 1-179.

Department of Health. (2008). *Raising the profile of long term conditions care: A compendium of information.* Retrieved 28th July 2015 from: http://ww.dh.gov.uk/publications

DiClemente, R.J., Wingood, G.M., Harrington, K.F., Lang, D.L., Davies, S.L., Hook III, E. W., *et al.* (2004). Efficacy of an HIV prevention intervention for African American adolescent girls: a randomized controlled trial. *Journal of the American Medical Association*, *292*(2), 171-179.

DiMatteo, M.R. (2004). Variations in patients' adherence to medical recommendations: A quantitative review of 50 years of research. *Medical Care, 42*(3), 200-209.

DiMatteo, M.R., Hays, R.D., Gritz, E.R., Bastani, R., Crane, L., Elashoff, R., *et al.* (1993). Patient adherence to cancer control regimens: scale development and initial validation. *Psychological Assessment*, *5*(1), 102.

DiMatteo, M.R., Giordani, P.J., Lepper, H.S., & Croghan, T.W. (2002). Patient adherence and medical treatment outcomes. *Medical Care, 40*(9), 794-811.

Downs, S.H., & Black, N. (1998). The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *Journal of Epidemiology and Community Health*, *52*(6), 377-384.

Dunbar-Jacob, J., Burke, L.E., Pucznski, S. (1995). Clinical assessment and management of adherence to medication regimens. In: Nicassio, P.M., Smith. T.W., (Eds). *Managing chronic illness: A biopsychosocial perspective*. Washington, DC: American Psychological Association.

Dunbar-Jacob, J., & Mortimer-Stephens, M. (2001). Treatment adherence in chronic disease. *Journal of Clinical Epidemiology*, *54*(12), S57-S60.

Eveleigh, R.M., Muskens, E., van Ravesteijn, H., van Dijk, I., van Rijswijk, E., & Lucassen, P. (2012). An overview of 19 instruments assessing the doctor-patient relationship: different models or concepts are used. *Journal of Clinical Epidemiology*, *65*(1), 10-15.

* Evon, D.M., & Burns, J.W. (2004). Process and outcome in cardiac rehabilitation: an examination of cross-lagged effects. *Journal of Consulting and Clinical Psychology*, *72*(4), 605.

Ezrachi, O., Ben-Yishay, Y., Kay, T., DiUer, L., & Rattok, J. (1991). Predicting employment in traumatic brain injury following neuropsychological rehabilitation. *Journal of Head Trauma Rehabilitation*, *6*(3), 71-84.

Freud, S. (1958). The dynamics of transference. In J. Starchey (Ed.), *The standard edition of the complete psychological works of Sigmund Freud* (pp. 99-108). London: Hogarth Press. (Original work published 1912).

* Fuertes, J.N., Anand, P., Haggerty, G., Kestenbaum, M., & Rosenblum, G.C. (2015). The Physician–Patient Working Alliance and Patient Psychological Attachment, Adherence, Outcome Expectations, and Satisfaction in a Sample of Rheumatology Patients. *Behavioral Medicine*, *41*(2), 60-68.

* Fuertes, J.N., Boylan, L.S., & Fontanella, J.A. (2009). Behavioral indices in medical care outcome: the working alliance, adherence, and related factors. *Journal of General Internal Medicine*, *24*(1), 80-85.

* Fuertes, J.N., Mislowack, A., Bennett, J., Paul, L., Gilbert, T. C., Fontan, G. *et al.* (2007). The physician–patient working alliance. *Patient Education and Counseling*, *66*(1), 29-36.

Gillum, R.F., & Barsky, A.J. (1974). Diagnosis and management of patient noncompliance. *Journal of American Medical Association*, *228*(12), 1563-1567.

Goldstein, M.J., DePue, J., & Kazura, A.N. (2009). Models of provider-patient interaction and shared decision making. In S.A. Shumaker, J. K. Ockene, and K. A. Riekert (Eds.) *The Handbook of Health Behavior Change* (3rd ed) NewYork: Springer Publishing.

Gonzalez, J.S., Safren, S.A., Cagliero, E., Wexler, D.J., Delahanty, L., Wittenberg, E., *et al.* (2007). Depression, self-care, and medication adherence in type 2 diabetes relationships across the full range of symptom severity. *Diabetes Care*, *30*(9), 2222-2227.

Greenson, R.R. (1965). The working alliance and the transference neurosis. *The Psychoanalytic Quarterly.*

Hall, M.A., Zheng, B., Dugan, E., Camacho, F., Kidd, K.E., Mishra, A., *et al.* (2002). Measuring patients' trust in their primary care providers. *Medical Care Research and Review, 59*(3), 293-318

Haynes, R. B. (2001). Improving patient adherence: state of the art, with a special focus on medication taking for cardiovascular disorders. *Compliance in Healthcare and Research.* Armonk, New York: Futura, 3-21.

Haynes, R.B., Ackloo, E., Sahota, N., McDonald, H.P., Yao, X. (2008). Interventions for enhancing medication adherence. *Cochrane Database of Systematic Reviews, 2,* 1-166.

Hays, R.D., Kravitz, R.L., Mazel, R.M., Sherbourne, C.D., DiMatteo, M.R., Rogers, W.H. *et al.* (1994). The impact of patient adherence on health outcomes for patients with chronic disease in the Medical Outcomes Study. *Journal of Behavioral Medicine*, *17*(4), 347-360.

Holman, H.R., Lorig, K.R., Sobel, D.S., Stewart, A.L., & Brown Jr, B.W. (1997). Evidence that an education program for self-management of chronic disease can improve health status while reducing health care costs: a randomized trial. In *Abstract Book/Association for Health Services Research* (Vol. 14, pp. 19-20).

Horvath, A.O., & Bedi, R.P. (2002). *The alliance*. In. C. Norcross (Ed.), Psychotherapy relationships that work: Therapist contributions and responsiveness to patients (pp. 37-69).

Horvath, A.O., & Greenberg, L.S. (1986). Development of the Working Alliance Inventory. In L.S. Greenberg & W.M. Pinsoff (Eds.), *The psychotherapeutic process: A research handbook* (pp. 529-556). New York: Guilford.

Horvath, A.O., & Greenberg, L.S. (1989). Development and validation of the Working Alliance Inventory. *Journal of Counseling Psychology, 36*, 223-233.

Horvath, A.O., & Symonds, B.D. (1991). Relation between working alliance and outcome in psychotherapy: A meta-analysis. *Journal of Counseling Psychology, 38*(2), 139.

Howard, I., Turner, R., Olkin, R., & Mohr, D.C. (2006). Therapeutic alliance mediates the relationship between interpersonal problems and depression outcome in a cohort of multiple sclerosis patients. *Journal of Clinical Psychology*, *62*(9), 1197-1204.

Ingersoll, K.S., & Heckman, C.J. (2005). Patient–clinician relationships and treatment system effects on HIV medication adherence. *AIDS and Behavior*, *9*(1), 89-101.

Jahng, K.H., Martin, L.R., Golin, C.E., & DiMatteo, M.R. (2005). Preferences for medical collaboration: patient–physician congruence and patient outcomes. *Patient Education and Counseling, 57*(3), 308-314.

Julius, R.J., Novitsky Jr, M.A., & Dubin, W.R. (2009). Medication adherence: a review of the literature and implications for clinical practice. *Journal of Psychiatric Practice*, *15*(1), 34-44.

Kim, S.S., Kaplowitz, S., & Johnston, M.V. (2004). The effects of physician empathy on patient satisfaction and compliance. *Evaluation & the Health Professions, 27*(3), 237-251.

Klein, D.N., Schwartz, J.E., Santiago, N.J., Vivian, D., Vocisano, C., Castonguay, L.G. *et al.* (2003). Therapeutic alliance in depression treatment: controlling for prior change and patient characteristics. *Journal of Consulting and Clinical Psychology*, *71*(6), 997.

Kohler, J.C., & Baghdadi-Sabeti, G. (2011). *The world medicines situation 2011*. Geneva: World Health Organization.

Lee, Y.Y., & Lin, J.L. (2009). The effects of trust in physician on self-efficacy, adherence and diabetes outcomes. *Social Science & Medicine*, *68*(6), 1060-1068.

Lehmann, A., Aslani, P., Ahmed, R., Celio, J., Gauchet, A., Bedouch, P. *et al.* (2014). Assessing medication adherence: options to consider. *International Journal of Clinical Pharmacy*, *36*(1), 55-69.

Leventhal, H., & Cameron, L. (1987). Behavioral theories and the problem of compliance. *Patient Education and Counseling*, *10*(2), 117-138.

Luborsky, L. (1976). Helping alliances in psychotherapy. *Successful Psychotherapy,* 92-116.

Mack, J.W., Block, S.D., Nilsson, M., Wright, A., Trice, E, Friedlander, R. *et al.* (2009). Measuring therapeutic alliance between oncologists and patients with advanced cancer. *Cancer, 115*(14), 3302-3311.

Martin, D.J., Garske, J.P., & Davis, M.K. (2000). Relation of the working alliance with outcome and other variables: A meta-analytic review. *Journal of Consulting and Clinical Psychology, 68*(3), 438.

Mickey, M.L., Owen, S.V., & Froman, R.D. (1992). Instrument development: cardiac diet and exercise self-efficacy. *Nursing Research*, *41*(6), 347-353.

Morisky, D.E., Green, L.W., & Levine, D.M. (1986). Concurrent and predictive validity of a self-reported measure of medication adherence. *Medical Care*, *24*(1), 67-74.

Prigatano, G.P., Klonoff, P.S., O'Brien, K.P., Altman, I.M., Amin, K., Chiapello, D. *et al.* (1994). Productivity after neuropsychologically-oriented milieu rehabilitation. *The Journal of Head Trauma Rehabilitation*, *9*(1), 91-102.

Rand, C.S. (2000). I took the medicine like you told me, doctor: self-report of adherence with medical regimens. *The science of self-report: Implications for research and practice*, 257-276.

Rosenthal, R. (1979). The "file drawer problem" and the tolerance for null results. *Psychological Bulletin, 86*(3), 638-641.

Rutten, G.M., Degen, S., Hendriks, E.J., Braspenning, J.C., Harting, J., & Oostendorp, R.A. (2010). Adherence to clinical practice guidelines for low back pain in physical therapy: do patients benefit?. *Physical Therapy*, *90*(8), 1111-1122.

Sabaté, E. (2003). *Adherence to long-term therapies: evidence for action*. Geneva: World Health Organization.

Schaefer, D., Seizer, R.H., Rosenfeld, F., Darnell, C., & Blankenhorn, D.H. (1992). Quick Check for Fat: A bar-coded food frequency analysis to accompany blood cholesterol screening. *Nutrition, Metabolism, and Cardiovascular Diseases*, *2*, 171-177.

* Schönberger, M., Humle, F., & Teasdale, T.W. (2006b). The development of the therapeutic working alliance, patients' awareness and their compliance during the process of brain injury rehabilitation. *Brain Injury*, *20*(4), 445-454.

* Schönberger, M., Humle, F., Zeeman, P., & Teasdale, T.W. (2006a). Working alliance and patient compliance in brain injury rehabilitation and their relation to psychosocial outcome. *Neuropsychological Rehabilitation*, *16*(3), 298-314.

* Stanton, A.L., Petrie, K.J., & Partridge, A.H. (2014). Contributors to nonadherence and non-persistence with endocrine therapy in breast cancer survivors recruited from an online research registry. *Breast Cancer Research and Treatment*, *145*(2), 525-534.

Stewart, M.A. (1995). Effective physician-patient communication and health outcomes: A review. *Canadian Medical Association Journal, 152*(9), 1423.

Tarlov, A.R., Ware, J.E., Greenfield, S., Nelson, E.C., Perrin, E., & Zubkoff, M. (1989). The Medical Outcomes Study: an application of methods for monitoring the results of medical care. *Journal of the American Medical Association, 262*(7), 925-930.

Thompson, L., & McCabe, R. (2012). The effect of clinician-patient alliance and communication on treatment adherence in mental health care: a systematic review. *BioMed Central Psychiatry, 12*(1), 87.

Tracey, T.J., & Kokotovic, A.M. (1989). Factor structure of the working alliance inventory. *Psychological Assessment*, *1*(3), 207.

* Trevino, K.M., Fasciano, K., & Prigerson, H.G. (2013). Patient-oncologist alliance, psychosocial well-being, and treatment adherence among young adults with advanced cancer. *Journal of Clinical Oncology*, *31*(13), 1683-1689.

Vermeire, E., Hearnshaw, H., & Van Royen, P., & Denekens, J. (2001). Patient adherence to treatment: Three decades of research. A comprehensive review. *Journal of Clinical Pharmacy and Therapeutics, 26*, 331-342.

World Health Organization. (2003). *Adherence to long-term therapies: Evidence for action.* Geneva: World Health Organization. Retrieved 9th August 2015 from: www.who.int/chronic_conditions/adherencereport/en

Zolnierek, K.B.H., & DiMatteo, M.R. (2009). Physician communication and patient adherence to treatment: a meta-analysis. *Medical Care*, *47*(8), 826.

* Denotes studies included in this review

Part 2: Research Report

The Development of the Working Alliance in Self-Management Education (WASME) Scale

1. ABSTRACT

1.1 Objective

The examination of working alliance between patient and healthcare professionals within psychological therapy is extensive, with more recent consideration of its impact in physical healthcare. The role of working alliance in the growing intervention of self-management education is under researched, limited by an absence of a measure specific to this setting. This study aimed to develop and examine the structure and psychometric properties of the Working Alliance in Self-Management Education (WASME) scale and to explore relationships between it and measures of educator empathy and satisfaction with the service.

1.2 Method

The development of the WASME scale was a collaborative, iterative process involving educators, self-management research staff and a clinical sample across five phases. Following the development and revision of initial items, 59 participants were recruited from a series of six-hour diabetes self-management group courses (aged 25-79 years old, 56% males). Participants also completed the Consultations and Relational Empathy Measure (CARE) and the Client Satisfaction Questionnaire (CSQ-8) to access validity through correlational analyses. Preliminary exploration of the WASME scale's factor structure and internal reliability was also undertaken.

1.3 Results

Exploratory factor analysis suggested a 15-item unidimensional scale with high internal consistency (Cronbach's alpha = .94) best fitted the data. The WASME scale demonstrated good convergent validity through correlational analysis with the empathy measure (r_s = .69). Additionally, the WASME scale was positively correlated with the measure of satisfaction (r_s = .59) suggesting concurrent validity. No confounding factors were identified.

1.4 Conclusions

Despite the small sample size, evidence supported the reliability and validity of the WASME scale. Preliminary findings of positive relationships with satisfaction highlight the utility of the WASME for improving the efficacy of self-management programs and facilitating further empirical research. Methodological limitations and clinical implications of the study are discussed. Directions for future research are outlined.

2. INTRODUCTION

2.1 Chronic Conditions

Chronic health conditions are those which "have one or more of the following characteristics: they are permanent, leave residual disability, are caused by non-reversible pathological alteration, require special training of the patient for rehabilitation, or may be expected to require a long period of supervision, observation or care" (WHO, 2003) (p.3). They present a growing challenge to care systems internationally. Chronic disease is now the greatest cause of morbidity and mortality in Europe, with between 25% and 40% of the population aged 15 years and over reporting chronic health problems (TNS Opinion & Social, 2007). Prevalence rates are likely to increase in high-income countries (Mathers & Loncar, 2005), as populations age (Pomerleau *et al*. 2008), and with lifestyle factors such as poor diet, inactivity, alcohol and drug use (Suhrcke *et al*. 2006). Proliferation of these conditions have been accompanied by reforms to health provision in the UK, as services move from hospitals into the community. The pervasiveness of chronic diseases has also caused concern in a context of fiscal austerity - a predicted funding gap of £30 billion by 2020/21 (NHS England, 2014) is driving strategies to address financial burden.

Chronic diseases have adverse impacts on individuals' ability to work (Vaughan-Jones & Barham, 2009), emotional well-being (National Collaborating Centre for Mental Health, 2010), personal/family quality of life (Golics *et al*. 2013; Guyatt *et al*. 1993), as well as detrimental financial consequences for the individual, their household, and the wider economy (Kohler & Baghdadi-Sabeti, 2011). These difficulties are magnified for the rising population of those with multimorbid conditions - approximately half of all those with chronic diseases (Smith *et al*. 2012). In England alone, approximately 15 million people live with a chronic condition, accounting for 70% of the total health and social care expenditure (Department of Health, 2010). The rise in incidence and related cost of chronic disease correspond to an increased focus on their prevention and management in a cost-effective manner (Barnett *et al*. 2012).

Common chronic diseases include cardiovascular disease, diabetes, stroke and asthma, and due to improved treatments may now include cancer, AIDS/HIV, and dementia. These conditions are lifelong and often progressive in nature. They cannot be cured but can be self- managed by individuals through use of medication, symptom monitoring, dietary

adjustments, exercise regime, and by attending primary and secondary care health appointments to reduce complications and slow progression of their illness (Sabaté, 2003). Patients with chronic diseases make the majority of decisions about their health without any contribution from healthcare professionals, meaning they are the primary managers of their health (Mensing & Norris, 2003). Adherence to such self-management principles can significantly reduce morbidity and mortality; but adherence is challenging - up to 50% of patients are insufficiently adherent, irrespective of the chronic condition (WHO, 2003; DiMatteo *et al*. 2002: Haynes, 2001).

2.2 Self-Management Education

Self-management has been defined as an ability to manage the symptoms, treatment regimen, impact on physical and psychological wellbeing, social consequences, and lifestyle modifications integral to living with a chronic illness (Barlow *et al*. 2002). It involves completion of day-to-day tasks to mitigate the effect of the disease on health status and requires adequate understanding of the condition and treatment (Clark *et al*. 1991). Analysis of qualitative data suggests that self-management involves three tasks and five core skills (Lorig, 2003); tasks being medical management (taking medication or following a diet), adapting/creating new behaviours and roles (such as accepting help or support) , and managing the emotional consequences of having a chronic condition. Skills required for self-management are; problems solving, decision making, resource utilisation, forming a patient-health professional partnership, and taking action (Lorig, 2003). Patients who follow self-management principles are shown to have better disease control and outcomes compared to those who do not adhere to treatment recommendations (DiMatteo *et al*. 2002). To improve condition management and adherence, self-management education programs have been developed to promote and enhance self-care.

Self-management education encompasses diverse health promotion and patient education programs conducted individually or in groups. A mounting evidence base suggests it can improve clinical outcomes across long-term conditions such as arthritis, diabetes, heart disease and cancer (Clark *et al*. 2000; Lorig *et al*. 2001; Scain *et al*. 2009; Smeulders *et al*. 2009; Warsi *et al*. 2003), through enhancing confidence in ability to manage long term conditions (Barlow *et al*. 1998; Bodenheimer *et al*. 2002), increasing self-care behaviours (Brown, 1990), enriching quality of life (Wattana *et al*. 2007), and reducing healthcare utilisation (Lorig *et al*. 1993). Disease-specific self-management education approaches

appear to demonstrate more positive results than generic chronic disease programs (Gibson *et al*. 2002; Riemsma 2003). Given the personal and financial implications of non-adherence (and emphasis on cost-effectiveness within the NHS), self-management education is emerging as a critical component of healthcare.

Whilst there is growing evidence suggesting a positive impact of self-management education, the process by which education programs facilitate change is unclear. Self-management education programs are complex interventions, and may vary in their goals, approach, content, duration, and delivery (Dennis *et al*. 2008), with some less effective than others (Kennedy *et al*. 2007; Monninkhof *et al.* 2003; Norris, Lau e*t al.* 2002). The logistical attributes of programs may have less impact on the effectiveness of self-management programs than other common factors such as the relationship with educators and social support. Findings that information alone does not produce behaviour change suggests that process factors may be central to promoting self-care (Norris, Nichols *et al.* 2002). Given the limited resources allocated to healthcare, it is important to understand what elements of self-management education programs foster efficient and effective change. More detailed information about what makes a self-management program effective could facilitate the development of more successful programs, improve the ability to evaluate and standardise courses, and help to secure ongoing investment based on the evidence of positive outcomes.

2.3 Working Alliance
One factor that is largely unexplored in self-management education but may be of potential significant influence, is the working alliance. This dynamic concept has its origins in several psychotherapy models (Bordin, 1979; Bowlby, 1988; Freud, 1958; Greenson, 1965; Luborsky, 1976; Rogers, 1957; Strong, 1968), and is most commonly defined as a collaborative and emotional relationship between the therapy dyad (Bordin, 1979). Bordins' pan-theoretical concept of working alliance embraces three elements. Firstly, a collaborative agreement of a clients' difficulties is required for setting treatment goals. Secondly, agreement on the necessary actions or tasks needed to achieve these goals should be reached. Thirdly, development of trust and an emotional attachment, referred to as an affective bond (liking each other, mutual respect, understanding, and committing to goals and tasks), between patient and therapist should occur and be proportionate to the task. Theoretically, these features work in parallel to and independent of any specified

treatments (Gaston, 1990). Working alliance is known as a common factor as it is a component shared across all therapeutic relationships (Lambert & Barley, 2002). Conversely, specific factors are elements that are unique to the therapeutic method used (Wampold, 2010). Thus working alliance does not replace healthcare professionals' skills and techniques, but allows the patient to engage in change.

2.4 The Role of Working Alliance and Treatment Outcomes

In individual psychotherapy, abundant empirical evidence exists revealing the strong positive relationship between working alliance and treatment outcomes across diverse clinical problems (Castonguay *et al*. 2006; Horvath & Luborsky, 1993; Horvath & Bedi, 2002). In the first review of the alliance-outcome relationship using meta-analytic methods to review 20 studies, a significant aggregated correlation coefficient of $r = .26$, and a medium effect size of .54, accounting for seven percent of the outcome variance was revealed (Horvath & Symonds, 1991). A larger review of 79 studies identified a smaller alliance-outcome correlation of .22, accounting for five percent of the outcome variance associated with the alliance (Martin *et al*. 2000). More recently, a further meta-analysis of 190 studies confirmed working alliance as a robust predictor of treatment outcome ($r = .28$) accounting for eight percent of the total variability in the outcome (Horvath *et al*. 2011). This review highlighted variability in the alliance-outcome relationship, given differing conceptualisation of the alliance, assessment at different time points, and ratings from various perspectives (patient, therapist, observer). Despite the heterogenity of data Horvath and colleagues (2011) confirmed that the alliance-outcome relationship is pervasive regardless of the measure of alliance used, whose perspective it is rated from, the model of therapy used, and across different outcomes. Furthermore, the positive correlation between alliance and outcomes remains even when previous change is controlled for (Barber *et al*. 2000, Klein *et al*. 2003). Research suggests that working alliance is significantly associated with positive outcomes in 66-70% of studies of different theoretical perspectives and treatment formats within psychotherapy (Luborsky & Auerbach, 1985; Martin *et al*. 2000; Orlinsky *et al*. 1994). Causality between alliance and outcome has also been investigated with studies indicating that measures of alliance taken early in treatment predict post-treatment outcomes (Castonguay *et al*. 2006).

Although most evaluation of the impact of working alliance has been undertaken in individual psychotherapy, more recently, its positive impact on treatment outcomes has

been suggested in other settings such as in group psychotherapy (Lo Coco *et al.* 2012; Taft *et al.* 2004; Tasca & Lampard, 2012). In physical healthcare, patient-clinician working alliance has been positively associated with adherence (Fuertes *et al.* 2015; 2009); satisfaction (Kim *et al.* 2008); health-related quality of life (Bennet *et al.* 2011); and health outcomes (Attale *et al.* 2010). Furthermore, there is preliminary evidence of its positive influence in family psychoeducation for patients with schizophrenia (Smerud & Rosenfarb, 2008). Working alliance thus appears to be a correlate of outcomes in physical healthcare and group settings although research in this area is in its infancy.

2.5 Measurement of Working Alliance

The increasing interest in working alliance has prompted the development of a wide variety of psychometrically-robust assessment tools to quantify it and investigate its relationship with outcomes. Currently, there are several frequently used instruments available encapsulating different rater's perspectives (client, therapist, or observer), and conceptualised from differing theoretical backgrounds (Horvath & Bedi, 2002). Client self-report scales have been identified as the most effective method of predicting outcomes (Horvath, 2000; Horvath & Symonds, 1991; Wampold, 2010). Research that explored the relationship between variance in working alliance scores attributed to clients and therapists, found therapists' variance rated by clients accounted for a significant alliance-outcome relationship but not vice-versa (Baldwin *et al.* 2007). This highlights the importance of the therapist's role in building positive working relationships with their clients.

A review of the psychometric properties of existing measures capturing working alliance (Elvins & Green, 2008), identified three of the most commonly used measures of working alliance to have good validity, reliability, and ability to predict outcomes: The Working Alliance Inventory (WAI; Horvath & Greenberg, 1989); California Scales (CALPAS; Marmar *et al.* 1989); Vanderbilt Scales (VTAS; Hartley & Strupp, 1983). In a recent meta-analysis, the WAI was identified as the most commonly used measure of the alliance-outcome relationship in psychotherapy of studies identified between 1973 and 2009 (Horvath *et al.* 2011). Despite its common use, some studies employing Confirmatory Factor Analysis have not found an adequate model fit as suggested by Bordins' (1979) theory (Hatcher & Gillaspy, 2006; Tracey & Kokotovic, 1989; Andrusyna *et al.* 2001). This questions the three distinct subscales as fundamental to the construct of working

alliance. Since the WAI and other working alliance scales have been designed for use in psychotherapy settings to examine client-therapist relationship, their focus on this therapeutic setting render them inappropriate to assess working alliance in self-management education. Currently, there is no psychometrically-robust, validated tool available to measure working alliance in the delivery of self-management education.

2.6 Summary and Study Rationale

Self-management education has potential to benefit patients, and facilitate behaviour change to mitigate costs, however there is little understanding of what makes self-management education effective. One factor that may influence the outcome of a self-management program is the working alliance between individuals and educators leading these programs. In psychotherapy, the construction of valid and reliable scales to measure working alliance have facilitated decades of research and revealed working alliance as having an integral relationship to the prediction of treatment outcomes across a variety of clinical problems (Horvath & Luborsky, 1993, Martin *et al.* 2000, Horvath *et al.* 2011). Given that no equivalent tool is available to examine working alliance in self-management education, development of a tailored measure would enable process factors to be captured and permit future research to aid evaluation and enhancement of such programs. In particular, understanding the role of working alliance in self-management education could underpin quality improvement of existing programs and inform interventions.

2.7 Study Aims and Objectives

The present study aimed to develop the Working Alliance in Self-Management Education (WASME) Scale. The application of psychometric principles for scale construction was utilised to create a reliable and valid measure of working alliance applicable to self-management education programs. More specifically, the aims were to:

1. Develop a brief, pragmatic and clinically-grounded questionnaire to assess the working alliance between individuals attending self-management education courses and educators. The novel scale should be easy to administer and score.

2. Examine the psychometric properties of the new measure, including its internal consistency, convergent validity, and concurrent validity.

3. Explore the factor structure of the WASME scale and identify if the construct of working alliance in self-management education resembles Bordins' (1979) three-factor model conceived in psychotherapy.

4. Investigate any relationships or differences between participant and educator demographics and WASME scale ratings.

3. METHOD

The development of the WASME scale took place within the setting of the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) courses. (Skinner *et al.* 2006). The DESMOND course is grounded in psychological models and philosophical statements summarised as 'informed choice'. The program runs over six hours on one day and is facilitated by two trained educators (See Appendix F for further details on the course). Attendees of these courses report greater weight loss, increased rates of smoking cessation and fewer depressive symptoms than those receiving usual care (Davies *et al*, 2008). DESMOND Courses have been found to be cost-effective (Gillett *et al*. 2010).

3.1 Procedure Overview

The development of the WASME Scale involved five phases (See Fig. 1) using an empirical approach to scale development and following psychological testing guidelines (DeVellis, 2011, Gregory, 2007; Kaplan & Saccuzzo, 2012). Firstly, the concept of working alliance in self-management education was operationalised. The scaling method was based on this definition, and by reviewing existing scales. An initial item pool was generated by the trainee through consultation with clinical and research staff, review of existing literature, empirical studies, and measures used to assess working alliance in other contexts. These pilot items were examined, rated and amended by educators and research staff. A developmental clinical sample completed the questionnaire in the fourth stage of the scale development. Finally, the scale items were evaluated for performance, psychometric properties, and factorial structure. Refinement of items and optimisation of length took place.

Fig 1. Phases of Scale Construction

- **Phase 1**
  - **Operationalising the construct of working alliance**
  - Open-ended interviews of educators and course attendees

- **Phase 2**
  - **Selecting a scaling method**
  - Review existing scales and operationalise construct

- **Phase 3**
  - **Item development**
  - Utilise expert judges to rate items on relevance and clarity

- **Phase 4**
  - **Administer scale to developmental sample**
  - Trial scale items on clinical sample

- **Phase 5**
  - **Evaluation of Scale items**
  - Investigate the scale stucture and psychometric properties to create final scale

3.2 Ethical Approval

Ethical Approval was obtained from the NRES Committee London- City Road and Hampstead through Proportionate Review (REC reference 15/LO/00336; Appendix G). Approval was granted from the hospital trusts' research and development department (Appendix H). The risk of this study leading to patients experiencing adverse effects was deemed to be low however if participants experienced any distress during or after the study, they were advised to contact their local GP for support. All participants were given local contact numbers for the Patient Information and Liaison Service (PILS) as well as a contact number for the trainee should they have any queries or concerns regarding the study. All questionnaires were anonymous and identifiable only through their unique study ID to assure patient confidentiality.

3.3 Phase 1 - Operationalising the Construct

Following psychometric theory (DeVellis, 2011; Gregory, 2007), the first step involved creating a working definition of working alliance in accordance with its theoretical conceptualisation (Bordin, 1979; Safran & Muran, 2000), and the existing empirical research (Horvarth *et al*. 2011; Martin *et al*. 2000). During this phase efforts were made to ensure face and content validity. Thought was given to the differences in context between working alliance in psychotherapy and in self-management education by consulting with research and clinical staff.

3.3.1 Participants

The trainee met with a convenience sample of eight DESMOND educators and eleven DESMOND research staff. Members of the research team provided feedback in a group format following a team meeting. The researcher met with educators in pairs following their facilitation of a self-management education course.

3.3.2 Procedure

Educators and research staff were contacted by email to notify them of the study and of opportunities to contribute to the development of the WASME scale. Before their participation, the researcher gave a presentation to both the research team and the educators to provide a context of the planned study and summarise prior research capturing working alliance. Working alliance was defined broadly as a collaborative and emotional relationship between the individual attending self-management education and the educator. During brief interviews participants were asked to provide verbal feedback on factors that they felt were important in the development of a strong working alliance between an individual attending self-management education and an educator leading the program in order to operationalise the construct. The trainee facilitated interviews and documented individual responses during discussions. Participants were encouraged to speak freely, and the absence of right or wrong answers was emphasised to encourage participation. The trainee summarised participants' feedback throughout the interview and checked their remarks had been accurately understood. Responses provided through consultation were analysed using a qualitative process informed by thematic analysis. Thus responses were coded into themes to aid a clear conceptualisation of working alliance and to inform the item development (Braun & Clarke, 2006).

3.3.3 Results of Consultation

Through the process of consultation, five main themes were identified as relevant to the evolution of a strong working alliance between an individual attending a self-management education course and an educator. These themes were used to construct potential items. The themes identified were:

1. *Participants feel heard*: This theme included responses about the educator taking the time to listen and understand the individual's story, opinion, difficulties and concerns.

2. *Educators' warmth and communication*: This theme involved the educators' ability to respond to the individual with warmth and the participant feeling they could trust the educator.

3. *Educators' skills and approach*: This theme was constructed of responses about the educators' skill in being flexible to participants needs, not appearing to judge them, answering relevant questions in a way that was meaningful to them, and managing the group.

4. *Collaboration to identify goals and plans:* This theme incorporated ideas about the educator helping the participant with difficulties, developing and agreeing on beneficial goals, and helping identify barriers and strategies to overcome these.

5. *Participants feel empowered:* This theme encompassed responses regarding participants feeling more knowledgeable, resourceful, able to cope with their difficulties, and becoming optimistic about their future.

3.4 Phase 2 – Selecting a Scaling Method

Based on Bordins' (1979) conceptualisation of working alliance, a review of existing working alliance measures with good psychometric properties (CALPAS: Marmar *at al*. 1989; Penn Scales: Alexander & Luborsky, 1986; VTAS: Hartley & Strupp, 1983; WAI: Horvath & Greenberg, 1989), and the design of the current study; a seven-point Likert-type scale was identified as appropriate to measure participants' ratings of working alliance.

3.5 Phase 3 – Item Development

Items were generated based on the themes identified by research staff and educators during the conceptualisation phase. Item generation was also informed by existing measures of working alliance and relevant literature and began by the trainee recording items that reflect each dimension of working alliance identified by staff during the conceptualisation stage. Following guidelines by DeVellis (2011), as many as three to four times the number of items desired in the final scale were created. An item was constructed to express ideas related to the construct of working alliance and then rewritten in several different ways by the trainee. The trainee then critically assessed, revised and discarded items according to their conceptual relevance and linguistic clarity, creating a total of 47 preliminary items. Reverse wording was used for several of the items. This was to ensure that subsequent respondents would read the questions carefully, and to help identify respondents who

might agree with all items, suggesting a lack of engagement and accuracy of their responses. Items were examined and re-phrased, with the assistance of two academic researchers with knowledge of both working alliance and self-management education, to assure items conceptual consistency and reword items that were unambiguous. Effort was taken to ensure items were understandable to adults with poor literacy by reducing statement length and complexity during the item creation before further evaluation for clarity by DESMOND research staff.

3.5.1 Participants

Once the items had been generated and preliminarily evaluated by the trainee and two supervisors they were reviewed by fourteen DESMOND research staff to rate via forms (See Figure 2).

Figure 2. Sample Rating Scale to Examine Content and Face Validity

3.5.2 Procedure

In order to evaluate content and face validity, rating forms containing 47 items were emailed to DESMOND research employees and educators (See Appendix I for a full review of the rating form and the 47 preliminal items). Respondents were asked to judge each item on the form by rating them on a four-point scale for their relevance and clarity as suggested by Hambleton (1991) and Bausell (1986), and comment on any alternative wording or further suggestions. Once completed respondents placed forms in a feedback box or emailed the form to the trainee. A mean score of three or less out of four for any item resulted in its elimination from the item pool, or rephrasing to reduce sources of error

variance and strengthen content validity of the scale. Thought was given to items which share a common cause, common consequence or emergent variables to arrive at items that clearly reflected the concept of working alliance. Through this critical analysis process, item quantity was reduced while clarity and homogeneity were improved to create the scale for the test sample.

3.5.3 Results of Item Development Ratings

Of the 47 items initially reviewed, seven items scored a mean rate of three or below for relevance and eight items scored below this threshold on clarity (one of which also scored below three on relevance). The trainee reviewed these 14 items, eliminating ten, rewording two, combining one item with another similar item, and retaining one unchanged. Raters provided comments for all but two of the scale items, which resulted in modification of wording in eight further items. Four similar items were merged to make two items, and eleven further items were removed due to similarity with other items (See Appendix J for further details of preliminary item refinement). The revised scale thus contained 26 items.

3.6 Phase 4 - Administer Scale to Developmental Sample

3.6.1 Participants

Participants met eligibility for recruitment if they completed a six-hour DESMOND course between October 2015 and January 2016 running from a single hospital site. Individuals attending DESMOND programs may have Type 2 diabetes or may be attending with a family member who had Type 2 diabetes. Therefore, a person with or without diabetes was eligible to participate.

3.6.2 Eligibility Criteria

Inclusion Criteria

Participants were eligible if over 18 years of age, had attended the entire six-hour program, were able and willing to give informed consent, and could understand English.

Exclusion Criteria

Exclusion criteria for this study included: diagnosis of dementia, substance use disorder, or an inability to complete questionnaire due to poor eyesight, illiteracy or cognitive problems.

3.6.3 Procedure

All participants received Participant Information Sheets regarding the study at least 24 hours prior to a DESMOND course (Appendix K). Directly after completion of the self-management education course the researcher reminded all eligible participants about the information sheet regarding the study and provided an opportunity for further questions. Participation was voluntary, and all questionnaires were completed anonymously and were confidential. Eligible participants completed informed consent forms prior to their participation (Appendix L).

Questionnaire booklets were completed immediately after the self-management course, and contained; socio-demographic questions, two copies of the novel 26-item WASME scale to be completed in respect of the two educators conducting the course (Appendix M), two copies of an empathy measure and one satisfaction questionnaire. Questionnaires were issued and collected by the trainee to minimise any desirability bias that may occur following the return of questionnaires to educators. Consent forms were removed and stored separately to the completed questionnaires to maintain the anonymity of participants. Educators were asked to provide basic information on their age, gender, training background, and duration of role as an educator. Response rates were completed to ensure minimum sampling bias.

3.6.4 Additional Measures

Socio-demographic Information

Participants were asked to identify themselves as having diabetes or attending the course with a family member with diabetes. Further information regarding their time since diagnosis, gender, age, ethnicity, relationship status, smoking status, current employment status, weight, and height were requested to help assess the representativeness of the developmental sample. Participants' weight and height were used to calculate their Body Mass Index (BMI). Individuals with BMI $\geq 25 \text{kg/m}^2$ are at greater risk of developing diabetes mellitus (Bays *et al.* 2007).

Empathy

Assessment of convergent validity was achieved through using an empathy scale given its conceptual overlap with working alliance. The Consultations and Relational Empathy

measure (CARE; Mercer *et al.* 2004) is a client-rated empathy measure identified as appropriate for this study. This measure has been through two pilot versions before being validated on 3044 outpatients under 26 different GP practices. Its sound psychometric properties (Cronbach's α = .93) have resulted in its adoption as part of the routine appraisal of general practitioners' consultation skills in Scotland. Furthermore, this 10-item measure is brief and free to use (Appendix N).

Satisfaction

Roter and Larson (2001) suggested that a positive physician-patient relationship is central to patient satisfaction. A more recent study found that working alliance predicted one-third of patients' general satisfaction (Kim *et al.* 2008). Further studies have shown that dissatisfied patients are less likely to comply with physician's treatment recommendations (Ley, 1988). Given these findings, patient satisfaction was measured to investigate concurrent validity of the working alliance in a self-management scale. Patient satisfaction was assessed by the Client Satisfaction Questionnaire (CSQ-8; Larsen *et al.* 1979), a self-administered questionnaire extensively studied and with good psychometric properties (Cronbach's α = .80 to .94). The CSQ-8 is an eight-item, unidimensional measure which uses a four-point Likert scale to elicit homogenous estimates of general satisfaction, with higher scores suggesting greater satisfaction (Appendix O).

3.7 Phase 5 - Evaluation of Scale Items

3.7.1 Sample Size

A sufficiently large sample is needed to reduce sample bias and improve statistical power. Recommendations about sample size required to perform factor analysis remains unclear due to given guidelines based on limited theoretical and empirical foundations (Fabrigar & Wegener, 2011). There is some consensus that a minimum of 100 participants (or five times the number of participants per item included in the scale) are required (Gorsuch, 1983; Hatcher, 1994; MacCallum *et al.* 1999). Where data fulfils optimal properties including high communalities between items (.70 or greater), and three to five variables substantially loading on each factor, smaller sample sizes may prove adequate (Fabrigar & Wegener, 2011; Preacher & MacCallum, 2002). As the WASME scale included 26 items, a sample size of 130 participants was originally deemed satisfactory and feasible for a doctoral project given the frequency of DESMOND courses and quantity of participants

enrolled in each course. However, during the period of research, access to DESMOND courses was curtailed by the unanticipated termination of tender by commissioners. Thus recruitment was prematurely terminated resulting in a reduced sample size of 59 participants. Despite this reduced sample size, it was decided to continue with an Exploratory Factor Analysis as previous reviews of the literature had found that 40.5% of studies conducting EFA for scale development used subject-to-item ratio of 5:1 or less (Costello & Osborne, 2011). Kline (1995) recommends a minimum of a 2:1 subject to item ratio for research purposes which is achieved in this study. Furthermore, factor analysis has been shown to be reliable even in sample sizes below 50 (De Winter *et al.* 2009).

3.7.2 Missing Values

Data were checked for missing values, and missing data were replaced with mean response for each item within the WASME scale, CARE measure and CSQ-8, where less than 10% of the data were missing (Gorsuch, 1983; Field, 2009). Cases were removed from analyses where greater than 10% of the data were missing for any one scale.

3.7.3 Summary of Analysis

Exploratory Factor Analysis

The project aimed to test the hypothesis that the WASME scale reflects the latent construct of working alliance in self-management education. Accordingly, structural analysis was conducted using a Principal Axis Exploratory Factor Analysis to identify the underlying dimensions of the scale, determine the number of factors that exist, and the patterns of association between groups of variables. Exploratory Factor Analysis (EFA) was conducted as the WASME scale is being developed in a new area and may not map on to the theoretical model of existing scales due to the change in context, patient group, and role of the educators.

EFA offers greater understanding of scale dimensionality, necessary as scales may have high internal consistency even when they are multidimensional constructs (John & Benet-Martínez, 2000). This form of analysis therefore allowed the trainee to explore the construct structure rather than impose it according to existing theory through confirmatory factor analysis. EFA allowed the psychometric properties of the scale to be investigated by exploring items loading values on factors and identify items which are pure measures of the working alliance construct (Kline, 2005). Iterative principal axis factoring was selected

over principal components analysis following recommendations of Fabrigar and Wegener (2011). Additionally, principal axis factoring has been identified as useful in recovering weak factors (MacCallum *et al*. 2007), for small sample sizes (De Winter & Dodou, 2012) and where data violates the assumption of multivariate normality (Fabrigar *et al*. 1999). A Direct Oblimin rotation of the factor axes was undertaken as this rotational procedure is favoured in the investigation of psychological theory as it allows factors to be correlated (Cattell, 1978).

Analyses were performed using SPSS statistical software, Version 20 (SPSS Inc., 2011), with statistical significance set at $p < .05$. Descriptive analyses were carried out to describe the demographic and clinical characteristics of the sample group. Checks for the normal distribution of data and to establish that assumption to conduct parametric tests were performed before undertaking analysis (Stuart & Kendall, 1968). Eigenvalues, factor loadings, and examination of the scree plot were used to determine item inclusion in the final version of the novel working alliance scale. Recognised criteria (Clark & Watson, 1995; Tabachnick & Fidell, 2001) of retaining items with Eigenvalues above 1 (Kaiser Criteria) and factor loading above 0.4 were used to aid item selection. Data was examined with knowledge of research indicating that examination of the scree plot is a more accurate technique than the Kaiser criteria in deciding the number of factors to retain (Zwick & Veliver, 1986).

Reliability

Test homogeneity was used to assess the reliability of the scale. To achieve a homogenous scale, a process of removal of those items poorly correlated with the total score was undertaken (Gregory, 2007). Items which did not correlate at a 5% level of significance were excluded. Cronbach's procedure (1951) was be used to investigate internal consistency, with a value of .70 as the lower acceptable bound for Alpha (Nunnally, 1978).

As the self-management program used to develop the scale comprised a course delivered on a single day, the WASME scales test-retest reliability was not investigated. Additionally, as working alliance has been shown to change over-time, it would be difficult to establish if changes in scores reflected the reliability of the WASME scale or were due to variations in the patient-educator relationship over time. Therefore, assessment of test-retest reliability was not deemed applicable to the WASME scale.

<u>Validity</u>

Validation of the scale was achieved through correlational analysis to assess convergent and concurrent validity. A recommendation of a sample of 68 participants to significantly detect a medium correlation ($r = .3$) was made by Cohen (1992). Convergent validity was assessed by examining the relationship between the items of the WASME scale and the CARE measure. As empathy is similar but not identical it would be expected that there should be a moderate correlation between items which reflect warmth, trust and liking and the empathy scale.

Criterion validity was not assessed since there are currently no measures that assess working alliance in self-management education. An existing measure created in psychotherapy could have been used, however it would require modification to an extent which would invalidate its psychometric properties. To examine if the working alliance for use in self-management scale has adequate concurrent validity, the association between WASME scale and the CSQ-8 was examined using correlational analysis.

4. RESULTS

4.1 Participants

Participants comprised 59 (of 86 eligible) volunteers attending a diabetes self-management education course (69%). One participant's data was excluded from analysis due to greater than 10% of data missing leaving a sample of 58 participants. The majority of those who declined participation cited time constraints as a reason for not taking part (17%); six participants did not provide a reason for not participating (7%); four stated that they did not want to participate as they were attending to support a family member (5%); and two reported that they did not want to participate in research (2%). The majority of participants were male and white British although minority ethnic groups were represented in the sample (34.5%). The sample was largely made up of those with diabetes (91%) diagnosed between one month and 20 years prior to the course. Mean Body Mass Index (BMI) of participants was 30.6 kg/m^2 which is in the obese range (WHO, 2003). Frequencies and percentages for sample characteristics are shown in Table 1.

Table 1. Sample Characteristics

Age (Years)	Median = 57 (SD 12)	Range = 25-79	
Gender		*Frequency*	*Percentage*
	Male	34	58.6
	Female	24	41.4
Race/Ethnicity	White British	38	65.5
	Black African	5	8.6
	Black Caribbean	1	1.7
	Indian	11	19
	Pakistani	1	1.7
	Other Asian	2	2.4
Relationship Status	Single	10	17.2
	In a relationship	5	8.6
	Married	33	56.9
	In a civil union	1	1.7
	Divorced	5	8.6
	Widowed	4	6.9
Employment Status	Employed full-time	22	38.6
	Employed part-time	4	6.9
	Self-employed	5	8.6
	Retired	19	32.8
	Missing Data	1	1.7
Diabetes Status	Diabetes	53	91.4
	No diabetes	5	8.6
Smoking Status	Smoker	3	5.2
	Ex-Smoker	22	37.9
	Non-Smoker	32	55.2
	Missing Data	1	1.7
Time since diabetes diagnosis (Months)	Median = 5 (SD 77)	Range 1-240	
Body Mass Index (BMI)*	Mean = 30.6 (SD 5.7)	Range = 19.5-44	82% > BMI 25
			47% > BMI 30
			22% > BMI 35

* 3 participants did not report BMI (N=55)

4.2 Preliminary checks

4.2.1 Missing values

Six values from the WASME scale were missing and mean values were inputted. One participant had not completed several items on one of the CARE measures and was removed from analyses. Eight missing values were identified on the CARE measure and mean values substituted where there were no more than two missing variables for the questionnaire (as stated in scoring guidelines). No missing values were evident on the CSQ measure.

4.2.2 Outliers

Outlier data was identified and investigated. Since outliers entered in error could not be distinguished from participant's true beliefs they were kept in during preliminary analyses.

A greater percentage of outliers were evident on negatively worded items of the WASME scale.

4.2.3 Suitability for Factor Analysis

As each participant completed two WASME scales concerning their relationship with each of the two educators, these two data sets were analysed separately as to not duplicate the data for each participant. There was a strong correlation ($r_s = .88$, $p < .001$) between working alliance rating for educator one and educator two. WASME variable data were not normally distributed (Shipiro-Wilko = 0.00). Exploration of histograms identified all WASME items as negatively skewed. Principal axis factoring was employed which makes no assumption about data distribution (Fabrigar *et al*. 1999).

Prior to Exploratory Factor Analysis, preliminary assessment of the scale reliability and item-total correlation was conducted. The 26-item scale had good internal reliability for data on educator one ($\alpha = .88$) and for educator two ($\alpha = .90$). Multicollinearity and singularity of data were investigated by scanning the correlation matrix for extremely high ($> .9$) or extremely low ($< .3$) correlations and data was deemed suitable for both data sets. The corrected item-total correlation was also explored to identify items with low correlations. A correlation of greater than Rho = .4 with the total scale is recommended by Nunnally & Bernstein (1994). Each time an item was removed, reliability analysis was conducted to identify any changes in internal consistency of the scale (Field, 2009). Through this process four items were identified with low item-total correlations, and were removed from the item pool prior to factor analysis for data on educator one (Item 7, $r = .10$; Item 21, $r = .16$; Item 10, $r = .25$; Item 22, $r = .20$). Examination of the item-total correlation for the working alliance data for educator two resulted in five items being removed (Item 7, $r = .28$; Item 10, $r = .28$; Item 22, $r = .30$; Item 20, $r = .19$; Item 21, $r = .19$). This process improved the internal reliability for data in relation to ratings of working alliance for educator one ($\alpha = .93$) and educator two ($\alpha = .95$).

4.3 Factor Structure of the Scale

Factor analysis was undertaken on the remaining 22-item data for working alliance ratings for educator one and the 21-item data set of working alliance ratings completed in relation to the second educator. The Kaiser-Meyer-Measure of Sampling Adequacy was in the good and great range (Hutcheson & Sofroniou, 1999) indicating patterns of correlations

are close and factor analysis is appropriate for ratings of educator one (KMO = .78) and educator two (KMO = .84). Bartlett's Test of Sphericity was significant for ratings of educator one ($\chi 2$= 998, df= 231, p <.001) and educator two ($\chi 2$= 1055, df= 210, p <.001), highlighting the presence of relationships between variables and the suitability of factor analysis.

4.3.1 Factor structure of Working Alliance ratings for Educator One

During preliminary analysis a five-factor solution was identified for ratings of educator one. Factor one had an extracted eigenvalue of 10.24, accounting for 45.2% of the total variance, while the other four factors accounted for 6.93%, 5.98%, 3.82% and 3.17%. The determinant of the R-Matrix was checked to identify multicollinearity of the variables and was found to be 1.2 x 10_7 significantly less than the $1x10_5$ required to reach an acceptable level of multicollinearity. To reduce the high degree of multicollinearity in the data, items which had a factor loading of below .4 and those which loaded on more than one factor greater than .3 were deleted from analyses (Nunnally & Bernstein, 1994). Following guidelines for factor analysis, factors with less than three items loading on them were deemed unsuitable to be retained (Loewenthal, 2001). After completion of this iterative process, a two-factor solution was forced due to less than three items loading on the other three factors. Four items were removed from analysis due to low loadings values (Item 20, Item 8, Item 2, Item 14), creating an 18-item scale.

Goodness of fit remained highly significant for this model ($\chi 2$ = 833, df = 153 p <.001) as did sampling adequacy (KMO = .82). Multicollinearity remained high for the scale as the determinant of the R-Matrix was 6.1 x 10_8. Correlation between the two factors was moderate (r = .56). All 18 items loaded above .4, each on only one of the two factors (See Table 2). The two factors accounted for 57% of the variance, with Factor one accounting for 49% of the variance and Factor two accounting for 8% variance. Reliability analysis of the 18-item scale identified high internal consistency of the scale (α = .92).

4.3.2 Factor Structure of Working Alliance Ratings for Educator Two

A similar process was conducted to analyse the dimensionality of ratings for educator two. During preliminary analysis a three-factor solution was identified for ratings of educator two, based on Kaisers criterion of eigenvalues greater than one. Similar to factor analysis

Table 2. Factor loadings for WASME scale items

Item No.	Item	2-Factor Solution Educator One			1-Factor Solution Educator Two	
		F1	F2	Item-Total Rho	F1	Item-Total Rho
1	*The educator listened to me	**.511**	.175	.62	**.736**	.71
3	The educator gave me the opportunity to share my experiences	.085	**.856**	.68	**-**	-
4	*The educator facilitated the group well	-.017	**.885**	.61	**.720**	.69
5	*The educator made me feel that I could share as much or as little as I wanted	-.034	**.749**	.49	**.743**	.70
6	*The educator wanted to know my point of view	.154	**.599**	.57	**.804**	.77
8	*The educator was interested in my difficulties and concerns	-	**-**	-	**.762**	.75
9	*The educator agreed on what were important goals for me	**.596**	.270	.76	**.766**	.75
11	*The educator helped me recognise things I could do differently to achieve my goals	**.756**	-.024	.68	**.797**	.76
12	*I felt comfortable asking the educator questions	**.556**	.270	.65	**.757**	.72
13	The educator was respectful of my opinions and beliefs	**.830**	.028	.78	-	-
15	*I felt supported and encouraged by the educator	**.810**	.098	.82	**.840**	.82
16	*The educator understood me	**.876**	-.163	.70	**.873**	.85
17	*The educator was interested in my whole life	**.557**	-.097	.45	**.471**	.46
18	The educator enabled discussion about issues that were important to me	**.452**	.032	.45	-	-
19	*The educator made me feel resourceful and capable	**.810**	.057	.78	**.843**	.82
23	*The educator helped me identify barriers to making changes	**.683**	.121	.74	**.723**	.71
24	The educator helped me think about how I may overcome barriers to making changes	**.813**	-.052	.73	-	-
25	*I felt valued and respected by the educator	**.681**	-.019	.62	**.669**	.66
26	*The educator helped me to identify how I could deal with future concerns and queries	**.846**	.021	.80	**.686**	.67
% Variance Explained		**49.4%**	**8%**	*α =.93*	**56.5%**	*α =.94*

Indicates items that were retained in the final WASME scale

of the ratings of educator one, factor one accounted for the majority of the total variance (53.6%), while factor two and factor three accounted for a much smaller proportion (5.3% and 4.2% respectively). The determinant of the R-Matrix was 4.8 x 10_9 indicated multicollinearity of the variables. To reduce multicollinearity exploration of items loading values were examined. Two items were removed due to low loading values (Item 18, 24) and four items were removed due to cross loading on factors (Item 3, Item 13, Item 14). Item 2 was removed from the analysis as it was a duplicate of Item 12, however item 12 had a greater loading value.

The elimination of items improved the determinant of multicollinearity (5.1 x 10_7) although still unacceptably low, goodness of fit remained highly significant for this model ($\chi2= 741$, df= 105 p <.001) as did sampling adequacy (KMO = .86). The removal of these items resulted in a two-factor solution being produced. On exploration of the loading on factors it was found that four items cross-loaded on both factors (Item 1, Item 4, Item 5, item 6) and along with the small amount of variance accounted by factor-two it was decided to force a one-factor solution. This appeared to be more suitable for the data as item loading values increased in size. All 15-items loaded above .4 accounting for 56.5% of the total variance (see Table 2). Reliability analysis of the 15-item unidimensional scale identified a high internal consistency of the scale ($\alpha = .94$).

4.4 Conceptualising the Factor Structure

As EFA identified different factor structure in the two data sets, the conceptual basis for the two-factor and one-factor solution was examined in order to guide understanding of the dimensionality of the WASME scale. The four items making up factor-two of the ratings on educator one (Item 3, 4, 5, 6) appeared to conceptually overlap with other items in factor one. For example, Item 3 "the educator gave me the opportunity to share my experiences" was the item with the largest loading value on factor-two and did not appear conceptually dissimilar to Item 16 "the educator was interested in my whole life" and Item 17 "The educator enabled discussion about issues that were important to me" seen in factor one. This along with the small amount of variance accounted by factor-two and the slightly higher internal consistency of the one-factor scale provided rationale for deciding that the WASME scale was a unidimensional scale and using the ratings on educator two to assess the validity of the scale. The 15-item WASME scale had a maximum score of 105. The mean score for the scale was 94.4 (SD 8.3) and the range for the scale was 75-105. This suggests that participants rated their working alliance with educators as strong.

4.5 Exploratory Validity Analyses

Preliminary validity analyses of the pilot WASME scale was conducted to assess convergent and concurrent validity. Data from all three questionnaires violated the assumption of normality: WASME, CARE and CSQ-8. Transformation (reflect and square root) did not result in normally distributed data and therefore non-parametric tests were conducted.

4.5.1 Convergent validity

Convergent validity of the WASME scale was accessed through correlation with the CARE total score (Table 3). The CARE measure was completed by 58 participants however one participant was removed from analysis due to several missing values. The maximum score for the ten-item empathy questionnaire was 50. The medium response was 46 and the interquartile range was between 40 and 50. Therefore the majority of participants rated educators as being empathetic. A Spearman's rank-order correlation identified a statistically significant positive relationship between the CARE total score and the WASME total score (r_s (57) =.63, $p < .001$).

Table 3. Correlations to Access the Validity of the WASME Scale

	N			Correlation with WASME total	sig.
CARE Total	57	Interquartile Range	40-50	$r_s = .625$	$p <.001$
		Median	46		
		Mean(SD)	44.5(6.0)		
CSQ total	58	Interquartile Range	28-32	$r_s = .589$	$p <.001$
		Median	31		
		Mean (SD)	29.6(3.3)		
		SD	3.3		

4.5.2 Concurrent validity

A Spearman's rank-order correlation was run to determine the relationship between the WASME total score and the CSQ total score, in order to investigate the relationship between working alliance and satisfaction (Table 3). The maximum score for the eight-item satisfaction questionnaire was 32. The medium response of participants on this

questionnaire was 31 and the interquartile range was between 28 and 32. This suggests that participants were highly satisfied with the service they had received. There was a moderate positive correlation between the total WASME scale and the CSQ, which was statistically significant (r_s (58) =.59, $p < .001$).

4.5.3 Assessment of Potential Confounding Variables

Participants' demographics were investigated to identify possible confounding variables of the WASME scale. Participants' age, gender, ethnicity, time since diagnosis, relationship status, smoking status, employment status, BMI and their total score on the WASME scale were investigated. No significant relationships or differences were found between participants' variables and the total WASME score, suggesting that these factors did not confound their scoring of the WASME scale (Table 4).

Table 4: Investigation of Potential Confounders

Potential Confounders	N	Statistical Test	Test Result	Significance value(2-tailed)
Participant Variables				
Age	58	Spearman's rho	$r = -.042$	.757
Gender	58	Mann-Whitney U Test	U = 359.5	-.769
Ethnicity	58	Kruskal-Wallis Test	$\chi^2(5) = 1.596$	.902
Smoking Status	57	Kruskal-Wallis Test	$\chi^2(2) = .758$	.685
Relationship status	58	Kruskal-Wallis Test	$\chi^2(5) = 5.051$	.410
Diabetes Status	58	Mann-Whitney U Test	U = 101	.381
Time since diagnosis	53	Spearman's rho	$r = .156$	.265
Employment status	57	Kruskal-Wallis Test	$\chi^2(4) = 5.419$	.247
BMI	55	Spearman's rho	$r = -.100$	.467
Educator Variables				
Age	58	Spearman's rho	$r = -.041$	.659
Gender	58	Mann-Whitney U Test	U = 97	.323
Ethnicity	58	Kruskal-Wallis Test	$\chi^2(3) = 1.724$	.632
Training Background	58	Kruskal-Wallis Test	$\chi^2(3) = 1.329$	.722
Time as Educator	58	Spearman's rho	$r = .079$	.554

The influence of educator information on participants' rating of the WASME score was also investigated to ascertain if educators' attributes, training and time as educator affected participant's rating on the WASME scale. No statistically significant relationships or differences were evident suggesting that these variables did not impact participants working alliance rating (Table 4). Furthermore, no significant relationships or differences

were identified between potential participant or educator confounding variables and the CSQ.

5. DISCUSSION

5.1 Aims of the Present Study

The aims of the present study were to develop a new measure of working alliance specific to self-management education, and conduct preliminary investigations of its psychometric properties with a developmental sample. The WASME scale has two main purposes. Firstly, it is designed to provide feedback to educators running self-management courses, enabling them to gain insight into how they are perceived by those attending the course. This may be useful for identifying educators training needs, monitoring progress, appraising staff and ensuring fidelity and quality control of self-management programs. Secondly, the WASME scale can be used as a research instrument in order to further investigate the role of working alliance in self-management education. This could enrich understanding about self-management programs' effectiveness and tailor components which improve working alliance. As with psychological therapy, working alliance may relate to patients' health outcomes however this is still to be established.

5.2 Summary of Findings

5.2.1 Scale Construction

In line with psychological test construction, the scale was developed in a systematic process over five phases which included informal interviews, formal rating of preliminary items, piloting the scale with a clinical sample, and assessment of the scales reliability, validity and factor structure. The WASME scale was developed through an inductive and iterative process with diabetes research staff and educators to elicit qualitative themes of working alliance within the context of self-management education. During the preliminary stages of the model five themes emerged as pertinent to the operationalisation of working alliance in self-management education: Feeling heard; Educators' warmth and communication; Educators skills and approach; Collaboration to identify goals and plans; and feeling empowered. It was hoped that involving research staff and educators from the beginning of the process would increase the specificity, content, and face validity of the

56

WASME scale. At this stage the conceptualisation of working alliance in self-management education already showed differences from that hypothesised by Bordin (1979), the most prominent model in this area. Although it included elements from the goals, task and bond subscales, themes generated by staff also included features of empowerment, educators' ability to manage a group, adaptability to individuals' needs, and answering questions in a meaningful way which are not part of other measures. These factors appeared to be more specific to processes implicit in self-management education rather than psychotherapy.

The role of bond was less evident in initial discussions with staff which may be due to the brevity of the self-management intervention and the reduced focus on aspects such as emotional expression and trust compared with psychotherapy. Instead, ideas generated by staff appeared to encompass elements of the five skills outlined by Lorig (2003) - problems solving, decision making, resource utilisation, forming a patient-health professional partnership, and taking action. Additionally, educator's ability to take a humanistic approach to collaborate with and empower individuals appeared central to the conceptualisation of the WASME scale which maps on the philosophy of the DESMOND course (Skinner *et al.* 2006). This highlights the importance of self-management programs having a clear psychological and philosophical underpinning which encompasses clear guidelines regarding alliance building to support healthcare professionals to acknowledge its fundamental role in chronic health interventions. Self-management programs that adopt an approach where a strong alliance with individuals is fundamental to all interactions are best placed to support the individual with chronic disease to manage and live with their condition.

5.2.2 Psychometric Evaluation of the WASME scale

The 26-item preliminary measure was administered to 58 participants who each completed the questionnaire twice in reference to the two educators running the self-management course. Difficulties arose following a loss of the tendered DESMOND self-management course curtailing recruitment significantly which highlights the impact of the current political and economic agenda of a free market on long-standing NHS services. Evidence suggests that healthcare staff perceptions of job insecurity has a detrimental impact on staff's psychological wellbeing (Burke *et al*. 2015), which has been directly associated with nursing staffs' performance, and patient outcomes (Spetz & Herrera, 2010). The current climate of increased job insecurity for healthcare professionals may reduce the

ability of staff to build strong working alliance with individuals. Therefore, current efforts to reduce costs by outsourcing services may have detrimental effects on patient's health outcomes. This further highlights the need for a measure of working alliance in self-management education to promote and maintain high quality care.

Initial checks for normality of data identified all questionnaire data to be negatively skewed suggesting that participants were more likely to be positive about their perceived working alliance with educators, the perceived empathy of educators, and their satisfaction with the self-management course. Previous studies using working alliance measures have also found participant responses to be skewed towards positive ratings (Horvath & Greenberg, 1989; Mack *et al.* 2009; Marmar *et al.* 1989). This skew may reflect course quality but may also indicate respondents' socially desirable answers, common in self-report questionnaires assessing attitudes, perceptions and evaluations (King & Brunner, 2000). Positive responses may have arisen on these questions from fear of hurting the educator's feelings or because negative repercussions for future healthcare might ensue. In order to minimise the risk of social desirability bias time was taken to explain to participants that their entries were confidential and that single responses would not be fed back to educators. It may have been useful to include a social desirability measure such as the Marlow-Crowne Social Desirability Scale (Crowne & Marlowe, 1960) to identify participants more susceptible to answering questions positively rather than truthfully.

This study used an empirical approach over a theory-based approach to create items and examine the factor structure in order to develop the theory of working alliance within self-management education. It was hoped that factor analysis would reveal a factor structure to offer greater understanding of the dimensionality of working alliance which may inform future interventions. Through EFA a two factor solution and a one-factor solution were suggested for the WASME scale however due to less multicollinearity, increased reliability and conceptual fit, the one-factor model appeared to more appropriately fit the data. The final scale included 15-items and contained items reflecting elements that were consistent with the goals, task and bond of Bordin's (1979) model of working alliance. It was noticeable that bond in self-management education reflects educator's ability to enable good communication rather than including factors related to liking or trusting often seen in working alliance measures in psychotherapy (WAI: Horvath & Greenberg, 1989). Items focused more on the ability of educators to facilitate participant's expression of their difficulties, experiences and their ability to take a holistic approach. This change of focus

of bond is likely to be due to the change in context as self-management education is a brief group intervention where emotional connection with educators is likely to be limited. Additionally, the WASME scale included two items which reflected empowerment and one item which reflected the educators' ability to manage the group not seen in existing working alliance measures. These differences in the emphasis and items included in the WASME scale provides further support for constructing a specific measure of working alliance for this setting.

Previous research has provided evidence for working alliance as both a unidimensional and multidimensional construct. Tracey and Kokotovic (1989) identified a four-factor model with one general alliance factor accounting for most variance alongside three smaller specific factors related to task, goal and bond. In parent management training, parent-rated alliance as measured by the WAI-S (Horvath & Greenberg, 1989) was found to generate a three-dimensional model of alliance (Hukkelberg *et al.* 2015). A two factor solution has been identified in observer-rated working alliance in Cognitive-Behavioural, with Goals and Tasks loading on one large factor and bond items loading on a smaller factor, accounting for 73% of the variance (Andrusyna *et al*. 2001). A one-factor model has been identified in observer- rated youth alliance measures in psychotherapy (Fjermestad *et al.* 2012; Hogue *et al.* 2006). These studies question the applicability of a tripartite theory suggested by Bordin (1979) and indicates that working alliance may have different psychometric properties depending on the setting and patient group.

It is notable that all reverse-scored items were removed from the final WASME scale since these items loaded poorly on factors, or had low item-total correlations. It was also observed that outliers tended to occur disproportionately on the reverse-scored items suggesting the possibility of acquiescence and response bias (Rorer, 1965; Baumgartner & Steenkamp, 2001). Although the use of both positive and negative words is often suggested in scale development guidelines, there is a lack of evidence that this reduces bias. It has been suggested that the use of negative worded items can lead participants to misinterpret the question which reduces the internal reliability and validity of the scales (Schriesheim & Hill, 1981; Van Sonderen *et al.* 2013). Furthermore, it was found that negatively worded items loaded particularly low on factors compared to positively worded items of the Working Alliance Inventory, resulting it all negatively-worded items being removed in the Working Alliance Inventory-Short-Form Revised (WAI-sr; Hatcher and

Gillaspy, 2006). Consequently, it may be a strength of the WASME scale that it does not include any negatively worded items.

5.2.3 Reliability and Validity of the WASME Scale

The inclusion of the final items for the scale was confirmed through the examination of the alpha coefficients. The internal consistency of the final scale was high ($\alpha = .94$). This high internal consistency of the total scale suggests that there is significant overlap between items which would be expected when attempting to measure a latent construct such as working alliance and provides further evidence for the WASME scale being a one-dimensional construct.

Face validity of the WASME scale was accessed at a number of points in the construction of the scale. The themes from which the items were derived were all elicited from staff working in self-management education and therefore it can be assumed that these were felt by staff to be relevant to the construct. Opportunities to systematically evaluate the items regarding relevance were also provided, with any irrelevant items removed from the exploratory WASME scale. This was useful in highlighting any issues early in the process of development. Participants appeared to complete the questionnaire with ease despite the content of the questionnaire being somewhat different to the usual satisfaction questionnaire they may be accustomed to, suggesting further face validity and clarity.

No correlation was found between any of the participant or educator demographics and working alliance. This may be due to the low variability in ratings of alliance as the majority of participants rated the self-management program highly. High ratings of the program may suggest ceiling effects of the measure. Although there was a high participation rate in this study it may be that those who declined participation were also those who developed a poorer alliance with the educators therefore leading to a greater proportion of positive responses than reflective of the course. Ceiling effects of working alliance measures have however been well documented in the literature (Ferreira *et al.* 2013; Hall *et al.* 2012; Tryon *et al.* 2007). Further research is necessary to determine whether the high alliance rating is due to the efficacy of the course or due to ceiling effects of the scale.

Convergent validity was assessed via exploration of the relationship between the newly created working alliance scale and total score on an empathy measure. The correlation

between the two scales was strong and positive. This finding supports the small to strong positive relationship found between other working alliance measures and empathy in psychological therapy (Watson & Geller, 2005; Zuroff *et al.* 2000). Support for the concurrent validity of the WASME scale was provided by its moderate positive correlation with a measure of satisfaction consistent with previous findings in rheumatology (Bennett *et al.* 2011), and psychotherapy (Hawley & Weisz, 2005). These findings suggest that the WASME scale is a valid measure of working alliance and its correlations with empathy and satisfaction suggest that this tool may be able to provide further information about processes within self-management education. Causality between these variables were not assessed due to the non-normality of data and the lack of confounding variables. It may be therefore that peoples' satisfaction with the service and their rating of the educators' empathy predict their alliance ratings.

5.3 Study Limitations

The WASME scale appears to be reliable and valid however due to a relatively small sample size the results should be interpreted with some caution. The proposal for this study outlined recruitment of 150 participants however this was unfortunately unable to be achieved. The reduced sample size may have impacted the effectiveness of the analysis conducted however preliminary explorations of the data's suitability for factor analysis supported the appropriateness of this analysis. Nevertheless it would be beneficial for confirmatory factory analysis to be conducted with a larger sample to allow firmer conclusions about the factor structure of the WASME scale. Opportunities to continue the data collection to strengthen the assessment of factor structure and psychometric properties of this scale are currently being discussed.

It is important to mention that, like all self-report measures, the WASME scale is limited by respondents' ability to recognise and accurately report interpersonal factors with the educator. For individuals who find it difficult to notice how they relate to others, or who are inclined to please those whom they are rating, it may be particularly challenging to achieve accurate scores. Future studies may want to investigate alternative methods of accessing working alliance in self-management education such as utilising observer rating. The study is also limited that it only assessed the working alliance from the perspective of the individual attending the course and not from the educator's point of view. Previous studies in psychotherapy have found the patients' rated working alliance to be more highly

correlated to outcomes than therapists or observers (Horvath & Symonds, 1991) which provides a rationale for the use of only individuals attending the diabetes self-management course. It would have been advantageous to involve participants attending self-management course earlier in item development rather than relying on educators and researchers to generate items for the WASME scale. Participants may have focused on or identified alternative factors associated with developing a good working alliance.

The demographics of the present sample appear to signify a representative participant group from the self-management programme. Although the sample was a convenience sample as the trainee could only attend the course on predetermined days, participation rate was relatively high which will have reduced selection bias. Those who are attending self-management courses may be those who are motivated to improve their health and hence the participant who attend the self-management courses may differ in demographics than the general population of those with a chronic illness. Participants had a mean BMI of 30 kg/m^2 in this sample which was slightly about the mean found in analysis of two national surveys of diabetes which were 27.8 kg/m^2 and 27.9 kg/m^2 (Bays *et al.* 2007). This greater than average BMI suggests that participants attending a program may have significantly more difficulty following self-care guidelines such as dietary changes and increased physical exercise.

5.4 Clinical Implications

Given the increased prevalence of chronic conditions, improvements to self-management education are important due to their potential to increase self-care behaviours (Brown, 1990), enrich quality of life (Wattana *et al.* 2007), and reduce healthcare utilisation (Lorig *et al.* 1993). The evidence that working alliance can predict outcomes such as adherence in psychological and physical health settings (Fuertes *et al.* 2009; 2015; Horvath *et al.* 2011) emphasises the importance of being able to assess working alliance in self-management education. The development of this scale permits self-management programs to monitor the ability of educators to build a strong working alliance with individuals attending the course. This may identify educators who require further training to improve skills and could also identify skilled educators able to share expertise. Improvements in educators' ability to build strong alliances with individuals may lead to improved program efficiency and effectiveness.

The WASME scale may help identify currently unexplained variance in individual's adherence to treatment recommendations and their physical and mental health outcomes. The tool could be used as a fidelity measure for course quality, a tool for educator's appraisals and may facilitate the standardisation of programs. With increasing demands on services to provide outcome measures in order to continue providing their service, the working alliance may be one tool that can pick up some of the process factors that signify a services quality and staff expertise in delivery which is failed to be picked up by more traditional outcome measures. By identifying any difficulties in alliance building this will allow programs as a whole as well as individual educators to take steps towards improvement through revisiting course processes and ascertaining how working alliance can become an integral component of the course philosophy and all interactions.

5.5 Suggestions for Future Research

As this study only piloted and explored the factor structure of the WASME scale, it is necessary to confirm the factor structure in a larger sample. This study was conducted in diabetes self-management programs but since possibly applicable to other self-management courses, it should be examined across clinical problems where self-management education is a central component of treatment to assess its reliability and validity. As some self-management programs run across several weeks it will be necessary for the test-retest reliability of the scale to be investigated as this was not feasible on the one-day course the WASME scale was constructed for. Follow-up studies could ascertain the impact of working alliance on patient's outcomes and confounding factors of this relationship which would contribute considerably to the current lack of research in this field. In particular, further research may want to investigate the role of working alliance in predicting adherence to self-care guidelines, or use biomedical indicators at follow-up to assess the impact of any behavioural changes made following attending a self-management education course. Additionally, it is recommended that future research utilises additional measures to capture relevant outcomes such adherence or adherence self-efficacy and uses more specific measures to assess satisfaction such as the Medical Interview Satisfaction Questionnaire (MISS-21; Meakin & Weinman, 2002) to expand on the current study.

5.6 Conclusion

The WASME scale was developed to meet a need for a specific tool to measure working alliance in self-management education. The newly developed WASME scale offers a brief

assessment of working alliance and provides preliminary evidence of good reliability and validity. The exploration of the working alliance in self-management education is hoped to contribute to research on the processes involved in self-management education with the aim to increase understanding of the factors impacting programs efficacy. Given the increasing prevalence of chronic disease and the accompanying financial burden, self-management education plays a key role in supporting patients to manage their own health and the WASME scale may prove beneficial in enhancing the quality and cost-effectiveness of programs. This study provided preliminary evidence for a positive relationship between working alliance and satisfaction, highlighting the utility of the WASME scale. Further research is required to determine the relationship between working alliance and program outcomes. Clinically, this tool can be used to guide development and quality appraisal of self-management programs and identify educators training needs. Measuring relationship processes is a complex task, especially within group settings, due to the existence of multiple perspectives, theories and definitions existing. It is hoped that the WASME scale will support further research to develop the knowledge of this area where much is still to be understood.

6. REFERENCES

Alexander, L.B., & Luborsky, L. (1986). The Penn Helping Alliance Scales. In L. Greenberg & W. Pinsof (Eds.), *The Psychotherapeutic Process: A Resources Handbook* (pp. 325-266). New York: Guilford Press.

Andrusyna, T.P., Tang, T.Z., DeRubeis, R.J., & Luborsky, L. (2001). The factor structure of the working alliance inventory in cognitive-behavioral therapy. *Journal of Psychotherapy Practice and Research, 10*(3), 173-178.

Attale, C., Lemogne, C., Sola-Gazagnes, A., Guedeney, N., Slama, G., Horvath, A.O., *et al.* (2010). Therapeutic alliance and glycaemic control in type 1 diabetes: a pilot study. *Diabetes & Metabolism*, *36*(6), 499-502.

Baldwin, S.A., Wampold, B.E., & Imel, Z.E. (2007). Untangling the alliance-outcome correlation: Exploring the relative importance of therapist and patient variability in the alliance. *Journal of Consulting and Clinical Psychology*, *75*(6), 842.

Barlow, J., Wright, C., Sheasby, J., Turner, A., & Hainsworth, J. (2002). Self-management approaches for people with chronic conditions: a review. *Patient Education and Counseling*, *48*(2), 177-187.

Barber, J.P., Connolly, M.B., Crits-Christoph, P., Gladis, L., & Siqueland, L. (2000). Alliance predicts patients' outcome beyond in-treatment change in symptoms. *Journal of Consulting and Clinical Psychology*, *68*(6), 1027.

Barlow, J.H., Turner, A.P., & Wright, C.C. (1998). Long-term outcomes of an arthritis self-management program. *Rheumatology*, *37*(12), 1315-1319.

Barnett, K., Mercer, S.W., Norbury, M., Watt, G., Wyke, S., & Guthrie, B. (2012). Research paper. Epidemiology of multimorbidity and implications for healthcare, research, and medical education: a cross-sectional study. *The Lancet, 380*(9836), 37-43.

Bausell, R. B. (1986). *A practical guide to conducting empirical research*. Harper Collins Publishers.

Baumgartner, H., & Steenkamp, J.B.E. (2001). Response styles in marketing research: A cross-national investigation. *Journal of Marketing Research, 38*(2), 143-156.

Bays, H.E., Chapman, R.H., & Grandy, S. (2007). The relationship of body mass index to diabetes mellitus, hypertension and dyslipidaemia: comparison of data from two national surveys. *International Journal of Clinical Practice, 61*(5), 737-747.

Bennett, J.K., Fuertes, J.N., Keitel, M., & Phillips, R. (2011). The role of patient attachment and working alliance on patient adherence, satisfaction, and health-related quality of life in lupus treatment. *Patient Education and Counseling*, *85*(1), 53-59.

Bodenheimer, T., Lorig, K., Holman, H., & Grumbach, K. (2002). Patient self-management of chronic disease in primary care. *The Journal of the American Medical Association, 288*(19), 2469-2475.

Bordin, E.S. (1979). The generalizability of the psychoanalytic concept of the working alliance. *Psychotherapy: Theory, Research & Practice, 16*(3), 252.

Bowlby, J. (1988). Attachment, communication, and the therapeutic process. *A Secure Base: Parent-Child Attachment and Healthy Human Development*, 137-157.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77-101.

Brown, S.A. (1990). Studies of educational interventions and outcomes in diabetic adults: A meta-analysis revisited. *Patient Education and Counseling, 16*(3), 189-215.

Burke, R.J., Ng, E.S., & Wolpin, J. (2015). Economic austerity and healthcare restructuring: correlates and consequences of nursing job insecurity. *The International Journal of Human Resource Management*, *26*(5), 640-656.

Castonguay, L.G., Constantino, M.J., & Holtforth, M.G. (2006). The working alliance: Where are we and where should we go?. *Psychotherapy: Theory, Research, Practice, Training*, *43*(3), 271.

Cattell, R.B. (1978). *The scientific use of factor analysis*. New York: Plenum Press.

Clark, N.M., Becker, M.H., Janz, N.K., Lorig, K., Rakowski, W., & Anderson, L. (1991). Self-management of chronic disease by older adults a review and questions for research. *Journal of Aging and Health*, *3*(1), 3-27.

Clark, N.M., Janz, N.K., Dodge, J.A., Schork, M.A., Fingerlin, T.E., Wheeler, J.R., *et al.* (2000). Changes in functional health status of older women with heart disease: Evaluation of a program based on self-regulation. *The Journals of Gerontology. Series B, Psychological Sciences and Social Sciences, 55*(2), S117-26.

Clark, L.A., & Watson, D. (1995). Constructing validity: Basic issues in objective scale development. *Psychological Assessment*, *7*(3), 309.

Cohen, J. (1992). A Power Primer. *Psychological Bulletin*, 112, 155-159.

Costello, A.B., & Osborne, J.W. (2011). Best practices in exploratory factor analysis: four recommendations for getting the most from your analysis. *Practical Assessment, Research, Evaluation, 10*(7).

Cronbach, L.J. (1951). Coefficient alpha and the internal structure of tests. *Psychometrika*, *16*(3), 297-334.

Crowne, D. & Marlowe, D. (1960). A new scale of social desirability independent of psychopathology. *Journal of Consulting Psychology, 24*(4), 349-354.

Davies, M.J., Heller, S., Skinner, T.C., Campbell, M.J., Carey, M.E., Cradock, S., et al. (2008). Effectiveness of the diabetes education and self-management for ongoing and newly diagnosed (DESMOND) program for people with newly diagnosed type 2 diabetes: Cluster randomised controlled trial. *British Medical Journal (Clinical Research Ed.), 336*(7642), 491-495.

De Winter, J.C., & Dodou, D. (2012). Factor recovery by principal axis factoring and maximum likelihood factor analysis as a function of factor pattern and sample size. *Journal of Applied Statistics*, *39*(4), 695-710.

De Winter, J.C., Dodou, D. I., & Wieringa, P.A. (2009). Exploratory factor analysis with small sample sizes. *Multivariate Behavioral Research*, *44*(2), 147-181.

DiMatteo, M.R. (2004). Variations in patients' adherence to medical recommendations: A quantitative review of 50 years of research. *Medical Care, 42*(3), 200-209.

DiMatteo, M.R., Giordani, P.J., Lepper, H.S., & Croghan, T.W. (2002). Patient adherence and medical treatment outcomes. *Medical Care, 40*(9), 794-811.

Dennis, S.M., Zwar, N., Griffiths, R., Roland, M., Hasan, I., Davies, G.P., *et al.* (2008). Chronic disease management in primary care: From evidence to policy. *Medical Journal of Australia, 188*(8), 53.

Department of Health (2010). Report. *Long-term conditions compendium of Information*: 3rd *Edition*. Retrieved 12th January 2015 from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216528/dh_134486.pdf

DeVellis, R. F. (2011). *Scale development: Theory and applications*. Sage Publications.

Elvins, R., & Green, J. (2008). The conceptualization and measurement of therapeutic alliance: An empirical review. *Clinical Psychology Review*, *28*(7), 1167-1187.

Fabrigar, L.R., & Wegener, D.T. (2011). *Exploratory factor analysis*. Oxford University Press.

Fabrigar, L.R., Wegener, D.T., MacCallum, R.C., & Strahan, E.J. (1999). Evaluating the use of exploratory factor analysis in psychological research. *Psychological Methods*, *4*(3), 272.

Ferreira, P.H., Ferreira, M.L., Maher, C.G., Refshauge, K.M., Latimer, J., & Adams, R.D. (2013). The therapeutic alliance between clinicians and patients predicts outcome in chronic low back pain. *Physical Therapy*, *93*(4), 470-478.

Field, A. (2009). *Discovering Statistic Using SPSS* (3rd ed). London: Sage.

Fuertes, J.N., Anand, P., Haggerty, G., Kestenbaum, M., & Rosenblum, G.C. (2015). The Physician–Patient Working Alliance and Patient Psychological Attachment, Adherence, Outcome Expectations, and Satisfaction in a Sample of Rheumatology Patients. *Behavioral Medicine*, *41*(2), 60-68.

Fuertes, J.N., Boylan, L.S., & Fontanella, J.A. (2009). Behavioral indices in medical care outcome: the working alliance, adherence, and related factors. *Journal of General Internal Medicine*, *24*(1), 80-85.

Fjermestad, K.W., McLeod, B.D., Heiervang, E.R., Havik, O.E., Öst, L.G., & Haugland, B. S. (2012). Factor structure and validity of the therapy process observational coding system for child psychotherapy–alliance scale. *Journal of Clinical Child & Adolescent Psychology*, *41*(2), 246-254.

Freud, S. (1958). The dynamics of transference. In J. Starchey (Ed.), *The standard edition of the complete psychological works of Sigmund Freud* (pp. 99-108). London: Hogarth Press. (Original work published 1912).

Gaston, L. (1990). The concept of the alliance and its role in psychotherapy: Theoretical and empirical considerations. *Psychotherapy: Theory, Research, Practice, Training, 27*(2), 143.

Gibson, P. G., Powell, H., Coughlan, J., Wilson, A. J., Hensley, M. J., Abramson, *et al.* (2002). Limited (information only) patient education programs for adults with asthma. *Cochrane Database of Systematic Review*, *2*.

Gillett, M., Dallosso, H., Dixon, S., Brennan, A., Carey, M., Campbell, M., *et al.* (2010). Delivering the diabetes education and self management for ongoing and newly diagnosed (DESMOND) program for people with newly diagnosed type 2 diabetes: Cost effectiveness analysis. *British Medical Journal, 341*.

Golics, C.J., Basra, M.K., Salek, M.S., & Finlay, A.Y. (2013). The impact of patients' chronic disease on family quality of life: an experience from 26 specialties. *International Journal of General Medicine*, *6*, 787-798.

Gorsuch, R.L. (1983). *Factor analysis* (2nd ed.). Hillsdale, NJ: Erlbaum.

Greenson, R.R. (1965). The working alliance and the transference neurosis. *The Psychoanalytic Quarterly.*

Gregory, R.J. (2007). *Psychological testing: History, principles and applications. (*5th ed.*). London: Pearson.*

Guyatt, G.H., Feeny, D.H., & Patrick, D.L. (1993). Measuring health-related quality of life. *Annals of Internal Medicine*, *118*(8), 622-629.

Hall, A.M., Ferreira, M.L., Clemson, L., Ferreira, P., Latimer, J., & Maher, C.G. (2012). Assessment of the therapeutic alliance in physical rehabilitation: a RASCH analysis. *Disability and Rehabilitation*, *34*(3), 257-266.

Hambelton, R.K., Swaminathon, H., & Rogers, H.J. (1991). *Fundamentals of item response theory.* Newbury Park, CA: Sage.

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.

Hatcher, L. (1994). *A Step-by-Step Approach to Using the SAS® System for Factor Analysis and Structural Equation Modeling*. Cary, North Carolina: SAS Institute, Inc.

Hatcher, R.L., & Gillaspy, J.A. (2006). Development and validation of a revised short version of the working alliance inventory. *Psychotherapy Research, 16,* 12-25.

Hawley, K.M., & Weisz, J.R. (2005). Youth versus parent working alliance in usual clinical care: Distinctive associations with retention, satisfaction, and treatment outcome. *Journal of Clinical Child and Adolescent Psychology*, *34*(1), 117-128.

Haynes, R.B. (2001). Improving patient adherence: state of the art, with a special focus on medication taking for cardiovascular disorders. *Compliance in Healthcare and Research*, 3-21.

Hogue, A., Dauber, S., Stambaugh, L.F., Cecero, J.J., & Liddle, H.A. (2006). Early therapeutic alliance and treatment outcome in individual and family therapy for adolescent behavior problems. *Journal of Consulting and Clinical Psychology*, *74*(1), 121.

Horne, R., & Weinman, J. (1999). Patients' beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. *Journal of psychosomatic research*, *47*(6), 555-567.

Horne, R., & Weinman, J. (2002). Self-regulation and self-management in asthma: exploring the role of illness perceptions and treatment beliefs in explaining non-adherence to preventer medication. *Psychology and Health*, *17*(1), 17-32.

Horvath, A. O. (2000). The therapeutic relationship: from transference to alliance. *Journal of clinical psychology*, 56(2), 163-173.

Horvath, A.O. & Bedi, R.P. (2002). The alliance. In J.C. Norcross (Ed.), *Psychotherapy relationships that work: Therapist contributions and responsiveness to patients* (pp. 37-69). Oxford University Press: London.

Horvath, A.O., Del Re, A.C., Fluckiger, C., & Symonds, D. (2011). Alliance in individual therapy. *Psychotherapy, 48*(1), 9-16.

Horvath, A.O., & Greenberg, L.S. (1989). Development and validation of the Working Alliance Inventory. *Journal of Counseling Psychology*, *36*(2), 223-233.

Horvath, A.O., & Luborsky, L. (1993). The role of the working alliance in psychotherapy. *Journal of Consulting and Clinical Psychology, 61*(4), 561-573.

Horvath, A.O., & Symonds, B.D. (1991). Relation between working alliance and outcome in psychotherapy: A meta-analysis. *Journal of Counseling Psychology*, *38*(2), 139-149.

Hukkelberg, S.S., & Ogden, T. (2015). The short Working Alliance Inventory in parent training: Factor structure and longitudinal invariance. *Psychotherapy Research*, 1-8.

Hutcheson, G.D., & Sofroniou, N. (1999). *The multivariate social scientist: Introductory statistics using generalized linear models*. Sage.

John, O.P., & Benet-Martínez, V. (2000). Measurement: Reliability, construct validation, and scale construction. *Handbook of research methods in social and personality psychology.* Cambridge: Cambridge University Press.

Kaplan, R., & Saccuzzo, D. (2012). *Psychological testing: Principles, applications, and issues.* Cengage Learning.

Kennedy, A., Reeves, D., Bower, P., Lee, V., Middleton, E., Richardson, G., *et al.* (2007). The effectiveness and cost effectiveness of a national lay-led self care support program for patients with long-term conditions: A pragmatic randomised controlled trial. *Journal of Epidemiology and Community Health, 61*(3), 254-261.

Kim, S.C., Kim, S., & Boren, D. (2008). The quality of working alliance between patient and provider predicts general satisfaction. *Military Medicine, 173*(1), 85-90.

King, M. & Bruner, G. (2000). Social desirability bias: a neglected aspect of validity testing. *Psychology and Marketing, 17*(2), 79–103.

Klein, D.N., Schwartz, J.E., Santiago, N.J., Vivian, D., Vocisano, C., Castonguay, L. G., *et al.* (2003). Therapeutic alliance in depression treatment: controlling for prior change and patient characteristics. *Journal of Consulting and Clinical Psychology*, *71*(6), 997.

Kline, T.J. (2005). *Psychological testing: A practical approach to design and evaluation.* Sage Publications.

Kohler, J.C., & Baghdadi-Sabeti, G. (2011). The world medicines situation 2011. *World Health Organization.*

Lambert, M.J. & Barley, D.E. (2002). Research summary on the therapeutic relationship and psychotherapy outcome. In Norcross, J.C. (Ed.), *Psychotherapy relationships that work: Therapist contributions and responsiveness to patients* (pp. 17-32). Oxford: Oxford University Press.

Larsen, D.L., Attkisson, C.C., Hargreaves, W.A., & Nguyen, T.D. (1979). Assessment of client/patient satisfaction: Development of a general scale. *Evaluation and Program Planning, 2*(3), 197-207.

Ley, P. (1988). *Communicating with patients: Improving communication, satisfaction and compliance.* Croom Helm.

Lo Coco, G., Gullo, S., & Kivlighan Jr, D.M. (2012). Examining patients' and other group members' agreement about their alliance to the group as a whole and changes in

patient symptoms using response surface analysis. *Journal of Counseling Psychology, 59*(2), 197.

Loewenthal, K.M. (2001). *An introduction to psychological tests and scales*. Psychology Press.

Lorig, K.R., & Holman, H.R. (2003). Self-management education: history, definition, outcomes, and mechanisms. *Annals of Behavioral Medicine*, *26*(1), 1-7.

Lorig, K.R., Mazonson, P.D., & Holman, H.R. (1993). Evidence suggesting that health education for self-management in patients with chronic arthritis has sustained health benefits while reducing healthcare costs. *Arthritis & Rheumatism, 36*(4), 439-446.

Lorig, K.R., Ritter, P., Stewart, A.L., Sobel, D.S., Brown Jr, B.W., Bandura, A., *et al.* (2001). Chronic disease self-management program: 2-year health status and healthcare utilization outcomes. *Medical Care, 39*(11), 1217-1223.

Luborsky, L. (1976). Helping alliances in psychotherapy. *Successful Psychotherapy,* 92-116.

Luborsky, L., & Auerbach, A. (1985). *The therapeutic relationship in psychodynamic psychotherapy: The research evidence and its meaning for practice.* In R.Hales & A.Frances (Eds.), *Psychiatry update annual review* (pp. 550– 561). Washington, DC: American Psychiatric Association.

MacCallum, R.C., Browne, M.W., & Cai, L. (2007). *Factor analysis models as approximations* (pp. 153-175). Lawrence Erlbaum, Mahwah, New Jersey.

MacCallum, R.C., Widaman, K.F., Zhang, S., & Hong, S. (1999). Sample size in factor analysis. *Psychological Methods*, *4*(1), 84.

Mack, J.W., Block, S.D., Nilsson, M., Wright, A., Trice, E., Friedlander, R., *et al.* (2009). Measuring therapeutic alliance between oncologists and patients with advanced cancer. *Cancer*, *115*(14), 3302-3311.

Marmar, C.R., Weiss, D.S., & Gaston, L. (1989). Toward the validation of the California Therapeutic Alliance Rating System. *Psychological Assessment: A Journal of Consulting and Clinical Psychology*, *1*(1), 46.

Mathers, C.D., Loncar, D. (2005). Updated projections of global mortality and burden of disease, 2002–2030: Data sources, methods and results. Geneva: *World Health Organization*. Retrieved on the 05th December 2015 from http://www.who.int/healthinfo/statistics/bod_projections2030_paper.pdf,).

Martin, D.J., Garske, J.P., & Davis, M.K. (2000). Relation of the working alliance with outcome and other variables: A meta-analytic review. *Journal of Consulting and Clinical Psychology, 68*(3), 438.

Meakin, R., & Weinman, J. (2002). The 'Medical interview satisfaction scale'(MISS-21) adapted for British general practice. *Family Practice*, *19*(3), 257-263.

Mensing, C.R., & Norris, S.L. (2003). Group education in diabetes: effectiveness and implementation. *Diabetes Spectrum*, *16*(2), 96-103.

Mercer, S.W., Maxwell, M., Heaney, D., & Watt, G.C. (2004). The consultation and relational empathy (CARE) measure: development and preliminary validation and reliability of an empathy-based consultation process measure. *Family Practice*, *21*(6), 699-705.

Monninkhof, E., van der Valk, P.D.L., Van der Palen, J., Van Herwaarden, C., Partridge, M. R., & Zielhuis, G. (2003). Self-management education for patients with chronic obstructive pulmonary disease: a systematic review. *Thorax*, *58*(5), 394-398.

Munder, T., Wilmers, F., Leonhart, R., Linster, H.W., & Barth, J. (2010). Working alliance Inventory-Short revised (WAI-SR): Psychometric properties in outpatients and inpatients. *Clinical Psychology & Psychotherapy, 17*(3), 231-239.

National Collaborating Centre for Mental Health (UK). (2010). *Depression in adults with a chronic physical health problem*. British Psychological Society.

Norris, S.L., Lau, J., Smith, S.J., Schmid, C.H., & Engelgau, M.M. (2002). Self-Management education for adults with type 2 Diabetes A meta-analysis of the effect on glycemic control. *Diabetes Care*, *25*(7), 1159-1171.

Norris, S.L., Nichols, P.J., Caspersen, C.J., Glasgow, R.E., Engelgau, M.M., Jack, L., *et al.* (2002). Increasing diabetes self-management education in community settings: a systematic review. *American Journal of Preventive Medicine*, *22*(4), 39-66.

Nunnally, J. (1978). *Psychometric Theory*. New York, McGraw-Hill.

Nunnally, J.C., & Bernstein, I.H. (1994). *Psychometric Theory* (3rd ed.). New York: McGraw Hill.

Orlinsky, D.E., Grawe, K., & Parks, B.K. (1994). Process and outcome in psychotherapy. In S.L. Garfield & A.E. Bergin (Eds.), *Handbook of Psychotherapy and Behaviour Change* (4th ed., pp. 270–376). New York: John Wiley & Sons.

NHS England. (2014a). *Five Year Forward View*. Retrieved on 11th March 2015 from: http://www.england.nhs.uk/ourwork/futurenhs/#doc.

Pomerleau, J., Knai, C., & Nolte, E. (2008). The burden of chronic disease in Europe. In: Nolte E, McKee M (eds). *Caring for people with chronic conditions: A health system perspective.* Maidenhead: Open University Press,15–42.

Preacher, K.J., & MacCallum, R.C. (2002). Exploratory factor analysis in behavior genetics research: Factor recovery with small sample sizes. *Behavior Genetics*, *32*(2), 153-161.

Riemsma, R.P., Kirwan, J.R., Taal, E., & Rasker, J.J. (2003). Patient education for adults with rheumatoid arthritis. *Cochrane Database of Systematic Reviews*, *2*.

Rogers, C.R. (1957). The necessary and sufficient conditions of therapeutic personality change. *Journal of Consulting Psychology, 21*(2), 95.

Rorer, L.G. (1965). The great response-style myth. *Psychological Bulletin, 63*, 129–156

Roter, D.L., & Larson, S. (2001). The relationship between residents' and attending physicians' communication during primary care visits: An illustrative use of the roter interaction analysis system. *Health Communication, 13*(1), 33-48.

Sabaté, E. (2003). *Adherence to long-term therapies: evidence for action*. World Health Organization.

Safran, J.D., & Muran, J.C. (2000). *Negotiating the therapeutic alliance: A relational treatment guide*. Guilford Press.

Scain, S.F., Friedman, R., & Gross, J.L. (2009). A structured educational program improves metabolic control in patients with type 2 diabetes: A randomized controlled trial. *The Diabetes Educator, 35*(4), 603-611.

Schriesheim, C.A., & Hill, K.D. (1981). Controlling acquiescence response bias by item reversals: The effect on questionnaire validity. *Education and Psychological Measurement, 41*(4), 1101–1114.

Skinner, T. C., Carey, M. E., Cradock, S., Daly, H., Davies, M. J., Doherty, Y., *et al.* (2006). Diabetes education and self-management for ongoing and newly diagnosed (DESMOND): process modelling of pilot study. *Patient Education and Counseling*, *64*(1), 369-377.

Smerud, P.E., & Rosenfarb, I.S. (2008). The working alliance and family psychoeducation in the treatment of schizophrenia: An exploratory prospective change process study. *Journal of Consulting and Clinical Psychology, 76*(3), 505.

Smeulders, E.S., van Haastregt, J.C., van Hoef, E.F., van Eijk, J.T., & Kempen, G.I. (2006). Evaluation of a self-management program for congestive heart failure patients: Design of a randomised controlled trial. *BMC Health Services Research, 6*(1), 91.

Smith, S.M., Soubhi, H., Fortin, M., Hudon, C., & O'Dowd, T. (2012). Managing patients with multimorbidity: systematic review of interventions in primary care and community settings. *British Medical Journal, 345*, e5205.

Spetz, J., & Herrera, C. (2010). Changes in nurse satisfaction in California, 2004 to 2008. *Journal of Nursing Management*, *18*(5), 564-572.

Strong, S. R. (1968). Counseling: An interpersonal influence process. *Journal of Counseling Psychology, 15*(3), 215.

Stuart, A., & Kendall, M. G. (1968). *The advanced theory of statistics*. Charles Griffin.

Suhrcke, M., Nugent, R.A., Stuckler, D., & Rocco, L. (2006). *Chronic disease: an economic perspective*. London: Oxford Health

Tabachnick, B.G., & Fidell, L S. (2001). Principal components and factor analysis. *Using Multivariate Statistics*, 582-652.

Taft, C.T., Murphy, C.M., Musser, P.H., & Remington, N.A. (2004). Personality, interpersonal, and motivational predictors of the working alliance in group cognitive-behavioral therapy for partner violent men. *Journal of Consulting and Clinical Psychology, 72*(2), 349.

Tasca, G.A., & Lampard, A.M. (2012). Reciprocal influence of alliance to the group and outcome in day treatment for eating disorders. *Journal of Counseling Psychology, 59*(4), 507.

TNS Opinion & Social (2007). *Health in the European Union*. Special Eurobarometer 272e. Brussels: European Commission.

Tracey, T.J., & Kokotovic, A.M. (1989). Factor structure of the Working Alliance Inventory. *Psychological Assessment, 1*, 207-210.

Tryon, G.S., Blackwell, S.C., & Hammel, E.F. (2007). A meta-analytic examination of client–therapist perspectives of the working alliance. *Psychotherapy Research*, *17*(6), 629-642.

World Health Organization. (2003). *Adherence to long-term therapies: Evidence for action.* Geneva: World Health Organization. Retrieved 9th August 2015from: www.who.int/chronic_conditions/adherencereport/en

Van Sonderen, E., Sanderman, R., & Coyne, J.C. (2013). Ineffectiveness of reverse wording of questionnaire items: Let's learn from cows in the rain. *Public Library of Science One*, *8*(7), e68967.

Vaughan-Jones, H. & Barham, L. (2009). *Healthy Work: Challenges and Opportunities to 2030.* Retrieved on 18th August 2015 from: http://www.theworkfoundation.com/DownloadPublication/Report/216_216_Bupa_report.pdf.

Wampold, B.E. (2010). The research evidence for the common factors models: A historically situated perspective. In B.L. Duncan, S.D. Miller, B.E. Wampold & M.A. Hubble (Eds.), *The heart & soul of change: Delivering what works in therapy* (2nd ed.). Washington, DC: American Psychological Association.

Warsi, A., LaValley, M.P., Wang, P.S., Avorn, J., & Solomon, D.H. (2003). Arthritis self-management education programs: A meta-analysis of the effect on pain and disability. *Arthritis & Rheumatism, 48*(8), 2207-2213.

Wattana, C., Srisuphan, W., Pothiban, L., & Upchurch, S. L. (2007). Effects of a diabetes self-management program on glycemic control, coronary heart disease risk, and quality of life among thai patients with type 2 diabetes. *Nursing & Health Sciences, 9*(2), 135-141.

Watson, J.C. & Geller, S.M. (2005). The relation among the relationship conditions, working alliance, and outcome in both process-experiential and cognitive behavioral psychotherapy. *Psychotherapy Research, 15*(1-2), 25-33.

Zuroff, D.C., Blatt, S.J., Sotsky, S.M., Krupnick, J.L., Martin, D.J., Sanislow, C.A., *et al.* (2000). Relation of therapeutic alliance and perfectionism to outcome in brief outpatient treatment of depression. *Journal of Consulting & Clinical Psychology, 68*(1), 114-124.

Zwick, W.R., & Velicer, W.F. (1986). Comparison of five rules for determining the number of components to retain. *Psychological Bulletin, 99*(3), 432–442.

Part 3: Critical Appraisal

CRITICAL APPRAISAL

1. Introduction

This paper aims to provide personal and professional reflections on the origins, development, recruitment and dissemination of conducting doctorate-level empirical research. Reflections on challenges and learning that took place during the research process have been guided by a reflective diary and research supervision notes kept throughout the course of the study.

2. Origins of the Literature Review and Research Questions

The current study, which sought to develop and validate a working alliance scale for use in self-management education, arose from a long-standing interest in clinical health psychology. Through previous experience of conducting research examining health beliefs of diabetic patients during my master's degree I discovered that despite self-management guidelines, patients often felt that they had no control of their disease and found it difficult to adhere to treatment guidelines. During this time, I saw little evidence of medical staff discussing or acknowledging the psychological impact of disease with patients and I wondered about the effect of this on the patients. This research made me aware of the importance of conducting psychological research with this growing client group with the objective of adding to the knowledge base in clinical health psychology. I hoped that this research may help to raise the profile of psychology in medical settings and highlight the relevance and importance of psychological factors in managing long-term conditions such as diabetes.

Familiarising myself with self-management education began following discussion with my supervisor on research ideas within clinical health psychology. My preliminary reading raised questions for me about what makes a course effective. It appeared that psychological process factors were neglected in this field as research of self-management programs tended to focus on the content of the course and outcomes such as patient satisfaction and adherence. Programs appeared to improve outcomes although there was little nuanced understanding of what factors predicted these outcomes. I began to consider what psychological theories may be applicable to self-management education to explain some of the variance in patient outcomes. Through further discussion in supervision I began to read the vast amount of research in psychotherapy finding the positive correlation

between a strong alliance and positive outcomes from therapy (Castonguay *et al.* 2006; Martin *et al.* 2000). By contrast such process issues have received little consideration in self-management education. It interested me that despite healthcare systems' objective to understand all illness and disease from a bio-psycho-social perspective, this was absent in the delivery of self-management programs despite growing recognition of the psychological impact of chronic conditions (NICE, 2009).

3. Conducting the Literature Review

The observation of the gap in the understanding of what makes self-management education effective presented an opportunity to investigate the role of relationship factors. During a literature search it was clear that this was an under-researched area. This was surprising as corresponding with the growing prevalence of chronic condition there had been an increased investment in self-management courses. Furthermore, the current economic climate has resulted in a focus on cost-effectiveness which has led services to demonstrate their efficacy through outcome measures and continuous appraisal of their quality. As I could not identify any research on the role of working alliance in self-management education I decided to focus my literature review on the relationship between clinician-patient working alliance on adherence in patients with long-term conditions. I felt that this would provide a clear rationale for developing a working alliance measure due to the overlaps in patient population and the relevance of adherence to self-management education.

Previous experience of conducting literature reviews has taught me that they are time consuming and require precision, prompting me to commence the process in the latter part of my second year. I encountered some difficulties defining working alliance and adherence due to previous research using numerous definitions and measurements of these concepts which have also been acknowledge in prior reviews of the literature (Norcross, 2002). An initial scoping exercise revealed that papers investigating working alliance used diverse terms including 'therapeutic alliance', 'working alliance', 'therapeutic relationship', 'collaboration', and 'patient-physician partnership'.

Additionally, many papers that were identified through the search strategy were not relevant as they only measured aspects of working alliance such as communication, and trust. I decided to exclude papers which focused solely on overlapping constructs such as empathy, collaboration, and communication in order to focus my search and produce a

more manageable number of papers to be reviewed. This was a lesson for me in the importance of having specific search terms and inclusion/exclusion criteria in order to make paper selection systematic.

4. Development of the Project

The initial stages of development of the research project involved reviewing vast amounts of relevant literature to identify if any similar studies existed and critical appraise their methodology in order to inform the research question and design. I found it difficult to decipher what direction I should go in during this part of the project. With the help of my field supervisor I began initial meetings regarding the project and attended the diabetes self-management course and the training for educators to gain insight into the program. I found this a valuable experience and learnt a lot about the philosophy of the course, the training provided for educators and observed interpersonal factors for myself. I was pleasantly surprised at the quality of the course and the training provided for educators. The experience of attending these courses allowed me to assess the feasibility of conducting a study in this setting and ask further questions about the course. I feel this was instrumental in the development of the research project as it allowed me to think logistically about planning and conducting research in this area.

I was aware that the project would have to be something I could get educators, research staff, and the diabetes centre to support and this shaped my project in a number of ways. It was important that the research question had face validity to those working in this area in order to attain their backing. I was also aware that the project would need to be feasible to conduct, have minimal impact to the educators' work, and brief enough to reduce participation bias. As I began to consult with my academic and field supervisor I was able to focus the question around working alliance in self-management education however this led to further questions regarding measurement.

It proved challenging to identify appropriate measures to utilise in this research project as I could identify no previous research of working alliance in self-management education. I had originally considered examining the role of working alliance in predicting outcomes such as satisfaction, adherence self-efficacy or BMI. This plan was abandoned primarily because I could not identify a suitable tool to measure working alliance that had undergone psychometric testing within the context of self-management education. As a result of the lack of applicable measures and through discussions during peer-review of my research

proposal it was suggested that I consider constructing a new measure of working alliance specific to self-management education. This highlights how my research ideas developed from my original research ambitions due to the lack of existing research in this area.

I had no experience of scale development and knew that I would need to spend a considerable amount of time reviewing literature on test construction. I was worried about understanding the statistical methods that would need to be employed for sound psychometric analysis. On reflection, my initial apprehension was likely to be due to wanting to avoid the unknown of undertaking something which felt outside of my comfort zone. Nevertheless, I quickly focused my attention on the new area of research and was motivated to put my new research proposal into action.

5. Obtaining Ethical and Local Research Approval

Gaining ethical approval for this study was more time consuming than I had originally anticipated as I was not familiar with the Integrated Research Application System (IRAS). I found this system difficult to navigate and it seemed that I was often on the phone to clarify that I had taken required actions. The procedure of completing the necessary paperwork for this process was useful in that it allowed me to reflect on my proposal, the rationale, and the logistical factors of conducting research in self-management education. This gave me clarity on some elements of my proposal and allowed me to take ownership of the project. Following completion of the paperwork, approval was surprisingly easy as I was advised to obtain ethical process through the new Proportionate Review process. I received feedback from the proportionate review meeting within a few weeks and only had a few minor amendments which did not impact the study design.

Originally I had contemplated having educators recruiting participants at the end of the courses they were facilitating. This may have assisted me in achieving a greater sample size as I could not attend all courses due to being on placement. However, there were several reasons why I decided against educator involvement in recruitment. Firstly, I decided that educators recruiting participants may have implications for the validity caused by an increased likelihood of social desirability bias. Secondly, during my Masters research project my efforts to get other health professionals involved in recruitment proved unfruitful due to time-constrained staff not being able to prioritise research. Thirdly, I was conscious of wanting to maintain engagement in the project and minimise disruption to the service. Lastly, after discussion with the NHS Research and Development (R&D)

department I became aware that all individuals involved in the recruitment process were required to have undertaken Good Clinical Practice training. This involved several hours training which was unfeasible for the majority of educators. I therefore took on sole recruitment responsibilities which had some advantages as it meant that I did not need to train or manage others in the research protocol, and could explain the value and purpose of the study to each participant which may have led to a higher participation rate.

My experience of obtaining NHS approval was complicated and drawn-out. I made contact with the local NHS R&D department prior to commencing ethical approval in order for them to flag any concerns or difficulties that I may not have anticipated. This process seemed lengthier than necessary as I had assumed that having an integrated research system would have streamlined this procedure. The process could have progressed quicker if I had obtained information regarding the addition of local NHS logos on project documents and obtaining consent training that was required for approval during my earlier contact. Although I had spoken to several different advisors by telephone it may have been more useful if I arranged a meeting so that I could establish the requirements for approval and completed tasks simultaneously. The last step of the R&D approval was to obtain the Clinical Management Group (CMG) lead's approval which I was informed would involve an email confirming that the study could go ahead. The CMG lead wanted to meet to discuss the project and during this meeting I was informed that as the study involved staff time that approval should be sought for adoption to the departments research portfolio through the National Institute for Health Research (NIHR) Clinical Research Network (CRN). This meant that I had to terminate the Research and Development approval and begin a new process which required additional work such as gaining two independent peer reviews from clinicians.

Following this change in approval process I experienced conflicting information about what steps I had to take next in order to progress. This had the result of further impacting my planned start date. I had to become very assertive and persistent to ensure my study was progressing as quickly as possible. My difficulties with obtaining approval seemed to have occurred due to staff working in a system of constant change making it difficult for them to remain aware of new procedures for conducting research within the department. It may be difficulties like these which may put off clinicians from engaging in research following qualifications.

6. Constructing the Scale

As I was dealing with the challenges of local approval to recruit the clinical sample I was able to begin developing the scale. I presented the study protocol at two meetings with educators and research staff in order to ascertain feasibility and gain support for the project. I also presented the study at a diabetes conference which strengthened my presentation skills. I was worried that staff may be hesitant to be involved due to the measure assessing the educator's alliance building skills or that they would fail to see any relevance of the study to their work. These concerns led me to be clear about the rationale for the study, its possible clinical implications, how staff could be involved and assess whether the requests for involvement were reasonable. I was surprised at how interested staff were in the research and how many people were happy to be involved. Scale construction commenced through arranging meetings with educators and research staff to ascertain what they felt was important in building a working alliance with patients. I made the decision to provide a broad short definition of working alliance and deliberately tried not to elaborate on this to prevent biasing their view of what relationship factors they felt were important. I had thought about conducting more structured interviews or focus groups but felt that an informal collaborative process with minimal prompting would produce the information I required and encourage greater involvement of staff.

As the scale was being constructed from the educators and research staff ideas this provided a useful opportunity to meet with staff and explain the study further. It would have been useful to have obtained some early feedback from the people attending the self-management courses at this time but due to time constraints and delays in approval it was not possible to conduct any focus groups with individuals on the self-management course. When it came to rating the scale items I had a limited response through emailing staff members. I therefore decided to attend a further meeting and provide hard copies of the scale items to staff members present which was more successful. I tried to make each step as easy as possible for staff to participate as I felt that my research may be low in their priorities and as I was not on placement in this setting I had to work hard to maintain a presence so that the study was not forgotten about. I was pleased that so many members of staff agreed to complete the rating form and gave useful feedback to help me construct the pilot scale. I think without this process I would have found it difficult to decide which items to retain in the pilot scale.

7. Recruitment

The first attempt at recruitment did not go well as although administration staff had kindly sent out participant information sheets prior to the course, educators were unaware that I would be attending at the end of their course. Participants therefore rushed past me to go home as I was patiently waiting to recruit my first participant. I was able to alert this to the attention of the administration team who promptly told all educators on days where I planned to recruit and asked them to remind participants of my attendance at the end of the course. I also talked to educators who advised me it would not be disruptive if I slipped in to the meeting room when I arrived as I would act as a reminder.

The data collection itself I found quite enjoyable. I found some people where interested in the study and asked me questions while others appeared in a rush to complete the questionnaire despite it being voluntary. I had imagined that staff may feel guarded due to the study assessing their relationship with the people attending the course however they appeared relaxed and were helpful in facilitating this research. This may have been due to their inclusion in the study from the beginning and my efforts to explain the rationale for the research and that no educator would be identifiable. Furthermore, there was a culture of conducting research on this program and staff were accustomed to being observed as part of their training so my presence did not appear to impact the educators greatly.

Following the delays in my research project due to changing research approval pathway I predicted that it was unlikely that I would be able to obtain the proposed number of participants however sample size was further impacted by additional unforeseen difficulties. In January, I was notified that the tender had been lost for running the self-management program and therefore it would be run by a private company from March 2016. Although I was due to terminate my recruitment in March this impacted me as another study was due to begin recruiting following my study and therefore I had to end recruitment in the middle of January in order to allow them to recruit their minimum numbers before March. This highlights the impact of privatisation of the NHS on research as unproven private providers can outbid NHS services with an excellent record of providing a high quality care and can result in research projects that have taken a long time to implement having to stop. This process of tendering for services can therefore be detrimental to supporting research projects which may in turn impact the quality of services received.

8. Data Analysis

Although I had previous experience of quantitative analysis I was somewhat pessimistic about whether my planned exploratory factor analysis would be suitable due to the smaller than expected sample size. I was relieved when the statistical tests indicated that it was appropriate to run factor analysis however I was surprised at how much subjective decision making was necessary to decipher which rotation, how many factors should be included, and which items to retain in the final scale. I found guidelines useful for justifying my interpretation but it was clear to me that there was not always an obvious or right answer as it depended on whether your findings made theoretical sense. It meant that each time a decision was made I had to think about what this implied theoretically as well as being logical from a statistical perspective. Despite my initial concerns in my ability to conduct the analysis required for scale development I felt this process greatly improved my understanding of statistics and its limitations.

I took a positive empiricist stance when conducting this research in order to meet the aims of the study. I remained aware throughout the project that my approach could be criticised for trying to reduce a complicated experience and interaction into a 15-item scale which was not able to pick up nuances and the depth of individuals experiences. I feel by creating the WASME scale working alliance can now be studied in time efficient, comparable and with reduced researcher subjectivity within self-management education. A strength of the study is that the items of the WASME scale were created through a collaborative process which increased the validity of the scale by making it representative of what was important to those who work in the field rather than imposed by me. This could have been further enhanced by participant involvement from the beginning.

9. Learning Outcomes

If I was designing the study again I would make several adjustments. Firstly, seeking approval from the research site took much longer due to being advised at a later stage of the process that I was required to go through an alternative procedure to obtain study approval. In future, I think it would be useful to meet with the head of the department earlier to ensure any new research policies are being adhered to. This seemed unnecessary at the time as I had met with other senior research staff however an earlier email may have prevented the increased work I undertook regarding the approval process. Secondly, I would consider the possibility of involving another researcher in the recruitment of

participants. There were days when I was on placement in which I was unable to attend the course and having another researcher would have increased my sample size. I am not sure how feasible this would have been but it may have been worth negotiating with the department especially following the change in research approval pathway. Thirdly, I had not anticipated that losing the tender for providing the self-management course was a possibility as the service had been running successfully for many years. If I was to conduct a similar project, I would ask about the contract for the service and try to understand the security of this. This may become a more regular occurrence in the current NHS due to current financial pressures resulting in commissioners being more likely to try new services if they can offer a similar service at a cheaper price. Finally, I found the analysis of the data collected more challenging than I had perceived it to be. I could have spent more time thinking about this process and discussing with experts prior to the final write up. Nevertheless, working through issues of non-normality, and small sample size had not been predicted and have increased my statistical knowledge and given me confidence in my analysis abilities.

10. Conclusions

Constructing a scale to measure a construct which involves the subjective experience of the interpersonal and intrapersonal processes is challenging. I have learnt a great deal, both personally and professionally, from undertaking this project. Learning about scale development and working with a service to promote engagement in my project has given me confidence in my ability as a researcher. My ability to manage challenges and overcome barriers with the research process has made me feel capable at dealing with setbacks which is an important transferable skill in the field of clinical psychology but also in my personal life.

I feel that my ability to communicate with others throughout the project through informal discussions and more formal presentations was instrumental in promoting the study and I will endeavour to improve upon these skills in any future research I may conduct. This study has also informed my clinical work as I found the research in working alliance and therapy fascinating and persuasive. It has made me reflect further on my own alliance building skills with clients. Furthermore, I feel I am more inclined to use evaluative measures in my own clinical practice such as the Session Rating Scale (Duncan *et al*.

2003) to provide feedback following the strong evidence for its effects on clients'
outcomes.

Personally, I feel that my management and organisational skill have improved due to
having to balance conflicting demands of my clinical, research and personal roles. These
skills will continue to be of benefit to me in my future career. Additionally, I feel I have
become a more assertive person through this process. I felt when challenges arose I was
able to act quickly and find out what I needed to do to get the project back on track. I was
also able to use research supervision to manage my own anxieties about the project and to
guide my decision making. The process of undertaking this project gave me a greater
appreciation of conducting research, increased my understanding of the processes
involved, and improved my confidence in my research abilities.

11. References

Bordin, E.S. (1979). The generalizability of the psychoanalytic concept of the working
alliance. *Psychotherapy: Theory, Research and Practice*, *16*, 252– 260.

Castonguay, L.G., Constantino, M.J., & Holtforth, M.G. (2006). The working alliance:
Where are we and where should we go?. *Psychotherapy: Theory, Research, Practice,
Training, 43*(3), 271.

Duncan, B.L., Miller, S.D., Sparks, J.A., Claud, D.A., Reynolds, L.R., Brown, J., *et al.*
(2003). The Session Rating Scale: Preliminary psychometric properties of a "working"
alliance measure. *Journal of brief Therapy*, *3*(1), 3-12.

Martin, D.J., Garske, J.P., & Davis, M.K. (2000). Relation of the therapeutic alliance with
outcome and other variables: A meta-analytic review. *Journal of Consulting and Clinical
Psychology*, *68*, 438-450.

NICE. (2009). Depression in adults with a chronic physical health problem: treatment and
management.   Retrieved   from: http://www.nice.org.uk/nicemedia/pdf/
CG91FullGuideline.pdf on 12th January 2012

Norcross, J.C. (2002). Empirically supported therapy relationship. In J.C. Norcross (Ed.),
*Psychotherapy relationships that work: Therapist contributions and responsiveness of
patients* (pp. 3−16). New York: Oxford University Press.

Appendices

Appendix A: Target Journal Guidelines

Patient Education and Counselling

Guidelines retrieved April 2015 from: https://www.elsevier.com/journals/patient-education-and-counseling/0738-3991/guide-for-authors

1. Aims and Scope
Patient Education and Counseling is an interdisciplinary, international journal for patient education and health promotion researchers, managers, physicians, nurses and other health care providers. The journal seeks to explore and elucidate educational, counseling and communication models in health care. Its aim is to provide a forum for fundamental as well as applied research, and to promote the study of the delivery of patient education, counseling, and health promotion services, including training models and organizational issues in improving communication between providers and patients.

Patient Education and Counseling is the official journal of the European Association for Communication in Healthcare (EACH) and the American Academy on Communication in Healthcare (AACH).

2. Manuscript Categories
During online submission, the author can select a category from the following list: Research Paper, Review Article, Short Communication, Reflective Practice, Discussion or Correspondence. The type of manuscript should be indicated in the cover letter.

Research Papers: Preference is given to empirical research which examines such topics as provider-patient communication, patient education, patient participation in health care, adherence to therapeutic regimens, social support, decision-making, health literacy, physiological changes, health/functional status etc. Maximum 4000 words. Please note that manuscript word counts EXCLUDE the following: Abstract, acknowledgements, references, tables, figures, conflict of interest statements. Both descriptive and intervention studies are acceptable. Each Research Paper will also require a heading selected from the following to identify the section of the journal to which it best applies: Communication Studies, Patient Education, Healthcare Education, Healthcare and Health Promotion, Patient and User Perspectives and Characteristics, Assessment and Methodology.
Review Articles: In-depth reviews of the empirical research in an area relevant to the journal, including analytical discussion of contemporary issues and controversies (maximum 5000 words not including references and tables)
Short Communications: Brief articles in any of the above categories will also be considered (maximum 1500 words not including references and tables).
Reflective Practice: We welcome personal narratives on caring, patient-clinician relationships, humanism in healthcare, professionalism and its challenges, patients' perspectives, and collaboration in patient care and counseling. Most narratives will describe personal or professional experiences that provide a lesson applicable to caring, humanism, or relationships in health care. No abstract is needed. No (section) headings, no numbering. Maximum 1500 words. Submissions are peer-reviewed. For further information, see the editorial published in PEC: Hatem D, Rider EA. Sharing stories:

narrative medicine in an evidence-based world. Patient Education and Counseling 2004;54:251-253.

Discussion Forum - Papers in the Discussion Forum will include two categories: Discussion Papers up to 3000 words with discussion and commentary on relevant topics within the Aims and Scope of the journal. A Discussion paper should elucidate a theory, concept or problem in an area relevant to the journal.

Correspondence Papers: (up to 1500 words) with brief comments on articles in previous issues of the journal.

3. **Guidelines**

We encourage authors to consult appropriate guidance, depending on the design of their study. For randomized trials, consult CONSORT (Consolidated Standards Of Reporting Trials) http://www.consort-statement.org/

For systematic reviews and meta-analyses consult PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) http://www.prisma-statement.org/

For statistical analysis and reporting, consult SAMPL (Basic Statistical Reporting for Articles Published in Biomedical Journals: The "Statistical Analyses and Methods in the Published Literature") http://www.equator-network.org/reporting-guidelines/sampl/

For qualitative studies, see specific editorials published in PEC: Finset A. Qualitative methods in communication and patient education research. Patient Educ Couns, Volume 73, Issue 1, October 2008, Pages 1-2. DOI: 10.1016/j.pec.2008.08.004

Salmon P. Assessing the quality of qualitative research. Patient Educ Couns Volume 90, Issue 1, January 2013, Pages 1-3. DOI: 10.1016/j.pec.2012.11.018

4. **Article structure**

Subdivision - numbered sections

Divide your article into clearly defined and numbered sections. Subsections should be numbered 1.1 (then 1.1.1, 1.1.2, ...), 1.2, etc. (the abstract is not included in section numbering). Use this numbering also for internal cross-referencing: do not just refer to 'the text'. Any subsection may be given a brief heading. Each heading should appear on its own separate line.

Manuscripts should be organized as follows:

Title page, Abstract, 1. Introduction, 2. Methods, 3. Results, 4. Discussion and Conclusion, References, Legends.

Introduction

State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

Material and methods

Provide sufficient detail to allow the work to be reproduced. Methods already published should be indicated by a reference: only relevant modifications should be described.

Results

Results should be clear and concise.

Discussion and Conclusion

Discussion and Conclusion should be headed as one section and divided into three parts. Example: 4. Discussion and Conclusion, 4.1. Discussion, 4.2. Conclusion. 4.3 Practice Implications

Practice Implications
Articles should include a paragraph or paragraphs entitled 'Practice Implications' as part of the discussion and conclusion, which outlines the implications for practice suggested by the study. Authors should take care that these implications follow closely from the data presented, rather than from other literature. In the event that an article presents very preliminary data or conclusions, these paragraphs may be omitted

Appendices
If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

5. Essential title page information

• *Title.* Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.
• *Author names and affiliations.* Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.
• *Corresponding author.* Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. Ensure that the e-mail address is given and that contact details are kept up to date by the corresponding author.
• *Present/permanent address.* If an author has moved since the work described in the article was done, or was visiting at the time, a 'Present address' (or 'Permanent address') may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

Abstract
A structured abstract, by means of appropriate headings, should provide the context or background for the research and should state its purpose, basic procedures (selection of study subjects, observational and analytical methods), main findings (giving specific effect sizes and their statistical significance, if possible), principal conclusions and practice implications. Abstracts should adhere to the following format: Objective, Methods, Results, Conclusion, Practice Implications. The word limit for abstracts is 200.

Highlights
Highlights are mandatory for this journal. They consist of a short collection of bullet points that convey the core findings of the article and should be submitted in a separate editable file in the online submission system. Please use 'Highlights' in the file name and include 3 to 5 bullet points (maximum 85 characters, including spaces, per bullet point). You can view example Highlights on our information site.

Units
Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

Footnotes
Footnotes should be used sparingly. Number them consecutively throughout the article. Many word processors can build footnotes into the text, and this feature may be used. Otherwise, please indicate the position of footnotes in the text and list the footnotes themselves separately at the end of the article. Do not include footnotes in the Reference list.

6. Tables

Please submit tables as editable text and not as images. Tables can be placed either next to the relevant text in the article, or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules.

7. References

Citation in text
Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Any references cited in the abstract must be given in full. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the

publication date with either 'Unpublished results' or 'Personal communication'. Citation of a reference as 'in press' implies that the item has been accepted for publication.

Reference links

Increased discoverability of research and high quality peer review are ensured by online links to the sources cited. In order to allow us to create links to abstracting and indexing services, such as Scopus, CrossRef and PubMed, please ensure that data provided in the references are correct. Please note that incorrect surnames, journal/book titles, publication year and pagination may prevent link creation. When copying references, please be careful as they may already contain errors. Use of the DOI is encouraged.

A DOI can be used to cite and link to electronic articles where an article is in-press and full citation details are not yet known, but the article is available online. A DOI is guaranteed never to change, so you can use it as a permanent link to any electronic article. An example of a citation using DOI for an article not yet in an issue is: VanDecar J.C., Russo R.M., James D.E., Ambeh W.B., Franke M. (2003). Aseismic continuation of the Lesser Antilles slab beneath northeastern Venezuela. Journal of Geophysical Research, http://dx.doi.org/10.1029/2001JB000884i. Please note the format of such citations should be in the same style as all other references in the paper.

Web references

As a minimum, the full URL should be given and the date when the reference was last accessed. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be given. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list.

Reference style

Text: Indicate references by number(s) in square brackets in line with the text. The actual authors can be referred to, but the reference number(s) must always be given.
Example: '..... as demonstrated [3,6]. Barnaby and Jones [8] obtained a different result ....'
List: Number the references (numbers in square brackets) in the list in the order in which they appear in the text.
Examples:
Reference to a journal publication:
[1] J. van der Geer, J.A.J. Hanraads, R.A. Lupton, The art of writing a scientific article, J. Sci. Commun. 163 (2010) 51–59.
Reference to a book:
[2] W. Strunk Jr., E.B. White, The Elements of Style, fourth ed., Longman, New York, 2000.
Reference to a chapter in an edited book:
[3] G.R. Mettam, L.B. Adams, How to prepare an electronic version of your article, in: B.S. Jones, R.Z. Smith (Eds.), Introduction to the Electronic Age, E-Publishing Inc., New York, 2009, pp. 281–304.

Reference citations should be numbered consecutively throughout using Arabic numerals in parentheses or square brackets (not superscripts). References should be double-spaced and start on a separate page. References should conform to the system used in Uniform Requirements for Manuscripts Submitted to Biomedical Journals (Brit Med J

1991;302:338-41; N Engl J Med 1991;324:424-8), using standard abbreviations of the journal titles cited in Current Contents.

Note All authors' names should be listed. Issue numbers should not be included.

Appendix B: Data Extraction Form

Author	
Study Title	
Study design	
Participants (Number, Age Range, Gender, Ethnicity)	
Setting	
Aim of study	
Method of recruitment of participants	
Constructs measured	
Person measuring/reporting	
Measures used	
Are outcome tools validated	
Withdrawals/dropouts	
Missing data	
Analysis used (What statistical method was used? Was power calculated?)	
Significant results	
Non-significant results	
Limitations	

Other comments	

Appendix C: Study Quality Checklist

Reporting

1. Is the hypothesis/aim/objective of the study clearly described?

2. Are the main outcomes to be measured clearly described in the introduction or methods section?

3. Are the characteristics of the patients included in the study clearly described?

4. Are the main findings of the study clearly described?

5. Have actual probability values been reported?

External validity

6. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?

Internal validity

7. Did the study indicate how many people asked to take part did so?

8. Were the statistical tests used to assess the mains outcomes appropriate?

9. Were adequate adjustments for confounding in the analyses from which the main findings were drawn?

10. Was the measure of working alliance valid and reliable?

11. Was the measure of adherence valid and reliable?

Power

12. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance less than 5%?

Study design

13. Are the results of this study directly applicable to the patient group targeted in this guideline?

14. Can the study identify causality?

Max Score 14

Appendix D: Summary of Reviewed Studies

No	Study, Date and Location	Aim and Design	Patient Characteristics	Recruitment	Working Alliance Measure/ Rater (R)	Adherence Measure/ Rater (R)	Outcome	Limitations
1	**Stanton et al. (2014)** **California, USA**	To identify potential contributors to nonadherence and non-persistence with endocrine therapy in breast cancer patients. Prospective correlational design	*N:* 1371 women taking endocrine therapy and 94 'non-persisters' with recommended medication following breast cancer. *Age:* M=56 years *Sex:* F=100% *Ethnicity:* 94% non-Hispanic white	Participants identified through women's research registry Online survey 14 days post-therapy adherence items were completed online.	WAI-S-C (10 items only) (R) Patient Patient-Oncologist relationship	Medication Adherence Adapted Morisky Medication Adherence scale / Participants identified selves as non-persisters (R) Patient	Poor WA with oncologist significantly associated with adherence to medication ($r = -.24$, $p < .01$). Non-persisters reported a significantly poorer quality relationship with oncologist ($p <.001$) than adherers.	Cross-sectional design Non-systematic sampling Self-report Solely female sample Lack of ethnic diversity
2	**Bennet et al. (2011)** **English speaking countries**	To examine if patients' attachment style and WA with physicians, predicts adherence, satisfaction, and health-related quality of life in patients with SLE. Cross-sectional Correlational design	*N:* 193 adults with a diagnosis of SLE. *Age:* M=43 *Sex:* F=97% *Ethnicity:* 79% non-Hispanic white	Participants recruited from lupus-oriented websites targeted at the English-speaking world	PPWA - Modification of WAI-S-C (R) Patient Patient-Physician relationship Physician seen min. of 3 times in the last year	The General Adherence Inventory (GAI) (R) Patient	Significant positive correlation between WA and adherence ($r =.29$, $p < .001$)	Sample not diverse Cross-sectional design Self-report

#	Author (Year) Location	Aim	Sample	Recruitment	WA Measure	Adherence Measure	Key Findings	Limitations
3	**Fuertes et al. (2015)** **New York, USA**	To examine the psychological, emotional and behavioural dimensions of patients' WA with their physicians, along with patients' attachment styles in relation to rheumatology patients' adherence to treatment plans, outcome expectations, and satisfaction. Cross-sectional Correlational design	*N:* 101 adult outpatients from a rheumatology clinic. *Age:* M=49 *Sex:* F=83% *Ethnicity:* 45% Hispanic, 33% African American, 16% Caucasian, 3% Asian American, 3% other	Convenience sample recruited over a nine-month period at a rheumatology outpatient clinic	PPWA Scale-adapted from the WAI-S-C (R) Patient Patient-Physician relationship	5-item idiosyncratic scale for general adherence - (R) Physician Treatment adherence self-efficacy - (R) Patient	Positive correlation between WA and patient reported adherence self-efficacy ($r =.46, p < .01$) WA positively correlated to physician-rated adherence ($r =.25, p < .01$) A strong indirect relationship between WA and patient adherence to treatment via patient satisfaction.	Reliant on self-report Convenience sample may impact generalizability Physician rated adherence measure was not a validated measure Majority of sample female
4	**Trevino et al. (2013)** **Boston, USA**	To evaluate the relationships between the patient-oncologist WA, psychosocial wellbeing, and treatment adherence in young adults with advance cancer Cross-sectional Correlational design	*N:* 95 young adults (20-40 years) with incurable, recurrent, or metastatic cancer. *Cancer Diagnosis:* 33% Breast, 16% Brain tumour, 11% Leukaemia, 8% soft tissue, 4% colon, 27% other. *Age:* M=33 *Sex:* F=68%	Participants identified through electronic medical records at a tertiary cancer care centre Participation rate of 41% Measures conducted face-to-face	THC scale (R) Patient Patient-Oncologist relationship	Willingness to adhere assessed through two items from the CTSQ Adherence to oral cancer medication assessed using a single item from CTSQ (R) Patient	Stronger WA was significantly predicted by less frequent thoughts of stopping cancer treatment ($\beta = -.06, p < .001$) and better adherence to cancer medication ($\beta=.04, p < .005$) after controlling for confounders. A stronger alliance was not related to more frequent thoughts that treatment is worth the	Alliance measure was validated on an older adult sample Self-report measure Adherence measure was a single item and only applied to taking oral medication

	Author	Aim/Design	Sample	Recruitment	WA Measure	Adherence Measure	Results	Notes
			Ethnicity: 86% white, 5% Hispanic, 4% Asian America, 4% African American.				adverse effects when controlled for confounding variables ($\beta = .03$, $p = .038$).	
5	**Fuertes *et al.* (2007)** **New York, USA**	To examine the physician-patient WA in relation to patients perceived usefulness of treatment, adherence self-efficacy, adherence and satisfaction. Cross-sectional correlational design	*N:* 118 adults with a chronic physical illness. *Diagnosis*: 15% HIV+/AIDS, 13% hypertension, 12% diabetes, 10% asthma, 5% thyroid problems and 4% cancer. The diagnosis of the remaining participants not provided. *Age*: M=39 *Sex:* F=57% *Ethnicity:* 62% Euro-American, 19% African-American, 5% Asian-American, 9% Hispanic, 5% other.	Recruited through research participation website within specific region Screened by telephone Completed survey in person at University	C-WAI Items were reworded to refer to the medical relationship (R) Patient Patient-Physician relationship	Adherence Self-Efficacy was measure through a single Likert scale item Five items from the MOS. Assessed patient adherence behaviours over the past 4 weeks. (R) Patient	WA was moderate positively correlated to adherence self-efficacy ($r = .47$, $p < .001$), and adherence ($r = .53$, $p < .001$). Regression analyses indicated that working alliance was a significant predictor of patient adherence.	All patients were medically stable All measures were self-report No indication of physician rated working alliance or adherence Participation rate not reported
6	**Fuertes *et al.* (2009)** **New York, USA**	To examine the relationship between the physician-patient WA and patient ratings of empathy, physician	*N:* 152 outpatients at a neurology clinic *Diagnosis:* One or more chronic medical conditions, Diagnoses not specified.	Consecutive recruitment during an outpatient neurology clinic. Participation rate	PPWA- adapted from the WAI-S-C Have seen the same physician at least twice in	Treatment Adherence Self-Efficacy Scale Measured by four items from the MOS.	WA was significantly positively associated with medical treatment adherence self-efficacy ($r = .44$, $p <.001$) and patient self-reported adherence ($r = .35$,	All measures were self-report Only had to see the physician two times in last six months.

No.	Author (Year) Location	Aim / Design	Sample	Recruitment	WA Measure	Outcome Measure	Results	Design / Limitations
		multicultural competence, perceived utility of treatment and patient's adherence self-efficacy. Ex-post facto field correlation design	*Age:* M=45 *Sex:* F=47% *Ethnicity:* 22% Euro-American, 43% African-American, 29% Hispanic, 4% Asian-American, 2% other.	approx. 80%	the last six months. (R) Patient Patient-physician relationship	Assessed patient adherence behaviours over the past 4 weeks. (R) Patient	$p < .001$). A regression analyses and path analysis identified that working alliance ($p = .9$) did not predict patient adherence with treatment.	Correlational design
7	**Evon & Burns (2004)** **Illinois, USA**	To determine whether diet and exercise self-efficacy and patient-staff WA predicted outcomes such as activity level, diet and weight in a cardiac rehabilitation program. Prospective correlational design	*N:* 80 cardiac outpatients enrolled on a 12-week cardiac rehabilitation program *Age:* M=63 *Sex*: M=100% *Ethnicity:* 96% Caucasian, 3% Hispanic, 1% African American	Consecutively recruited from two community hospital 12-week cardiac rehabilitation programs Participation rate 45%	WAI-Short form Completed after 3 sessions Adapted scale to refer to the patient-program staff relationship (R) Patient	Exercise and diet self-efficacy – assessed confidence about adhering to an exercise regime and low fat, low cholesterol diet. Diet- amount of saturated and total fat consumer was assessed by the Quick Check for Diet progress (R) Patient	Early to mid-treatment changes in diet and exercise self-efficacy were not significantly associated with early to mid-treatment changes in WA. No correlation between WA and diet were observed. Hierarchical regression analyses showed early to mid-adherence to exercise self-efficacy predicted late WAI rather than the reverse.	Cross-sectional design Study had inadequate power to detect small correlations. Sample only included men. Tried to measure patient's WA with all program staff which may be problematic as it doesn't account for difference in relationships.

8	**Schonberger** *et al* **(2006a)** **Copenhagen, Denmark**	To investigate the impact of the WA and patients' compliance on the outcome of holistic neuropsychological outpatient rehabilitation. Retrospective correlational design	*N:* 98 patients at a 4 day a week multidisciplinary rehabilitation program which can for four months. Diagnoses: Traumatic brain injury (N=26), cerebrovascular incident (N=58) and other (N=14) Age: M=44 Sex: F=42% Ethnicity: Not specified	Consecutive recruitment at single specialist rehabilitation centre. Participation rate 95%	Priganto Scales Dichotomised into "poor or fair" and "good or excellent" working alliance Retrospectively rated. (R)Neuropsychologist (R)Physiotherapist Patient-Neuropsychologist and patient-physiotherapist relationship	Three questions related to patient engagement, acceptance of programme elements and objectives, and following the therapist's advice. Patients were divided into three groups of low, average and high compliance (R)Neuropsychologist (R)Physiotherapist.	WA was significantly related to compliance for both raters (Cramer's V =.79 and .76 for the neuropsychologist and the physiotherapist respectively)	Rater memory bias. Low inter-rater reliability Dichotomising WA and adherence may over simplify a complex process.
9	**Schonberger** *et al.* **(2006b)** **Copenhagen, Denmark**	To examine the development and relationship between WA, patient's compliance and awareness during the process of brain injury rehabilitation. Prospective correlational design	*N:* 86 patients at a holistic outpatient rehabilitation four-month programme *Diagnoses:* traumatic brain injury (N=27), a cerebrovascular accident (N=49) or other neurological insult (N=10) *Age:* M=45	Consecutive recruitment at single outpatient rehabilitation centre which ran for approx. 4 months four days a week. Participation rate 82%	WAI –Short Form (R)Patient & (R)Primary therapist Patient-Primary Therapist relationship Primary therapist was a psychologist,	Adherence was measured using a five item scale developed for the study (R)Primary therapist Ratings completed at week 2, 6, 10 and 14	A significant positive relationship was found between patient rating of WAI bond (r =.30, p < .05) mid treatment and adherence scores. No other significant relationship between WAI and compliance were indicated. Regression analyses showed no direct	No table of correlations was provided. Split WAI into subscales to investigate correlations rather just looking at the scale total. Measure WAI several times

	Sex: F=36%	physiotherapist, speech	relationship between clients rated total WAI	during the program and
	Ethnicity: Not specified	pathologist, occupational therapist or a special education teacher.	however found an indirect relationship mediated by patient awareness.	only found one significant association.

Abbreviations: WA: Working Alliance; WAI: Working Alliance Inventory; WAI-S-C: Working Alliance Inventory Short Form Client; SLE: Systemic lupus erythematosus; PPWA: Patient-physician working alliance scale; THC: The Human Connection Scale; CTSQ- Cancer Therapy Satisfaction Questionnaire; C-WAI: Client Working Alliance Inventory; MOS: Medical Outcome Study; TAS: Treatment Alliance Scale.

Appendix E: Quality Assessment of Included Studies

Study	Reporting	External Validity	Internal Validity	Power	Study Design	Study Quality Score %
Stanton et al. (2014)	5/5	1/1	3/5	0/1	0/2	64%
Bennet et al. (2011)	5/5	0/1	4/5	1/1	2/2	86%
Fuertes et al. (2015)	4/5	1/1	5/5	1/1	1/2	86%
Trevino et al. (2013)	5/5	1/1	4/5	0/1	1/2	79%
Fuertes et al. (2007)	5/5	0/1	4/5	1/1	1/2	79%
Fuertes et al. (2009)	4/5	0/1	4/5	0/1	2/2	64%
Evon & Burns (2004)	5/5	1/1	4/5	1/1	2/2	93%
Schonberger et al. (2006a)	5/5	1/1	3/5	0/1	0/2	64%
Schonberger et al. (2006b)	5/5	1/1	2/5	0/1	1/2	64%

Appendix F: Overview of DESMOND Self-Management Education

DESMOND is a collaborative name for a group of self-management education courses and toolkits for individuals with Type 2 diabetes, or those at risk of developing it. Courses are delivered in a variety of setting throughout the country. This project was conducted on the DESMOND course for newly diagnosed individuals running in Leicester General Hospital. Courses are run by two Healthcare professionals in groups of up to ten participants. Educators are usually practice nurse, diabetes specialist nurses or dieticians.

Content
DESMOND-Newly Diagnosed is a six-hour course held over one day. The course has a detailed written curriculum to ensure consistency. The content includes:
- The patients story
- Exploring the emotional impact of diabetes
- Learning about diabetes and glucose
- Understanding the risk factors and complications associated with diabetes
- Learning how to monitor and understand medication
- How to take control through food choices and physical activity
- Making an action plan

Philosophy and Theoretical underpinnings
The DESMOND philosophy has been outlined as "that of 'informed choice', which the collaborative believe to be the key to empowerment, and based on a humanistic view of the individual" (Skinner *et al.* 2006, p. 371). This paper articulates the key roles of healthcare professionals in order to implement this philosophy. The content and process of the course was based around three psychological models/concepts:
- The Common Sense Model of Illness (Leventhal *et al.* 1984; Leventhal *et al.* 2003).
- Social Learning Theory (Bandura, 1977).
- Zone of Proximal Development (Vygotsky, 1978).

Delivery Style
Courses aim to be non-didactic and interactively delivered. Participants are supported to discover and find out the information they need to make health-related decisions. Educators support individuals to identify their own risk factors to help them create their own personalised goal and recognise tasks required to achieve this goal.

Training and Quality Development Program for Educator
The DESMOND collaborate have a developed a Quality Development (QD) process involving both internal and external processes. Internal processes involved the educator engaging in personal and peer reflection on their practice after completing training. The external process involves the use of review tools to assess the extent to which an educator

is demonstrating the content and process indicators of the course. These tools have helped the program access quality.

Related Publications

- Davies, M.J., Heller, S., Skinner, T.C., Campbell, M.J., Carey, M.E., Cradock, S., *et al.* (2008). Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial. *British Medical Journal*, *336*(7642), 491-495.
- Gillett, M., Dallosso, H.M., Dixon, S., Brennan, A., Carey, M.E., Campbell, *et al.* (2010). Delivering the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cost effectiveness analysis. *British Medical Journal*, *341*, c4093.
- Khunti, K., Heller, S., Skinner, T.C., Gray, L.J., Dallosso, H., Realf, K., *et al.* (2010). Randomised controlled trial of the DESMOND structured education programme for people newly diagnosed with type 2 diabetes: follow-up results at three years. *Diabetic Medicine*, *27*(1), 22.
- Skinner, T.C., Carey, M.E., Cradock, S., Dallosso, H.M., Daly, H., Davies, M.J., *et al.* (2011). Comparison of illness representations dimensions and illness representation clusters in predicting outcomes in the first year following diagnosis of type 2 diabetes: results from the DESMOND trial. *Psychology and Health*, *26*(3), 321-335.

References

Bandura, A. (1977). Social Learning Theory. Englewood Cliffs, New Jersey: Prentice Hall.

Leventhal, H., Brissette, I., Leventhal., E. (2003). The common-sense model of self-regulation of health and illness. In: Cameron, L.D., Leventhal, H., (Eds.) *The self-regulation of health and illness behaviour*(pp.42-65). London/ New York: Routledge.

Leventhal, H., Nerenz, D., Steele, D.J., Taylor, S.E., Singer J.E. (1984). Illness representation and coping with health threats. In: Baum A., (Ed.) *Handbook of psychology and health.* (pp. 219-252). New Jersey: Lawrence Erlbaum Associates Inc.

Vygotsky LS. (1978). In: Cole, M., John-Steiner, V., Scribner, S., Souberman, E., (Ed.) *Mind in society: the development of higher psychological processes.* Cambridge, MA: Harvard University Press.

For further information, please visit the DESMOND Website:
www.desmond-project.org.uk

Appendix G: Research Ethics Approval Letter

NRES Committee London - City Road & Hampstead
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117342 1339

17 March 2015

Miss Lynsey Cobane

Dear Miss Cobane

Study title:	**The Working Alliance in Self-Management Education (WASME) Scale Development.**
REC reference:	**15/LO/0336**
IRAS project ID:	**169783**

Thank you for your letter of 05 March 2015, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Miss Maeve Groot Bluemink, nrescommittee.london-cityroadandhampstead@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

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

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

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.

<u>Registration of Clinical Trials</u>

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the 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).

<u>Ethical review of research sites</u>

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" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	Version	Date
Covering letter on headed paper [Cover Letter]	V1	05 March 2015
IRAS Checklist XML [Checklist_06022015]		06 February 2015
IRAS Checklist XML [Checklist_09022015]		09 February 2015
IRAS Checklist XML [Checklist_08032015]		08 March 2015
IRAS Checklist XML [Checklist_11032015]		11 March 2015
Letters of invitation to participant [Letter of invitation]	V2	04 March 2015
Letters of invitation to participant [Letter of invitation]	V2 (tracked)	04 March 2015
Non-validated questionnaire [Demographic Information Questionnaire]	1	20 January 2015
Other [CARE validated questionnaire]		
Participant consent form [Consent form]	V2	04 March 2015
Participant consent form [Consent form]	V2 (tracked)	04 March 2015
Participant information sheet (PIS) [Participant Information Sheet]	V2	04 March 2015
Participant information sheet (PIS) [Participant Information Sheet]	V2 (tracked)	04 March 2015
REC Application Form [REC_Form_06022015]		06 February 2015
Research protocol or project proposal [WASME Research Protocol]	2	05 March 2015
Research protocol or project proposal [WASME Research Protocol]	V2 (tracked)	05 March 2015
Summary CV for Chief Investigator (CI) [LC research CV]	1	02 January 2015
Summary CV for supervisor (student research) [NR research CV]	1	30 January 2015
Validated questionnaire [Client-Satisfaction Questionaire (CSQ-8)]		

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 HRA 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 HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

15/LO/0336	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

pp
Dr David Slovick
Chair

Email: nrescommittee.london-cityroadandhampstead@nhs.net

Enclosures: *"After ethical review – guidance for researchers"* [SL-AR2]

Copy to: *Dr David Clarke*
                         Carolyn   Maloney, University Hospital Leicester NHS Trust

Appendix H: Research and Development Approval Letter

DIRECTORATE OF RESEARCH & INNOVATION

Research & Innovation Office
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Director:	**Professor Nigel Brunskill**
Assistant Director:	**Dr David Hetmanski**
Head of Research Operations:	**Carolyn Maloney**

Direct Dial: (0116) 258 8351
Fax No: (0116) 258 4226

07 October 2015

Dr Yvonne Doherty
Senior Research Associate
Consultant Clinical Psychologist
Leicester Diabetes Centre
Leicester General Hospital
Leicester
LE5 4PW

Dear Dr Yvonne Doherty

Ref:	**UHL 169783**
Title:	**The Working Alliance in Self-Management Education (WASME) Scale Development**
Project Status:	**Approved**
End Date:	**30/04/2016**

Date of Valid Application: 06/10/2015
Days remaining to recruit first patient: 69 Days

I am pleased to confirm that with effect from the date of this letter, the above study has Trust Research & Development permission to commence at University Hospitals of Leicester NHS Trust. The research must be conducted in line with the Protocol and fulfil any contractual obligations agreed between UHL & the Sponsor. If you identify any issues during the course of your research that are likely to affect these obligations you must contact the R&I Office.

In order for the UHL Trust to comply with targets set by the Department of Health through the 'Plan for Growth', there is an expectation that the first patient will be recruited within 70 days of receipt of a Valid Application. The date that a Valid application was received is detailed above, along with the days remaining to recruit your first patient**. It is essential that you notify the UHL Data Management Team as soon as you have recruited your first patient to the study either by email to RIData@uhl-tr.nhs.uk or by phone 0116 258 4573.**

If we have not heard from you within the specified time period we will contact you not only to collect the data, but also to record any issues that may have arisen to prevent you from achieving this target. It is essential that you get in touch with us if there is likely to be a problem in achieving this target so that we can discuss potential solutions. The Trust is contractually

obliged to meet the 70 day target and if an adequate reason acceptable to the NIHR has not been submitted to explain the issues preventing the recruitment of your first participant, the Trust will be financially penalised.

In addition, we are required to publish the Title, REC Reference number, local target recruitment and actual recruitment as well as 70 days data for this study on a quarterly basis on the UHL publicly accessed website.

All documents received by this office have been reviewed and form part of the approval. The documents received and approved are as follows:

Document Title	Version	Date	REC Approval
REC favourable opinion letter	N/A	17/03/15	N/A
REC Acknowledgment Letter – Minor amendment 1	Minor AM1	14/09/15	N/A
Letters of invitation to participant [Letter of invitation]	2.0	04/03/15	17/03/15
Non-validated questionnaire [Demographic Information Questionnaire]	1.0	20/01/15	17/03/15
Other [CARE validated questionnaire]	N/A	N/A	17/03/15
Participant consent form [Consent form]	2.0	04/03/15	17/03/15
Participant information sheet (PIS) [Participant Information Sheet]	2.0	04/03/15	17/03/15
Research protocol or project proposal [WASME Research Protocol]	2.0	05/03/15	17/03/15
Validated questionnaire [Client-Satisfaction Questionnaire (CSQ-8)]	N/A	N/A	17/03/15

Please be aware that any changes to these documents after approval may constitute an amendment. The process of approval for amendments should be followed. Failure to do so may invalidate the approval of the study at this trust.

Undertaking research in the NHS comes with a range of regulatory responsibilities. Please ensure that you and your research team are familiar with, and understand the roles and responsibilities both collectively and individually.

Documents listing the roles and responsibilities for all individuals involved in research can be found on the R&I pages of the Public Website. It is important that you familiarise yourself with the Standard Operating Procedures, Policies and all other relevant documents which can be located by visiting www.leicestershospitals.nhs.uk/aboutus/education-and-research

The R&I Office is keen to support and facilitate research where ever possible. If you have any questions regarding this or other research you wish to undertake in the Trust, please contact this office. Our contact details are provided on the attached sheet.

This study has been reviewed and processed by the East Midlands Clinical Research Network (EM CRN) (Leicester Office) using the Coordinated System for gaining Trust Permission (CSP). If you require any further information on the approval of this study please contact the EM CRN office on 0116 258 6185 making reference to the CSP number which is located at the top of this letter.

We wish you every success with your research.

Version 14, 03/06/2015

114

Yours sincerely

Carolyn Maloney
Head of Research Operations

Encs: .R&I Office Contact Information

Appendix I: 47 Item rating scale

Reviewer: Date:

Role:

The working alliance has been defined a "collaborative and emotional bond between patient and therapist" (Martin et al., 2000, p. 438). Please indicate each item's relevance to this definition within the context of self-management education and with reference to the participant-educator relationship. Items should be judged solely on the basis of the match between its content and the content of the definition of which it is meant to measure. Each item should also be rated on its clarity. Please provide any additional comments to aid scale development. Please rate each item using the following rating scale:

1	2	3	4
Not relevant	Somewhat relevant	Quite relevant	Very relevant

1	2	3	4
Not clear	Somewhat clear	Quite clear	Very clear

Questions	Relevance	Clarity	Comments
The educator took time to listen to me			
The educator paid attention to what I was saying			
The educator ignored me			
The educator gave me the opportunity			

WASME STUDY Version 2 20/07/2015

to share my story			
The educator was curious about my difficulties and concerns			
The educator was keen to know my view			
The educator disregarded my opinion			
The educator was interested on the impact of my health on my whole life			
I felt able to ask the educator questions			
The educator responded to me with warmth			
The educator seemed genuinely interested in me			
I liked the educator			
It was difficult to discuss my concerns with the educator			
The educator made me feel that I could share as much or as little as I wanted			

WASME STUDY Version 2 20/07/2015

I felt that the educator was kind and considerate			
The educator was genuine with me			
I felt that the educator cared about me			
The educator was concerned with my quality of life			
I did not trust the educator			
The educator created a safe space where I felt valued and respected			
The educator was respectful of my opinions and choices			
I felt that the educator judged my lifestyle			
The educator appeared organised and purposeful			
I had confidence in the educators' ability to help me			
The educator was able to answer my			

questions			
The educator discussed issues that were relevant and important to me			
The educator communicated ideas in a way that was meaningful to me			
I was not interested in what the educator was talking about			
I felt the educator managed the group well			
I felt the educator did not treat all members of the group equally			
The educator helped me with my difficulties			
The educator helped me develop some goals			
The educator and I agreed about the things I need to do to manage my health			
The educator helped me develop a plan to put my goals into action			
The educator and I disagreed on the			

types of changes that would be good for me			
The educator helped me recognise things I could do differently			
The educator helped me identify barriers to managing my health			
The educator helped me think about how I may overcome barriers to managing my health			
The educator helped me make informed decisions			
The educator helped improve my knowledge			
I felt supported and encouraged by the educator			
The educator made me feel able to manage my health			
I felt valued and respected by the educator			
The educator made me feel resourceful and capable			

WASME STUDY Version 2 20/07/2015

The educator helped me to identify how I could deal with future concerns and queries			
The educator helped me to develop the confidence to ask health care professionals questions			
The educator made me feel optimistic about my future			

Please identify any other questions which you feel are necessary to capture the quality of the participant-educator working alliance in self-management education:

Additional Comments:

If you have any additional comments or queries that you would like to discuss further please contact Lynsey Cobane (Principal Investigator) by emailing lc316@le.ac.uk

Appendix J: Item Reduction following Staff Feedback

Appendix: Justification for Item Reduction following Staff feedback

The below table outlines the process of item retention, rewording or removal following ratings from research staff.

	Question	Relevance(M)	Clarity(M)	Outcome
1	The educator took time to listen to me	3.86	3.57	Retained
2	The educator paid attention to what I was saying	3.50	3.29	Removed due to comments highlighting item redundancy and overlap with item 1.
3	The educator ignored me	3.50	3.29	Removed due to comments highlighting item redundancy and overlap with item 1.
4	The educator gave me the opportunity to share my story	3.86	3.64	Reworded as comments highlighted that individuals may be confused by the word 'story' and so it was replaced by the work 'experiences'.
5	The educator was curious about my difficulties and concerns	3.14	**2.14**	Reworded and combined with item 13 to create 'the educator was interested in my difficulties and concerns'.
6	The educator was keen to know my view	3.36	3.14	Reworded to "The educator wanted to know my point of view" following comments.
7	The educator disregarded my opinion	3.50	3.14	Removed as feedback stated people may not understand the word 'disregarded' and criticised need for a positive and negative version of the same question.
8	The educator was interested on the impact of my health on my whole life	3.57	**2.93**	Staff felt this was too "wordy" and so this item was removed.
9	I felt able to ask the educator questions	3.79	3.86	Rewording following suggestions that the word 'able; was "a bit ambiguous" and therefore was replaced with 'comfortable'.
10	The educator responded to me with warmth	3.43	3.29	Removed due to comments highlighting item redundancy and overlap with item 15.
11	The educator seemed genuinely interested in me	3.57	3.43	Reworded as comments removal of the word 'genuine' and the item was reworded to the negative 'the educator did not care about me'.
12	I liked the educator	**2.71**	3.64	Removed as feedback suggested that people did not feel this was relevant to the working alliance in self-management education
13	It was difficult to discuss my concerns with the educator	3.57	3.64	Reworded (see item 5 outcome)
14	The educator made me feel that I could share as much or as little as I wanted	3.86	3.71	Retained
15	I felt that the educator was kind and considerate	3.43	3.71	Removed due to comments suggesting that this was not relevant.
16	The educator was genuine with me	3.43	**2.79**	Removed due to clarity score
17	I felt the educator cared about me	3.29	3.50	Reworded to 'the educator understood me' following comments.
18	The educator was concerned with my quality of life	3.57	**3.00**	Reworded following comments about the word 'concerned. Item changed to 'the educator was interested in my whole life'
19	I did not trust the educator	3.57	3.79	Retained
20	The educator created a safe space where I felt valued and respected	4.00	3.50	Removed due to comments regarding 'safe space' and overlap with item 43.
21	The educator was respectful of my opinions and choices	3.93	3.57	Reworded to 'the educator was respectful of my opinions and beliefs'.
22	I felt that the educator judged my lifestyle	3.79	3.57	Retained with slight rewording to 'I felt the educator judged my lifestyle and choices'.
23	The educator appeared organised and purposeful	**2.71**	**3.00**	Removed as not felt to be relevant to working-alliance.
24	I had confidence in the educator's	**2.79**	3.21	Removed as comments suggested that

	ability to help me			this was not relevant. Largely due to educators not taking the "expert" role
25	The educator was able to answer my questions	**2.79**	3.86	Removed as feedback stated that this was not the focus of the DESMOND and not relevant to working alliance in self-management education.
26	The educator discussed issues that were relevant and important to me	3.57	3.71	Reworded to 'the educator enabled discussion about issues that were important to me'.
27	The educator communicated ideas in a way that was meaningful to me	3.64	3.43	Reworded to 'the educator communicated ideas in a way I understood' following comments.
28	I was not interested in what the educator was talking about	3.21	3.36	Removed as deemed too similar to item 26.
29	I felt the educator managed the group well	3.50	3.57	Retained with slight rewording for consistency to 'The educator facilitated the group well'.
30	I felt the educator did not treat all members of the group equally	3.64	3.57	Retained with slight rewording for consistency to 'the educator did not treat all members of the group equally'.
31	The educator helped me with my difficulties	3.21	**2.86**	Removed due to low clarity and comments suggesting that educators take more of a supportive role which was covered in other items.
32	The educator helped me develop some goals	3.50	3.29	Combined with item 33 to create 'the educator agreed on what were important goals for me'.
33	The educator and I agreed about the things I need to do to manage my health	**2.86**	3.29	Combined with item 32 as comments suggested that 'manage my health' was ambiguous.
34	The educator helped me develop a plan to put my goals into action	3.36	3.57	Removed as deemed similar too similar to item the outcome of item 36.
35	The educator and I disagreed on the types of changes that would be good for me	**2.57**	3.36	Removed due to low relevance rating.
36	The educator helped me recognise things I could do differently	3.21	3.29	Reworded to 'The educator helped me recognise things I could do differently to achieve my goals' following suggestions.
37	The educator helped me identify barriers to managing my health	3.79	3.64	Retained
38	The educator helped me think about how I may overcome barriers to managing my health	3.71	3.43	Reworded to 'the educator helped me think about how I may overcome barriers to making changes'.
39	The educator helped me make informed decisions	3.36	**3.00**	Removed due to clarity rating.
40	The educator helped improve my knowledge	**2.93**	3.50	Removed due to relevance rating.
41	I felt supported and encouraged by the educator	3.79	3.86	Retained.
42	The educator made me feel able to manage my health	3.57	3.36	Removed as deemed too similar to item44.
43	I felt valued and respected by the educator	3.86	3.79	Retained.
44	The educator made me feel resourceful and capable	3.43	**2.93**	Retained – Despite slightly low on clarity after reviewing items from other working alliance scales the trainee felt it was appropriate to keep this item.
45	The educator helped me to identify how I could deal with future concerns and queries	3.50	3.14	Retained
46	The educator helped me to develop the confidence to ask health care professionals questions	3.36	3.36	Removed as similar to item 44 and 45
47	The educator made me feel optimistic about my future	3.79	3.86	Removed as overlapped with item 44.

Two additional Items added in to item list came from additional feedback from staff. These items were:

- I felt comfortable asking the educator questions
- The educator ignored my opinion

Appendix K: Participant Information Sheet

Participant Information Sheet

Study Title: Working Alliance in Self-Management Education (WASME) Scale Development

Principal Investigator: Lynsey Cobane

You are being invited to volunteer to take part in a research study. Before you decide whether to take part you should fully understand why the research is being done and what it will involve. Please read the following information carefully and discuss it with your family and friends. If there is anything that is not clear or if you would like more information please contact us at the address at the end of this leaflet.

What is the purpose of this study?
The aim of this study is to develop a new questionnaire to investigate the importance of the relationship between people attending a self-management education course and the educators facilitating the course. Other studies have shown that the relationship between a patient and health care professionals is related to patients' outcomes. Currently there is no questionnaire available to investigate the importance of the relationship between people attending and the educators leading self-management education programs.

Why have I been invited?
You have been invited to take part in this study as you are due to attend a diabetes self-management education course. Both people with diabetes and their family members or partners that attend the self-management education course may participate in this study.

Do I have to take part?
It is your right to decide whether or not you would like to take part in this study. Your medical care will not be affected by whether or not you take part. You can withdraw from the study at any point by contacting the principal investigator. You do not need to give a reason to withdraw. If you do withdraw then the information collected so far cannot be erased and may still be used in the project analysis

What will be involved if I take part?
You will be asked to sign a form to say that you have agreed to take part (this is not a contract and does not mean you definitely have to take part, you can stop taking part at any point during the study). This is called 'informed consent'. If you agree to participate in the study you will be asked to complete some questionnaires at the

end of completing the self-management education course. The questionnaires should take approximately 15 minutes to complete.

What are the potential disadvantages and risks of taking part?
There are no risks in taking part, however you will be asked to stay longer than those not wishing to participate in order to give you time to complete the questionnaires. In the unlikely event that you become upset during the study you will be reminded of your right to withdraw at any time and advised to contact your GP for further support.

What are the potential benefits of taking part?
We cannot promise the study will help you however the information we gain from this study may help to improve future self-management programs, so you and others could benefit in the future.

What information about me will be taken and will it be confidential?
You will be asked to complete questions relating to the relationship between yourself and each educator and your satisfaction with the course. There are no right or wrong answers to these questions. Some basic demographic information such as your age, gender, ethnicity, smoking status, height and weight will also be collected. All information will be kept strictly confidential, stored in a secure and locked office, and on a password protected computer database. Any information used in analysis will have your name removed (anonymised) and a unique code will be used so that you cannot be identified. Only a small number of the research team will have access to the information to link patient names and unique codes which will be stored securely. Any identifiable data (Name) will be disposed of securely as soon as possible. All other data will be kept securely for 5 years before also being disposed of securely. During this time all precautions will be taken to maintain confidentiality by the research team. Study data may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

Will I get any payment and/or expenses reimbursed?
Participants will not be paid to participate in the study.

How long will the study last?
It is estimated that it should take approximately 15 minutes to complete the study questionnaire. After completion of these questionnaires no further involvement is required from study participants.

What will happen to the results of the study?
The results of this research may be published in a scientific journal and presented at research meetings or conferences. All data will be analysed and displayed collectively. All results will be presented as averages and a single person's data will not be presented.

Will my GP be informed of my participation in the study?
Your GP will not be notified of your involvement in this study and information collected during the study will not be passed on to them.

Who is responsible for this research?

LDC PIS
WASME Study PIS V2 04.03.2015

This research is being carried out by the University of Leicester. The Principal Investigator, who will take responsibility for the study, is Lynsey Cobane.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by London – City Road and Hampstead Research Ethics Committee.

What if I am harmed by the study?

It is very unlikely that you would be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to Lynsey Cobane (0116 223 1639) who will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient Information & Liaison Service at pils.complaints.compliments@uhl-tr.nhs.uk. The Firs, c/o Glenfield Hospital, Groby Road, Leicester. LE3 9QP Freephone: 0808 1788337

What do I do if I decide to volunteer?

We are pleased that you have decided to find out more about our research study. The Principle Investigator will be available to answer any further questions on the day you are due to attend the diabetes self-management education course.

In the meantime, if you still have any questions about the study please feel free to contact:

Lynsey Cobane
Department of Clinical Psychology
University of Leicester
104 Regent Road
Leicester
LE1 7LT

lc316@le.ac.uk

Thank you for taking the time to read this leaflet

Appendix L: Participant Consent form

Centre Number:

Study Number: IRAS 169783

Patient Identification Number for this trial:

_____

CONSENT FORM

_____

Title of Project: Working Alliance in Self-Management Education (WASME) Scale Development

Principle Investigator: Lynsey Cobane

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 04.03.2015 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and/or study data may be looked at by responsible individuals from the study team, the sponsor, NHS Trust or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential.

4. I understand that my personal details and study data may be stored on a secure University of Leicester computer.

5. I agree to take part in the above study.

_____   _____   _____
Name of Participant   **Date**   **Signature**

_____   _____   _____
Name of Person   **Date**   **Signature**
taking consent.

WASME Study consent form V2 04.03.2015

128

Appendix M: Participant Questionnaire Booklet

Working Alliance in Self-Management

Education (WASME) Scale Development

Questionnaire Booklet

(Participant)

Demographic Information

Please do not write your name on this form. All information provided is anonymised.

For the following items, please select the *one* response that is most descriptive of you or fill in the blank as appropriate.

1. Please identify yourself as

    A person with diabetes ☐

    A friend or family member of someone with diabetes ☐

2. Time since diagnosed with diabetes in months (If applicable): _____

3. Gender:

    Female ☐   Male ☐   Transgender ☐

4. Age: _____

5. Ethnicity:

    White British ☐   Other White background ☐   Black British ☐

    Black African ☐   Black Caribbean ☐   Other Black background ☐

    Indian ☐   Pakistani ☐   Bangladeshi ☐

    Other Asian Background ☐   More than one race (specify):_____

6. Relationship status:

    Single ☐   In a relationship ☐   Married ☐   In a Civil Union ☐

    Separated ☐   Divorced ☐   Widowed ☐

7.   Smoking status:

Smoker ☐   Ex-Smoker ☐   Non-Smoker ☐

8.   Current employment status:

Employed - full time ☐   Employed – part time ☐   Self-employed ☐

Student ☐   In-training ☐   Not employed ☐   Retired ☐

9.   Weight: _____

10.   Height: _____

Working Alliance in Self-Management Education (WASME) Scale

On the following pages there are statements which describe some of the thoughts or feelings that you may have had towards your educator. Each statement has seven possible answers. Please tick the box which best corresponds to your views. Please complete one form for <u>each</u> educator. Please respond to <u>every</u> statement.

Please complete this form in relation to **Educator One**.

Statements	Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree or Disagree	Somewhat Agree	Agree	Strongly Agree
1. The educator listened to me							
2. I felt comfortable asking the educator questions							
3. The educator gave me the opportunity to share my experiences							
4. The educator facilitated the group well							
5. The educator made me feel that I could share as much or as little as I wanted							
6. The educator wanted to know my point of view							
7. The educator did not care about me							

WASME Scale Version 1.0   20.10.15

Statements	Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree or Disagree	Somewhat Agree	Agree	Strongly Agree
8. The educator was interested in my difficulties and concerns							
9. The educator agreed on what were important goals for me							
10. The educator ignored my opinion							
11. The educator helped me recognise things I could do differently to achieve my goals							
12. I felt comfortable asking the educator questions							
13. The educator was respectful of my opinions and beliefs							
14. The educator communicated ideas in a way that I understood							
15. I felt supported and encouraged by the educator							
16. The educator understood me							
17. The educator was interested in my whole life							

WASME Scale Version 1.0   20.10.15

Statements	Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree or Disagree	Somewhat Agree	Agree	Strongly Agree
18. The educator enabled discussion about issues that were important to me							
19. The educator made me feel resourceful and capable							
20. I did not trust the educator							
21. I felt that the educator judged my lifestyle and choices							
22. The educator did not treat all members of the group equally							
23. The educator helped me identify barriers to making changes							
24. The educator helped me think about how I may overcome barriers to making changes							
25. I felt valued and respected by the educator							
26. The educator helped me to identify how I could deal with future concerns and queries							

133

Appendix N: Empathy Measure

CARE Patient Feedback Measure for
*** Type name of Practitioner here ***

Please write today's date here:

☐☐ / ☐☐ / ☐☐
D D   M M   Y Y

Please rate the following statements about today's consultation.

Please mark the box like this ✔ with a ball point pen. If you change your mind just cross out your old response and make your new choice. Please answer every statement.

How good was the practitioner at...	Poor	Fair	Good	Very Good	Excellent	Does not apply
1) Making you feel at ease (introducing him/herself, explaining his/her position, being friendly and warm towards you, treating you with respect; not cold or abrupt)	☐	☐	☐	☐	☐	☐
2) Letting you tell your "story" (giving you time to fully describe your condition in your own words; not interrupting, rushing or diverting you)	☐	☐	☐	☐	☐	☐
3) Really listening (paying close attention to what you were saying; not looking at the notes or computer as you were talking)	☐	☐	☐	☐	☐	☐
4) Being interested in you as a whole person (asking/knowing relevant details about your life, your situation; not treating you as "just a number")	☐	☐	☐	☐	☐	☐
5) Fully understanding your concerns (communicating that he/she had accurately understood your concerns and anxieties; not overlooking or dismissing anything)	☐	☐	☐	☐	☐	☐
6) Showing care and compassion (seeming genuinely concerned, connecting with you on a human level; not being indifferent or "detached")	☐	☐	☐	☐	☐	☐
7) Being positive (having a positive approach and a positive attitude; being honest but not negative about your problems)	☐	☐	☐	☐	☐	☐
8) Explaining things clearly (fully answering your questions; explaining clearly, giving you adequate information; not being vague)	☐	☐	☐	☐	☐	☐
9) Helping you to take control (exploring with you what you can do to improve you health yourself; encouraging rather than "lecturing" you)	☐	☐	☐	☐	☐	☐
10) Making a plan of action with you (discussing the options, involving you in decisions as much as you want to be involved; not ignoring your views)	☐	☐	☐	☐	☐	☐

Comments: If you would like to add further comments on this consultation, please do so here.

4571132878

Appendix O: Satisfaction Measure

CS CALES®   CLIENT SATISFACTION QUESTIONNAIRE
CSQ-8

Please help us improve our service by answering some questions about the help that you have received. We are interested in your honest opinions, whether they are positive or negative. *Please answer all of the questions*. We also welcome your comments and suggestions. Thank you very much. We appreciate your help.

CIRCLE YOUR ANSWERS

1. How would you rate the quality of service you received?

4 *Excellent*	3 *Good*	2 *Fair*	1 *Poor*

2. Did you get the kind of service you wanted?

1 *No, definitely not*	2 *No, not really*	3 *Yes, generally*	4 *Yes, definitely*

3. To what extent has our service met your needs?

4 *Almost all of my needs have been met*	3 *Most of my needs have been met*	2 *Only a few of my needs have been met*	1 *None of my needs have been met*

4. If a friend were in need of similar help, would you recommend our service to him or her?

1 *No, definitely not*	2 *No, I don't think so*	3 *Yes, I think so*	4 *Yes, definitely*

5. How satisfied are you with the amount of help you received?

1 *Quite dissatisfied*	2 *Indifferent or mildly dissatisfied*	3 *Mostly satisfied*	4 *Very satisfied*

6. Have the services you received helped you to deal more effectively with your problems?

4 *Yes, they helped a great deal*	3 *Yes, they helped somewhat*	2 *No, they really didn't help*	1 *No, they seemed to make things worse*

7. In an overall, general sense, how satisfied are you with the service you received?

4 *Very satisfied*	3 *Mostly satisfied*	2 *Indifferent or mildly dissatisfied*	1 *Quite dissatisfied*

8. If you were to seek help again, would you come back to our service?

1 *No, definitely not*	2 *No, I don't think so*	3 *Yes, I think so*	4 *Yes, definitely*

WRITE ANY COMMENTS OVERLEAF

Appendix P: Statement of Epistemological Position

The research was designed and conducted from a positivist epistemological stance which assumed that working alliance and adherence could be observed and empirically measured in populations with a long-term physical health conditions. This position suggested a quantitative methodological design to measure working alliance in self-management education and to investigate its relationship with empathy and satisfaction.

Appendix Q: Chronology of Research Process

Date	Activity
January 2014	Meeting with field supervisor and research supervisor to discuss potential projects
February 2014 – March 2014	Observed DESMOND course and educator training course
May 2014	Draft research proposal submitted
June 2014	Research Panel Review
August 2014	Decision to develop a new scale of working alliance; redrafting of research proposal
September 2014	Presented study to diabetes research leads
November 2014	Peer review and submission to Service User Reference Group
January 2015	Submission of IRAS form
February 2015	Ethical approval granted
February 2015	Began R&D approval
March 2015 – April 2015	Educators and research staff inform scale development
June 2015	Began Literature Review
July 2015	Meeting with CCG lead– resulted in applying for the study to be adopted to the research portfolio and CRN approval
August 2015	Research team feedback on provisional scale
September 2015	Present study at Research Conference
October 2015	NHS Permission Granted Began recruitment
January 2016	Early termination of recruitment due to DESMOND course loss of tender
February 2016	Literature review completed Data entry and analysis completed
March –April 2016	Thesis completed