PROFESSIONAL DOCTORATES

End-Stage Renal Disease: Exploring the Impact of Treatment on Body-Image and Investigating the Psychological Factors of Treatment Adherence

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End-Stage Renal Disease: Exploring the Impact of Treatment on Body-Image and Investigating the Psychological Factors of Treatment Adherence

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Jessica Gordon

Submitted as partial fulfilment of the Doctorate in Clinical Psychology

Thesis Abstract

This thesis explores psychological factors of End-Stage Renal Disease (ESRD) treatments across three chapters.

A systematic literature review explores the impact of ESRD treatments on body-image. The review clearly highlighted a significiantly higher rate of body-image dissatisafaction/disturbance in the ESRD population compared to the general population. The majority of studies, which compared treatment modalities, found that body-image dissatisfaction was significantly greater in the haemodialysis population, than peritoneal dialysis or kidney transplant populations. A strong association was also found between body-image and psychological distress. However, there were numerous methodological concerns that should be considerd when interpreting the findings.

An empirical study investigates the implications of anxiety, depression and attachment styles on adherence to ESRD treatment. A significant correlation was found between age, depression and fearful-insecure attachment styles. Collectively, age, depression and attachment accounted for a significant proportion of variance in treatment adherence. However, attachment was not independently predictive. The clinical recommendations of the study include that depression should be routinely screened for within services. The results justify the need for further research on attachment and suggests that services should be mindful of attachment styles when supporting patients who are non-adherent to treatment.

The final chapter explores the impact of the findings from the review and empirical papers. This chapter considers the relationship between the findings and theoretical understanding, as well as the implications for future research. Additionally, the chapter explores the clinical implication of the findings, including the continued need for psychology provision within renal services. Finally, the chapter contains personal reflections of the process of completing the thesis.

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Chapter One

Literature Review

Body-image in End-Stage Renal Disease Treatments: A Systematic Review

Body-image in End-Stage Renal Disease Treatments: A Systematic Review

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Abstract

Background: Patients with End-Stage Renal Disease (ESRD) undergo a number of significant bodily changes as a result of their treatments. Research has been undertaken to explore the psychological impact of changes in body-image as a result of ESRD treatments. Given the close relationship between body-image dissatisfaction and mental health difficulties, research has also explored this relationship within the renal population.

Aim: To carry out a systematic review of literature exploring body-image dissatisfaction in patients with ESRD.

Method: A systematic search of three databases, ProQuest, PsychNet and Ovid, and additional hand searches were completed. Thirteen studies were identified that met criteria.

Results: Evidence suggests that there is a high prevalence of body-image dissatisfaction within the ESRD population, which is significantly higher than the general population. However, the measures and methodology used between the studies reviewed was inconsistent. When considering the variety of treatment options, the majority of studies found body-image dissatisfaction was significantly greater in the haemodialysis (HD) population than the peritoneal dialysis (PD) and transplantation populations. However, no studies compared PD and transplant recipients. A number of studies also highlight a strong relationship between psychological distress, such as anxiety and depression, and body-image dissatisfaction with the ESRD population.

Conclusions: Body-image dissatisfaction is prevalent within the ESRD population, with higher levels reported than the general population, and has a strong relationship with experiences of anxiety and depression. The limitations of the studies reviewed, clinical implications and suggestions for future research are reported.

Keywords: kidney, renal, body-image, dialysis, transplant.

1.0 Introduction

Body-image was viewed by Schilder (1950) as a perceptual construct and a reflection of attitudes and interactions with others that are impacted by a person's perceived body size and feelings of lightness and heaviness (Schilder, 1950, cited in Grogan, 2016). An evolved understanding of body-image encompasses a wider range of factors such as weight satisfaction, size perception accuracy, appearance satisfaction and evaluation, and body esteem, appreciation, concern and acceptance (Grogan, 2016). Collectively, the definition of body-image refers to an individual's perceptions, thoughts and feelings about their body (Grogan, 2016).This can include psychological concepts of one's experience of embodiment and perceptions and attitudes towards the body (Yagil, Geller, Sidi, Tirosh, Katz et al., 2015).

Body-image can include positive and negative reflections of the self, yet much theory, research and intervention focuses on negative aspects (Cash & Smolak, 2011). This may be due to the mental health risk factors associated with the consequences of negative body-image or body dissatisfaction and the close links with body-image disturbance, eating disorders, anxiety and depression (Thompson & Stice, 2001). In 2012, The All Parliamentary Group on body-image published a report outlining the prevalence of body-image dissatisfaction and possible interventions to promote and enhance a healthy body-image across the UK. The report estimates that 60% of adults in the UK are ashamed of their bodies (The All Parliamentary Group, 2012). Body-image dissatisfaction is associated with the development of a number of physical, emotional and social health needs including depression, eating disorders, low self-confidence, social isolation, drug and alcohol use and unemployment (The All Parliamentary Group, 2012).

Chronic Kidney Disease (CKD) is an irreversible loss of kidney function that can lead to End-Stage Renal Diease (ESRD) and kidney failure (National Kidney Foundation, 2017). ESRD is the last stage of kidney disease, where a person's kidneys are no longer functioning

at a rate that can support their body and medical intervention is required (American Kidney Fund, 2017). Treatment options include different forms of dialysis or kidney transplantation, each resulting in procedures which alter the physical form of a person's body.

Haemodialysis (HD) is a treatment used for ESRD and allows blood to be filtered through a dialysis machine, removing waste, extra fluid and cleaning the blood. In order to strengthen vascular access for regular needle use, patients undergo minor surgery to create an AV fistula, which combines an artery and a vein in a patient's arm. Alternatively, an AV graft can be used, where a plastic tube is inserted to connect an artery to a vein. Peritoneal dialysis (PD) is another treatment option whereby blood can be cleaned with dialysing solution using the lining of the abdomen. In order to undergo the treatment a catheter must be inserted into the abdomen via minor surgery for daily access. Additionally, some patients may have a neckline, where a catheter is inserted into the neck for access. Collectively, these treatment options require patients to adjust to significant changes in addition to a fistula or catheter, such as scarring, weight gain, bloating and fluid retention. Alternatively, patients may undergo a kidney transplant operation which is considered to be the gold standard treatment for ESRD (Kidney Patients UK, 2008). This operation will understandably leave patients with scarring. However, additionally, patients are required to take transplant medication which can result in side effects such as weight gain, hirsutism (excessive hair growth) and gingival hyperplasia (overgrowth of gum tissue).

The effect on body-image can influence a patient's choices about their treatment and therefore the National Institute for Health and Care Excellence (NICE) guidance for ESRD states that body-image should be a discussion point when supporting patients in making decisions about their care (NICE, 2014). The impact of organ transplantation on body-image has been considered across a variety of chronic health conditions, with varying results, but is considered to be an important factor in decision making about whether to pursue other non-

life threatening transplants, surgery types and immunosuppressant medications post-surgery (Zimbrean, 2015).

Negative body-image has also been associated with the development of mental health difficulties, such as anxiety and depression, in patients with medical conditions (Thombs, Haines, Bresnick, Magyar-Russell, Fauerback et al., 2007; Himelein & Thatcher, 2006; Blashill & Vander Wal, 2010). Research suggests that mental health problems are highly prevalent within the ESRD population and this is consistent across treatment options. Cukor, Coplan, Brown, Friedman, Newville et al., (2008) tested a sample size of 70 participants receiving haemodialysis for anxiety and depression using the Hospital Anxiety and Depression Scale (HADS; Snaith & Zigmond, 1994). Results illustrated that 71% of participants met diagnostic criteria for anxiety (45.7%) and/or a mood disorder (40%). Similarly, a study by Szeifert, Molnar, Ambrus, Koczy, Kovacs et al., (2010) assessed 854 kidney transplant recipients and 176 kidney waiting-list recipients for depression using the Center for Epidemiologic Studies Depression Scale (CES-D: Radloff, 1977). Results illustrated that 33% of waiting list patients and 22% post transplant participants met clinical significant scores for depression. Given the known relationship between body-image dissatisfaction and mental health difficulties and the prevalence of these difficulties within ESRD, it is important to consider whether a relationship exists between body-image dissatisfaction, and anxiety and depression.

1.1 Rationale

The rationale for this review is threefold: i) to explore body-image within the ESRD population; ii) to look collectively at the three most common treatment options for ESRD, as previous research tends to focus on body-image for either dialysis or transplant patients; iii) to conduct a systemic review of research evidence from all relevant studies since 1995.

1.2 Research Questions

The present systemic review aims to answer the following questions:

- What changes in body-image do patients with ESRD report?
- What is the prevalence of body-image dissatisfaction for patients with ESRD?
- What is the experience of body-image for ESRD patients in comparison to the general population?
- Does the experience of body-image dissatisfaction differ between haemodialysis, peritoneal dialysis and kidney transplantation?
- What is the association between body-image dissatisfaction and mental health difficulties in patients with ESRD?

2. 0 Method

2.1 Definitions: Body-image Dissatisfaction and Disturbance

Body-image dissatisfaction (BID) is a negative evaluation of one's appearance, shape and weight. In the context of developmental theory, it can be influenced by cultural, developmental, biological and historical factors (Pearson, Heffner & Follette, 2010). BID can impact both men and women, and includes subclinical levels of conditions such as eating disorders or body dysmorphic disorder (Pearson, Heffner & Follette, 2010). Additionally, the studies reviewed also consider Body-image Disturbance which can be defined as "a persistent report of dissatisfaction, concern and distress that is related to an aspect of appearance...and some degree of impairment in social relations, social activities or occupational functioning (Bowe, Doyle Crerand, Margolis & Shalita, 2011). Body-image disturbance is the result of persistent body-image dissatisfaction which impacts on an individual's functioning. Both body-image dissatisfaction and disturbance have been considered within this review, given the similarity between definitions.

2.2 Measuring Body-image

A number of tools have been developed to measure self-reported body-image perceptions. Such tools measure disturbances of body-image, appearance, body shame, body ideals and the gap between what is viewed to be a person's ideal body-image and the perception they have of their own image. The measuring tools used within the studies reviewed in this report are explored within section 3.1.3. In addition to the use of quantitative measurement, some studies also made use of qualitative research methods to identify themes of body-image within patient's experiences.

2.3 Search strategy

A systematic search of literature was conducted between October 2016 and March 2017. The initial stage of the process included searching electronic databases, including PsychNet, ProQuest (including PsycInfo) and Ovid (including MEDLINE). A number of search terms were inputted into the databases using a variety of combinations of the words; 'kidney,' 'dialysis,' 'body-image,' 'renal,' 'transplant,' and other deviations (e.g. transplant*). These combinations including 'body-image in renal dialysis,' 'body-image and kidney transplant', 'body-image in haemodialysis,' 'body-image in peritoneal dialysis,' and 'body-image in renal transplantation.' Each abstract and reference was reviewed using the following inclusion criteria:

- Adult participants receiving dialysis or post kidney transplant
- Consideration of the impact of body-image through qualitative interviewing qualitative responses to questionnaires or quantitative measurement
- Papers were written in English language
- Written from 1995 onwards.

The resulting studies were examined to ensure that the content of each piece of research had considered patient's perspectives of their body-image in relation to their ESRD

treatment, as opposed to perspectives of the clinician, for example, comparing types of incision or developments in surgical procedures. Studies were excluded if they focussed on the experiences of body-image for transplant donors, as they could not be sufficiently compared to ESRD patients.

Following this, each paper which had met the inclusion criteria was hand-searched for references and citations. Any further papers which met the criteria were added to the review. Figure 1 represents each stage of the search strategy as outlined by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, (Moher, Liberati, Tetzlaff & Altman, 2009). Thirteen studies were selected and included in the review.

[INSERT FIGURE 1]

2.4 Quality Assessment

This review chose to encompass both qualitative and quantitative methodologies in order to allow the integration of quantitative perspectives with a qualitative understanding of people's lives and view points (Thomas, Harden, Oakley, Sutcliffe, Rees et al., 2004). Therefore, given the broad range of methodologies and designs featured within the review, a traditional tool to measure study quality was not used.

The quality of the studies chosen for review were assessed individually in order to consider the robustness of each of the outcomes, including consideration of study design, bias, measures, participant recruitment and sampling. For qualitative studies, analysis styles such as IPA, thematic analysis or grounded theory were considered, including the strengths and weaknesses of each style. Additionally, potential biases were considered such as the relationship between the participants and researchers.

For quantitative studies, a variety of study designs were reviewed when assessing quality. The majority of studies considered for the review utilised a cross-sectional or longitudinal design. The strengths and weaknesses of each were considered, such as the benefit of increased reliability and minimised cohort effects from a longitudinal design, compared to a cross-sectional design, which offers cost effective and fast data collection. Potential biases were also considered when assessing quality. This included the choice of outcome measures, such as being mindful of the rates of reliability and validity and consideration of whether the measures were applicable to the population. Details of the measures used are discussed in section 3.1. Sampling methodology across studies was also assessed, such as the use of convenience sampling, which is opportunistic but may not provide a representative sample, compared to other forms of sampling, such as random and stratified, which are less commonly used, but are more representative of the wider population. Statistical issues, such as sample size and power analyses were also reviewed across studies to assess quality.

2.5 Data synthesis

Given the variety of methods, designs, measures and outcomes data featured, results of the review are presented in a narrative form which lends itself best to the broad range of studies included. The review results are presented in stages including study design, participant characteristics, measures, experienced of body-image, body-image compared to the general population, prevalence of body-image dissatisfaction, differences in treatment modalities and associations with body-image and mental health.

3.0 Results

3.1 Description of studies

3.1.1 Design and Methods

[INSERT TABLE 1]

A summary of study design, methods, measures, population and outcomes for each paper selected is displayed in Table 1. Nine of the thirteen studies selected utilised quantitative research methods. Four studies (Beer, 1995; Curtin, Johnson & Shatell, 2004; Yodchai, Dunning, Hutchinson, Oumtance & Savage, 2011; Finnegan-John & Thomas, 2013) utilised qualitative research methods through structured interviewing. Of the quantitative studies, seven utilised a cross-sectional design. Of these studies, body-image was explored between HD and PD participants (Juergensen, Wuerth, Finkelstein, Juergensen, Bekui et al., 2006; Partridge & Robertson, 2011; Leonard, 2013), between HD, PD and a control group (Öyekçin, Gülpek, Sahin & Mete, 2012; Shahgholian, Tajdari &Nasiri, 2012), between living-related donor transplant recipients and cadaveric transplant recipients (Yagil, Geller, Sidi, Tirosh, Katz et al., 2015) and between HD and transplant recipients (Sadeghian, Roudsari, Seyedfatemi & Rafiei, 2016). The remaining two quantitative studies utilised a longitudinal design which considered body-image in transplant recipients (Matas, Halbert, Barr, Helderman, Hricik et al., 2002) and HD and PD patients (Wu, Fink, March-Manzi, Meyer, Finkelstein et al., 2004) over time.

3.1.2. Sample Characteristics

The studies recruited participants from hospital units where patients had been receiving treatment for ESRD, either dialysis or transplant. All studies included both male and female patients who were aged 18 or above.

[INSERT TABLE 2]

Table 2 provides a summary of participant demographics. The majority of studies were conducted within the UK (4) and USA (4), with the remaining studies conducted in Iran

(2), Turkey, Israel and Thailand. Although the majority of studies reported race and ethnicity of participants (Matas et al., 2002; Wu et al, 2004; Juergensen et al., 2006; Partridge & Robertson, 2011; Yodchai, Dunning, Hutchinson, Oumtance & Savage, 2011; Finnegan-John & Robertson, 2011; Leonard, 2013), no studies reported the religious beliefs of participants. Six studies reported the age range of participants, of which ages ranged from 19 to 90 years of age. The mean age of ESRD participants ranged from 36.85 to 69.6 years across all studies reviewed, where age was reported. Seven studies reported demographics related to marital status, which suggested that the majority of participants were married or in a relationship (Matas et al., 2002; Wu et al, 2004; Juergensen et al., 2006; Yodchai, Dunning, Hutchinson, Oumtance & Savage, 2011; Öyekçin et al., 2012; Shahgholian et al., 2012; Yagi et al., 2015). Some studies provided information regarding education, which suggested that most participants had completed high school or proceeded to further education (Matas et al., 2002; Wu et al, 2004; Juergensen et al., 2006; Yodchai, Dunning, Hutchinson, Oumtance & Savage, 2011; Öyekçin et al., 2012; Shahgholian et al., 2012; Yagi et al., 2015). Several studies reported information related to diagnosis or intervention, such as number of years post transplant or length of time receiving dialysis. However, the type of data collected was widely inconsistent between studies.

3.1.3. Body-Image Measures

As previously mentioned, four studies adopted a qualitative approach using structured questioning, which included questions such as “do you feel that your body has changed in any way since you started dialysing/received your transplant” (Beer, 1995). Two papers made use of the Body-image Disturbance Questionnaire (BIDQ: Cash, Phillips, Santos & Hrabosky, 2004). This tool is a self-report measure which uses a Likert scale to rate concerns about appearance of body parts and the effect on social functioning. The measure is reported to have good test-retest reliability of 0.80 to 0.92 (Cash & Grasso, 2005).

Four studies generated their own questionnaire which assessed body-image. Matas et al., (2002) developed two self-report questionnaires, The Life Satisfaction Index (LSI) and The Transplant Care Index (TCI) which collected demographic, transplant and quality of life data, which included questions related to adverse physical side effects such as usual hair growth/loss, changes in body shape, overgrown gums and more (Matas et al., 2002). However, the study did not report any testing of reliability or validity. Similarly, Juergesen et al., (2006) also developed a self-report questionnaire, generated by a team of clinicians and utilised a Likert scale to rate satisfaction from 1-10. The questionnaire asked participants to rate how dialysis had impacted on a number of areas of their lives including mood, stress levels, social life and body-image. Although the measure offers some important information on patients' perspectives of body-image and dialysis, it is important that results are interpreted with caution as only one question was administered on body-image and no reliability or validity testing was reported. Shahgholian et al., (2012), also developed a self-reported questionnaire which included rating physical and psychological self-concepts, including body-image. The tool was reported to have been validated by a panel of experts and reliability was calculated at 96.7% using Cronbach's alpha coefficient (Shahgholian et al., 2012).

The questionnaire developed by Sadeghian et al., (2016) looks comprehensively at body-image disturbance, including perceptions of the body and impact on functioning. Scores between 0-20, 21-40 and 41-80 indicated low, moderate and high levels of body-image disturbance, respectively. The questionnaire's content was assessed by clinicians and reported at 91.2% and the alpha coefficient of internal consistency was reported as 0.96. The study did not offer a qualitative description of the reliability and validity of the measure.

Additional measures used related to body-image included the Appearance Schema Inventory – Revised (ASI-R; Cash, 2003), the Self-Consciousness Scale (SCS; Carver &

Glass, 1976), the Body-image Scale (BIS; Secord & Jourard, 1953), Derriford Appearence Scale – Short Form (DAS-24; Carr, Moss & Harris, 2005), Experience of Shame Scale (ESS; Andrews, Qian & Valentine, 2002) and the Body-image Ideals Questionnaire (BIIQ; Szymanski & Cash, 1995). High internal consistency was reported for the ASI-R and DAS-24 (Cash, 2003; Carr, Moss & Harris, 2005) and satisfactory consistency reported for the SCS and BIIQ (Carver & Glass, 1976; Szymanski & Cash, 1995). When used in full, the ESS is reported to have good reliability and validity, (0.94 Conbrach's alpha). However, Leonard (2013) only administered four items of the scale and added four novel items in line with the same format as the remaining questions. The BIS has been assessed for reliability and validity in Turkey (Öyekçin et al., 2012). However, the results of the testing could not be retrieved by the author.

3.1.4 Mental Health Measures

In addition to body-image, several studies also assessed mental health, including anxiety and depression. Partridge and Robertson (2011) and Leonard (2013) utilised the HADS in order to measure psychological distress without influence from health factors which can present within the physical health population (Snaith & Zigmond, 1994). The HADS is reported to have satisfactory internal consistency and test-retest reliability (Snaith & Zigmond, 1994). Öyekçin et al., (2012) utilised the Beck's Depression Inventory (BDI: Beck, Ward, Mendelson, Mock & Erbaugh, 1961) and Beck's Anxiety Scale (BAS: Beck, Epstein, Brown, & Ster, 1988) to measure anxiety and depression. Both the HADS and BDI have been found to be valid tools for screening for depression within the ESRD population (Loosman, Siegert, Korzec & Honig, 2010). However, measurement of anxiety amongst ESRD and other physical health conditions has been found to be more problematic, due to the overlap between somatic symptoms of anxiety and possible physical health symptoms, such as dizziness (Julian, 2011).

Leonard (2013) and Yagil et al., (2015) utilised the Short Form 36 Health Survey (SF-36; Ware 1993) and Short Form 12 Health Survey (SF-12; Ware, Kosinski & Keller, 1996). The measures provide an assessment of quality of life (QOL), including psychological distress, and are found to be one of the most suitable measures of QOL for the renal population (de Jonge, Ruinemans, Huyse & ter Wee, 2003). Additional mental health measures used include the Structured Clinical Interview for the Diagnostic and Statistical Manual-IV (DSM-IV) assessment of Axis-I diagnoses (SCID-I: First, Spitzer, Gibbon & Williams, 1997) utilised by Öyekçin et al., (2012) and the Brief Symptoms Inventory (BSI; Derogatis & Melisaratos, 1983) utilised by Yagil et al., (2015), which provides an assessment of psychological distress, including anxiety and depression. The studies that developed their own questionnaire also included questions related to psychological wellbeing, (Matas et al., 2002; Juergesen et al., 2006; Shahgholian et al., 2012). The limitation of these questionnaires was discussed in section 3.1.3.

3.1.5. Additional Measures

Studies collected a variety of demographic information through measurement, a summary of which can be found in Table 2. Some studies administered additional measures, depending on the aims of the study, including assessment of disgust sensitivity through the Disgust Scale Revised (DS-R; Olatunji, Williams, Tolin, Sawchuck, Abramowitz et al., 2007, utilised by Leonard, 2013), assessment of adjustment between couples through the Dyadic Adjustment Scale (DAS; Spanier, 1976, utilised by Öyekçin et al., 2012) and assessment of sexual functioning by the Golombok-Rust Inventory of Sexual Satisfaction (GRISS; Rust & Golombok, 1986, utilised by Öyekçin, et al., 2012).

3.2 Outcome data on body-image in ESRD

3.2.1 Changes in body-image reported by patients with ESRD

The earliest study conducted within the group of reports was by Beer (1995). The study allowed the opportunity to collect the views and experiences of the participants. From the interviews with the participants, the theme of 'desire for body-image integrity' was evident. For the patients who had had a fistula made for HD, the change to their body had left them feeling self-conscious and resulted in behavioural changes, such as changing the way they dressed to cover up their bodies (Beer, 1995). An enlarged abdomen as a result of peritoneal dialysis had a similar impact on participants, who also found themselves changing the way they dressed to hide the changes of their body (Beer, 1995). Participants used emotive language to reflect how these bodily changes felt such as "I hate it," "I just look disgusting" and "I felt I had been mutilated," (Beer, 1995). The prevalence of this theme was reported to have been present across all participants (Beer 1995). The study provided important patient perspectives of their body as a result of their ESRD treatments, but body-image was not measured or compared to the general population and the extent of body-image disturbance could not be determined, particularly due to the small sample size.

Finnegan-John & Thomas (2013) and Yodchai, Dunning, Hutchinson, Oumtance & Savage, 2011; found similar findings which echoed those of Beer (1995). The thematic analysis of participant interviews highlighted body-image concerns within the theme of 'impact of treatment,' within Finnegan-John & Thomas (2013). The fitting of a fistula or catheter left patients feeling that they looked unsightly, impacted on their self-esteem and led them to dress in a way that allowed them to cover up (Finnegan-John & Thomas, 2013; Yodchai, Dunning, Hutchinson, Oumtance & Savage, 2011;). Patient's had similar concerns related to side effects of medication, such as weight gain (Yodchai, Dunning, Hutchinson, Oumtance & Savage, 2011; Finnegan-John & Thomas, 2013). The Finnegan-John & Thomas (2013) study benefits from a larger sample size of 118 participants, which adds further evidence to the finds of Beer (1995) on the prevalence of body-image concerns. Whereas,

Yodchai et al., (2011) only included 5 participants within the study. Curtin, Johnson and Schatell (2004) found similar concerns of body-image, where patients commented that their bodily changes made them feel 'disgusting.'

Matas et al., (2002) recruited a large sample size from the Transplant Learning Centre (TLC), beginning with an initial sample size of 4247 participants, meaning the findings are more likely to be generalised to the larger kidney transplant population. However, due to the longitudinal design of the study, by the final cycle of data collection, the study had experienced a dropout rate of approximately 86%. Although the study did not directly measure body-image in terms of participant's self-perception and feelings about their body, the study recorded the prevalence of physical changes they experienced as a result of their kidney transplant. Results indicated that 69.9% experienced unusual hair growth, 55.5% experienced change in body-shape, 47.2% experienced facial changes, 43.6% developed acne and/or rashes, 31.5% experienced bleeding and/or overgrown gums and 18.7% experienced unusual hair loss (Matas et al., 2002). From these results, it cannot be determined how these experiences of change effected body-image perception, but does highlight the high prevalence of physical and appearance changes patient's experienced, making the possibility of negative impacts on body-image more likely.

3.2.2. Body-image dissatisfaction for ESRD patients compared to the general population

Partridge and Robertson (2011) found that, compared to the general population, dialysis patients who participated in the study experienced body-image disturbance at a higher rate than the general population (males $p<0.000$, females p,0.045). Additionally, measures of appearance schema and self-consciousness within the sample significantly correlated with body-image disturbance (Partridge and Robertson, 2011). However, of the

164 eligible to participate in the study, only 63% of the HD population and 53% of the PD population responded to the study, meaning the results only represented part of the population. Similarly, Shahgholian et al., (2012) also found HD and PD patients' experience of self-concept was significantly lower than that of the healthy control group, which includes the concept of the physical self. However, it is important to consider that this tool does not directly assess body-image.

Results reported by Leonard (2013) found that when body-image disturbance was compared to normative sample data, body-image disturbance was significantly greater for the renal population for both males ($z=-4.67$, $p=0.001$) and females ($z=-5.22$, $p=0.001$) suggesting ESRD treatment has a negative impact on body-image. Positively, these results were compared to the data reported by Partridge and Robertson (2011) which illustrated consistency between samples, as no significant difference in body-image was found between renal populations and both samples were significantly greater than the normative population. However, results from Leonard (2013) must be interpreted with caution, as a relatively low response rate was obtained for the study of 32.75%, meaning the data is only representative of a fraction of the intended population. Positively, Leonard (2013) also assessed body shame within the sample and found that medium levels of body shame were also presenting within the renal population. Scores for body shame and body-image disturbance were significantly positively correlated. The Limitations of the validity and reliability of this measure have been considered in section 3.1.3. Additional caution should be given to the study, as it is yet to be published in a peer reviewed journal.

3.2.3. Prevalence of body-image dissatisfaction

Sadeghian et al., (2016) considered the levels of body-image disturbance in HD and transplant populations. Within the HD group, 64.3%, 19% and 16.7% of participants reported

low, moderate and high levels of body-image disturbance, respectively (Sadeghian et al., 2016). A significant negative correlation was found between age and body-image disturbance. Within the transplant group, similar low levels of body-image disturbance were recorded (64.3%), a higher rate of moderate levels (26.2%) and lower rates of higher levels (4.8%) (Sadeghian et al., 2016). The maximum score on the BIDQ was 80. However, scores above 40 were considered to represent the cut off for high levels of body-image disturbance. This could be considered a sensitive score for determining high rates of disturbance. The authors considered that the study was based on a convenience sample as participation was voluntary, which may have led to a selection bias (Sadeghian et al., 2016).

Results from Wu et al., (2004) recorded changes in body-image dissatisfaction over time. Within the HD group, 19% of participants reported a worsening in body-image, 17% reported an improvement and 64% experienced no change over a 12 month period (Wu et al., 2004). The PD sample reported experiencing similar changes, 18% reported a worsening, 13% reported an improvement and 69% reported no change (Wu et al., 2004). The data on body-image was obtained from only one question amongst a larger questionnaire. The study did not report levels of body-image dissatisfaction or compare scores to the general population, meaning it provides limited understanding to the extent of which body-image dissatisfaction is prevalent and the effects of ESRD treatment on body-image.

3.2.4. Differences between treatment modalities

Several studies considered the difference between treatment modalities and body-image, including HD, PD and kidney transplantation. Öyekçin et al., (2012) compared levels of body-image dissatisfaction between PD, HD and control groups. Results indicated that participants within the HD sample scored significantly higher than the PD and control group (Öyekçin et al., 2012). The difference between HD and PD groups was statistically

significant, suggesting that participants who are treated for ESRD by HD experience higher levels of body-image dissatisfaction than patients receiving peritoneal dialysis ($p=0.02$). Within this study, the PD group had a greater number of participants (36 and 54), which may have impacted upon the results. However, body-image variance within the PD group was also impacted by other variables, including mental health and sexual functioning, whereas body-image in HD was not impacted by any other factors, yet HD participants had higher rates of BID (Öyekçin et al., 2012).

Similarly, Sadeghian et al., (2016) compared levels of body-image disturbance between HD and transplant participants and found that HD participants had significantly higher levels of body-image disturbance ($p<0.05$) (Sadeghian et al., 2016). The HD and transplant groups differed between which statements within the questionnaire generated the highest and lowest mean scores. Within the transplant group, the statement which yielded the highest mean response was "I would like to know the views of others about my appearance," whereas the highest mean score within the HD group was for the statement "I am concerned about the changes in my appearance" (Sadeghian et al., 2016). Within the transplant group, the statement which yielded the lowest average response was "I try to divert the attention of others from my appearance using jewellery or embellishment," whereas the statement "I try to deny negative changes in my appearance" yielded the lowest response in the HD group (Sadeghian et al., 2016). This suggests that aspects of body-image perception differ between treatment groups, but overall the HD groups score significantly higher.

Additional studies compared body-image between HD and PD groups. Juergensen et al., (2006) compared participants' ratings of their body-image between dialysis treatment groups, the results of which suggested that HD patients were more negatively impacted than PD groups for body-image on average, although the results were not statistically significant.

However, other studies such as Patridge and Robertson (2011) and Shahgholian et al. (2012) found no difference between body-image levels for dialysis types, although both studies found higher rates of body-image disturbance than control groups. Similarly, Wu et al., (2004) compared HD and PD participant's changes in body-image perception over a 12 month period. Results indicated that body-image, on average, improved more for HD patients over time than PD patients. However, results were close to significant but did not meet the threshold for significance, p=0.05.

From the studies selected, only Beer (1995) and Finnegan-John and Thomas (2013) included transplant, peritoneal and haemodialysis patients. However, no comparison of body-image levels was made between groups. Curtin, Johnson & Shatell (2004) only included PD participants and Yodchai et al, (2011) HD patients, and therefore no comparison was made within each of these studies. None of the studies compared peritoneal dialysis to transplant groups. Although Yagil et al, (2015) included different types of transplant populations, the study did not report group differences.

3.2.5 Associations between Body-image and Mental Health

Partridge and Robertson (2011) found that 24% of the participants included in the study met clinical levels of moderate to severe anxiety and 18.6% of participants met criteria for moderate to severe levels of depression. Scores on the body-image questionnaire were highly significantly correlated with total HADS scores. As the level of body-image disturbance increased by 1 point on the BIDQ, scores for anxiety, depression and HADS total scores increased by 2.875, 2.242 and 5.169 points, respectively, highlighting the strength of the relationship (Partridge & Robertson, 2011). Results also indicated that body-image disturbance accounted for 34.4%, 33.8% and 40.4% of variance for anxiety, depression and total HADS scores. The study also included measures of self-consciousness. All self-

consciousness subscales were significantly correlated with anxiety. Within the self-consciousness measure, subscales of private self-consciousness and public self-consciousness were correlated with depression (Partridge & Robertson, 2011). Self evaluation was highly correlated with body anxiety and depression.

Correlations between body-image and mental health problems were also observed within results from Leonard (2013). Scores for body-image disturbance were significantly correlated with anxiety (0.73, $p<0.01$) and depression (0.54, $p<0.05$). Additionally, body-image, body disgust and shame were also found to be highly correlated with anxiety and depression. These variables accounted for 53% of variance for anxiety and 30% of variance for depression on the HADS (Leonard, 2013).

Similar results were also reported by Öyekçin et al., (2012). The study reported that 30.6% and 13.0% of HD and PD participants, respectively, had a diagnosis of major depressive disorder. Within the HD group, 11.1% and 2.8% had a diagnosis of adjustment disorder with depressive mood and anxiety disorder. Within the PD group, 14.8% of participants had a diagnosis of adjustment disorder with depressive mood. No significant difference was reported between groups. Further results illustrated a positive correlation between body-image dissatisfaction and scores on the BDI and BAS within the HD group ($p<0.01$). Within the PD group, body-image dissatisfaction was also correlated with anxiety (Öyekçin et al., 2013). Less consistent results were reported by Yagil et al., (2015) which identified a significant association between ideal and actual body-image and anxiety, but no correlation with depression. However, a significant association between the importance attributed to the gap between ideal and actually body-image and depression was identified, but there was no association with anxiety.

Within the qualitative studies reviewed, no formal measure of mental health, such as anxiety or depression scales, were administered. However, themes around the relationship between mental health and body-image were reported by participants within their interviews. Beer (1995) , Curtin, Johnson & Schatell (2004) and Finnegan-John and Thomas (2013), reported that changes in a participants body-image, such as insertion of a catheter, weight gain and scarring, had led to a decrease in self-confidence and self-esteem.

3.2.6. Additional Variables

Several studies observed a relationship between body-image and sexuality. Beer (1995), Yodchai et al., (2011) and Finnegan-John and Thomas (2013) reported that changes in body-image had impacted negatively on libido, which had affected participants' sexual relationships with their partners. This relationship was also observed by Öyekçin et al., (2012), as body-image disturbance was correlated with sexual functioning, determined by results on the GRISS.

A relationship between quality of life and body-image was also observed in some studies. Matas et al., (2002) found that participants' perceptions of body shape changes were significantly correlated with quality of life. In contrast, Yagil et al., (2015) found no significant association between actual-ideal body-image gap and QOL dimensions, or the importance attributed to the gap and quality of life. However, a significant correlation was found between body-image and four quality of life dimensions, including physical pain, general health perception, role emotional and social functioning (Matas et al., 2002).

4.0 Discussion

4.1 Summary of findings

This review aimed to explore what body-image changes patients with ESRD report to experience, as well as the prevalence of BID within the ESRD population and in comparison to the general population. In addition to the scarring patients experience as a result of the creation of a fistula, transplantation scarring or insertion of a catheter, patients also report a variety of additional body-image changes such as unusual hair growth or loss, facial and body shape changes, acne, rashes and overgrown gums (Matas et al., 2002). Patient's reflected that these changes altered their body-image perception, making them feel "disgusting" and "mutilated," leading them to cover their bodies by changing their clothing (Beer, 1995; Finnegan-John & Thomas, 2013; Yodchai, et al., 2011). Sadeghian et al., (2016) reflected a high prevalence rate of this body-image dissatisfaction within the population, with moderate level of BID ranging from 19-26.2% and high levels ranging from 4.8-16.7%. However, more data on prevalence rates is required. When comparing these rates of body-image dissatisfaction to the general population, results showed significantly higher levels within the ESRD population (Partridge & Robertson, 2011; Leonard, 2013).

The review also aimed to considered body-image differences between treatment modalities and the relationship with mental health difficulties. The majority of studies highlight significantly higher rates of BID in the HD population compared to the transplant and PD population. This is perhaps due to the fact that HD access most often requires the creation of a fistula in the arm, which may be considered to be more difficult to conceal that PD or transplant scarring. Throughout treatment options, a relationship between BID, and anxiety and depression appears to exist.

4.2 Limitations of reviewed studies

From the studies reviewed, a number of limitations of various measures used have been discussed in section 3.1.3. However, giving the ongoing considerations of body-image

measuring tools and whether tools are measuring the same thing (Thompson, Altabe, Johnson & Stormer, 1994), it is also important to consider the variety of different measures used across studies. With the exception of Leonard (2013) and Partridge and Robertson (2011), which both utilised the BIDQ, each of the studies reviewed measured body-image differently. Consequently, comparing results between studies is challenging, due to inconsistency of how body-image perspectives have been measured, such as accounting for differences in cut off scores. Additionally, no studies measured body-image prior to ESRD treatment, meaning it is difficult to consider whether previous body-image concerns may have impacted upon results.

A number of methodological issues are clear within the studies reviewed, including sample sizes, a lack of control over possible confounding variables and sample characteristics. In order to ensure ethical consideration is made and adhered to when collecting data, the majority of studies utilised a convenience sampling approach, meaning data was only collected from specific renal facilities close to the researchers' area of work or only from participants who had chosen to engage. Although this importantly ensures ethical consideration of all participants and allows data to be generated quickly, these sampling methods lead to difficulties generalising the data and may result in selection bias, which does not adequately reflect the intended population (Schuster & Powers, 2005).

Furthermore, the majority of studies appeared to have higher rates of participation from males than females (Partridge & Robertson, 2006; Öyekçin et al., 2012; Shahgholian et al., 2012; Finneghan-John & Thomas; 2013; Leonard, 2013; Yagil et al., 2015). Although this is representative of the higher rates of ESRD for male than females (UK Renal Registry, 2014), on average there are higher rates of body-image concerns in women than men (All Parliamentary Group, 2014). With this in mind, the higher rates of participation of males may have impacted the results. Additionally, when patients make choices about the types of ESRD treatment options available, either HD or PD, patients who are concerned about body-image

often choose PD, as this treatment is often easier to conceal (Muringai, Noble, McGowan & Chamney, 2008). However, the majority of samples were over represented by HD patients, such as in Wu et al (2004) whose initial sample included 698 HD participants, compared to 230 PD participants. Again, this inequality in sample sizes across studies may have impacted results.

In the majority of studies, demographic data was collected, such as length of treatment and additional physical health conditions such as diabetes or mental health diagnoses. However, typically, studies did not control for these additional variables and therefore their impact upon results was unknown within the majority of studies reviewed.

4.3 Clinical Implications

Body-image concerns and the consequential impact on mental health should be a high priority within renal services and important within the assessment and treatment process (NICE, 2014). Renal patients who are seen for anxiety/depression and other emotional distress should routinely be asked about their body-image perceptions as part of the assessment and support they receive, given that body-image has been demonstrated to account for a significant component of anxiety and depression variance.

The NICE (2014) guidelines for ESRD treatment stipulates that body-image should be a discussion point when supporting patients to make decisions about their treatment and, given the implications of body-image concerns, should be routinely screened for. Unlike most other chronic health conditions, ESRD patients have a lot of contact time with their nephrology nurses and clinicians. Therefore, working alongside the multidisciplinary team, nurses should have an understanding of the psychological impacts of treatments and teams have a vital role in preparing patients for bodily changes (Muringai et al., 2008).

4.4 Future Research

Body-image research in ESRD is scarce and there are numerous concerns related to quality issues of the present studies, including issues raised regarding measures, sample size, sampling methods and controlling for additional variables. However, the current research clearly identifies the existence of body-image disturbance within the ESRD population and therefore future research should focus on expanding our understanding. Studies so far have only been completed in the UK, USA, Turkey, Iran, Israel and Thailand with only a handful of studies in each. Therefore future research should be replicated within different countries or compared between services, taking into consideration cultural differences and impacts of religious and cultural beliefs. Given the impact of the media on body-image, future research may wish to consider the relationship between media and media access, as well as the publicity of ESRD and how this impacts upon body-image.

Future research should consider measuring body-image prior to and post treatment, in order to establish whether treatment directly impacts on body-image dissatisfaction by assessing changes from baseline. It may also be useful to compare the impact of treatment modalities in more detail. Currently, HD has been compared to PD and transplant. However, little is known about body-image differences between PD and transplant treatments, as well as comparing fistula access to graft access.

It is well documented that adherence to treatment in ESRD is problematic (Schneider, Friend & Whitaker, 1991), including attendance at dialysis appointments, medication compliance and fluid restrictions. Future research may wish to consider the role of body-image in adhering to treatment and whether avoidance of treatment serves a role for patients in managing body-image changes.

Suggested interventions for body-image disturbance and clinical levels of body dysmorphic disorder include group and individual Cognitive Behavioural Therapy (NICE, 2015). However, interventions for body-image concerns in the renal population are yet to be explored and further research is needed.

5.0 Conclusion

Given the limited number of studies, inconsistency between methodologies and study limitations such as sample size, and methodological issues, it is difficult to draw definitive conclusions. Additionally, given the inconsistency between the countries, cultures and locations data was collected in, issues with response rates and sampling strategies, it is difficult to conclude whether results are representative of the wider ESRD population and how the results could be adapted into clinical practice. Despite these limitations, it can be clearly concluded that body-image dissatisfaction and disturbance exists within the ESRD population at a more prevalent rate than the general population. Largely, results suggest that body-image concerns are prevalent throughout treatment options, including haemodiaysis, peritoneal dialysis and kidney transplantation. However, body-image concerns appear to have higher prevalence rates within the HD population, on average. Evidence also suggests that a relationship exists between body-image concerns in ESRD patients and mental health difficulties, including anxiety and depression. These concerns must be addressed within renal services and included within the assessment and monitoring process. Further research is needed to expand our understanding of the subject area and particularly attention should be paid to interventions.

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Table 1. Summary of study findings, measures, design and sample information.

No	Study	Sample Size Total	Population	Country	Design	Measures	Study Findings
1	**Beer (1995)**	12	HD n=4 PD n=4 Transplant n=4	UK	Q	Structured Interviews	Themes of acceptance, desire for body integrity, quality of life (including work, physical effects, relationships, health, eating, holidays and activities of daily living), sexuality and gender differences emerged from the data. Participants negative experiences of body-image included not wanting to accept or think that they looked similar to other patients they came into contact with, changing the way they dressed to cover up their body, feeling as if their body had been mutilated and how physical body changes effected confidence when having sex with their partner, reducing libido.
2	**Matas et al. (2002)**	Cycle 1 n=4247 Cycle 6 n=598	Transplant Recipients	USA	L	Self-designed questionnaire	Results showed that 69.9% experienced unusual hair growth, 55.5% experienced changes in body shape, 47.2% experienced facial changes, 43.6% developed acne and/or rashes, 31.5% experiencing bleeding and/or overgrown gums and 18.7% experienced unusual hair loss. Changes in body shape accounted for 13.6% of variance of quality of life.
3	**Wu et al. (2004)**	928 at baseline, 585 after 12 months	Baseline = HD n=698; PD n=230 12 months = HD n=452; PD n=133	USA	L	SF-36 CHEQ	Body-image for ESRD participants improved from baseline to 12 months, but the change was not statistically significant. Body-image improved more for HD participants compared to PD participants, but the difference was not significant. Within the HD population, 19% of participants experienced a worsening of Body-image of time, 17% experienced an improvement and 64% experienced no change. Within the PD population, 18% of participants experienced a worsening of Body-image of time, 13% experienced an improvement and 69% experienced no change. The overall difference in change was compared between PD and HD and was close to significant (p=0.05).
4	**Curtin, Johnson & Schatell (2004)**	18	PD= 18	USA	Q	Structured Interviewing	Patient's felt "disgusting" as a result of the changes in their body, but adjusted and felt less ashamed over time. Body changes were viewed as necessary.
5	**Juergensen et al. (2006)**	146	HD n=84 PD n=62	USA	CS	Self-designed questionnaire	HD participants scored higher than PD in terms of negative impact on body-image. However, the difference was not statistically significant.

No.	Study	Sample Size Total	Population	Country	Design	Measures	Study Findings
6	**Partridge & Robertson (2011)**	97	HD n=53;PD n=44	UK	CS	HADS BIDQ ASI-R SCS	Twenty-four (24%) of participants met clinical levels of moderate to severe anxiety and 18.6% participants met criteria for moderate to severe levels of depression. No significant difference between dialysis types. HD and PD groups scored significantly higher on BIDQ compared to the community, with no difference between dialysis types. Scores on BIDQ were highly significantly correlated with HADS scores. Levels of BIDQ were responsible for 34.4%, 33.8% and 40.4% of the variance in anxiety, depression and total HADS scores. All SCS were significantly correlated with anxiety and BIDQ. Only Private and Public Self-consciousness significantly correlated with depression. Self-evaluation was highlight significantly correlated with anxiety, depression and BIDQ.
7	**Yodchai et al. (2011)**	5	All HD	Thailand	Q	Structured Interviewing	Themes of planning, adjustment and avoidance, belief of religion and superstition and living with hope were identified. Participants felt that their HD treatment had altered their body-image and covered their fistula with clothing. Self-confidence and self-esteem was impacted.
8	**Öyekçin, et al. (2012)**	120	HD n=36; PD n=54; Control Group n=30	Turkey	CS	BIS BDI BAS GRISS SCID DAS	HD participants scored significantly higher than PD and control groups of BDI, p=0.001. BIS scores of HD participants were significantly higher than both groups, p=0.005. No group differences for anxiety, dyadic adjustment and sexual satisfaction. Statistically significant difference determined between BIS scores for HD and PD (p=0.02). Significant positive correlation between BIS scores and scores on BDI and BAS within the HD group (ps<0.01). Significant positive correlations found between BIS and BAS and GRISS scores. An inverse relationship was found between duration of PD and BIS scores.
9	**Shahgholian et al. (2012)**	132	HD n=44 PD n=44 Control n=44	Iran	CS	Self-designed Questionnaire	Significantly higher levels of BID were identified in both dialysis groups compared to the health control group. No body-image differences between HD and PD were observed
10	**Finnegan-John & Thomas (2013)**	130	ESRD patients n=118 Carers n=12	UK	Q	Structured Interviews	Having a fistula or catheter was viewed as unsightly and impacted on body-image and self-esteem. Patients felt uncomfortable displaying their fistula and hid it with clothes. They became more accepting of this over time,

No.	Study	Sample Size Total	Population	Country	Design	Measures	Study Findings
							but continued to be aware of attention attracted to it in public. Physical changes to the body such as catheter, weight gain and scarring led to an undermining of self-confidence and self-esteem, which impacted upon relationships and sexuality.
11	**Leonard (2013)**	93	HD n=66.7; PD n=33.4	UK	CS	HADS SF-36 BIDQ DAS-24 ESS DS-r	Both male and female scores on the BIDQ were significantly greater than the general population. Scores on the DAS24 indicated significantly higher rates of appearance concern than the general population (p=0.01). Measurement of 'body disgust' suggested low levels present within the population. BID was significantly correlated with anxiety and depression. Body-image, body disgust, BID and shame were significantly correlated with anxiety and depression. The independent variables of body-image, body disgust, BID and shame accounted for 53% of variance for HADS anxiety scores and 33% of depression scores. Similarly, these variables accounted for 61% of the variance in body-image disturbance scores, significantly predicting body-image disturbance (p=0.01).
12	**Yagil et al. (2015)**	45	Kidney transplant recipients (living related recipients n=17; cadaveric recipients n=28)	Israel	CS	BIIQ SF-12 BSI	No significant association between the actual-ideal body-image gap and QOL dimensions, or the importance attributed to the gap and QOL. Significant correlation found between total BIIQ score and four QOL dimensions (physical pain, general health perception, role emotional and social functioning). Significant association between actual ideal body-image gap and most BSI symptoms (not interpersonal sensitivity, depression, phobic anxiety or PSDI). Significant correlation with importance attributed to gap and most BSI symptoms (not anxiety or obsession-compulsion). Significant correlation between total BIIQ score and all BSI symptoms.
13	**Sadeghian et al. (2016)**	84	HD n=42; Transplant Recipients n=42	Iran	CS	Self-designed Body-image Disturbance (BID) Questionnaire	Within the HD group, 64.3%, 19% and 16.7% of participants reported low, moderate and high levels of body-image disturbance, respectively. Statistically significant difference between male and female BID, higher levels in female participants. Statistically higher rates of BID in single compared to married participants. Significant negative correlation reported between age and BID. Within transplant group, 69%, 26.2% and 4.8% of participants reported low, moderate and high levels of BID, respectively. Statistically significant higher levels of BID in HD group compared to transplant recipients.

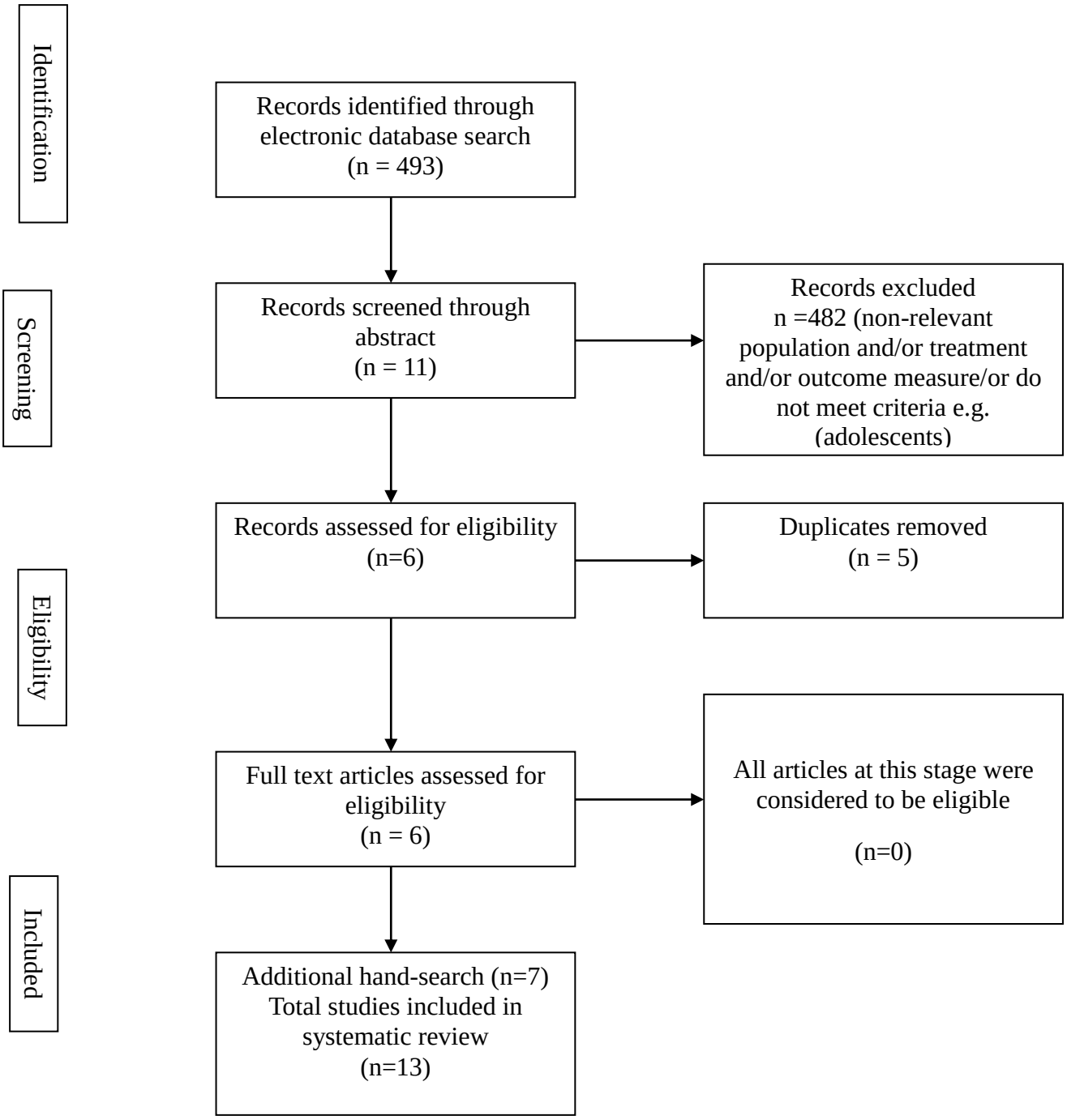
Note: CS = Cross-sectionall; Q= Qualitative; L= Longitudinal

Table 2. Sample characteristics and demographic information

No.	Study	Gender		Age			Ethnicity	Relationship Status	Education
		Male	Female	Mean	SD	Range			
1	**Beer (1995)**	6	6	41.5	-	22-64	-	-	-
2	**Matas et al. (2002)**	2022	2225	51.0	13.0	-	White n= 3069 Black n=551 Hispanic n=247 Asian n=127 Other n=237	Partner 63.3% Single 36.7%	89.8% Completed High School Education
3	**Wu et al. (2004)**	35%	47%	Baseline HD = 59 PD = 54 12 months HD = 59 PD = 54	-	<40 – 80+	Baseline HD White = 63% PD White = 81% HD Black = 32% PD Black = 15% HD Other = 5% PD Other = 5% 12 months HD White = 61% PD White = 81% HD Black = 33% PD Black = 15% HD Other = 6% 4 PD Other = 4%	Married 30% Not married 45%	71% completed high school
4	**Curtin, Johnson & Schatell (2004)**	10	8	54.4	-	33-86	-	-	-
5	**Juergensen et al. (2006)**	-	-	HD = 69.6 PD = 55	HD = 13.3 PD = 14		HD Black = 77% HD White = 80% PD Black = 20% PD White = 17%	Married HD = 60% PD = 57%	< High School HD = 21 PD=18 High School HD =32 PD= 32 >High School HD =48 PD = 50
6	**Partridge & Robertson (2011)**	55.6%	36.1%	59.29	15.401	19-87	White = 78.7% White-mixed = 3.1% Asian = 13.5% Black = 5.1%	-	-

No.	Study	Gender		Age			Ethnicity	Relationship Status	Education
		Male	Female	Mean	SD	Range			
7	**Yodchai et al. (2011)**	3	2	45.4		24-66	-	60% single	2 = degree 2 = complete high school 1 = no qualifications
8	**Öyekçin et al. (2012)**	HD = 22 PD = 27 C = 13	HD = 14 PD = 27 C = 17	HD =37.63 PD = 36.85 C = 36.63	HD = 9.13 PD = 9.66 C = 7.98	-	-	Married Single HD = 33 HD = 3 PD = 44 PD = 10 C = 28 C = 2	HD= 5.86 yr PD = 8.46yr C = 8.2
9	**Shahgholian et al. (2012)**	HD = 24 PD = 29 C = 24	HD = 21 PD = 16 C = 20	HD = 45.6 PD = 48.2 C = 43.8	HD = 15.2 PD = 12.7 C = 14.8	-	-	Married HD = 80.7% PD = 57% C = 75%	>High School < High School HD = 25 22 PD = 26 19 C = 23 22
10	**Finnegan-John & Thomas (2013)**	74	44	55	-	-	Black and minority ethnic = 40%	-	-
11	**Leonard (2013)**	63.4%	36.6%	58.61	16.39	20-90	White = 64.5% Black = 2.2% Asian = 28.0% Chinese = 1.1% Other = 2.2% Prefer not to say = 2.2%	-	-
12	**Yagil et al. (2015)**	28	17	53.2	12.84	22-78	-	Married = 30 Not Married = 15	<12yr education = 30 12yr> education = 15
13	**Sadeghian et al. (2016)**	HD = 52% Transplant = 62%	HD = 48% Transplant = 38%	HD = 44.4 Transplant= 45.4	HD = 13.2 Transplant = 11.9	-	-	-	-

Figure 1. PRISMA diagram showing the process of study selection.



Chapter 2

Empirical Study

Treatment Adherence in End-Stage Renal Disease: Exploring Attachment Styles, Anxiety and Depression as predictors.

Treatment Adherence in End-Stage Renal Disease: Exploring Attachment Styles, Anxiety and Depression as predictors.

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Abstract

Background: Poor treatment adherence in End-Stage Renal Disease (ESRD) is a wide spread problem. Psychological factors associated with treatment adherence have been explored within the ESRD population, including anxiety and depression. Research within other chronic health conditions have considered of the impact of attachment styles on treatment adherence. However, this is yet to be explored within the ESRD population.

Aim: To explore the relationship between treatment adherence and attachment styles, alongside symptoms of anxiety and depression, within the ESRD population.

Method: Thirty-one participants, who were receiving hospital-based haemodialysis, were recruited across North Wales to complete a questionnaire. A series of measures assessing self-reported treatment adherence, anxiety, depression and attachment were implemented.

Results: Correlational analysis identified a significant relationship between depression and treatment adherence, and insecure-fearful attachment styles and adherence. Regression analysis identified that collectively, age, depression and attachment significantly contributed to variance of treatment adherence, ($ps<0.05$). However, attachment styles were not significantly predictive of adherence over and above the portion of variance explained by depression and age.

Conclusion: The findings suggest that patients who present with symptoms of depression and/or features of an insecure-fearful attachment style, are more likely to be non-adherent to aspects of their ESRD treatment regimens. Services would benefit from routinely screening for depression in order to improve treatment outcomes. The results justify the need for further research on attachment and suggest that services should be mindful of attachment styles when supporting patients who are non-adherent to treatment.

Keywords: Renal Failure, Treatment Adherence, Attachment, Depression, Anxiety.

Introduction

End-Stage Renal Disease (ESRD) or Kidney Failure, is the final stage of chronic kidney disease when an individual's kidneys are no longer functioning or have stopped working well enough for the individual to survive without a kidney transplant or kidney dialysis (American Kidney Fund, 2017). Haemodialysis (HD) is a form of dialysis treatment provided for patients who have ESRD and involves diverting blood into an external machine, where it is filtered before being returned to the body (National Health Service (NHS) Choices, 2015). Haemodialysis is a therapy in which adherence to diet, fluid and medication recommendations are critically important in determining continuing survival and preserving health (Denhaerynck, Manhaeve, Dobbels, Garzoni, Nolte, et al., 2007).

A patient's regime whilst receiving haemodialysis can be severely restrictive, including the restriction of fluid which can be as severe as 500mls daily, depending on size and weight, as well as restricting foods that are high in sodium, potassium and protein (Denhaerynck, et al., 2007). In addition, patients can be prescribed a range of medications, including medications to treat or prevent a range of comorbid conditions and to balance blood mineral levels, such as the use of phosphate binders (Denhaerynck, et al., 2007). Patients utilising hospital based haemodialysis are required to attend regular dialysis sessions at their renal clinic between three to four times per week, with each session taking place for an average of four hours. The regime for treatment is very complex. However, patients are aware that if they were to deviate from their prescribed regimens it can result in adverse physical health problems or fatal consequences, (Sherman, Cody, Rogers & Solanchick, 1995, cited in, Vlaminck, Maes, Jacobs, Reyntjens & Evers, 2001). Despite the associated risks, non-adherence in patients with ESRD is a widespread problem (Schneider, Friend & Whitaker, 1991).

Denhaerynck et al., (2007) completed a systemic literature review in order to explore the prevalence of treatment non-adherence in ESRD. The review considered attendance, fluid, diet and medication adherence and reviewed 17 published articles. The results indicated that rates of patients who are non-adherent to fluid restrictions ranged from 30-74% across studies, dietary non-adherence ranged from 2-39% for potassium intake and 19-57% for phosphate intake, and medication non-adherence ranged from 19-99% (Denhaerynck, et al., 2007). Non-adherence to dialysis appointments ranged from 0-35% for patients who miss treatments and 7-32% for patients who shorten treatments against medical advice (Denhaerynck, et al., 2007). More recent studies suggest non-adherence to be as high as 80-85% (Clark, Farrington & Chilcott, 2014). These results highlight that reporting of non-adherence differs significantly between studies.

Due to the significant risks associated with non-adherence, psychological researchers have begun to investigate the psychological factors that may contribute to patterns of adherence in order to better support patients and prevent a deterioration of health. DiMatteo, Lepper and Croghan (2000) completed a meta-analysis which looked at the effects of anxiety and depression on treatment adherence for patients with chronic health conditions, including renal disease. The study analysed the results of twelve articles about depression and thirteen articles about anxiety and treatment adherence. The results suggested that there was little evidence to support anxiety as a predictor of treatment non-adherence. Research on the effects of anxiety and treatment adherence in ESRD is limited and is yet to offer any conclusive understanding of the relationship (Mellon, Regan & Curtis, 2013). However, Mellon, Regan and Curtis (2013) found that higher levels of anxiety was predictive of good adherence to phosphate restrictions, suggesting anxiety was useful in improving adherence to one aspect of ESRD treatment (r=0.39, p<0.01).

Contrastingly to the findings for anxiety, Dimatteo, Lepper and Croghan (2000) found the relationship between depression and adherence was highly significant ($p<0.001$). Patients who met clinically significant scores for depression were, on average, three times more likely to be non-adherent to treatment than non-depressed patients (DiMatteo, Lepper & Croghan, 2000). Looking more specifically at the ESRD population, Cukor, Rosenthal, Jindal, Brown, & Kimmel (2009) found that depression was a significant predictor in non-adherence to medication during haemodialysis and following successful kidney transplantation ($p=0.001$). Similarly, Nabolsi, Wardam and Al-Halabi (2013) found a negative relationship between depression and adherence to all aspects of treatment, including haemodialysis attendance, diet, fluid and medication ($p=0.001$). A systematic review estimated the prevalence of depression to range from 25.8 to 68.1% within the dialsys population (Garcia-Llana, Remer, del Paso & Selgas, 2014).

In addition to exploring the effects of anxiety and depression on treatment adherence in ESRD, the impact of patients' access to social support and positive relationships has also been considered. Consistently, studies have highlighted that having access to good social support is a predictive factor in treatment adherence (Kiley, Lam & Pollack, 1993; Kutner, Zhang, McClellan, & Cole, 2002) and that lower levels of social support are associated with increased mortality rate (Kimmel, Peterson, Weihs, Simmens, Alleyne, et al., 1998). Moreover, better adherence to treatment was also found to be influenced by whether or not patients felt they had a good relationship with their doctor (Kiley, Lam & Pollack, 1993). The ability to form and maintain social relationships has been found to be influenced by an individual's attachment style. As social support has already been considered in great detail in previous research, the present study looked to consider the role of attachment.

Attachment is the social and emotional bond developed between a child and their caregiver in infancy, which supports an infant's social development and spans time and space (Martin, Carlson & Buskist, 2007). The quality of attachment in early child development can influence emotional and behavioural presentations in childhood, adolescence and adulthood (Martin, Carlson & Buskist, 2007). Initial development of attachment theory began in the 1930's and was a product of collaborative work by John Bowlby and Mary Ainsworth, who began to make links between the relationship, or 'attachment,' developed between a child and their primary caregiver, how this impacted on personality development and how a person may relate to others (Bretherton, 1992). Ainsworth's 'Strange Situation' study identified different forms of attachment style, including secure attachment, anxious-avoidant attachment and anxious-ambivalent attachment (Ainsworth, 1979). These were later re-categorised by Bartholomew and Horowitz (1991) into four main styles of adult attachment including secure, pre-occupied, dismissive, and fearful attachments, as presented in Figure 1, (Weiten & Lloyd, 2006).

Figure 1. *Bartholomew's model of adult attachment (Weiten & Lloyd, 2006)*

		Image of Self	
		Positive	Negative
Image of Others	Positive	**Secure** Comfortable with intimacy and autonomy	**Preoccupied** Preoccupied with relationships.
	Negative	**Dismissing** Dismissing of intimacy. Counter-dependent	**Fearful** Fearful of intimacy. Socially avoidant.

Given the influences of social support and relationships on good treatment adherence, attachment styles have been considered as a psychological factor in predicting adherence to treatment in chronic health conditions. Hooper, Tomek, Roter, Carson Mugoya, et al., (2016)

considered the relationship between attachment style and medication adherence in a range of primary care level physical health conditions, such as hypertension. The study made use of the Relationship Questionnaire (RQ: Bartholomew & Horowitz, 1991) and Relationship Scale Questionnaire (RSQ: Griffin & Bartholomew, 1994) to determine patterns in adult attachment styles and compared this to treatment adherence. Results suggested that insecure-dismissing attachment styles were associated with lower medication adherence and mediated the relationship between depression and medication adherence ($p<0.02$; Hooper et al., 2016). Similarly, Ciechanowski, Katon, Russo and Walker (2001) considered the relationship between diabetes treatment adherence and attachment, including secure, fearful, avoidant and preoccupied attachment styles, also utilising the RQ and RSQ. The results suggested that those patients who reported higher rates of insecure-dismissive attachment styles had poorer treatment adherence.

ESRD research is yet to look at the relationship between attachment styles and patterns in treatment adherence. Given that a number of studies have now acknowledged the importance of family, social and professional relationships, exploring attachment style may be beneficial in understanding patterns in adherence in ESRD. Therefore, the current study aimed to explore adult attachment styles in relation to treatment adherence in ESRD, including attendance at dialysis appointments, fluid and dietary restrictions and medication adherence. As previous research has illustrated the significance of depression as a contributory factor in non-adherence, depression was included in the study. Given that the role of anxiety is yet to be fully understood within the subject area, the current study also aims to consider the impact of anxiety, alongside attachment and symptoms of depression.

Method

Participants

A minimum sample size of 29 was identified for the study (α=0.05, β=0.2 and r=0.5). Thirty-one individuals who were receiving hospital-based haemodialysis were recruited. The population for the study consisted of approximately 220 potential participants. However, as the initial stages of recruitment were facilitated by the nursing teams, it is unclear how many patients were approached by the nurses or how many patients declined to accept a copy of the patient information sheet and consent form. All participants were aged between 34 and 90 years and were receiving ongoing support and treatment from one of four haemodialysis centres across North Wales in the United Kingdom. All participants' care plans included attending haemodialysis treatment appointments a minimum of three times per week at their allocated unit. Further demographic information, including length of time receiving haemodialysis, is outlined in Table 1. All four haemodialysis centres were National Health Service (NHS) provisions. However, some of the nursing provision was provided by a private organisation which works alongside the NHS to provide a range of haemodialysis services.

Table 1. *Demographic characteristics of participants*

	All Participants
Number of participants	31
Age *(M, [S.D])*	65.03 [12.72]
Range	34-90
Median	69
Gender (N, %)	
Male	27 (87.1%)
Female	4 (12.9%)
Time Receiving Dialysis (years)	
(M, [S.D])	4.11 [4.79]
Range	0.7-24
Median	2.5

The study followed exclusion criteria in order to control for confounding variables. Participants were excluded from the study if they had been receiving haemodialysis for a period of less than 12 weeks. This was in order to ensure that difficulties which may present for patients adjusting to haemodialysis treatment were not mistaken for non-adherence behaviours. Participants were also excluded if they were below the age of 18 or were 'holiday patients' at the service. Some patients receiving haemodialysis treatment will arrange to use local service provisions when they are visiting a different area away from home, such as on holiday. Issues to do with their adherence to treatment may have been in part to do with their interactions and packages of care in their own service and therefore could impact upon the data collected. By only including patients who regularly access care from the targeted service provisions, the homogeneity of the data was protected. Additionally, some participants may have required follow up support, as identified by their responses to the measures, and this could not be guaranteed from their own services.

Measures

End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ)

The ESRD-AQ was adapted and used to measure self-reported adherence to treatment in ESRD. The measure was developed by Kim, Evangelista, Phillips, Pavlish and Kopple (2010) as an instrument to measure adherence to haemodialysis attendance, medication, fluid restrictions and dietary regimens among ESRD patients. The original questionnaire includes 46 items and utilises a combination of Likert scale, multiple choice and "yes/no" format questions. The item content validity was scored at 0.99 on average, out of a possible 1.00, indicating high levels of content validity (Kim et al., 2010). Reliability testing of the instrument indicated strong test-retest reliability, ranging from 0.83 to 1.00 (Kim et al., 2010). However, the measure of internal

consistency reliability was omitted as the instrument does not possess homogeneous items (Kim, et al., 2010).

Given the number of items on the ESRD-AQ and the estimated completion time of 20-40 minutes, a decision was made by the research team, which consisted of two Consultant Clinical Psychologists and one Trainee Clinical Psychologist, to only administer a selection of items, particularly as administration of the ESRD-AQ alongside the additional measures would have significantly increased the demand on a participant's time and engagement with the study. Questions such as, "what type of transport do you use to get to dialysis" were omitted and nine core questions were selected, which covered each of the four areas of ESRD treatment. This included items 14-15, 17-20, 26-27, 31 and 46 of the ESRD-AQ. The items selected for this study are the only items from the original ESRD-AQ which provide a measureable response and generate a value for adherence. Therefore, the results from this study can be compared to other studies which utilised the ESRD-AQ. The scores were summed in total to provide an overall score for treatment adherence. Higher scores indicated greater levels of treatment non-adherence. For each question where an individual indicated they were non-adherent to an aspect of their treatment, they were asked to provide a reason why, which was taken into consideration. For example, participants may indicate that they shortened their dialysis treatment on one occasion, but explained that this was a staff decision due to difficulties related to blood clotting. In circumstances such as these, a participant's response was not rated as non-adherent, as they were acting based on medical advice.

Patient Health Questionnaire – Version 9 (PHQ-9)

The PHQ-9 (Kroenke, Spitzer & Williams, 2001) is a depression scale taken from the larger Patient Health Questionnaire (PHQ; Spitzer, Kroenke & Williams, 1999) and encompasses

9 items based upon the Diagnostic and Statistical Manual – Fourth Edition (DSM-IV) criteria for depressive disorders. The measure utilises a Likert scale, with each item ranging from scores of 0-3. Total scores on the PHQ-9 are categorised into minimal (0-4), mild (5-9), moderate (10-14), moderately severe (15-19) and severe (20-27) levels of depression (Kroenke, Spitzer & Williams, 2001). All participants who met clinical cut-off scores of moderate levels of depression, or more, were offered a referral to the renal clinical psychology service for an assessment, or their GP was notified, with the participant's consent.

The internal reliability of the PHQ-9 was scored at a Cronbach's α of .89 and test-retest reliability correlation of 0.84, suggesting high levels of reliability (Kroenke, Spitzer & Williams, 2001). The PHQ-9 has since been validated within the dialysis population as a reliable screening tool for depression (Watnick, Wang, Demadura & Ganzini, 2005).

General Anxiety Disorder Questionnaire - Version 7 (GAD-7)

The GAD-7 was developed by Spitzer, Kroenke, Williams and Lowe (2006) and was established as a brief measure for assessing symptoms of generalised anxiety disorder within a clinical population. The measure consists of seven items and utilises a Likert scale, with each item ranging from scores of 0-3. Total scores on the GAD-7 are categorised into minimal (0-4), mild (5-9), moderate (10-14) and severe (15-21) levels of anxiety. As with the PHQ-9, all participants who met clinical cut-off scores of moderate levels of anxiety, or more, were offered a referral to the renal clinical psychology service for an assessment, or their GP was notified, with the participants consent. The internal consistency measure of the GAD-7 yielded a Cronbach's α score of .92 and test-retest reliability was correlated at 0.83, indicating high levels of reliability.

Relationship Questionnaire (RQ) and Relationship Scales Questionnaire (RSQ)

The RSQ (Griffin & Bartholomew, 1994) and the RQ (Bartholomew & Horowitz (1991) were administered in order to determine patterns in attachment styles for each participant. The RSQ is a 30-item instrument, which utilises a Likert scale and encompasses a range of questions indicative of secure, fearful, preoccupied and avoidant attachment styles (Griffin & Bartholomew, 1994). The RQ is a four item questionnaire in which the participants are required to read paragraphs describing characteristics of the four aforementioned attachment styles and rate how well each passage describes them using a 7 point Likert scale (Bartholomew & Horowitz, 1991). The RSQ and RQ were combined by averaging z-scores of the two measures. Testing of each instrument has reported high levels of reliability and validity (Griffin & Bartholomew, 1994; Scharfe & Bartholomew, 1994; Ciechanowski, Katon, Russo, & Walker, 2001). However, it is advised that the tool is not used as a categorical measure of attachment, which has been adhered to within this study.

Procedure

Following approval from each of the services, ethical approval was sought from the NHS Research Ethics Committee, NHS Research and Development Offices and The School of Psychology at Bangor University. Following ethical approval, the lead researcher met with the nursing teams at each unit in order to explain the aims and procedures of the study and ask for their co-operation in identifying and approaching potential participants. The nursing teams were provided with nursing information sheets in English and Welsh, which included the full details of the study. Following this, potential participants who met the inclusion criteria were identified and approached by a regular member of their nursing team to determine their interest in taking

part in the study. The nursing teams provided a verbal summary of the study and distributed participant information sheets, in Welsh and English, and consent forms.

Participants were given time to consider taking part in the study and were asked to return their consent form to the nursing team. After the consent forms had been obtained, the researcher arranged to meet with the participants during one of their routine haemodialysis appointments. Verbal consent was obtained again and the psychometrics and questionnaires were distributed to participants. Participants were given the choice to complete the questionnaires independently or with support from the researcher. The duration of questionnaire completion time ranged between 30 and 70 minutes, depending on the level of support patients required. All participants were then debriefed following the completion of the measures. The researcher immediately scored the results of the GAD-7 and PHQ-9. Participants who met the clinical cut-off scores for moderate to severe levels of depression or anxiety were informed by the researcher and offered the choice to receive a referral to the Renal Clinical Psychology Service for an assessment, or for their GP to be notified of the concerns, which was facilitated by the researcher. With consent, the researcher wrote to each of the participants' GPs to notify them of their participation in the study.

Statistical Analysis

The statistical software package IBM SPSS Version 22 (IBM Corp, 2016) was used to complete all statistical analyses of the data. The researcher explored the descriptive statistics of the data, considering means and ranges of participants' demographics and questionnaire responses. The first stage of the analysis looked at the normal distribution of variables. Shapiro-Wilks test of normality identified a number of variables were not normally distributed. Therefore, as this violates parametric assumptions, when determining a relationship between variables, Spearman's rank correlation was used as this is a non-parametric analysis. Following this, a regression

analysis was implemented to establish whether attachment styles explained variance in adherence to treatment, above and beyond variables known from previous research to be predictive: age and depression. The analysis was used to establish whether variance in treatment adherence differed between those variables already identified as predictive from initial stages of analysis and previous research. Therefore, anxiety was not included as previous research and results from this study have been inconsistent. The Shapiro-Wilks test of normality indicated that the variance in residuals was normally distributed and therefore met the necessary assumptions for regression. Attachment styles were inputted into the regression analysis at the final stage, in order to establish whether additional variance in treatment adherence could be explained by attachment styles.

Results

Across the sample, results indicated that 12.90% of participants reported to have shortened dialysis, 6.45% reported to have skipped dialysis sessions, 19.35% reported to have been non-adherent to medication, 45.16% of participants reported to have been non-adherent to fluid restrictions and 41.94% reported to have been non-adherent to dietary restrictions. The mean scores of the PHQ-9 and GAD-7 were 3.87 and 2.13, respectively, indicating non-clinically significant levels of depression or anxiety, on average. However, three participants met the clinical cut-off score of moderate levels of depression, or higher, on the PHQ-9 and one participant met the clinical cut-off score for moderate levels of anxiety on the GAD-7. Descriptive statistics for all measures are outlined in Table 2. The impact of potential outliers is discussed in Appendix 7.

Table 2. *Descriptive statistics for measures*

	Mean	**Minimum**	**Maximum**	**Standard Deviation**
PHQ-9	3.87	0.00	20.00	4.27
GAD-7	2.13	0.00	10.00	2.60
ESRD-AQ	2.74	0.00	10.00	3.19
Composite Secure Attachment score	0.40	-1.33	1.15	.76
Secure RQ	5.24	1.00	7.00	1.99
Secure RSQ	15.62	9.00	20.00	3.10
Composite Fearful Attachment score	-.03	-.96	2.08	.86
Fearful RQ	2.31	1.00	7.00	2.00
Fearful RSQ	8.50	4.00	16.00	3.58
Composite Preoccupied Attachment Score	0.00	-1.20	1.78	.83
Preoccupied RQ	2.48	1.00	7.00	1.96
Preoccupied RSQ	9.80	4.00	17.00	3.53
Composite Dismissive Attachment score	-.02	-1.83	1.09	.76
Dismissive RQ	4.34	1.00	7.00	2.18
Dismissive RSQ	16.93	8.00	23.00	4.20

Correlational analysis indicated that participants who scored higher for symptoms of depression on the PHQ-9 tended to be less adherent to overall treatment, scoring higher on the ESRD-AQ, (r=.416, p=.025). In particular, patients with higher scores for depression were less adherent to fluid restrictions (r=.482, p=.022) and dietary restrictions (r=.387, p=.020). Participants who rated higher on features of insecure-fearful attachment style also tended to be less adherent to overall treatment (r=.407, p= .003). In particular, these participants were less likely to adhere to the fluid restrictions of their treatment (r=.510, p=0.006). Additionally, an analysis of participant demographics also highlighted a significant correlation between participant age and treatment adherence, suggesting that older participants were more adherent to treatment (r=-.518, p=0.003). Figure 2 and 3 illustrated the correlational relationships.

Figure 2. *Correlation between treatment adherence (ESRD-AQ total) and depression (PHQ-9*)

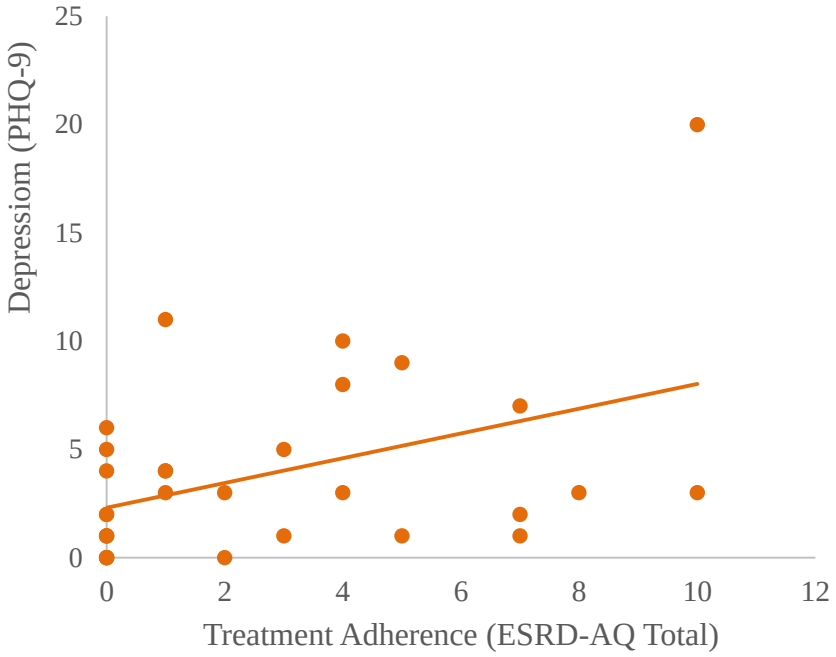
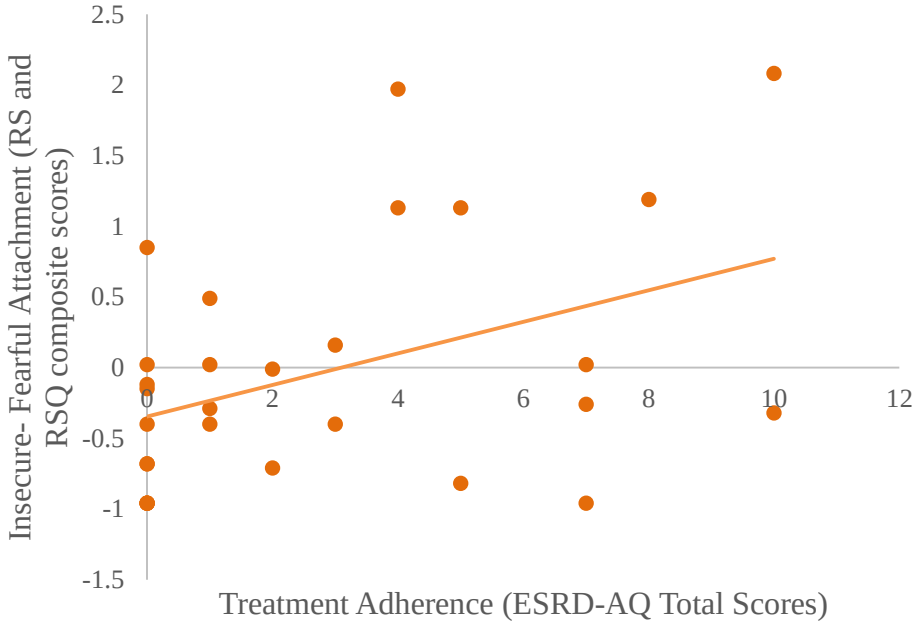


Figure 3. *Correlation between treatment adherence (ESRD-AQ total) and insecure-fearful attachment (RQ and RSQ z-scores)*



A multiple regression analysis was administered in order to determine predictive factors in treatment adherence. The Shapiro-Wilk test of normality indicated the residuals of the chosen variables were normally distributed ($p>0.05$), meeting the assumptions of normality necessary to administer multiple regression. Given the significance of age on treatment adherence highlightedwithin the initial correlational analysis, as well as previous research highlighting the significance of age, age was entered at stage one. Additionally, given the impact of depression on treatment adherence highlighted in previous research, as well as initial correlational analysis, depression was entered at stage two. Attachment styles were inputted at the third and final stage of the regression analysis in order to determine whether attachment is useful in predicting treatment adherence over and above age and depression. Given that no prior trends in attachment style have been explored within this population, five separate regression analysis were run; secure attachment, insecure-fearful attachment, insecure-preoccupied attachment, insecure-dismissive attachment and all attachment styles. These scores should thus be interpreted as exploratory.

The initial regression analysis looked at the relationship between age, depression and secure attachment as predictors of adherence. Age was shown to be significantly predictive of adherence at the first stage of the model, accounting for 25.4% of the variance, $F(1,26) = 8.835$, $p=0.006$. At the second stage of the model, the introduction of depression was also found to be statistically significant, accounting for an additional 13.9% of the variance, $F(2, 25) = 8.088$, $p=0.02$. At stage 3 of the model, the addition of secure attachment was also found to be statistically significant, accounting for 0.4% additional variance, $F(3, 24) = 5.264$, $p=0.06$. However, secure attachment did not significantly predict additional variance over and above age

and depression r^2=0.004, F(1,24) = 0.160, p=0.692. Table 3 represents a summary of these findings.

Table 3*. Summary of Hierarchical regression analysis for age, depression and secure attachment as predictors of adherence.*

	Model 1 (Age)			Model 2 (Depression)			Model 3 (Secure Attachment)		
Variable	*B*	*SE b*	*β*	*B*	*SE b*	*β*	*B*	*SE b*	*β*
Age	-0.139	0.047	-0.504*	-0.130	0.043	-0.472*	-0.129	2.980	-0.504*
Depression	-	-	-	0.280	0.043	-4.72*	0.249	0.142	0.333
Secure	-	-	-	-	-	-	-0.326	0.815	-0.076
Adjusted R^2		0.225*			0.344*			0.321	
R^2 Change		0.254*			0.139*			0.004	
F Change		8.835*			5.733*			0.160	

A second regression analysis looked at the relationship between age, depression and insecure-fearful attachment. Age was shown to be significantly predictive of adherence at the first stage of the model, accounting for 26% of variance, F(1,27) = 9.482, *p*=0.005. The addition of depression to the model was also significant, accounting for an additional 14.6% of variance, F(2,26)=8.811, *p*=0.001. The introduction of insecure-fearful attachment at the final stage was also significant, accounting for an additional 4.7% of variance, F=(3,25)=6.908, *p*=0.002. However, the introduction of insecure-fearful attachment did not significantly predict additional variance beyond age and depression r^2=0.047, F(1,25) = 2.166, *p*=0.154. Table 4 represents a summary of these findings.

Table 4. *Summary of Hierarchical regression analysis for age, depression and insecure-fearful attachment as predictors of adherence*

	Model 1 (Age)			Model 2 (Depression)			Model 3 (Secure Attachment)		
Variable	*B*	*SE b*	*β*	*B*	*SE b*	*β*	*B*	*SE b*	*β*
Age	-0.142	0.046	-0.510*	-0.132	0.042	-0.473*	-0.136	0.041	-0.489*
Depression	-	-	-	0.280	0.114	0.384*	0.139	0.150	0.186
Fearful	-	-	-	-	-	-	1.116	0.758	0.294
Adjusted R^2		0.233*			0.360*			0.388	
R^2 Change		0.260*			0.146*			0.047	
F Change		9.482*			6.387*			2.166	

The regression analysis considering age, depression and insecure-preoccupied attachment revealed that age and depression were again significantly predictive of adherence at the first and second stages of the model, with age accounting for 26% of variance and depression account for an additional 14.6% of variance, with F(1,27)=9.482, p=0.005 for age and F(2,26)= 8.881, p=0.01 for depression. The introduction of pre-occupied attachment at the final stage was also significant, accounting for an additional 1.3% of variance, F(3,25)=6.009, p=0.003. However, insecure-preoccupied attachment did not predict variance beyond that explained by age and depression, F(1,25)=0.564, p=0.460, $r^2 = 0.013$. Table 5 represents the results of the regression analysis.

Table 5. *Summary of Hierarchical regression analysis for age, depression and insecure-preoccupied attachment as predictors of adherence.*

	Model 1 (Age)			Model 2 (Depression)			Model 3 (Secure Attachment)		
Variable	*B*	*SE b*	*β*	*B*	*SE b*	*β*	*B*	*SE b*	*β*
Age	-0.142	0.046	-0.510*	-0.132	0.042	-0.473*	-0.130	0.043	-0.466*
Depression	-	-	-	0.287	0.114	0.384*	0.313	0.120	0.419*
Preoccupied	-	-	-	-	-	-	-0.470	0.625	-0.120
Adjusted R^2		0.233*			0.360*			0.349	
R^2 Change		0.260*			0.146*			0.013	
F Change		9.482*			6.387*			0.564	

The regression analysis for age, depression and insecure-dismissive attachment style found that age was again, significantly predictive of 26% of the variance at stage one, $F(1,27)=9.482$, $p=0.05$, and depression accounted for an additional 14.6% of variance at stage two, $F(2,26)=8.882$, which was statistically significant, $p=0.001$. The addition of insecure-preoccupied attachment accounted for 0.4% of additional variance, $F(3,25)=5.797$, $p=0.004$. However, the introduction of insecure-dismissive attachment did not predict variance over and above depression and age, $F(1,25)=0.186$, $p=0.670$, $r^2=0.004$, as represented in Table 6.

Table 6. *Summary of Hierarchical regression analysis for age, depression and insecure-dismissive attachment as predictors of adherence*

	Model 1 (Age)			Model 2 (Depression)			Model 3 (Secure Attachment)		
Variable	*B*	*SE b*	*β*	*B*	*SE b*	*β*	*B*	*SE b*	*β*
Age	-0.142	0.046	-0.510*	-0.132	0.042	-0.473*	-0.137	0.045	-0.492*
Depression	-	-	-	0.287	0.114	0.384*	0.279	0.117	0.373*
Dismissive	-	-	-	-	-	-	0.298	0.692	0.070
Adjusted R^2		0.233*			0.360*			0.339	
R^2 Change		0.260*			0.146*			0.004	
F Change		9.482*			6.387*			0.186	

The final regression analysis considered whether age, depression and all attachments styles collectively, were predictive of adherence, when secure, fearful, preoccupied and dismissive were added to stage 3 of the analysis. At the first stage, age was significantly predictive and accounted for 25.4% of variance, $F(1,26)=8.835$, $p=0.006$. At stage two, depression was also significant and accounted for an additional 13.9% of variance, $F(2,25)=8.088$, $p=0.002$. At the final stage, a combination of all attachment styles accounted for 9.8% of variance, $F(6,21)=3.382$, $p=0.017$. However, attachment styles were not predictive of

variance beyond that predicted by age and depression, $F(4,21)=1.018$, $p=0.421$, $r^2=0.99$, represented in Table 7.

Table 7. *Summary of Hierarchical regression analysis for age, depression and all attachment styles as predictors of adherence*

	Model 1 (Age)			Model 2 (Depression)			Model 3 (Secure Attachment)		
Variable	*B*	*SE b*	*β*	*B*	*SE b*	*β*	*B*	*SE b*	*β*
Age	-0.139	0.047	-0.504*	-0.130	0.043	-0.472*	-0.126	0.046	-0.457*
Depression	-	-	-	0.280	0.117	0.374*	0.280	0.117	0.374*
Secure	-	-	-	-	-	-	0.060	0.874	0.014
Fearful	-	-	-	-	-	-	1.831	1.118	0.487
Preoccupied	-	-	-	-	-	-	-0.860	0.682	-0.219
Dismissive	-	-	-	-	-	-	-0.439	1.013	-0.102
Adjusted R^2		0.225*			0.344*			0.346	
R^2 Change		0.254*			0.139*			0.099	
F Change		8.835*			5.733*			1.018	

Discussion

The current study aimed to explore how psychological factors of attachment style, anxiety and depression, may play a role in treatment adherence in ESRD. The rationale for the study stemmed from a collaboration of previous findings on attachment in other chronic health conditions, such as diabetes, (Hooper, et al., 2016; Ciechanowski et al., 2001), and depression (Nabolsi, et al., 2013) and anxiety (Mellon, Regan & Curtis, 2013) within ESRD.

In line with the findings from the meta-analysis completed by DiMatteo and colleagues (2000), the current study found no significant relationship between treatment adherence and anxiety ($p>0.05$). In contrast to the findings from Mellon, Regan & Curtis (2013), a significant relationship was not identified between anxiety and medication adherence. It is important to consider that although the study met the sample size requirements, in comparison to the aforementioned studies, the current study had a relatively small sample size and, therefore,

results should be interpreted with caution. The experience of anxiety can manifest in a number of different ways, including generalized anxiety, health anxiety, obsessive-compulsive disorder and phobias (DiMatteo et al., 2000). The present study utilised a measure which looked specifically at the core symptoms of generalised anxiety disorder and, therefore, may not have captured alternative presentations of anxiety. Future research should consider capturing a broader range of anxiety presentations and symptoms when considering the relationship with treatment adherence.

The results of the current study are consistent with previous findings for depression and treatment adherence from Nabolsi et al (2013) and DiMattteo et al (2000), as a significant relationship was found between total scores on the PHQ-9 and ESRD-AQ. More specifically, as symptoms of depression increased, participants were more likely to be non-adherent to treatment. Furthermore, the results illustrated that depression was found to be more likely to predict poorer treatment adherence relating to fluid and dietary restrictions, rather than medication, skipping dialysis sessions or shortening dialysis sessions, which were not significant when correlated independently ($p>0.05$). Given the growing evidence on the negative impact of depression on diet and healthy living, it is perhaps understandable why these aspects of treatment may be more susceptible to non-adherence than others (Opie, O'Niel, Itsiopoulos & Jacka, 2013). Additionally, age was identified as another contributing factor in treatment adherence. Younger participants tended to be less likely to be adherent to treatment, which was in line with previous findings (Hooper, et al., 2016; Mellon, Regan & Curtis, 2013).

In contrast to the findings of previous studies (Hooper, et al., 2016; Ciechanowski et al., 2001), the current study did not observe a relationship between insecure-dismissive attachment styles and treatment adherence ($p>0.05$). Nor did the study observe a relationship between secure attachment or insecure-preoccupied and treatment adherence, which was in line with previous

findings. However, a significant correlational relationship was observed between insecure-fearful attachment and treatment adherence ($p>0.05$). Individuals with an insecure-fearful attachment style may present with characteristics such as a fear of closeness or intimacy, may see themselves as unworthy of care from others and have poor self-esteem (Ciechanowski, Sullivan, Jensen, Romano, & Summers (2003). Unlike other forms of attachment styles, individuals with an insecure-fearful attachment are more likely to have a negative view of others, which may result in avoidance of healthcare and healthcare professionals (Ciechanowski, et al., 2003). Previous research on attachment and chronic pain identified that, although patients with an insecure-fearful attachment style are more likely to complain of physical illness, they are significantly less likely to present to healthcare services for support (Ciechanowski, Walker, Katon, & Russo, 2002b). Unlike other chronic health conditions, ESRD treatment could be viewed as unique when considering how much contact time patients receiving hospital-based haemodialysis may have with their renal teams and other patients. Within this study, patients spend on average 16 hours per week, or more, with their renal teams and other patients whilst receiving dialysis. It is appropriate to consider how an individual with traits of insecure-fearful attachment, who has difficulty maintaining relationships, has a reluctance to ask for support and feels unworthy of care, may find the haemodialysis treatment regimen difficult to adhere to.

Given the findings from previous studies, which highlighted the importance of social support and close relationships in treatment adherence (Kiley, Lam & Pollack, 1993; Kutner, et al., 2002), it could be considered surprising that a correlational relationship was not observed between secure attachment and treatment adherence, within this study and previous research findings. The results of the regression analysis did, however, highlight the importance of attachment in predicting variance in treatment adherence. Although attachment styles were not

predictive of variance over and above accounting for depression and age, each attachment style explained the same proportion of variance. Attachment, combined with depression and age, accounted for 49.1% of variance in treatment adherence within this study. Given that features of insecure attachment can increase the likelihood of depression, (Roberts, Gotlib & Kassel, 1996), it is conceivable that the variance in treatment adherence that attachment contributes to may largely overlap with the variance for depression. Furthermore, features of fearful-insecure attachment have been found to be strongly associated with episodes of clinical depression (Bifulco, Moran, Ball & Bernazzani, 2002). Given that a significant relationship between insecure-fearful attachment and adherence was identified from the correlational analysis, this may account for the overlap in variance.

A number of limitations of this study should be considered when interpreting the findings. It is important to consider that the sample was predominantly male, with only 4 female participants. Although patients with ESRD are more likely to be male, with 36.8% of the UK renal population identified as female (UK Renal Registry, 2016), the male to female ratio within this study was unrepresentative of the larger population, with just 12.9% identified as female. In addition, the data also appeared to be unrepresentative of levels of anxiety, depression and the prevalence of patients who skip haemodialysis appointments or shorten treatment, compared to previous studies. Denhaerynck et al., (2007) identified that some studies recorded up to 35% of patients skip or shorten treatments, whereas only 4 participants identifying skipping treatments and 2 participants identified shortening treatments, against medical advice, accounting for just 12.9% and 6.5% of the population, respectively. Although demographic information was not collected on race and ethnicity, subjectively, the large majority of the sample were white Caucasian and therefore, was not representative of a diverse population.

The nature of the study's methodology required patients to attend their haemodialysis appointments in order to be approached by the nursing team regarding participation in the study. With this in mind, it is possible that a number of patients who were non-adherent to their treatment in relation to attendance were not captured in the sample. In addition, the cross-sectional nature of the study only captures information related to adherence, attachment, depression and anxiety at one time point, and is not representative of changes in presentation overtime. Within this sample, patients reported to have received haemodialysis treatment for an average of 4.1 years and, therefore, future research should consider capturing information across time points. Additionally, consideration should be made for different methods of assessing adherence to ESRD treatment. Adherence could be monitored through collecting attendance information or fluid retention levels by accessing patient notes, as oppose to replying on self-report methods. In order to maintain homogeneity of the sample, this study only included hospital-based haemodialysis patients. However, adherence should be considered within other treatment options, such as home-based dialysis, peritoneal dialysis, or adherence to treatment following a kidney transplant.

Despite the study limitations, these results add value to the literature on the importance of considering psychological factors on treatment adherence within clinical practice. Although a relatively low level of depression was reported on average within this sample, there is a clear relationship between depression and treatment adherence, as within previous research. Therefore, patients should be routinely screened for symptoms of depression within clinical practice in order to help improve levels of adherence. In particular, a relationship was observed between depression and fluid and dietary restrictions. These non-adherent behaviours are less likely to be observed by clinicians, as they predominately occur outside of the ward environment. Therefore,

when screening for depression, clinicians should take particular note of physiological symptoms, such as changes in appetite. The study results illustrated a negative relationship between age and treatment adherence. Services should pay particular attention to younger patients, who are more likely to be non-adherent to treatment and may need more support in managing their treatment regimens.

The results of the study illustrated that attachment styles appear to be predictive of similar proportions of variance in adherence as depression and age. Although the results did not illustrate attachment as significantly predictive of variance in adherence independently, the results justify the need for further research and that a cautionary approach should be taken by services to consider attachment styles. Although the results are not strong enough to suggest that attachment should be routinely measured, services should be particularly mindful when patients present with traits of fearful-secure attachment, such as reluctance to access support and belief that they are unworthy of care. Given the association between depression and insecure attachment, it is plausible that, if depression can be identified and appropriate interventions provided, the impact of traits of insecure attachment on adherence may lessen. Therefore, the need for renal psychologists within services is supported. As previous research has illustrated the importance of the patient-doctor relationship in treatment outcomes, characteristics of insecure-fearful attachments should be considered when developing therapeutic relationships with patients.

Conclusion

In summary, the results of this study highlight the important role of age and depression within ESRD treatment adherence and justifies the need for further exploration of attachment styles in future research. However, a number of study limitations, such as sample size and self-report

methodology, should be considered when interpreting the findings. Services should consider routinely screening for symptoms of depression, in order to improve treatment outcomes. Although the role of attachment in adherence is not completely clear from the results of this study, there is some evidence to suggest that attachment styles could be considered with caution by services. Future research should consider the role of attachment in other forms of ESRD treatment, such as peritoneal dialysis and post-kidney transplant care.

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Appendicies

Appendix 1: ESRD Adherence Questionnaire

Appendix 2: Patient Health Questionnaire – (PHQ-9)

Appendix 3: Generalised Anxiety Disorder – (GAD-7)

Appendix 4: Relationship Questionnaire – (RQ)

Appendix 5: Relationship Scale Questionnaire – (RSQ)

Appendix 6: Ethics Submission

1. IRAS Form
2. Research Protocol
3. Participant Information Sheet - English
4. Participant Information Sheet – Welsh
5. Nursing Information Sheet – English
6. Nursing Information Sheet – Welsh
7. Consent Form
8. GP Notification Letter – English
9. GP Notification Letter - Welsh
10. REC Approval Letter
11. R&D Approval Letter
12. Bangor University Ethical Approval

Appendix 7: Outlier analysis

Appendix 1 - End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ)

These questions will ask about your survey asks for your dialysis treatment schedule and about medical recommendations related to medication, diet, and fluid intake. Please answer every question by ticking the appropriate box. If you are unsure about how to answer, please choose one best answer that applies to you.

1. *During the last month, **how many times** have you **shortened** your dialysis time?*

□ Not applicable: I have not shortened my dialysis time(1)
□ Once(2)
□Twice
□Three times
□Four to five times
□Other (Specify frequency):_____

2. *During the last month, when your dialysis treatment was shortened, what was the **average number of minutes?***

□ Not applicable: I have not shortened my dialysis time
□ Less than 10 minutes or 10 minutes
□ 11 to 20 minutes
□ 21 to 30 minutes
□ More than 31 minutes
□ Other (Specify)
(If you need to write two or more different time because you shortened dialysis more than once, please use this space):

3. *What was the main **reason** you have **shortened** your dialysis treatment?*

□ Not applicable: I have not shortened my dialysis time
□ Cramping
□ Bathroom use
□ Restlessness
□ Low blood pressure
□ Access clotted (graft, fistula, or catheter)
□ Medical appointment
□Personal business or emergency
□Work schedule
□Transportation problems
□ Staff decision (**Why? Please explain:** For example, poor blood flow, clotting dialyzer, machine malfunction, etc.): _____
□ Did not feel like staying
□ Other (Please specify): _____

4. *During the last month, how many **dialysis treatments** did you **miss** completely?*

□ No treatments were missed
□ One
□ Two
□ Three
□ Four or more

5. *What was the main **reason** you missed your **dialysis treatment** last month?*

□ Not applicable: I did not miss any treatment
□ Transportation problesms
□ I had other things to do
□ Haemodialysis access (graft, fistula, or catheter clotted)
□ Medical appointment
□I was in hospital for other reasons
□ I forgot
□ Other (Specifiy): _____

6. *During the past week, **how often** have you missed your **prescribed medication**?*

□ I never miss my medication
□ Not very often
□ About half of the time
□ Most of time
□ All of the time

7. *What was the main reason for not taking your prescribed **medication** this past week?*

□ Not applicable: I did not miss medicines
□Forgot to take medicines
□Forgot to get a new perscription
□Inconvenience
□I was in hospital
□Side effects
□ Other: _____

8. During the *past week*, how often have you followed the ***fluid restriction*** recommendations?
□All of the time
□Most of the time
□About half of the time
□Very seldom
□None of the time

*9. During the past week, how many times have you followed the **diet** recommendations?*
□All of the time
□Most of the time
□About half of the time
□Very seldom
□None of the time

Appendix 2

Patient Health Questionnaire—PHQ-9

A. Over the last **2 weeks**, how often have you been bothered by any of the following problems? Please tick the box that best applies to you for each question.

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	❑	❑	❑	❑
2. Feeling down, depressed, or hopeless	❑	❑	❑	❑
3. Trouble falling/staying asleep, or sleeping to much	❑	❑	❑	❑
4. Feeling tired or having little energy	❑	❑	❑	❑
5. Poor appetite or over eating	❑	❑	❑	❑
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	❑	❑	❑	❑
7. Trouble concentrating on things, such as reading the newspaper or watching television	❑	❑	❑	❑
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	❑	❑	❑	❑
9. Thoughts that you would be better off dead or of hurting yourself in some way	❑	❑	❑	❑
	Total Score: _____			

B. If you have been bothered by any of the 9 problems listed above, please answer the following:

How difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat Difficult	Very Difficult	Extremely Difficult
❑	❑	❑	❑

Appendix 3

GAD-7 Scale

A. Over the last **2 weeks**, how often have you been bothered by any of the following problems? Please tick the box that best applies to you for each question.

	Not at all	Several days	More than half the days	Nearly every day
7. Feeling nervous, anxious or on edge	❑	❑	❑	❑
8. Not being able to stop or control worrying	❑	❑	❑	❑
9. Worrying too much about different things	❑	❑	❑	❑
10. Trouble relaxing	❑	❑	❑	❑
11. Being so restless that it's hard to sit still	❑	❑	❑	❑
12. Becoming easily annoyed or irritable	❑	❑	❑	❑
10. Feeling afraid as if something awful might happen	❑	❑	❑	❑
	Total Score: _____			

B. If you have been bothered by any of the problems listed above, please answer the following:

How difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat Difficult	Very Difficult	Extremely Difficult
❑	❑	❑	❑

Appendix 4

RELATIONSHIP QUESTIONNAIRE

1. Following are descriptions of four general relationship styles that people often report. Please read each description and CIRCLE the letter corresponding to the style that best describes you or is closest to the way you generally are in your close relationships.

A. It is easy for me to become emotionally close to others. I am comfortable depending on them and having them depend on me. I don't worry about being alone or having others not accept me.

B. I am uncomfortable getting close to others. I want emotionally close relationships, but I find it difficult to trust others completely, or to depend on them. I worry that I will be hurt if I allow myself to become too close to others.

C. I want to be completely emotionally intimate with others, but I often find that others are reluctant to get as close as I would like. I am uncomfortable being without close relationships, but I sometimes worry that others don't value me as much as I value them.

D. I am comfortable without close emotional relationships. It is very important to me to feel independent and self-sufficient, and I prefer not to depend on others or have others depend on me.

2. Now please rate each of the following relationship styles according to the *extent* to which you think each description corresponds to your general relationship style.

A. It is easy for me to become emotionally close to others. I am comfortable depending on them and having them depend on me. I don't worry about being alone or having others not accept me.

Not at all like me			**Somewhat like me**		**Very much like me**	
1	**2**	**3**	**4**	**5**	**6**	**7**

B. I am uncomfortable getting close to others. I want emotionally close relationships, but I find it difficult to trust others completely, or to depend on them. I worry that I will be hurt if I allow myself to become too close to others.

Not at all like me			**Somewhat like me**		**Very much like me**	
1	**2**	**3**	**4**	**5**	**6**	**7**

C. I want to be completely emotionally intimate with others, but I often find that others are reluctant to get as close as I would like. I am uncomfortable being without close relationships, but I sometimes worry that others don't value me as much as I value them.

Not at all like me			Somewhat like me		Very much like me	
1	**2**	**3**	**4**	**5**	**6**	**7**

D. I am comfortable without close emotional relationships. It is very important to me to feel independent and self-sufficient, and I prefer not to depend on others or have others depend on me.

Not at all like me			Somewhat like me		Very much like me	
1	**2**	**3**	**4**	**5**	**6**	**7**

Appendix 5

RSQ

Please read each of the following statements and rate the extent to which you believe each statement best describes your feelings about close relationships.

		Not at all like me		Somewhat like me		Very much like me
1.	I find it difficult to depend on other people.	1	2	3	4	5
2.	It is very important to me to feel independent.	1	2	3	4	5
3.	I find it easy to get emotionally close to others.	1	2	3	4	5
4.	I want to merge completely with another person.	1	2	3	4	5
5.	I worry that I will be hurt if I allows myself to become too close to others.	1	2	3	4	5
6.	I am comfortable without close emotional relationships.	1	2	3	4	5
7.	I am not sure that I can always depend on others to be there when I need them.	1	2	3	4	5
8.	I want to be completely emotionally intimate with others.	1	2	3	4	5
9.	I worry about being alone.	1	2	3	4	5
10.	I am comfortable depending on other people.	1	2	3	4	5
11.	I often worry that romantic partners don't really love me.	1	2	3	4	5
12.	I find it difficult to trust others completely.	1	2	3	4	5
13.	I worry about others getting too close to me.	1	2	3	4	5
14.	I want emotionally close relationships.	1	2	3	4	5
15.	I am comfortable having other people depend on me.	1	2	3	4	5
16.	I worry that others don't value me as much as I value them.	1	2	3	4	5
17.	People are never there when you need them.	1	2	3	4	5
18.	My desire to merge completely sometimes scares people away.	1	2	3	4	5
19.	It is very important to me to feel self-sufficient.	1	2	3	4	5

	Not at all like me				Very much like me
20. I am nervous when anyone gets too close to me.	1	2	3	4	5
21. I often worry that romantic partners won't want to stay with me.	1	2	3	4	5
22. I prefer not to have other people depend on me.	1	2	3	4	5
23. I worry about being abandoned.	1	2	3	4	5
24. I am somewhat uncomfortable being close to others.	1	2	3	4	5
25. I find that others are reluctant to get as close as I would like.	1	2	3	4	5
26. I prefer not to depend on others.	1	2	3	4	5
27. I know that others will be there when I need them.	1	2	3	4	5
28. I worry about having others not accept me.	1	2	3	4	5
29. Romantic partners often want me to be closer than I feel comfortable being.	1	2	3	4	5
30. I find it relatively easy to get close to others.	1	2	3	4	5

Appendix 6 – Ethics Submission

NHS REC Form | Reference: 16/WA/0244 | IRAS Version 5.3.1

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Psychological Factors of Treatment Adherence in Renal Failure

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

(●) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

☐ England
☐ Scotland

☑ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◯ England
◯ Scotland
◉ Wales
◯ Northern Ireland
◯ This study does not involve the NHS

4. Which applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

☐ IRAS Form
☑ NHS/HSC Research and Development offices
☐ Social Care Research Ethics Committee
☑ Research Ethics Committee
☐ Confidentiality Advisory Group (CAG)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

5. Will any research sites in this study be NHS organisations?

◉ Yes ◯ No

6. Do you plan to include any participants who are children?

◯ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

◯ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

◯ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

(●) Yes ( ) No

Please describe briefly the involvement of the student(s):
The proposed research is being undertaken as part of the Doctorate in Clinical Psychology (DClinPsy) award. The student involved is employed by Betsi Cadwaladr University Health Board as a Trainee Clinical Psychologist. The trainee will be involved in all aspects of the study including recruitment, data collection, analysis and write-up.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

(●) Yes ( ) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (●) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

( ) Yes (●) No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

NHS Health Research Authority

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Psychological Factors of Treatment Adherence in Renal Failure

Please complete these details after you have booked the REC application for review.

REC Name:
Wales REC 5

REC Reference Number:
16/WA/0244

Submission date:
28/07/2016

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Treatment Adherence in End-Stage Renal Disease: Exploring Attachment Styles and Mood as predictors.

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Miss	Jessica	Gordon
Address	North Wales Clinical Psychology Programme		
	Brigantia Building, 43 College Road		
	Bangor, Gwynedd		
Post Code	LL57 2DG		
E-mail	psp4fc@bangor.ac.uk		
Telephone	01248388365		
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate in Clinical Psychology (DClinPsy)

Name of educational establishment:
Bangor University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Beth	Parry-Jones
Address	Renal Unit Glan Clwyd Hospital Sarn Lane, Rhyl		
Post Code	LL18 5UJ		
E-mail	blparry-jones@tiscali.co.uk		
Telephone	01745 445655		
Fax			

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Paul	Gardner
Address	Renal Service Ysbyty Gwynedd Penrhosgarnedd, Bangor, Gwynedd		
Post Code	LL57 2PW		
E-mail	paul.gardner@wales.nhs.uk		
Telephone	01248 363469		
Fax			

Academic supervisor 3

	Title	Forename/Initials	Surname
	Dr	Mike	Jackson
Address	North Wales Clinical Psychology Programme 43 College Road, Bangor University Bangor, Gwynedd		
Post Code	LL57 2DG		
E-mail	Mike.Jackson@bangor.ac.uk		
Telephone	01248388746		
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Miss Jessica Gordon	☑ Dr Beth Parry-Jones

☑ Dr Paul Gardner

☐ Dr Mike Jackson

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

◉ Student

○ Academic supervisor

○ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Miss	Jessica	Gordon
Post	Trainee Clinical Psychologist		
Qualifications	BSc (Hons) Criminology and Psychology, Liverpool John Moores University, 2011.		
Employer	Betsi Cadwaladr University Health Board (BCUHB)		
Work Address	North Wales Clinical Psychology Programme Brigantia Building, Bangor University Bangor, Gwynedd		
Post Code	LL57 2DG		
Work E-mail	psp4fc@bangor.ac.uk		
* Personal E-mail			
Work Telephone	01248372751		
* Personal Telephone/Mobile			
Fax			

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Mr	Hefin	Francis
Address	School of Psychology Brigantia Building, Penrallt Road Bangor University, Bangor		
Post Code	LL57 2AS		
E-mail	h.francis@bangor.ac.uk		
Telephone	01248388339		
Fax	01248382599		

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	N/A
Sponsor's/protocol number:	N/A
Protocol Version:	1
Protocol Date:	08/02/2016
Funder's reference number:	N/A
Project website:	N/A

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Haemodialysis is a form of dialysis treatment provided for patients who have end-stage renal disease (ESRD). A patient's regime whilst receiving haemodialysis can be severely restrictive, including minimal fluid intake, avoidance of foods that are high in sodium, potassium and phosphate and adhering to medication. Patients attend dialysis three to four times per week, with each session taking place for approximately four hours. Although patients are aware that deviation from their regime can result in adverse physical symptoms or fatal consequences, non-adherence in patients with ESRD is a widespread problem (Schneider, Friend & Whitaker, 1991).

Research has begun to investigate psychological risk factors associated with non-adherence. Symptoms of depression and anxiety have been found to be significant predictors of treatment adherence in numerous chronic health conditions, including renal disease (DiMatteo, Lepper & Croghan, 2000; Cukor, et al., 2009). In addition, factors such as a patient's social support and relationships have been found to be associated with treatment non-adherence in ESRD, leading to increased mortality rate, (Kutner et al., 2002)

Within other areas of research on alternative chronic health conditions, such as diabetes, attachment styles, including how a patient develops and maintains relationships with family, friends and professionals, can significantly influence their adherence to treatment (Ciechanowski, Katon, Russo & Walker, 2001). Given that a number of studies acknowledge the importance of family, social and professional relationships in ESRD treatment adherence, looking at attachment style may be beneficial in understanding patterns in adherence. Therefore, the aim of this study is to assess how a patient's attachment style can influence their treatment adherence in ESRD. Given that other studies have also shown mood to be useful in predicting treatment adherence, depression and anxiety will also be assessed to see whether a combination of these factors may predict variance in treatment adherence.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study*

and say how you have addressed them.

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Design and Procedures:

The study will apply a cross-sectional, correlational design. Correlation coefficients will be calculated to explore associations between anxiety, depression, attachment and adherence to ESRD haemodialysis treatment.

In the first instance, the investigator will attend Renal Dialysis Units situated across Betsi Cadwaladr University Health Board to inform the Renal Nursing Team of the project. Jessica will provide the team with all the necessary information regarding the study and answer any questions they may have. Jessica will circulate a Nursing Information Sheet to all the Nursing Staff so that they have a hard copy of the information relevant to the study. Jessica will then provide the Nursing Team with Participant Information Sheets and Consent Forms and will ask the staff to approach the patients within their service to inform them of the study and provide them with the associated information sheet. Should the participants have any additional questions regarding the study, the nursing staff will be equipped to answer these questions, but will be provided with Jessica's contact details and encouraged to contact her if any additional questions may arise. The participants will be asked to complete the Participant Consent Form if they agree to take part in the study and return the consent form to the Nursing Team. Once all consent forms have been obtained, Jessica will arrange an appropriate time to attend the ward to collect the forms. The nursing staff will introduce Jessica to the patients who have agreed to take part in the study during their regular hemodialysis treatment sessions on the ward. Jessica will introduce herself to the participants and re-emphasis the necessary elements of the study, including procedure, confidentiality and right to withdraw. The participants will then be asked to fill out the questionnaires and return them to Jessica or a member of nursing staff on the ward. Jessica will remain on the ward throughout completion of the questionnaires, in order to answer any questions that the participants may have or assist in any way necessary.

Participants will be asked to fill in self-report questionnaires related to symptoms of anxiety and depression, attachment styles and adherence to treatment. This will take place at their renal dialysis unit during one of their routine haemodialysis sessions and will take approximatley 45 minutes to complete. The Chief Investigator (CI) will remain on the ward with the patients to support them with any queries or difficulties they have whilst filling in the questionnaires. Participants will be recruited from NHS Renal Dialysis Units across North Wales.

Risks, Burdens and Benefits:

Whilst no direct risk of offence/distress to participants is anticipated, participants will be asked to fill out questionnaires which ask details about their current mood, including symptoms of anxiety and depression, and details of their relationships with others. This can occasionally bring distressing feelings to the front of one's mind. Participants will be made aware of this before consenting to participate in the study. Participants are advised to alert the investigator or a member of the renal nursing team if they become distressed as a result of taking part in the study and will be reminded that they can withdraw at any time. If required, the investigator will contact the participants to discuss any distress caused and in extreme cases, will advise the participant to contact their GP. With permission from the participant, the investigator can write to their GP or can make a referral to the Renal Psychology Service for an assessment.

If results of these questionnaires indicate that participants are experiencing moderate to severe levels of psychological distress, indicated by the numerical clinical cut offs of each questionnaire, Jessica will discuss this with Dr Beth Parry-Jones and Dr Paul Gardner and will contact the participant to inform them of this. They will then be referred to their GP or the Renal Psychology Service for assessment with their permission.

Benefits of taking part include contributing to the scientific evidence base, which may help to inform patient care and impact upon positive service development within renal care.

Burdens may include time spent participating in the study and the mental effort required.

Confidentiality:

Only members of the participant's care team at their Renal Service will approach the participant regarding taking part in the study in the initial stages. If the participant is interested in taking part, they will be asked to complete a consent form which will be returned to the investigator by the Renal Nursing Team. It is only at this stage that the investigator will be made aware of a participant's identifying information, which will be limited to their name and the Renal Service

that they receive treatment from. Once consent has been obtain, the participant will be assigned a unique identification number which will be used in all electronically stored data. Any identifiable information will be kept locked at the Renal Psychology Service at all times. Anonymised electronically stored data will be kept on the NHS database and will be password protected. The investigator will also have access to an encrypted memory stick provided by Bangor University. The investigator will comply with all BCUHB data protection policies and all data will be destroyed after a significant time period. All analysed data will be annonymised via the participant's unique identification number.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☑ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The main aim of this study is to determine if psychological factors, including symptoms of depression, anxiety and attachment styles, influence patterns in treatment adherence for patients with End Stage Renal Failure. Specifically, the first hypothesis predicts that symptoms of anxiety and depression will be associated with poor adherence to treatment. The second hypothesis predicts that insecure attachment styles, such as difficulty developing and maintaining relationships, will be associated with poor adherence to treatment.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

Not applicable

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Haemodialysis is a form of dialysis treatment provided for patients with end-stage renal disease, whose kidneys have extremely limited functioning or no ability to function (NHS Choices, 2015). Haemodialysis allows blood to be filtered of toxins externally and returns clean blood back to the body. Alongside hemodialysis, patients must adhere to a strict diet, fluid and medication regime as part of their treatment, as well as attending haemodialysis appointments 3 to 4 times per week for several hours at a time. Patients are aware that non-adherence can result in adverse consequences to their physical health and could ultimately result in death (Vlaminck, Maes, Jacobs & Reyntjens Evers, 2001). Despite this knowledge, non-adherence to treatment is a widespread problems. A literature review combining the results of a number of non-adherence studies across the UK, Europe and the US highlighted the extent of the problem. Self-reported measures completed by patients revealed that 30-74% of patients are non-adherent to fluid intake requirements, 2-57% are non-adherent to dietary requirements, 19-99% are non-adherent to medication requirements, 0-35% skip dialysis appointments and 7-32% shorten dialysis appointments against medication recommendations (Denhaerynck et al., 2007). These statistics suggest that the level of adherence is variable and highlights the extent of non-adherence in all areas of treatment. Studies have yet to look at levels of non-adherence

specifically within a Welsh population.

Given the widespread problem and significant risks associated with non-adherence, psychological factors influencing a patient's ability or willingness to engage in treatment has been explored. However, the subject area is relatively novel within research and results are inconsistent or have not yet looked specifically at patterns within ESRD directly.

Depression has been shown to be significantly predictive of poor treatment adherence in chronic health conditions more generally, such as diabetes and cancer treatments, illustrating that patients with symptoms of depression are up to three times more likely to be non-adherent to treatment (Diamatteo, et al., 2000). Within ESRD, patients presenting with symptoms of depression have been shown to be more likely to be hospitalised, resulting in fatal consequences (Hedayat, et al, 2008), more likely to be non-adherence to medication (Cukor, et al., 2009), and more likely to have higher fluid intake (Valderrama, et al., 2002), illustrating the potential for a relationship to exist between ESRD treatment adherence and depression. However, research has yet to look more broadly at the impact of depressive symptoms on all areas of ESRD treatment, including adherence to session attendance and session length. This project offers the opportunity to explore the impact of depression on multiple areas of ESRD haemodialysis treatment.

Although research on the impact of depression on ESRD treatment has begun to show signs that a relationship may exist, understanding the relationship between symptoms of anxiety and adherence is more inconsistent, with some studies having conflicting results (Dimatteo, et al., 2000). Symptoms of anxiety can include physiological experiences, such as problems sleeping, cold or sweaty hands or feet, shortness of breath and heart palpitations. However, the physiological consequences of non-adherence to treatments can result in many of the same symptoms. Therefore, there is a lack of clarity between whether anxiety may be impacting upon non-adherence, or whether non-adherence is presenting as physiological symptoms of anxiety. Therefore, more clarity is required within this area. This project offers the opportunity to explore whether a relationship exists between anxiety, including psychological as well as physiological symptoms, and adherence to treatment.

The presence of social support within ESRD treatment has shown to be significantly predictive of good treatment adherence (Kutner et al., 2002). Given the intense nature of the medical treatment associated with ESRD, patients have a lot more contact with their nursing and medical team than in other chronic health conditions, given that they are accessing services several times a week for up to 4 hours. Therefore, it is understandable that the relationship a patient has within their care team may impact on their willingness or ability to engage in treatment. Research has begun to recognise this, indicating that the perceived patient-doctor relationship is significantly predictive of increased adherence to treatment (Kiley, Lam & Pollack, 1993). With this in mind, it may be important to consider attachment styles in relation to treatment adherence, as this directly influences a person ability to develop and maintain relationships. Research into other chronic health conditions, such as diabetes, has shown that a patients attachment style can influence their engagement in treatment and that those patients who are more likely to have a dismissive avoidant attachment styles are more likely to be non-adherent (Ciechanowski, et al., 2001). The relationship between attachment styles and treatment adherence in ESRD is yet to be considered and this project offers the opportunity to develop our understanding in this area, in order to be able to consider the importance of familial and patient-carers relationships within treatment.

The current study aims to explore depression, anxiety and attachment in relationship to treatment adherence, which is inclusive of medication, diet, fluid, session attendance and session length. It is important to generate a better understanding of the psychological factors impacting upon treatment adherence in order to enable us to tailor treatment and services more effectively to improve treatment adherence, consequently reducing the significantly physical health risks associated.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

The CI, (Jessica Gordon) will attend Renal Dialysis Units situated across Betsi Cadwaladr University Health Board to inform the Renal Nursing Team of the project. Jessica will provide the team with all the necessary information regarding the study and answer any questions they may have. Jessica will circulate a Nursing Information Sheet to all the Nursing Staff so that they have a hard copy of the information relevant to the study. Jessica will then provide the Nursing Team with Participant Information Sheets and Consent Forms and will ask the staff to approach the patients within their service to inform them of the study and provide them with the associated information sheet. Should the participants have any additional questions regarding the study, the nursing staff will be equipped to answer these questions, but will be provided with Jessica's contact details and encouraged to contact her if any additional questions may arise. The participants will be asked to complete the Participant Consent Form if they agree to take part in the study and return the consent form to the Nursing Team. Due to the significant number of participants being approached for the study, participants will be given a period of 3 weeks to consider taking part and return their consent form.

Once all consent forms have been obtained, Jessica will arrange an appropriate time to attend the ward to collect the forms. The nursing staff will introduce Jessica to the patients who have agreed to take part in the study during their regular hemodialysis treatment sessions on the ward. Jessica will introduce herself to the participants and re-emphasis the necessary elements of the study, including procedure, confidentiality and right to withdraw. The participants will then be asked to fill out five questionnaires which will ask about their mood, relationships with others and their adherence to their ESRD treatment. This is estimated to take no longer than 45 minutes. Demographics information will be obtained from the participants. Each participant will be asked to complete a number of self-report questionnaires, including the Public Health Questionnaire (PHQ9), the Generalised Anxiety Disorder Questionnaire (GAD-7), the Relationships Questionnaire (RQ), the Relationship Scales Questionnaire (RSQ) and the End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ). The questionnaires will be returned to Jessica or a member of nursing staff on the ward. Jessica will remain on the ward throughout completion of the questionnaires, in order to answer any questions that the participants may have or assist in any way necessary.

Following completion and return of the questionnaires, Jessica will score the mood questionnaires relating to anxiety and depression within a period of 2 weeks. If the scores of these questionnaires indicate that a participant is presenting with moderate to severe levels of anxiety or depression, Jessica will contact the patient in order to discuss this with them. They will be offered the opportunity to attend a assessment session with the Renal Psychology Team or Jessica can contact their GP to inform them of the concerns with permission from the participant. Alternatively, Jessica can provide them with information on anxiety and depression.

Once the results have been collated, analysed and the project is complete (approximated completion June 2017) Jessica will summarise the outcomes of the study into a debrief leaflet which will be distributed to the patients via their Renal Nursing Team. The leaflet will summarise the results of the study and will inform participants on how they can access a copy of the project in full. The Nursing Team and other members of the Renal Multidisciplinary team will also be provided with leaflets for their information.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- ☐ Design of the research
- ☐ Management of the research
- ☐ Undertaking the research
- ☐ Analysis of results
- ☐ Dissemination of findings
- ☑ None of the above

Give details of involvement, or if none please justify the absence of involvement.
Currently, there is no service user involvement. However, Bangor University Clinical Psychology Department consults with a Service User group which includes individuals accessing renal services across North Wales. I will be contacting them in the coming weeks to discuss the study and utilise any advise/suggestions they may have.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

All patients above the age of 18 who are currently receiving hemodialysis treatment within a North Wales NHS Renal Service and have been for 3 months or more, will be invited to participate in the research. This is approximately 220 participants across several services in Betsi Cadwaladr University Health Board. This will capture a heterogeneous population of individuals, both male and female, of a variety of ages and from a variety of different cultures and backgrounds.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Participants who are under the age of 18 or have been receiving haemodialysis for less than three months will be excluded from the study. Participants who are new to dialysis may appear to be non-adherent on questionnaires, but

are simply adapting to their new treatment regime and therefore will be excluded from the study. In some of the units across North Wales, renal patients who are not from the local communities may temporarily use the North Wales Renal Services if they are in holiday in the local area and require hemodialysis. However, this is inconsistent throughout the year and accounts for a very small number of patients. Should a patient on holiday be present on the ward for dialysis at the time of data collection, they will be excluded from the study. Issues to do with their adherence to treatment may be in part to do with their interactions and packages of care in their own service and therefore could be inconsistent with the packages of care provided across North Wales, which may impact upon the data collected. By only including North Wales participants, the homogeneity of the study will be increased.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Seek Consent	1		5mins	Renal Nursing Team to approach participants at their NHS Renal Dialysis Unit during a routine appointment
Public Health Questionnaire (PHQ-9)	1		5mins	Self-report by participants with support from CI at the patients specified NHS Renal Dialysis Unit during a routine appointment
Generalised Anxiety Disorder Questionnaire (GAD7)	1		5mins	Self-report by participants with support from CI at the patients specified NHS Renal Dialysis Unit during a routine appointment
Relationships Questionnaire (RQ)	1		5mins	Self-report by participants with support from CI at the patients specified NHS Renal Dialysis Unit during a routine appointment
Relationships Scales Questionnaire (RSQ)	1		10mins	Self-report by participants with support from CI at the patients specified NHS Renal Dialysis Unit during a routine appointment
End Stage Renal Disease Adherence Questionnaire (ESRD-AQ)	1		5mins	Self-report by participants with support from CI at the patients specified NHS Renal Dialysis Unit during a routine appointment

A21. How long do you expect each participant to be in the study in total?

Approximately 12 months.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Whilst no direct risk of offence/distress to participants is anticipated, participants will be asked to fill out questionnaires which ask details about there current mood, including symptoms of anxiety and depression, and details of their relationships with others. This can occasionally bring distressing feelings to the front of one's mind. Participants will be made aware of this before consenting to participate in the study. Participants are advised to alert the investigator or a member of the renal nursing team if they become distressed as a result of taking part in the study and will be reminded that they can withdraw at any time. If required, the investigator will contact the participants to discuss any distress caused and in extreme cases, will advise the participant to contact their GP. With permission

from the participant, the investigator can write to their GP or can make a referral to the Renal Psychology Service for an assessment.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

◉ Yes ○ No

If Yes, please give details of procedures in place to deal with these issues:

Whilst the study is anticipated not to involve direct risk to participants, the questionnaires will ask them to answer questions about their mood and their relationships with other, which can occasionally cause some emotional discomfort. For example, the PHQ-9 will ask participants to rate how often they have experienced thoughts that they would "be better off dead" or of hurting themselves in anyway, in the last two weeks prior to completing the questionnaire. Participants will be informed prior to providing consent to participate in the study that some questions may be uncomfortable for them and appropriate measures will be put in place should they experience significant distress as a result.

A24. What is the potential for benefit to research participants?

Whilst there is no direct benefit for participants who take part in this study, their participation has the potential to benefit people in the future by improving our knowledge base within the area of renal treatment and consequently improving the support we offer within renal services.

A26. What are the potential risks for the researchers themselves? *(if any)*

There are no potential risks identified for the researcher.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

The supervisors for the project, Dr Beth Parry-Jones and Dr Paul Gardner, have contacted the responsible Nephrology Clinician at each of the Renal Services across Betsi Cadwaladr University Health Board to inform them of the study and seek their permission to complete the project within their services. Permission has been granted from each of these services. The Chief Investigator, Jessica Gordon, will arrange to meet with the Nursing Team at each of the service to inform them of the study and provide them with Staff Information Sheets to outline the project in full. The nursing team will then approach the patients at their service during a routine haemodialysis treatment session to inform them of the project and invite them to read a patient information sheet about the research. If they are interested in taking part, the nursing staff will provide them with a consent form which will be signed and collected by the nursing staff. The staff will be equipped to answer any additional questions that participants may have prior to consenting to the project. However, any additional questions can be answer by Jessica through liaising with the nursing team. Once informed consent has been obtain, Jessica will attend the unit and be introduced to the participants by the nursing team. At this stage, Jessica will remind the participants of the study and answer any additional questions they may have. Verbal consent will then be obtained in addition to the written consent forms before administering the questionnaires.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:

Nursing staff will be asked to only approach patients who have been receiving haemodialysis for three months or

more and are above the age of 18. No other review or screening of personal information is required.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◯ Yes ◉ No

A29. How and by whom will potential participants first be approached?

The renal nursing team at each of the renal services will approach the patients at their service during a routine haemodialysis treatment session to inform them of the project and invite them to read a patient information sheet about the research. If they are interested in taking part, the nursing staff will provide them with a consent form which will be signed and collected by the nursing staff.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ◯ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

The renal nursing team at each service will approach the potential participants to inform them of the study and ask if they would be interested in taking part. They will be given a participant information sheet which details all aspects of the study which they will be invited to read. Nursing Staff will be equipped to answer any additional questions they may have and the chief investigator will remain in contact with the nursing team to answer any additional questions that arise, if necessary. If the participants are happy to participate in the study, they will be provide with a consent for to read, sign and return to the nursing team. Once consent has been sought, the chief investigator will attend each renal service to collect the consent forms and will be introduced to the participants by the nursing team on a pre-scheduled day of data collection. The chief investigator will then reiterate the aspects of the study and informed consent will be sought again verbally. The chief investigator and their supervisors will be responsible for testing and analysis once consent has been given.

If you are not obtaining consent, please explain why not.

N/A

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ◯ No

A31. How long will you allow potential participants to decide whether or not to take part?

Due to the large sampling size, participants will be given a period of three weeks to decide whether or not to take part.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Participants deemed not able to provide consent(written) will not be approached to take part in the study. Capacity to consent will be determined by the patient's treating clinician and nursing team.

As the research is taking place in Wales, all written documentation will be available bilingually. The questionnaires for the study have not been validated in Welsh and therefore will only be available in English. This will be explained to participants.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

All documentation (i.e. consent forms, participant information sheets, nursing information sheets and debrief leaflets) will be available bilingually. The questionnaires used in the study are available in English only, as no validated Welsh Translations are available.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ○ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ◉ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

The study questionnaire will be completed at one time point. If consent given before this time is withdraw at this point then the participant will not be included in the study, as requested. If the participant no longer has the capacity to consent to participate in the study then they will no be asked to complete the questionnaires.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☐ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☐ Manual files (includes paper or film)
  - ☑ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers

☐ University computers

☐ Private company computers

☑ Laptop computers

Further details:
Electronic data will be password protected and stored on the NHS computer database. Electronic data will be anonymised on a secure NHS database computer. This will only be accessible to the Chief Investigator. In addition, the Chief Investigator will have access to an encrypted memory stick, provided by Bangor University, where the anonymised electronic data can also be stored in order to be analyzed at the North Wales Clinical Psychology Department at Bangor University on the password protected computer systems available at the department or the CI's own personal laptop which is password protected. Data will only be accessed on the Bangor University computers and personal laptop once the data has been fully anonymised and is unidentifiable. Following completion of the study any data stored on the memory stick will be deleted and the memory stick will be returned to the department. The chief investigator will adhere to BCUHB data protection policies. Upon completion of the project, all data will remain at the Renal Psychology Service and, inline with BCUHB policy, will be destroyed after a significant period of time.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Each participant will be assigned a unique identification number, which will be used for all paper and electronic data collected. Paper copies of questionnaire data will be stored at the Renal Psychology Service and will only include their identification number. No other identifying information will be recorded on questionnaires or electronic data. A list of identification numbers and corresponding identifying information (i.e. participants names) will be kept at the relevant Renal Service base securely, as it will only need to be accessed if a participant needs to be contacted for clinical reasons, such as scoring highly on a mood questionnaire. This will only be accessible to the Chief Investigator and their supervisors. Electronic data will be stored on a password protected document on NHS computer system. In addition, the Chief Investigator will have access to an encrypted memory stick, provided by Bangor University, where the anonymised electronic data can also be stored in order to be analyzed at the North Wales Clinical Psychology Department at Bangor University on the password protected computer systems available at the department or the CI's own personal laptop which is password protected. Data will only be accessed on the Bangor University computers and personal laptop once the data has been fully anonymised and is unidentifiable. Raw data, such as questionnaires, will be retained and subsequently destroyed after a significant period of time, in line with BCUHB data protection policies.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Only the research team, Jessica Gordon, Dr Parry-Jones and Dr Gardner, will have access to participants personal data during the study.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

○ Less than 3 months

◉ 3 – 6 months

○ 6 – 12 months

○ 12 months – 3 years

○ Over 3 years

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives

for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◉ Yes ○ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

A49-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?

◉ Yes ○ No

It should be made clear in the participant's information sheet if the GP/health professional will be informed.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
As the research is being undertaken for a Doctorate qualification, it will not be registered on a public database.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☐ Publication on website

☐ Other publication

☐ Submission to regulatory authorities

☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators

☐ No plans to report or disseminate the results

☑ Other (please specify)

A participant newsletter which outlines the results of the study will be distributed to participants who took part in the research once the study is complete.

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
A study findings summary sheet which outlines the results of the study will be distributed to participants who took part in the research once the study is complete. This will also be accessible to the Renal Teams.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

☐ Independent external review

☐ Review within a company

☐ Review within a multi−centre research group

☑ Review within the Chief Investigator's institution or host organisation

☐ Review within the research team

☑ Review by educational supervisor

☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The scientific quality of the research has been assessed by the research team at the North Wales Clinical Psychology Programme and was deemed as a suitable study for the purposes of the doctoral programme. The study has been reviewed by the School of Psychology Ethics Panel prior to the submission of this form and approval has been granted.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

☐ Review by independent statistician commissioned by funder or sponsor

☐ Other review by independent statistician

☐ Review by company statistician

☐ Review by a statistician within the Chief Investigator's institution

☐ Review by a statistician within the research team or multi−centre group

☑ Review by educational supervisor

☐ Other review by individual with relevant statistical expertise

☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not

required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	Mike	Jackson
Department	North Wales Clinical Psychology Programme - Research Team		
Institution	School of Psychology		
Work Address	North Wales Clinical Psychology Programme 43 College Road, Bangor University Bangor, Gwynedd		
Post Code	LL57 2DG		
Telephone	01248388746		
Fax			
Mobile			
E-mail	Mike.Jackson@bangor.ac.uk		

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

As the study is correlational in nature, with two hypotheses, the primary outcome measures are a) self-report clinical measures examining clinical symptomatology (i.e. anxiety and depression) b) measures assessing attachment styles and c) measures assessing adherence to end-stage renal disease treatment.

A58. What are the secondary outcome measures?*(if any)*

Not applicable.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 220

Total international sample size (including UK):

Total in European Economic Area:

Further details:
In order to increase validity of the studies outcome data, the research aims to recruit all patients currently receiving haemodialysis at a NHS renal service within BCUHB. In order for the statistical analysis to achieve a medium effect size, a minimum of 29 participants will be required for the study.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The sample size was determined pragmatically, based upon the number of patients receiving haemodialysis treatment across BCUHB.

However, a formal power analysis was conducted to inform a minimal requirement for sampling. In order to achieve a medium effect size within cross-sectional correlation design, a sample size of 29 participants will be required as a minimum, in ordered to achieve a more statistically reliable result. (α=0.05, β=0.2 and r=0.5).

A61. Will participants be allocated to groups at random?

◯ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Data will be analysed using SPSS. Correlations will be used to investigate associations between adherence to treatment (identified by the adherence questionnaire) and attachment styles and clinical symptomatology (identified through the mood and attachment questionnaires).

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Paul	Gardner
Post Qualifications			
Employer	Betsi Cadwaladr University Health Board		
Work Address	Renal Service Ysbyty Gwynedd Penrhosgarnedd, Bangor, Gwynedd		
Post Code	LL57 2PW		
Telephone	01248 363469		
Fax			
Mobile			
Work Email	paul.gardner@wales.nhs.uk		

	Title	Forename/Initials	Surname
	Dr	Beth	Parry-Jones
Post Qualifications			
Employer	Betsi Cadwaladr University Health Board		
Work Address	Renal Unit Glan Clwyd Hospital Sarn Lane, Rhyl		
Post Code	LL18 5UJ		
Telephone	01745 445655		
Fax			
Mobile			
Work Email	beth.parry-jones@wales.nhs.uk		

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status: ◯ NHS or HSC care organisation

◉ Academic

◯ Pharmaceutical industry

◯ Medical device industry

◯ Local Authority

◯ Other social care provider (including voluntary sector or private organisation)

◯ Other

Commercial status:

If Other, please specify:

Contact person

Name of organisation	School of Psychology, Bangor University
Given name	Hefin
Family name	Francis
Address	School of Psychology, Adeilad Brigantia, Penrallt Road, Bangor University
Town/city	Bangor
Post code	LL57 2AS
Country	UNITED KINGDOM
Telephone	01248388339
Fax	01248382599
E-mail	h.francis@bangor.ac.uk

Is the sponsor based outside the UK?

◯ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☐ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☑ No application for external funding will be made

What type of research project is this?

◯ Standalone project

◯ Project that is part of a programme grant

◯ Project that is part of a Centre grant

◉ Project that is part of a fellowship/ personal award/ research training award

◯ Other

Other – please state:

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

◯ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Dr	Rossela	Roberts
Organisation	Betsi Cadwaladr University Health Board		
Address	Clinical Academic Office, Clinical School Ysbyty Gwynedd		
Post Code	LL57 2PW		
Work Email	rossela.roberts@wales.nhs.uk		
Telephone	01248384877		
Fax	01248384877		
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/06/2016
Planned end date: 01/06/2017
Total duration:
Years: 1 Months: 0 Days: 1

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☐ England
- ☐ Scotland
- ☑ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 4

Does this trial involve countries outside the EU?

◯ Yes ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

- ☐ NHS organisations in England
- ☑ NHS organisations in Wales 1

- ☐ NHS organisations in Scotland
- ☐ HSC organisations in Northern Ireland
- ☐ GP practices in England
- ☐ GP practices in Wales
- ☐ GP practices in Scotland
- ☐ GP practices in Northern Ireland
- ☐ Joint health and social care agencies (eg community mental health teams)
- ☐ Local authorities
- ☐ Phase 1 trial units
- ☐ Prison establishments
- ☐ Probation areas
- ☐ Independent (private or voluntary sector) organisations
- ☐ Educational establishments
- ☐ Independent research units
- ☐ Other (give details)

Total UK sites in study: 1

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:* in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland**

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- ☐ NHS indemnity scheme will apply (NHS sponsors only)
- ☑ Other insurance or indemnity arrangements will apply (give details below)

Bangor University is a member of UM Associations Limited which certifies insurance for this project. A copy of the insurance document can be found in the supporting documentation.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- ☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- ☑ Other insurance or indemnity arrangements will apply (give details below)

Bangor University is a member of UM Associations Limited which certifies insurance for this project. A copy of the

insurance document can be found in the supporting documentation.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- [x] NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- [ ] Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	Betsi Cadwaladr University Health Board	Title	Dr
Department name	Renal & Diabetes Centre, Ysbyty Glan Clwyd	First name/ Initials	Beth
Street address	Sarn Lane	Surname	Parry-Jones
Town/city	Bodelwyddan, Rhyl		
Post Code	LL18 5UJ		
Institution name	Betsi Cadwaladr University Health Board	Title	Dr
Department name	Renal & Diabetes Centre, Wrexham Maelor	First name/ Initials	Beth
Street address	Croesnewydd Road	Surname	Parry-Jones
Town/city	Wrexham		
Post Code	LL13 7TD		
Institution name	Betsi Cadwaladr University Health Board	Title	Dr
Department name	Renal Unit	First name/ Initials	Paul
Street address	Penrhosgarnedd	Surname	Gardner
Town/city	Bangor, Gwynedd		
Post Code	LL57 2PW		
Institution name	Betsi Cadwaladr University Health Board	Title	Dr
Department name	Renal Unit	First name/ Initials	Paul
Street address	Ysbyty Alltwen, Penmorfa, Porthmadog	Surname	Gardner
Town/city	Gwynedd		
Post Code	LL49 9RR		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

◉ Chief Investigator

- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Miss Jessica Gordon on 27/07/2016 09:32.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	Bangor University
Email:	psp4fc@bangor.ac.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Mr Hefin Francis on 27/07/2016 11:31.

Job Title/Post:	School Manager for Psychology
Organisation:	Bangor University
Email:	h.francis@bangor.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Mike Jackson on 28/07/2016 08:55.

Job Title/Post:	clinical psychologist
Organisation:	bcuhb
Email:	mike.jackson@wales.nhs.uk

Academic supervisor 2

This section was signed electronically by Dr Paul Gardner on 28/07/2016 11:38.

Job Title/Post:	Consultant Clinical Psychologist - Renal & Pain Management Services (West)
Organisation:	BCUHB
Email:	paul.gardner@wales.nhs.uk

Academic supervisor 3

This section was signed electronically by Dr Beth Parry-Jones on 28/07/2016 13:48.

Job Title/Post:	Consultant Clinical Psychologist
Organisation:	BCUHB
Email:	beth.parry-jones@wales.nhs.uk

Research Protocol

1. Project Title

Treatment Adherence in End-Stage Renal Disease: Exploring Attachment Styles and Mood as predictors.

2. Supervisors

This project will be supervised by Dr Beth Parry-Jones and Dr Paul Gardner, Consultant Clinical Psychologists working with the North Wales Renal Service. Both supervisors will be providing supervision throughout the project, including access to the renal services that they currently work within.

3. Background

Haemodialysis is a form of dialysis treatment provided for patients who have end-stage renal disease (ESRD) and involves diverting blood into an external machine, where it is filtered before being returned to the body (NHS Choices, 2015). Haemodialysis is a therapy in which adherence to diet, fluid and medication intake are critically important in determining continuing survival and preserving health (Agashua, Lyle, Livesley, Slade, Winney & Irwin, 1997).

A patient's regime whilst receiving haemodialysis can be severely restrictive, including the restriction of fluid to 750mls to 1500mls per day, depending on size and weight, as well as restricting foods that are high in sodium, potassium and phosphate. Patients are required to attend regular dialysis sessions at their renal clinic between three to four times per week, with each session taking place usually for four hours. The regime for treatment is very complex, however, patients are aware that if they were to deviate from their prescribed regime it can result in adverse physical symptoms or fatal consequences, (Vlaminck, Maes, Jacobs, Reyntjens & Evers, 2001). Despite the associated risks, non-adherence in patients with ESRD is a widespread problem (Schneider, Friend & Whitaker, 1991).

Due to the significant risks associated with non-adherence, psychological researchers have begun to investigate the psychological and social factors that may contribute to the management of non-adherence in order to better support patients and prevent a deterioration of health. Depression has been found to be a significant predictor of treatment adherence in numerous chronic health conditions, including renal disease (DiMatteo, Lepper & Croghan, 2000). DiMatteo, Lepper and Croghan (2000) completed a meta-analysis which looked at the effect of anxiety and depression of patients being treatment for long term health conditions in relation to their adherence to treatment. The study analysed the results of twelve articles about depression and thirteen articles about anxiety and treatment adherence. The results suggested that although there was little evidence to support anxiety as a predictor of treatment non-adherence, the relationship between depression and non-adherence was highly significant (DiMatteo, Lepper & Croghan, 2000). Following this, studies have looked more specifically at the relationship between depression and treatment adherence in patients with renal disease. Cukor, et al., (2009) looked at the relationship between depression and self-

reported treatment adherence and found that depression was a significant risk factor in non-adherence to treatment during haemodialysis, as well as following a kidney transplant.

Research has also looked at patient's social support and relationships with others as a predictor for treatment non-adherence in ESRD. Kutner et al, (2002) looked at a variety of psychosocial predictors of ESRD treatment adherence and found that burden of kidney disease, including how much they feel a burden to others and social support were predictive of treatment non-adherence, as well as others factors including perceived control over future health and negative effect of kidney disease on daily life. Similarly, Kimmel et al., (1998) looked at the relationship between depression, perceptions of illness and social support as predictors of treatment non-adherence in ESRD. The results suggested that low levels of perceived social support were associated with treatment non-adherence, leading to increased mortality rate. In addition, Kiley, Lam and Pollak (1993) found perceived social and family support to be positively correlated with treatment adherence in ESRD. However, in addition to this, they found that the relationship between that patient and their Doctor to also be predictive of adherence, as they reported that a better relationship with their Doctor and the perception that the control of their health was in their hands was positively correlated with treatment adherence. In summary, research suggests that relationship family, social and professional relationships are predictive of treatment adherence in ESRD.

Social, familial and professional relationship have also been researched in relationship to adherence in other chronic health conditions, and more specifically, research has looked at the relationship between adherence and attachment styles. Ciechanowski, Katon, Russo and Walker (2001) looked at the relationship between diabetes treatment adherence and attachment styles, including secure, insecure dismissive and insecure preoccupied styles. The results suggested that those patient with a dismissive insecure attachment style had poor treatment adherence.

Research on treatment adherence in ESRD is yet to look at the relationship between attachment styles and patterns in treatment adherence. Given that many studies have now acknowledged the importance of family, social and professional relationships, looking at attachment style may be beneficial in understanding patterns in adherence. Therefore, the aim of this study is to assess secure attachment and a variety of insecure attachment styles in relationship to treatment adherence in ESRD. Given that mood studies have also shown mood to be useful in predicting treatment adherence, mood will also be assessed to see whether a combination of these factors may predict variance in treatment adherence.

4. Participant Recruitment

The participants will be recruited from the three renal services that are based in North Wales Wrexham Maelor Hospital, Glan Clwyd Hospital, Ysbyty Gwynedd and Alltwen Hospital. Information sheets will be distributed by the renal nurses to the patients receiving haemodialysis to inform them of the study. This will include approximately 220 patients. The information sheets will provide the patients with details on what will be taking place and will ask them whether they would be willing to take part in the study and if so, will be asked to provide their informed consent by signing the information sheet. The consent forms should be returned within 3 weeks of distribution. Previous research conducting within this population suggests that

return rates vary between 62.4% and 87.04% (Ciechanowski, Katon, Russo and Walker, 2001; Vlaminck, Maes, Jacobs, Reyntjens & Evers, 2001; Schneider, Friend & Whitaker, 1991; Kutner et al, 2002).

In some of the units across North Wales, renal patients who are not from the local communities may temporarily use the North Wales Renal Services if they are in holiday in the local area and require haemodialysis. However, this is inconsistent throughout the year and accounts for a very small number of patients. Should a patient on holiday be present on the ward for dialysis at the time of data collection, they will be excluded from the study. Issues to do with their adherence to treatment may be in part to do with their interactions and packages of care in their own service and therefore could be inconsistent with the packages of care provided across North Wales, which may impact upon the data collected. By only including North Wales participants, the homogeneity of the study will be increased.

5. Design and Procedures

Once the participants have been identified by providing their informed consent they will be approached whilst receiving their dialysis treatment, which usually takes place at their local renal centre three times per week, for up to four hours. The participants who have provided their consent will be identified by the nurses on the ward and will be introduced to the researcher. They will be reminded of the study and further verbal consent will be obtained. If the participant is still in agreement, they will be provided with some questionnaires to fill out, which will take approximately 10 minutes. The researcher will remain on the dialysis ward while the participants complete the questionnaires, in order to answer any questions they may have or provide support for those who have literacy or visual difficulties. Once completed, the questionnaires will be submitted into a collection box. Each participant will be given a participant identification number which corresponds to their consent forms and completed questionnaires in order for the participant to be identified. This is in order to be able to identify the patient if their responses to the PHQ-9 and GAD-7 indicate significant concern so appropriate support can be put in place.

The design of the research will be a cross-sectional correlation and will be analysed using a regression analysis. In order to achieve an effect size of 0.5 within cross-sectional correlation design, a sample size of 29 will be required in each participant group (α=0.05, β=0.2 and r=0.5).

6. Measures

The project will use a variety of measures including the Public Health Questionnaire (PHQ9), the General Anxiety Disorder Questionnaire (GAD-7), the Relationship Questionnaire (RQ), the Relationships Scale Questionnaire (RSQ) and the End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ). All measures are available online for free use. It is estimate that questionnaires will require approximately 45 minutes to complete.

7. Data management and analysis

Participant's questionnaires will be coded with a participant number once completed and will be kept in a secure environment in the Renal Clinical Psychology department in accordance with Data

Protection and Patient Confidentiality policies. The data will be inputted into SPSS, which will be stored onto NHS computer system and password protected. Some information will be stored on an encrypted pen drive provided by the NWCPP. The data will be analysed using a multiple regression analysis in order to see whether trends in adherence can be explained by attachment styles, measured by the RQ and RSQ, and depression and anxiety, measured by the GAD-7 and PHQ9. Adherence to treatment will be measured by the ESRD-AQ.

8. Diversity

All participants currently receiving haemodialysis within North Wales will be asked to take part in the study. This will capture a heterogeneous population of individuals, both male and female, of a variety of ages and from variety of different cultures and backgrounds. The only exclusion criteria identified for this project is that participants must have been receiving haemodialysis for a period of three months prior to the collection of data. Participants who are new to dialysis may appear to be non-compliant on questionnaires, but are simply adapting to their new treatment regime and therefore will be excluded from the study. In addition, patients who are temporarily using the renal service for dialysis due to being on holiday in the area will be excluded from the study in order to maintain homogeneity.

9. Ethical/Registration Issues

Participants will be approached whilst on the renal ward receiving their dialysis treatment, which can be viewed as a vulnerable position, as it will mean that they will be approached whilst attached to the relevant medical dialysing equipment. However, participants will be asked for their informed consent prior to being approached whilst on dialysis treatment and will be made aware of the date that the research will be taking place, as well as the fact that participants will be approached whilst receiving treatment. Therefore, they will be aware that they are going to be approached whilst receiving treatment and will be reminded of their right to withdraw at any time. Similar audit information has been collected in this way previously, which has been approved by the BCUHB audit team. Similar research conducted previously has also used this method to collect data.

10. Feedback

Feedback will be given to the participants through a letter summarising the results of the study and how the results will influence clinical practice or future research. The participants will be invited to contact the researcher regarding any specific questions they may have and will also be made aware of where they can find copies of the project in full, i.e. university library. Copies of the results of the study can be sent to the participants upon request.

11. Risk Assessment

Within the participant information sheet, the participants will be informed that if their responses to PHQ-9 and GAD-7 indicate concerns regarding their mental health, such as within the clinical range for anxiety or depression, this information will be passed onto a clinical professional in order to manage any possible risks.

This will include if responses to the PHQ-9 reach a score of 15 or above, which suggests moderate-severe to severe depression or if scores on the GAD-7 reach clinical 10 or above, which indicates moderate to severe anxiety. The participant will be given the choice to have their GP informed of these concerns or alternatively, a referral to the Renal Clinical Psychology Team. The participants will be informed whether notification to their GP or a referral to the psychology service is required.

12. Data Storage

The data collected from participants throughout the project will be coded with a participant information number, in order for participant's information to be unidentifiable by any other person other than the researchers. The data will be stored according to the Data Protection Act (1998) as well as the BCUHB confidentiality guidelines and data protection. This will include storing documents via password protection on the BCUHB computer network. Some use of an encrypted pen drives may be required, which will be provided by the university. Identifiable information, such as consent forms, will be destroyed six months after the project has been completed. The data will be retained by the renal psychology department for a period of ten years following completion of the study. The researcher and relevant supervisors will establish whether the data collected is required to remain on an NHS computer once it has been collected and coded with the participant information numbers.

13. Financial Information

Currently, costs for the project will be limited to the researcher's travel between the relevant NHS sites, which will be included as part of the researchers usual travel claims, and photocopying which will be completed on the NWCPP copier. Measures will be required, however those selected are available on the internet for free use.

Participant Information Sheet

Jessica Gordon is a Trainee Clinical Psychologist employed by Betsi Cadwaladr University Health Board. She is currently completing a Doctorate course with Bangor University to qualify as a Clinical Psychologist. As part of her clinical training she is conducting the research detailed below. This project is supervised by Dr Beth Parry-Jones and Dr Paul Gardner, Consultant Clinical Psychologists, who are currently working within Betsi Cadwaladr University Health Board (BCUHB) Renal Psychology Service.

Study title: Treatment Adherence in End-Stage Renal Disease: Exploring Attachment Styles and Mood as predictors.

What is the purpose of the research?

In comparison to other areas of Psychology, Renal Psychology is a relatively new branch of the profession. Our aim is to continue to develop our knowledge base of the area by conducting research to better understand how we can support patients who require care from renal services. More specifically, this study aims to better understand what psychological factors support patients and prevents patients from adhering to treatment regimes during End-Stage Renal Disease (ESRD). There is some research already published within this area however, the research is limited, inconsistent or has not yet been applied to a population of renal patients.

It is possible that psychological factors that influence adherence to treatment may include attachment styles, such as how we relate to others and develop and maintain relationships, and mood, including symptoms of anxiety and depression. We are aware of how restrictive and intense the treatment regime is for patients with renal failure and how this regime may impact upon psychological wellbeing. If we can better understand the psychological factors that support or prevent individuals from adhering to their treatment regimes, we can tailor our services to support people more effectively and prevent further deterioration of their physical health.

Why have I been invited to participate?

You have been invited to participate because you are currently receiving haemodialysis treatment at one of our North Wales Renal Services in Betsi Cadwaladr University Health Board and have been receiving this treatment for a period of three months or more and are 18+ years old. All patients who meet these criteria have been asked to participate.

What would taking part involve?

When you receive this information sheet you will also be provided with a consent form where you can choose to opt in or out of the study. Once you have read this information sheet, if you are still unsure about whether or not to take part in the study and would like more information, please inform one of the nurses in your renal service about your query. If the nursing team are unable to answer your question they will contact Jessica who will provide them with any information you require to support you to make a decision.

If you are interested in taking part, please sign and return the consent form to the nursing team in your service within ***two weeks*** of receiving this information. Once you have signed and returned the consent form, you will then be approached by Jessica within 8-12 weeks at your Renal Service during one session of your haemodialysis treatment. Jessica will provide you with four questionnaires which should take you no more than 45 minutes to complete. These questionnaires will ask you about your mood, details about how you relate to others and develop relationships, such as with family, friends and partners and recent experiences of adhering to your renal treatment regime. Jessica will remain on the ward throughout this time to assist you with any difficulties you may have in completing the questionnaires.

The questionnaires that you complete will be coded with a participant identification number, which will allow the researchers to identify which questionnaires are yours once you have completed them. This allows the researchers to identify you, but your information will be unidentifiable to anyone else. If the responses to your questionnaires suggest that that you are currently experiencing some level of emotional distress, Jessica will contact you within three weeks of completing the questionnaires to discuss this with you. Jessica will then notify your GP or will refer you to the Renal Clinical Psychology Team for an assessment, with your permission. If your responses to the questionnaires do not indicate any immediate concerns, Jessica will not contact you.

Your consent forms with your details on will be kept at the Renal Psychology Service where they will be locked away safely and destroyed within six months of completing the study. The results of the questionnaires will then be transferred to a computer database for analysis. Your details will be fully anonymised from this point onwards. This information will be password protected, encrypted and stored securely in the service for up to ten years, in accordance with the Data Protection Act (1999). The information you provide may be used in further research conducted by the Renal Service, but your details will remain anonymous.

Will I get the results of the tasks I take part in?

Feedback will be given to you and all other participants through a leaflet summarising the results of the study and how the results will influence clinical practice or future research. This will be distributed to you by the staff at your renal service. You will be informed of how to find a copy of the project in full at Bangor University Library. Alternatively, you will be

invited to contact Jessica, Dr Beth Parry-Jones or Dr Paul Gardner if you would like to request a copy of the study.

What if I don't want to take part, or I change my mind?
It is completely up to you whether you decide to take part or not. Your decision will not affect your care at the renal service, or any other service within the NHS.

You can change your mind at any time, you can also ask for your data to be removed after you have participated in the study.

What will I get out of it?
There is no direct benefit to you for taking part in this study but your participation has the potential to benefit people in the future by improving our knowledge base of how we can best support patients with renal failure.

Are there any disadvantages to taking part?
The questionnaires will ask you to talk about your mood and your relationships with others, which can very occasionally bring distressing thoughts or feelings to the front of your mind. If this is the case we advise you to alert Jessica by contacting her using the contact information provided below. Jessica can signpost you to different services for support and provide you with information. Alternatively, you can contact your GP or ask the team at your Renal Service to refer you to the Renal Psychology Team.

Who is funding and organising the research?
This research is organised and funded by the North Wales Clinical Psychology Programme, at Bangor University in partnerships with Betsi Cadwaladr University Health Board.

Who has reviewed the 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 a favorable opinion by the ****** Research Ethics Committee.

What if something goes wrong?
If you have a concern about any aspect of this study, you should contact Jessica Gordon on 01248 388059, or email psp4fc@bangor.ac.uk. You can also contact Dr Beth Parry-Jones by email on beth.parry-jones@wales.nhs.uk or Dr Paul Gardner on paul.gardner@wales.nhs.uk.

If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please contact Mr Hefin Francis, who is the Bangor University contact for complaints regarding research, at the following address:

Mr Hefin Francis, School of Psychology Manager,
School of Psychology,
Brigantia Building,
Penrallt Road,
Gwynedd. LL57 2DG.

Tel: 01248 388 339
E-mail: h.francis@bangor.ac.uk

Thank you for taking the time to read this information sheet, I look forward to answering any questions you may have.

Kind regards,

Jessica Gordon
Trainee Clinical Psychologist

Supervised by:

Dr Beth Parry-Jones
Consultant Clinical Psychologist

Dr Paul Gardner
Consultant Clinical Psychologist

Welsh Participant Information Sheet

3 Gorffennaf 2016 - Fersiwn 1

Taflen wybodaeth i gyfranogwyr

Mae Jessica Gordon yn Seicolegydd Clinigol dan Hyfforddiant a gyflogir gan Fwrdd Iechyd Prifysgol Betsi Cadwaladr. Ar hyn o bryd, mae hi'n astudio am ddoethuriaeth ym Mhrifysgol Bangor er mwyn cymhwyso fel seicolegydd clinigol. Fel rhan o'i hyfforddiant clinigol, mae hi'n gwneud yr ymchwil isod. Caiff yr astudiaeth ei goruchwylio gan Dr Beth Parry-Jones a Dr Paul Gardner, y ddau'n seicolegwyr clinigol ymgynghorol sy'n gweithio i Wasanaethau Seicoleg Arennol Bwrdd Iechyd Prifysgol Betsi Cadwaladr.

Teitl yr astudiaeth: Glynu wrth driniaeth yn ystod cyfnod olaf methiant yr arennau: Ymchwilio i arddull ymlyniad a hwyliau fel daroganwyr.

Beth yw pwrpas yr ymchwil?

O gymharu â rhannau eraill o faes seicoleg, mae seicoleg arennol yn gangen gymharol newydd o'r proffesiwn. Ein nod yw parhau i ddatblygu ein sylfaen wybodaeth am y maes trwy gynnal ymchwil i ddeall yn well sut gallwn gefnogi cleifion sydd angen gofal gan wasanaethau arennol. Nod yr astudiaeth hon yn fwy penodol yw deall yn well pa ffactorau seicolegol sy'n cynorthwyo cleifion ac yn eu rhwystro rhag glynu wrth driniaeth yn ystod cyfnod olaf methiant yr arennau. Ceir rhywfaint o ymchwil a gyhoeddwyd eisoes yn y maes hwn, ond mae'r ymchwil yn y maes yn gyfyngedig, yn anghyson neu nid yw wedi ei gymhwyso i boblogaeth o gleifion arennol.

Mae'n bosib y gall ffactorau seicolegol ddylanwadu ar ymlyniad i driniaeth, yn cynnwys arddulliau ymlyniad, megis sut rydym yn uniaethu ag eraill a datblygu a chynnal perthynas, a hwyliau, yn cynnwys symptomau pryder ac iselder. Rydym yn ymwybodol bod y driniaeth yn gyfyngol ac yn ddwys i gleifion sydd â methiant arennol a sut gallai'r driniaeth effeithio ar eu lles seicolegol. Os gallwn ddeall y ffactorau seicolegol sy'n cefnogi neu'n rhwystro unigolion rhag glynu wrth eu triniaeth yn well, gallwn deilwra ein gwasanaethau i gefnogi pobl yn fwy effeithiol ac atal dirywiad pellach yn eu hiechyd corfforol.

Pam y gofynnwyd imi gymryd rhan?

Rydych wedi cael gwahoddiad i gymryd rhan oherwydd eich bod yn cael triniaeth haemodialysis ar hyn o bryd yn un o wasanaethau arennol Bwrdd Iechyd Prifysgol Betsi Cadwaladr ac wedi bod yn cael y driniaeth am gyfnod o dri mis neu fwy ac rydych dros 18 oed. Gofynnwyd i bob claf sy'n bodloni'r meini prawf hyn i gymryd rhan.

Beth fydd cymryd rhan yn ei olygu?

Pan gewch gopi o'r daflen wybodaeth hon, cewch hefyd ffurflen gydsynio i gytuno neu i wrthod cymryd rhan yn yr astudiaeth. Ar ôl i chi ddarllen y daflen wybodaeth, os nad ydych yn siŵr a ydych eisiau cymryd rhan yn yr astudiaeth hon neu beidio, ac os hoffech ragor o wybodaeth, gofynnwch i un o'r nyrsys yn y gwasanaeth arennol. Os nad yw'r tîm nyrsio yn gallu ateb eich cwestiwn, byddant yn cysylltu â Jessica a fydd yn rhoi unrhyw wybodaeth sydd ei hangen arnoch i wneud penderfyniad.

Os oes gennych ddiddordeb cymryd rhan, llofnodwch y ffurflen gydsynio a'i dychwelyd i'r tîm nyrsio yn y gwasanaeth arennol cyn pen ***pythefnos*** ar ôl cael y wybodaeth hon. Ar ôl i chi lofnodi a dychwelyd y ffurflen gydsynio, bydd Jessica yn cysylltu â chi cyn pen 8-12 wythnos yn y gwasanaeth arennol yn ystod sesiwn o'ch triniaeth haemodialysis. Bydd Jessica yn rhoi pedwar holiadur i chi eu llenwi. Ni ddylai'r rhain gymryd mwy na 45 munud i'w llenwi. Bydd yr holiaduron yn gofyn am eich hwyliau ac am fanylion ynglŷn â sut rydych yn uniaethu ag eraill ac yn datblygu perthynas â hwy, megis gyda theulu, ffrindiau a phartneriaid a phrofiadau diweddar o lynu wrth eich triniaeth arennol. Bydd Jessica yn aros ar y ward trwy gydol yr amser er mwyn eich cynorthwyo gydag unrhyw anawsterau sydd gennych wrth gwblhau'r holiaduron.

Rhoddir rhif adnabod cyfranogwr ar yr holiaduron, a fydd yn caniatáu i'r ymchwilwyr nodi pa holiaduron yw eich rhai chi ar ôl i chi orffen eu llenwi. Mae hyn yn caniatáu i'r ymchwilwyr eich adnabod, ond ni fydd modd i unrhyw un arall eich adnabod o'r wybodaeth yn yr holiaduron. Os yw'r ymatebion i'r holiaduron yn awgrymu eich bod yn dioddef rhyw lefel o ofid yn gysylltiedig â'ch iechyd meddwl ar hyn o bryd, bydd Jessica yn cysylltu â chi cyn pen tair wythnos ar ôl i chi lenwi'r holiaduron i drafod hyn gyda chi. Bydd Jessica wedyn yn hysbysu eich meddyg teulu neu'n eich cyfeirio at y Tîm Seicoleg Glinigol Arennol am asesiad, gyda'ch caniatâd chi. Os nad yw eich ymatebion i'r holiaduron yn nodi unrhyw achos pryder, ni fydd Jessica yn cysylltu â chi.

Caiff y ffurflenni cydsynio gyda'ch manylion eu cadw yn y Gwasanaeth Seicoleg Arennol dan glo a chânt eu dinistrio cyn pen chwe mis ar ôl i'r astudiaeth ddod i ben. Caiff canlyniadau'r holiaduron eu trosglwyddo i gronfa ddata gyfrifiadurol i'w dadansoddi. Bydd eich manylion yn hollol ddienw o hynny ymlaen. Caiff y wybodaeth hon ei diogelu gan gyfrinair, ei hamgryptio a'i chadw'n ddiogel yn y gwasanaeth am hyd at ddeng mlynedd, yn unol â'r Ddeddf Diogelu Data (1999). Efallai y defnyddir y wybodaeth y byddwch yn ei rhoi mewn ymchwil pellach a gynhelir gan y Gwasanaeth Arennol, ond ni fydd modd eich adnabod o'r manylion.

A fyddaf yn cael gwybod canlyniadau'r astudiaeth?

Rhoddir taflen i chi ac i'r holl gyfranogwyr eraill fydd yn crynhoi canlyniadau'r astudiaeth ac yn nodi sut bydd y canlyniadau'n dylanwadu ar arfer clinigol neu ymchwil yn y dyfodol. Y staff yn y gwasanaeth arennol fydd yn rhoi'r daflen i chi. Cewch wybod sut i ddod o hyd i

gopi o'r project yn llawn yn llyfrgell Prifysgol Bangor. Fel arall, cewch wahoddiad i gysylltu â Jessica, Dr Beth Parry-Jones neu Dr Paul Gardner os hoffech gael copi o'r astudiaeth.

Beth os nad ydw i eisiau cymryd rhan neu os byddaf yn newid fy meddwl?
Chi sydd i benderfynu a ydych am gymryd rhan neu beidio. Ni fydd eich penderfyniad yn effeithio ar eich gofal gan y gwasanaeth arennol, na chan unrhyw wasanaethau arall yn y GIG.

Gallwch newid eich meddwl ar unrhyw adeg a hefyd gofyn i'ch data gael ei dynnu o'r astudiaeth ar ôl i chi gymryd rhan yn yr astudiaeth.

Beth fydd y manteision i mi?
Nid oes unrhyw fantais uniongyrchol i chi o gymryd rhan yn yr astudiaeth ond mae'n bosib y bydd eich cyfranogiad o fudd i bobl yn y dyfodol gan y bydd yn caniatau i ni wella ein gwybodaeth ynglŷn â'r ffordd orau o gefnogi cleifion sydd â methiant arennol.

A oes unrhyw anfanteision o gymryd rhan?
Bydd yr holiaduron yn gofyn i chi feddwl am eich hwyliau a'ch perthynas â phobl eraill, a gall hyn o bosib ddod â syniadau neu deimladau gofidus i'r wyneb. Os yw hyn yn digwydd, rydym yn eich cynghori i gysylltu â Jessica trwy'r manylion cysylltu isod. Gall Jessica eich cyfeirio at amrywiol wasanaethau am gefnogaeth a rhoi gwybodaeth i chi. Neu byddem yn gofyn i chi gysylltu â'ch meddyg teulu neu'n gofyn i chi roi gwybod i'r tîm yn y Gwasanaeth Arennol eich cyfeirio at y Tîm Seicoleg Glinigol Arennol.

Pwy sy'n ariannu a threfnu'r ymchwil?
Caiff yr ymchwil hwn ei drefnu a'i ariannu gan Raglen Seicoleg Glinigol Gogledd Cymru ym Mhrifysgol Bangor mewn partneriaeth â Bwrdd Iechyd Prifysgol Betsi Cadwaladr.

Pwy sydd wedi adolygu'r astudiaeth?
Edrychir ar bob ymchwil yn y GIG gan grŵp annibynnol o bobl, sef pwyllgor moeseg ymchwil, i warchod eich buddiannau. Mae'r astudiaeth hon wedi'i hadolygu a'i chymeradwyo gan Bwyllgor Moeseg Ymchwil ******.

Beth os aiff rhywbeth o'i le?
Os ydych yn pryderu am unrhyw agwedd ar yr astudiaeth hon, dylech gysylltu â Jessica Gordon ar 01248 388059, neu anfon e-bost ipsp4fc@bangor.ac.uk. Gallwch hefyd gysylltu â Dr Beth Parry-Jones trwy e-bost, beth.parry-jones@wales.nhs.uk , neu Dr Paul Gardner, paul.gardner@wales.nhs.uk.

Os ydych yn parhau i fod yn anhapus am yr astudiaeth ac/neu yn dymuno gwneud cwyn am unrhyw agwedd ar y ffordd y cawsoch eich gwahodd neu eich trin yn ystod yr astudiaeth

hon, cysylltwch â Mr Hefin Francis, sef cyswllt Prifysgol Bangor ar gyfer cwynion sydd yn ymwneud ag astudiaethau, ar y cyfeiriad canlynol:

Mr Hefin Francis, Rheolwr yr Ysgol Seicoleg,
Ysgol Seicoleg,
Adeilad Brigantia,
Ffordd Penrallt,
Gwynedd. LL57 2DG.

Ffôn: 01248 388 339
E-bost: h.francis@bangor.ac.uk

Diolch i chi am roi o'ch amser i ddarllen y daflen wybodaeth hon. Edrychaf ymlaen at ateb unrhyw gwestiynau fydd gennych chi.

Yn gywir,

Jessica Gordon
Seicolegydd Clinigol dan Hyfforddiant

Dan oruchwyliaeth:

Dr Beth Parry-Jones
Seicolegydd Clinigol Ymgynghorol

Dr Paul Gardner
Seicolegydd Clinigol Ymgynghorol

Nursing Team Information Sheet

Jessica Gordon is a Trainee Clinical Psychologist employed by Betsi Cadwaladr University Health Board. She is currently completing a Doctorate course with Bangor University to qualify as a Clinical Psychologist. As part of her clinical training she is conducting the research detailed below. This project is supervised by Dr Beth Parry-Jones and Dr Paul Gardner, Consultant Clinical Psychologists, who are currently working within the Betsi Cadwaladr University Health Board (BCUHB) Renal Psychology Service.

Study title: Treatment Adherence in End-Stage Renal Disease: Exploring Attachment Styles and Mood as predictors.

What is the purpose of the research?

In comparison to other areas of Psychology, Renal Psychology is a relatively new branch of the profession. Our aim is to continue to develop our knowledge base of the area by conducting research to better understand how we can support patients who require care from renal services. More specifically, this study aims to better understand what psychological factors support patients and prevent patients from adhering to treatment regimes during End-Stage Renal Disease (ESRD). There is some research already published within this and other areas of health psychology which have looked at adherence to treatment regimes for other chronic health conditions. However, the research in this area is limited, inconsistent or has not yet been applied to a population of renal patients.

It is possible that psychological factors that influence adherence to treatment may include attachment styles, such as how we relate to others and develop and maintain relationships, and mood, including symptoms of anxiety and depression. We are aware of how restrictive and intense the treatment regime is for patients with renal failure and how this regime may impact upon psychological wellbeing. If we can better understand the psychological factors that support or prevent individuals from adhering to their treatment regimes, we can tailor our services to support people more effectively and prevent further deterioration of their physical health.

Why have the nursing team been asked to assist with this study?

You have been asked to assist with recruiting participants for this study as, in accordance with NHS Ethics, researchers are not allowed to directly approach participants to ask them to take part in a research project. This is to avoid patients feeling pressured to take part and provide them with the opportunity to make an informed decision about whether or not to participate, without influence from the researcher.

As a nursing team, you are most likely to have the best professional relationship with this group of patients, particularly given the intense nature of haemodialysis treatment. Therefore, we have asked you to approach patients on our behalf to provide them with the information about the study and the opportunity to make an informed decision about taking part, in an environment that is most comfortable for them.

What will be the role of the nursing staff?

Jessica will attend your Renal Service to provide you with a summary of the study and the opportunity to ask questions about the research. Jessica will then provide you with information sheets, similar to this, and participant consent forms for the patients. You will be asked to distribute these documents to each of the patients who have been receiving haemodialysis on ward/unit for 3 months or more, whilst they are receiving their dialysis. You will be asked to briefly outline to the patients what the documents are for and ask them to read the information sheet and fill out the consent form if they wish to take part. They will be asked to sign and return the consent form to you within 2 weeks of receiving the information. We ask that you collect these forms and store them securely at your service. If the patients have any additional questions before making a decision that you are unable to answer, please contact Jessica who will endeavour to provide them with the information.

Once all consent forms have been completed and returned, Jessica will return to the service to begin data collection. Jessica will collect the completed forms of those patients who have opted to take part in the study and will ask you to identify who each patient is in relation to their consent form. Jessica will then be able to approach the relevant patients to begin data collection.

Why have these patients been invited to participate?

They have been invited to participate because they are currently receiving haemodialysis treatment at one of our BCUHB Renal Services; have been receiving this treatment for a period of three months or more; and are 18+ years of age. All patients who meet this criteria have been asked to participate.

What would taking part involve for the patients?

Once they have signed and returned the consent form, they will then be approached by Jessica within 8-12 weeks at your Renal Service during one session of their haemodialysis treatment. Jessica will provide them with four questionnaires which should take you no more than 45 minutes to complete. These questionnaires will ask about their mood, details about how they relate to others and develop relationships, such as with family, friends and partners and recent experiences of adhering to their renal treatment regime. Jessica will remain on the ward throughout this time to assist them with any difficulties they may have in completing the questionnaires.

The questionnaires that they complete will be coded with a participant identification number, which will allow the researchers to identify which questionnaires are theirs once they have completed them. This allows the researchers to identify them, but their information will be unidentifiable to anyone else. If the responses to their questionnaires suggest that they are currently experiencing some level of distress related to their mental health, Jessica will contact them within three weeks of completing the questionnaires to discuss this with them. Jessica will then notify their GP or will refer them to the Renal Clinical Psychology Team for an assessment, with their permission. If their responses to the questionnaires do not indicate any immediate concerns, Jessica will not contact them.

Their consent forms with their details on will be kept at the Renal Psychology Service where they will be locked away safely and destroyed within six months of completing the study. The results of the questionnaires will then be transferred to a computer database for analysis. Their details will be fully anonymised from this point onwards. This information will be password protected, encrypted and stored securely in the service for up to ten years, in accordance with the Data Protection Act (1999). The information they provide may be used in further research conducted by the Renal Service, but their details will remain anonymous.

Will the staff and the patients be provided with the results of the tasks they take part in?
Feedback will be given to the participants through a leaflet summarising the results of the study and how the results will influence clinical practice or future research. We will ask the nursing team to distribute these to the patients at your service. Feedback forms will also be provided for the staff at the service, but in addition to this, Jessica will attend your ward upon completion of the project to feedback the results in person. The participants and nursing staff will be informed of how to find a copy of the project in full at Bangor University Library. Alternatively, you will be invited to contact Jessica, Dr Beth Parry-Jones or Dr Paul Gardner if you would like a copy of the study.

What if the patients don't want to take part, or they change their mind?
It is completely up to them whether they decide to take part or not. Their decision will not affect their care at the renal service, or any other service within the NHS.

They can change their mind at any time and can also ask for their data to be removed after they have participated in the study.

What will the patients get out of taking part?
There is no direct benefit to the patients for taking part in this study but their participation has the potential to benefit people in the future by improving our knowledge base of how we can best support patients with renal failure. The results of the study has the potential to benefit the service, as any information we find may support us to make changes within the

service to better understand and support patients who struggle to maintain their treatment regime.

Are there any disadvantages to taking part for the participants?
The questionnaires will ask them to think about their mood and their relationships with others, which can very occasionally bring distressing thoughts or feelings to the front of their mind. If this is the case we advise them to alert Jessica by contacting her on the contact information provided below. Jessica can signpost them to different services for support and provided them with information. Alternatively, we will invite them to contact their GP or ask them to notify your team at the Renal Service to refer them to the Renal Psychology Team.

Who is funding and organising the research?
This research is organised and funded by the North Wales Clinical Psychology Programme, at Bangor University in partnership with Betsi Cadwaladr University Health Board.

Who has reviewed the 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 a favorable opinion by the ****** Research Ethics Committee.

What if something goes wrong?
If you or any of the participants have a concern about any aspect of this study, you should contact Jessica Gordon on 01248 388059, or email psp4fc@bangor.ac.uk. You can also contact Dr Beth Parry-Jones by email on beth.parry-jones@wales.nhs.uk or Dr Paul Gardner on paul.gardner@wales.nhs.uk.

If you or any of the participants remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please contact Mr Hefin Francis, who is the Bangor University contact for complaints regarding research, at the following address:

Mr Hefin Francis, School of Psychology Manager,
School of Psychology,
Brigantia Building,
Penrallt Road,
Gwynedd. LL57 2DG.

Tel: 01248 388 339
E-mail: h.francis@bangor.ac.uk

Thank you for taking the time to read this information sheet, I look forward to answering any questions you or any of your patients may have.

Kind regards,

Jessica Gordon
Trainee Clinical Psychologist

Supervised by:

Dr Beth Parry-Jones
Consultant Clinical Psychologist

Dr Paul Gardner
Consultant Clinical Psychologist

Taflen Wybodaeth i'r Tîm Nyrsio

Mae Jessica Gordon yn Seicolegydd Clinigol dan Hyfforddiant a gyflogir gan Fwrdd Iechyd Prifysgol Betsi Cadwaladr. Ar hyn o bryd, mae hi'n astudio am ddoethuriaeth ym Mhrifysgol Bangor er mwyn cymhwyso fel seicolegydd clinigol. Fel rhan o'i hyfforddiant clinigol, mae hi'n gwneud yr ymchwil isod. Caiff yr astudiaeth ei goruchwylio gan Dr Beth Parry-Jones a Dr Paul Gardner, y ddau'n seicolegwyr clinigol ymgynghorol sy'n gweithio i Wasanaethau Seicoleg Arennol Bwrdd Iechyd Prifysgol Betsi Cadwaladr.

Teitl yr astudiaeth: Glynu wrth driniaeth yn ystod cyfnod olaf methiant yr arennau: ymchwilio i arddull ymlyniad a hwyliau fel daroganwyr.

Beth yw pwrpas yr ymchwil?

O gymharu â rhannau eraill o faes seicoleg, mae seicoleg arennol yn gangen gymharol newydd o'r proffesiwn. Ein nod yw parhau i ddatblygu ein sylfaen wybodaeth am y maes trwy gynnal ymchwil i ddeall yn well sut gallwn gefnogi cleifion sydd angen gofal gan wasanaethau arennol. Nod yr astudiaeth hon yn fwy penodol yw deall yn well pa ffactorau seicolegol sy'n cynorthwyo cleifion ac yn eu rhwystro rhag glynu wrth driniaeth yn ystod cyfnod olaf methiant yr arennau. Ceir rhywfaint o ymchwil a gyhoeddwyd eisoes yn y maes hwn ac ym meysydd eraill seicoleg iechyd sy'n edrych ar ymlyniad i driniaeth ar gyfer cyflyrau iechyd cronig eraill. Ond mae'r ymchwil yn y maes yn gyfyngedig, yn anghyson neu nid yw wedi ei gymhwyso i boblogaeth o gleifion arennol.

Mae'n bosib y gall ffactorau seicolegol ddylanwadu ar ymlyniad i driniaeth, yn cynnwys arddulliau ymlyniad, megis sut rydym yn uniaethu ag eraill a datblygu a chynnal perthynas, a hwyliau, yn cynnwys symptomau pryder ac iselder. Rydym yn ymwybodol bod y driniaeth yn gyfyngol ac yn ddwys i gleifion sydd â methiant arennol a sut gallai'r driniaeth effeithio ar eu lles seicolegol. Os gallwn ddeall y ffactorau seicolegol sy'n cefnogi neu'n rhwystro unigolion rhag glynu wrth eu triniaeth yn well, gallwn deilwra ein gwasanaethau i gefnogi pobl yn fwy effeithiol ac atal dirywiad pellach yn eu hiechyd corfforol.

Pam y gofynnwyd i'r tîm nyrsio gynorthwyo gyda'r astudiaeth hon?

Gofynnwyd i chi ein cynorthwyo i recriwtio cyfranogwyr ar gyfer yr astudiaeth hon gan na chaniateir i ymchwilwyr, yn unol â moeseg y GIG, gysylltu'n uniongyrchol â chyfranogwyr i ofyn iddynt gymryd rhan mewn astudiaeth ymchwil. Diben hyn yw sicrhau nad yw cleifion yn teimlo dan bwysau i gymryd rhan a rhoi cyfle iddynt wneud penderfyniad gwybodus ynglŷn â chymryd rhan, heb ddylanwad gan yr ymchwilydd.

Fel tîm nyrsio, chi sydd fwyaf tebygol o fod â'r berthynas broffesiynol orau gyda'r grŵp hwn o gleifion, yn enwedig o ystyried natur ddwys triniaeth hemodialysis. Felly, rydym wedi

gofyn i chi siarad â chleifion ar ein rhan a rhoi gwybodaeth iddynt am yr astudiaeth a'r cyfle i wneud penderfyniad gwybodus ynglŷn â chymryd rhan, yn yr amgylchedd sydd fwyaf cyfforddus iddynt.

Beth fydd cyfraniad y staff nyrsio?
Bydd Jessica yn dod i'r Gwasanaeth Arennol i ddarparu crynodeb o'r astudiaeth a rhoi'r cyfle i chi ofyn cwestiynau am y gwaith ymchwil. Yna bydd Jessica yn rhoi taflenni gwybodaeth, yn debyg i hon, a ffurflenni cydsynio i chi eu rhoi i gleifion. Gofynnir i chi ddosbarthu'r dogfennau hyn i bob un o'r cleifion sydd wedi bod yn derbyn hemodialysis ar y ward/uned ers 3 mis neu fwy, tra byddant yn cael eu triniaeth dialysis. Gofynnir i chi egluro'n fras diben y dogfennau i'r cleifion hyn a gofyn iddynt ddarllen y daflen wybodaeth a llenwi'r ffurflen gydsynio os ydynt yn dymuno cymryd rhan. Bydd gofyn iddynt lofnodi a dychwelyd y ffurflen gydsynio cyn pen pythefnos ar ôl derbyn y wybodaeth. Gofynnwn i chi gasglu'r ffurflenni hyn a'u cadw'n ddiogel yn eich gwasanaeth. Os bydd gan y cleifion unrhyw gwestiynau ychwanegol na allwch eu hateb cyn iddynt wneud penderfyniad, cysylltwch â Jessica a gwnaiff geisio rhoi'r wybodaeth iddynt.

Unwaith y bydd yr holl ffurflenni cydsynio wedi eu llenwi a'u dychwelyd, bydd Jessica yn dod yn ôl i'r gwasanaeth i ddechrau casglu data. Bydd Jessica yn casglu'r ffurflenni a lenwyd gan y cleifion hynny sydd wedi dewis cymryd rhan yn yr astudiaeth a bydd yn gofyn i chi nodi pwy yw pob claf mewn perthynas â'i ffurflen gydsynio. Bydd Jessica wedyn yn gallu mynd at y cleifion perthnasol i ddechrau casglu data.

Pam y gofynnwyd i'r cleifion hyn gymryd rhan?
Maent wedi cael gwahoddiad i gymryd rhan oherwydd eu bod yn cael triniaeth haemodialysis ar hyn o bryd yn un o wasanaethau arennol Bwrdd Iechyd Prifysgol Betsi Cadwaladr ac wedi bod yn cael y driniaeth am gyfnod o dri mis neu fwy ac maent dros 18 oed. Gofynnwyd i bob claf sy'n bodloni'r meini prawf hyn gymryd rhan.

Beth fydd cymryd rhan yn ei olygu i'r cleifion?
Ar ôl iddynt lofnodi a dychwelyd y ffurflen gydsynio, bydd Jessica yn cysylltu â hwy cyn pen 8-12 wythnos yn y gwasanaeth arennol yn ystod sesiwn o'u triniaeth haemodialysis. Bydd Jessica yn rhoi pedwar holiadur iddynt eu llenwi. Ni ddylai'r rhain gymryd mwy na 45 munud i'w llenwi. Bydd yr holiaduron yn gofyn am eu hwyliau ac am fanylion ynglŷn â sut maent yn uniaethu ag eraill ac yn datblygu perthynas â hwy, megis gyda theulu, ffrindiau a phartneriaid a phrofiadau diweddar o lynu wrth eu triniaeth arennol. Bydd Jessica yn aros ar y ward trwy gydol yr amser er mwyn eu cynorthwyo gydag unrhyw anawsterau sydd ganddynt wrth gwblhau'r holiaduron.

Rhoddir rhif adnabod cyfranogwr ar yr holiaduron, a fydd yn caniatáu i'r ymchwilwyr nodi pa holiaduron yw rhai pob cyfranogwr ar ôl iddynt orffen eu llenwi. Mae hyn yn caniatáu i'r

ymchwilwyr eu hadnabod, ond ni fydd modd i unrhyw un arall adnabod cyfranogwyr o'r wybodaeth yn yr holiaduron. Os yw'r ymatebion i'r holiaduron yn awgrymu eu bod yn dioddef rhyw lefel o ofid yn gysylltiedig â'u hiechyd meddwl ar hyn o bryd, bydd Jessica yn cysylltu â hwy cyn pen tair wythnos ar ôl llenwi'r holiaduron i drafod hyn gyda hwy. Bydd Jessica wedyn yn hysbysu eu meddyg teulu neu'n eu cyfeirio at y Tîm Seicoleg Glinigol Arennol am asesiad, gyda'u caniatâd. Os nad yw eu hymatebion i'r holiaduron yn nodi unrhyw achos pryder, ni fydd Jessica yn cysylltu â hwy.

Caiff y ffurflenni cydsynio gyda'u manylion eu cadw yn y Gwasanaeth Seicoleg Arennol dan glo a chânt eu dinistrio cyn pen chwe mis ar ôl i'r astudiaeth ddod i ben. Caiff canlyniadau'r holiaduron eu trosglwyddo i gronfa ddata gyfrifiadurol i'w dadansoddi. Bydd eu manylion yn hollol ddienw o hynny ymlaen. Caiff y wybodaeth hon ei diogelu gan gyfrinair, ei hamgryptio a'i chadw'n ddiogel yn y gwasanaeth am hyd at ddeng mlynedd, yn unol â'r Ddeddf Diogelu Data (1999). Efallai y caiff y wybodaeth a gasglwyd ei defnyddio mewn ymchwil pellach a gynhelir gan y Gwasanaeth Arennol, ond bydd manylion y cyfranogwyr yn aros yn ddienw.

A gaiff y staff a'r cleifion weld canlyniadau'r astudiaeth?
Rhoddir taflen i'r cyfranogwyr fydd yn crynhoi canlyniadau'r astudiaeth ac yn nodi sut bydd y canlyniadau'n dylanwadu ar arfer clinigol neu ymchwil yn y dyfodol. Byddwn yn gofyn i'r tîm nyrsio ddosbarthu'r rhain i'r cleifion yn eich gwasanaeth. Darperir hefyd ffurflenni adborth i'r staff yn y gwasanaeth, ond yn ogystal â hyn, bydd Jessica yn dod i'r ward ar ôl cwblhau'r project i adrodd ar y canlyniadau yn bersonol. Caiff y cyfranogwyr a'r staff nyrsio wybod sut i ddod o hyd i gopi o'r project yn llawn yn llyfrgell Prifysgol Bangor. Fel arall, cewch wahoddiad i gysylltu â Jessica, Dr Beth Parry-Jones neu Dr Paul Gardner os hoffech gael copi o'r astudiaeth.

Beth os nad yw'r cleifion eisiau cymryd rhan, neu beth os ydynt yn newid eu meddyliau?
Y cleifion sydd i benderfynu a ydynt am gymryd rhan ai peidio. Ni fydd eu penderfyniad yn effeithio ar eu gofal gan y gwasanaeth arennol, na chan unrhyw wasanaethau arall yn y GIG.

Gallent newid eu meddyliau ar unrhyw adeg a hefyd gofyn i'w data gael ei dynnu o'r astudiaeth ar ôl iddynt gymryd rhan yn yr astudiaeth.

Beth fydd y manteision o gymryd rhan i gleifion?
Nid oes unrhyw fantais uniongyrchol i'r cleifion o gymryd rhan yn yr astudiaeth ond mae'n bosib y bydd eu cyfranogiad o fudd i bobl yn y dyfodol gan y bydd yn caniatau i ni wella ein gwybodaeth ynglŷn â'r ffordd orau o gefnogi cleifion sydd â methiant arennol. Mae'n bosib y bydd canlyniadau'r astudiaeth o fudd i'r gwasanaeth, gan y gall y wybodaeth byddwn yn ei chasglu ein cefnogi i wneud newidiadau i'r gwasanaeth er mwyn deall a chefnogi cleifion sy'n cael trafferth glynu wrth eu triniaeth.

A oes unrhyw anfanteision neu risgiau o gymryd rhan?
Bydd yr holiaduron yn gofyn iddynt feddwl am eu hwyliau a'u perthynas â phobl eraill, a gall hyn o bosib ddod â syniadau neu deimladau gofidus i'r wyneb. Os yw hyn yn digwydd, rydym yn eu cynghori i gysylltu â Jessica trwy'r manylion cysylltu isod. Gall Jessica eu cyfeirio at amrywiol wasanaethau am gefnogaeth a rhoi gwybodaeth iddynt. Neu byddem yn gofyn iddynt gysylltu â'u meddyg teulu neu'n gofyn iddynt ofyn i'r tîm yn y Gwasanaeth Arennol eu cyfeirio at y Tîm Seicoleg Glinigol Arennol.

Pwy sy'n ariannu a threfnu'r ymchwil?
Caiff yr ymchwil hwn ei drefnu a'i ariannu gan Raglen Seicoleg Glinigol Gogledd Cymru ym Mhrifysgol Bangor mewn partneriaeth â Bwrdd Iechyd Prifysgol Betsi Cadwaladr.

Pwy sydd wedi adolygu'r astudiaeth?
Edrychir ar bob ymchwil yn y GIG gan grŵp annibynnol o bobl, sef pwyllgor moeseg ymchwil, i warchod eich buddiannau. Mae'r astudiaeth hon wedi'i hadolygu a'i chymeradwyo gan Bwyllgor Moeseg Ymchwil ******.

Beth os aiff rhywbeth o'i le?
Os ydych chi neu unrhyw un o'r cyfranogwyr yn pryderu am unrhyw agwedd ar yr astudiaeth hon, dylech gysylltu â Jessica Gordon ar 01248 388059, neu anfon e-bost ipsp4fc@bangor.ac.uk. Gallwch hefyd gysylltu â Dr Beth Parry-Jones trwy e-bost, beth.parry-jones@wales.nhs.uk , neu Dr Paul Gardner, paul.gardner@wales.nhs.uk.

Os ydych chi neu unrhyw un o'r cyfranogwyr yn parhau i fod yn anhapus am yr astudiaeth ac/neu'n dymuno gwneud cwyn am unrhyw agwedd ar y ffordd y cawsoch eich gwahodd neu eich trin yn ystod yr astudiaeth hon, cysylltwch â Mr Hefin Francis, sef cyswllt Prifysgol Bangor ar gyfer cwynion sydd yn ymwneud ag astudiaethau, yn y cyfeiriad canlynol:

Mr Hefin Francis, Rheolwr yr Ysgol Seicoleg,
Ysgol Seicoleg,
Adeilad Brigantia,
Ffordd Penrallt,
Gwynedd. LL57 2DG.

Ffôn: 01248 388 339
E-bost: h.francis@bangor.ac.uk

Diolch i chi am roi o'ch amser i ddarllen y daflen wybodaeth hon. Edrychaf ymlaen at ateb unrhyw gwestiynau fydd gennych chi neu'r cleifion.

Yn gywir,

Jessica Gordon
Seicolegydd Clinigol dan Hyfforddiant

Dan oruchwyliaeth:

Dr Beth Parry-Jones
Seicolegydd Clinigol Ymgynghorol Ymgynghorol

Dr Paul Gardner
Seicolegydd Clinigol

CONSENT FORM

Name of researcher: Jessica Gordon, Trainee Clinical Psychologist

Supervised by: Dr Beth Parry-Jones, Consultant Clinical Psychologist

Dr Paul Gardner, Consultant Clinical Psychologist

Please initial box

1. I confirm that I have read the Participant Information Sheet dated ..... (Version 1) for the above study. ☐

2. I have had been provided with the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

3. I understand that my participation is voluntary and that I am free to withdraw at any time without reason. I am aware that withdrawal from the study will not affect my care anywhere in the NHS. ☐

4. I understand that if the information I provide during this study indicates to the researchers that I am currently experiencing some level of distress associated with my psychological wellbeing, the researcher will contact me within 3 weeks to discuss this. The researcher will then notify my GP or make a referral to the Renal Clinical Psychology Service for an assessment. ☐

5. I understand that the information collected about me will only be identifiable by the research team. Once my information has inputted onto a computerised database, my details will be made anonymous and stored securely on the Betsi Cadwaladr University Health Board computer system in accordance with the standards outlined under the Data Protection Act (1998). ☐

6. I understand that the anonymised information collected about me may be used to support other research in the future within the North Wales Renal Service. ☐

7. I agree to take part in the above study ☐

8. Please indicate if you are happy for the research team to notify your GP of your participation in this study.

Please delete as appropriate: I **do/do not** agree for my GP to be notified of my participation in this study.

Name of Participant	Date	Signature
Name of Person Taking Consent	Date	Signature

GP/Health Professional Notification Letter

Dear Dr ******

Re: Patient Name
DOB: 00/00/0000

Your patient is currently receiving haemodialysis at one of the Renal Services within Betsi Cadwaladr University Health Board and has provided their informed consent to take part in a study. The study is taking place as part of a thesis in a Doctorate course with Bangor University in Clinical Psychology. The project is supervised by Dr Beth Parry-Jones and Dr Paul Gardner, Consultant Clinical Psychologists, who are currently working within the North Wales Renal Psychology Service.

The study aims to better understand what psychological factors support patients and prevent patients from adhering to treatment regimes during end-stage renal failure. The study will utilise five questionnaires to assess whether psychological factors including attachment styles, such as how we relate to others and develop and maintain relationships, and mood, including symptoms of anxiety and depression, are influential in treatment adherence. This will include looking at a patient's adherence to four areas of their treatment, including their attendance at haemodialysis, use of medication and adherence to dietary and fluid restrictions. Your patient will complete these questionnaire during a routine haemodialysis appointment.

Your patient has been provided with an information sheet for the trial (copy enclosed) which explains why s/he has been approached to take part in the trial, that the participation is entirely voluntary, and emphasises that they are free to withdraw from the trial at any time without consequences to their current or future care.

Should you have any questions or require further information about this research, please do not hesitate to contact me on the details below.

Kind regards,

Jessica Gordon
Trainee Clinical Psychologist

Supervised by:

Dr Beth Parry-Jones

Dr Paul Gardner

Consultant Clinical Psychologist Consultant Clinical Psychologist

GP Notification - Welsh

Gwybodaeth i feddyg teulu/gweithiwr iechyd proffesiynol

Annwyl Dr ******

Parthed: Enw'r claf
DYDDIAD GENI: 00/00/0000

Ar hyn o bryd, mae eich claf yn cael haemodialysis gan un o wasanaethau arennol Bwrdd Iechyd Prifysgol Betsi Cadwaladr ac mae wedi rhoi cydsyniad gwybodus i gymryd rhan mewn astudiaeth. Cynhelir yr astudiaeth fel rhan o gwrs Doethuriaeth mewn Seicoleg Glinigol ym Mhrifysgol Bangor. Caiff yr astudiaeth ei goruchwylio gan Dr Beth Parry Jones a Dr Paul Gardner, y ddau'n seicolegwyr clinigol ymgynghorol sy'n gweithio i Wasanaethau Seicoleg Arennol Gogledd Cymru.

Nod yr astudiaeth yw deall yn well pa ffactorau seicolegol sy'n cynorthwyo cleifion ac yn eu rhwystro rhag glynu wrth driniaeth yn ystod cyfnod olaf methiant yr arennau. Bydd yr astudiaeth yn defnyddio pum holiadur i asesu a yw ffactorau seicolegol, yn cynnwys arddulliau ymlyniad, megis sut rydym yn uniaethu ag eraill ac yn datblygu a chynnal perthynas, a hwyliau, yn cynnwys symptomau pryder ac iselder, yn dylanwadu ar lynu wrth driniaeth. Bydd hyn yn cynnwys edrych ar ymlyniad y claf i bedair rhan o'u triniaeth, yn cynnwys eu presenoldeb yn haemodialysis, cymryd meddyginiaeth a chadw at gyfyngiadau o ran diet a hylif. Bydd eich claf yn llenwi'r holiaduron hyn yn ystod apwyntiad haemodialysis arferol.

Mae eich claf wedi cael taflen wybodaeth ar gyfer yr astudiaeth (copi amgaeedig) sy'n egluro pam y gofynnwyd iddo ef/hi gymryd rhan yn yr astudiaeth, bod cymryd rhan yn gwbl wirfoddol ac yn pwysleisio ei fod yn rhydd i dynnu'n ôl o'r astudiaeth ar unrhyw adeg heb i hynny gael unrhyw effaith ar ei ofal yn awr nac yn y dyfodol.

Os oes gennych unrhyw gwestiynau neu os hoffech ragor o wybodaeth am yr astudiaeth hon, mae croeso i chi gysylltu â mi trwy'r manylion cysylltu isod.

Dymuniadau gorau,

Jessica Gordon
Seicolegydd Clinigol dan Hyfforddiant

Dan oruchwyliaeth:

Dr Beth Parry-Jones
Seicolegydd Clinigol Ymgynghorol

Dr Paul Gardner
Seicolegydd Clinigol Ymgynghorol

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan **Lywodraeth Cymru**
Funded by **Welsh Government**

Pwyllgor Moeseg Ymchwil Cymru 5
Wales Research Ethics Committee 5
Bangor

Clinical Academic Office
Ysbyty Gwynedd Hospital
Betsi Cadwaladr University Health Board
Bangor, Gwynedd
LL57 2PW
Telephone/ Facsimile: 01248 - 384.877
Email: Rossela.Roberts@wales.nhs.uk

16 September 2016

Miss Jessica Gordon
Trainee Clinical Psychologist
North Wales Clinical Psychology Programme
Brigantia Building,Bangor University
Bangor, Gwynedd
LL57 2DG psp4fc@bangor.ac.uk

Dear Miss Gordon,

Study title:	**Treatment Adherence in End-Stage Renal Disease: Exploring Attachment Styles and Mood as predictors.**
REC reference:	**16/WA/0244**
Protocol number:	**N/A**
IRAS project ID:	**201868**

The Research Ethics Committee reviewed the above application at the meeting held on 15 September 2016. Thank you for attending to discuss the application.

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 Dr Rossela Roberts, rossela.roberts@wales.nhs.uk
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.

Ethical opinion

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

Conditions of the favourable opinion

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk 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 management permissions from host organisations.

Registration of Clinical Trials

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 the HRA. 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).

Ethical review of research sites

NHS Sites

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

Summary of discussion at the meeting

Ethical issues raised by the Committee in private discussion, together with responses given by you when invited to join the meeting

The Chairman welcomed you and introduced the Committee members.
The following issues were discussed:

Social or scientific value; scientific design and conduct of the study
The Committee considered whether the study objectives are important and necessary and will improve health and well-being or increase knowledge and concluded that the research question was highly appropriate.

The Committee discussed whether the design and methodology makes use of accepted scientific principles and methods (including statistical techniques) to produce reliable and valid data, and whether the conduct of the study is appropriately described in the protocol, the study design robust and the proposed analysis adequate to answer the research question.

A query was raised in relation to the principal objective of the study and whether the attachment style adds to what it already known about the link between anxiety and depression and non-adherence to treatment.
You clarified that exploring the attachment styles is a main study objective,
as patients have contact with unit staff for an average of 16 hours a week and generalised measures of anxiety are explored as predictors of adherence to treatment.

A further clarification was requested in relation to the statistical analysis plan; the protocol lists correlations but a regression analysis with adherence to treatment as an outcome measure would be more suitable.
You clarified that a regression analysis will be conducted and the team will also look for correlations between the different adherences (to medication, to diet, to dialysis, etc)

The Committee queried whether this would be patient reported adherence or is data being collected from the medical record.
You clarified that the published literature lists both subjective (patient reported) and objective outcome measures; the diary tracking adherence to medication and diet is completed by the patient at home, and adherence to dialysis is tracked by the clinic.

Public Involvement
The Committee noted the planned involvement of the Service User Group.

Informed Consent process and the adequacy and completeness of participant information
The Committee discussed the provision of information to research participants about the purpose of the research, its procedures, potential risks, benefits, and alternatives, and whether it includes all procedures as describe in the protocol.
The Committee noted that written informed consent is taken as part of a process - with participants having adequate time to consider the information, and opportunity to ask questions. The language used is understandable to the research participants, the information is clear as to what the participant consents to, and there is no inducement or coercion.

The Committee agreed that the procedures described in the protocol have been adequately addressed in the Information Sheet, consent is obtained to allow the GP to be informed and arrangements have been made to provide a Welsh language version of all participant-facing information.

The Chairman thanked you for your availability to speak to this submission and gave you an opportunity to ask questions. You did not raise any issues.
The Chairman confirmed that the Committee will deliberate and will be in touch shortly.

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting

Based on the information provided, the Committee was satisfied with the following aspects of the research:

- Social or scientific value; scientific design and conduct of the study
- Recruitment arrangements and access to health information, and fair participant selection
- Favourable risk benefit ratio; anticipated benefit/risks for research participants
- Care and protection of research participants; respect for participants' welfare and dignity
- Informed consent process and the adequacy and completeness of participant information
- Suitability of the applicant and supporting staff
- Independent review
- Suitability of supporting information
- Other general issues
- Suitability of the summary of the research

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University Insurance Certificate]	-	18 July 2016
GP/consultant information sheets or letters [GP Notification Letter]	1	13 July 2016
Other [Paul Gardner - CV]	-	-
Other [Mike Jackson - CV]	-	-
Other [Nursing Team Information Sheet]	1	03 July 2016
Participant consent form [Participant Consent Form]	1	03 July 2016
Participant information sheet (PIS) [Participant Information Sheet]	1	03 July 2016
REC Application Form [REC_Form_28072016]		28 July 2016
Research protocol or project proposal [Research Protocol]	1	03 July 2016
Summary CV for Chief Investigator (CI) [Jessica Gordon - CV]	-	03 July 2016
Summary CV for supervisor (student research) [Beth Parry-Jones - CV]	-	-
Validated questionnaire [Patient Health Questionnaire - PHQ9]	-	01 August 2003
Validated questionnaire [Generalized Anxiety Disorder Scale - GAD7]	-	-
Validated questionnaire [Relationship Questionnaire - RQ]	-	-
Validated questionnaire [Relationship Scales Questionnaire - RSQ]	-	-
Validated questionnaire [End-Stage Renal Disease Adherence Questionnaire - ESRD-AQ]	-	-

Membership of the Committee

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

No declaration of interest has been made in relation to this application.

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.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received 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/

HRA Training

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

16/WA/0244	**Please quote this number on all correspondence**

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

Yours sincerely

Rossela Roberts

Dr Jason Walker, MB BCh BAO, FRCA
Consultant Anaesthetist
Vice-Chair Wales REC5

E-mail: rossela.roberts@wales.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

SL-AR2 After ethical review - research oth

Copy to: Sponsor:

Hefin Francis
School of Psychology
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R&D Office:

Miss Debra Slater
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Academic Supervisor:

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Dr Mike Jackson
North Wales Clinical Psychology Programme
Betsi Cadwaladr University Health Board
43 College Road, Bangor University
Bangor, Gwynedd
LL57 2DG Mike.Jackson@bangor.ac.uk

Wales Research Ethics Committee 5

Attendance at Committee meeting on 15 September 2016

Committee Members

Name	*Profession*	*Capacity*	*Present*
Dr Karen BE Addy	Clinical Psychologist	Expert	Yes
Dr Swapna Alexander	Consultant Physician	Expert	No
Mrs Kathryn Chester	Research Nurse	Expert	Yes
Ms Geraldine Jenson	Retired College Vice-Principal	Lay +	Yes
Mr Eliezer Lichtenstein	Student	Lay +	Yes
Dr Mark G Lord	Consultant Pathologist	Expert	Yes
Dr Pamela A Martin-Forbes	WCRW Research Officer	Expert	No
Dr Paul G Mullins	Reader, MRI Physicist	Lay +	Yes
Mr Vishwanath Puranik	Associate Specialist ENT Surgeon	Expert	Yes
Mrs Lynn C Roberts	Matron, Emergency Department	Expert	Yes
Dr Judith L Roberts	Research Officer	Expert	Yes
Mrs Rachel L Roberts-Jones	Student	Lay +	No
Dr Jason D Walker	Consultant Anaesthetist (Vice-Chairman)	Expert	Yes
Dr Philip W White	General Practitioner (Chairman)	Expert	Yes
Ms Sydna A Williams	Lecturer	Lay +	Yes

In attendance

Name	*Position (or reason for attending)*
Dr Rossela Roberts	Clinical Governance Officer / RES Manager

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol
Betsi Cadwaladr
University Health Board

Panel Arolygu Mewnol Y&D - Canolog
R&D Internal Review Panel

Betsi Cadwaladr University Health Board
Ysbyty Gwynedd
Clinical Academic Office
Bangor, Gwynedd
LL57 2PW

Chairman/Cadeirydd – Dr Nefyn Williams PhD, FRCGP
Email: rossela.roberts@wales.nhs.uk
debra.slater@wales.nhs.uk
sion.lewis@wales.nhs.uk
Tel/Fax: 01248 384 877

Miss Jessica Gordon
North Wales Clinical Psychology Programme
Brigantia Building, 43 College Road
Bangor, Gwynedd
LL57 2DG psp4fc@bangor.ac.uk

29th November 2016

Dear Miss Jessica Gordon

Re: Confirmation that R&D governance checks are complete / R&D approval granted

Study Title	Psychological factors of treatment adherence in renal failure
IRAS reference	201868
REC reference	16/WA/0244

The above research project was reviewed by the BCUHB R&D Internal Review Panel.

The Panel is satisfied with the scientific validity of the project, the risk assessment, the review of the NHS cost and resource implications and all other research management issues pertaining to the revised application.

The Internal Review Panel is pleased to confirm that all governance checks are now complete and to grant approval to proceed at Betsi Cadwaladr University Health Board sites as described in the application.

The documents reviewed and approved are listed below:

Document:	Version:	Date:
R&D Form	V5.3.2	26/09/2016
SSI Form	V5.3.2	26/09/2016
Protocol	V1	03/07/2016
Participant Information Sheet – Nursing team	V1	03/07/2016
Consent form	V1	03/07/2016
GP information and letter	V1	13/07/2016
Questionnaire ESRDAQ: End stage renal disease adherence		-
Questionnaire RSQ		-
Questionnaire: Relationship		-
Questionnaire: PHQ9		Aug 2003
Questionnaire: GAD7 scale: Generated Anxiety Disorder (7-item)		-
Summary CV: Gordon		03/04/2016
Summary CV: Gardner		Undated
Summary CV: Parry-Jones		Undated
Summary CV: Jackson		Undated
Evidence of Insurance		Expires 31/07/2017
Risk Assessment		04/11/2016
REC favourable opinion letter		16/09/2016

All research conducted at the Betsi Cadwaladr University Health Board sites must comply with the Research Governance Framework for Health and Social Care in Wales (2009). An electronic link to this document is provided on the BCUHB R&D WebPages. Alternatively, you may obtain a paper copy of this document via the R&D Office.

Attached you will find a set of approval conditions outlining your responsibilities during the course of this research. Failure to comply with the approval conditions will result in the withdrawal of the approval to conduct this research in the Betsi Cadwaladr University Health Board.

If your study is adopted onto the NISCHR Clinical Research Portfolio (CRP), it will be a condition of this NHS research permission, that the Chief Investigator will be required to regularly upload recruitment data onto the portfolio database. To apply for adoption onto the NISCHR CRP, please go to: http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=31979. Once adopted, NISCHR CRP studies may be eligible for additional support through the NISCHR Clinical Research Centre. Further information can be found at:http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=28571 and/or from your NHS R&D office colleagues.

To upload recruitment data, please follow this link:
http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_recruitment.
Uploading recruitment data will enable NISCHR to monitor research activity within NHS organizations, leading to NHS R&D allocations which are activity driven. Uploading of recruitment data will be monitored by your colleagues in the R&D office. If you need any support in uploading this data, please contact debra.slater@wales.nhs.uk or sion.lewis@wales.nhs.uk

If you would like further information on any other points covered by this letter please do not hesitate to contact me.

On behalf of the Panel, I would like to take this opportunity to wish you every success with your research.

Yours sincerely,

Dr. Nefyn Williams PhD, FRCGP
Director of R&D

Copy to:

On behalf of Sponsor:	Mr Hefin Francis School of Psychology Brigantia Building, Penrallt Road Bangor University, Bangor LL57 2AS	h.francis@bangor.ac.uk
Academic Supervisors:	Dr Beth Parry-Jones Renal Unit Glan Clwyd Hospital Sarn Lane, Rhyl LL18 5UJ	blparry-jones@tiscali.co.uk
	Dr Paul Gardner Renal Service Ysbyty Gwynedd Penrhosgarnedd, Bangor LL57 2PW	paul.gardner@wales.nhs.uk

Dr Mike Jackson
North Wales Clinical Psychology Programme
43 College Road, Bangor University
Bangor, Gwynedd
LL57 2DG Mike.Jackson@bangor.ac.uk

Bangor University Ethical Approval

Dear Jessica,

2016-15696 Treatment Adherence in End-Stage Renal Disease: Exploring Attachment Styles and Mood as predictors.

Your research proposal number 2016-15696
has been reviewed by the Psychology Ethics and Research Committee
and the committee are now able to confirm ethical and governance approval for the above research on the basis described in the application form, protocol and supporting documentation. This approval lasts for a maximum of three years from this date.

Ethical approval is granted for the study as it was explicitly described in the application

If you wish to make any non-trivial modifications to the research project, please submit an amendment form to the committee, and copies of any of the original documents reviewed which have been altered as a result of the amendment. Please also inform the committee immediately if participants experience any unanticipated harm as a result of taking part in your research, or if any adverse reactions are reported in subsequent literature using the same technique elsewhere.

APPENDIX 7

Consideration of Outliers

A visual inspection of a matrix scatter graph of the correlation analyses was conducted. From the inspection, it was identified that when scores on the PHQ9 were compared against adherence and attachment styles, the scores on the PHQ provided by one participant was considered to be a potential outlier. The participant was removed from the data in order to compare results with and without the outlier.

With the removal of the outlier, the correlational analyses indicated that participants who scores higher for symptoms of depression on the PHQ9 still tended to be less adherent to overall treatment ($r= .396$, $p<.030$). Therefore, as the outlier was not deemed to have significantly impacted the results, the outlier was not removed in order to maintain authenticity of the data outcomes.

In order to identify whether potential outliers may have impacted the results of the regression analyses, Mahalanobis distances were calculated for each analysis and compared to the critical values outlined by Stevens (1984)[1]. The maximum distance for each analysis was less than the critical values identified for a multivariate sample and therefore no amendments were made to the data.

[1]Stevens, J.P. (1984). Outlier and Influential Data Points in Regression Analysis. *Psychological Bulletin, 95(2),* 334-344

Chapter 3

Contributions to Theory and Clinical Practice

Contributions to Theory and Clinical Practice

The current thesis aimed to explore the role of psychological factors of patients with End-Stage Renal Disease (ESRD), paying particular attention to ESRD treatments. The thesis has been categorised into three distinct chapters, with psychological factors of ESRD running centrally through each chapter. The first chapter consists of a systematic review of the current literature on the impact of ESRD treatments on body-image. The second chapter consists of an empirical study, which explores the relationship between attachment styles, anxiety and depression on adherence to ESRD treatment. Both chapters highlight how psychological factors are critical to the ESRD treatment process and should be considered within clinical practice. With this in mind, this third and final chapter discusses the implications of both papers, including implications for theory and recommendations for future research, clinical implications and personal reflections on the research process and outcomes.

Implications for theory and future research

The literature review explores the relationship between ESRD treatments and body-image, focussing predominately on the implications of haemodialysis, peritoneal dialysis and kidney transplantation on body-image dissatisfaction/disturbance (BID). The review highlights the presence of BID within the population, as well as the differences between treatment modalities and the relationship with mental health. Despite clear evidence of BID concerns generated from the review, with the exception of Sadeghian, Raidsari, Seyedfatemi and Rafiei (2016), who reported the levels of low, moderate and high BID within their sample, the selected studies offered limited data on the prevalence of BID. It is unclear why prevalence data was not reported across studies, with one possible explanation being inconsistencies in the way in which BID is measured.

From the thirteen studies selected for the review, only two papers (Leonard, 2013; Partridge & Robertson, 2011) utilised the same measure, the Body-image Disturbance Questionnaire (BIDQ: Cash, Phillips, Santos & Hrabosky, 2004). Each of the remaining studies measured BID differently, with some studies utilising structured interviewing, and others generating their own measure. Within the subject area of body-image exists a wide range of body-image questionnaires, assessing a variety of factors including body-focussed anxiety, cognition, avoidance behaviours and distress, for a variety of specific presentations, such as weight concerns, shape, muscle tone or diagnostic criteria for eating disorders (Thompson, Roehrig, Cafri & Heinberg, 2005). Thompson et al., (2005) highlights how, with over 30 forms of body-image measures available, selecting measures can be a daunting task for researchers and clinicians. With this is mind, it may be challenging to conclude prevalence rates, when BID is being measured so differently and inconsistently within clinical settings and research. It is important to bear in mind that for the ESRD client group, many of the common body image concerns, such as weight and body shape, are prevalent and addressed within body-image measures. However, the majority of measures have not been tested for reliability and validity for the ESRD population and do not account for bodily changes such as a fistula, scarring, insertion of a catheter, hair growth/loss or over-grown gums (Matas, Halbert, Barr, Helderman, Hricik et al., 2002). Future research may benefit from focussing on the development of a measure that is reliable and valid for this client group. If routinely used, an ESRD body-image measure may enhance understanding of the prevalence of BID, as well as accurately monitor fluctuations within a clinical setting.

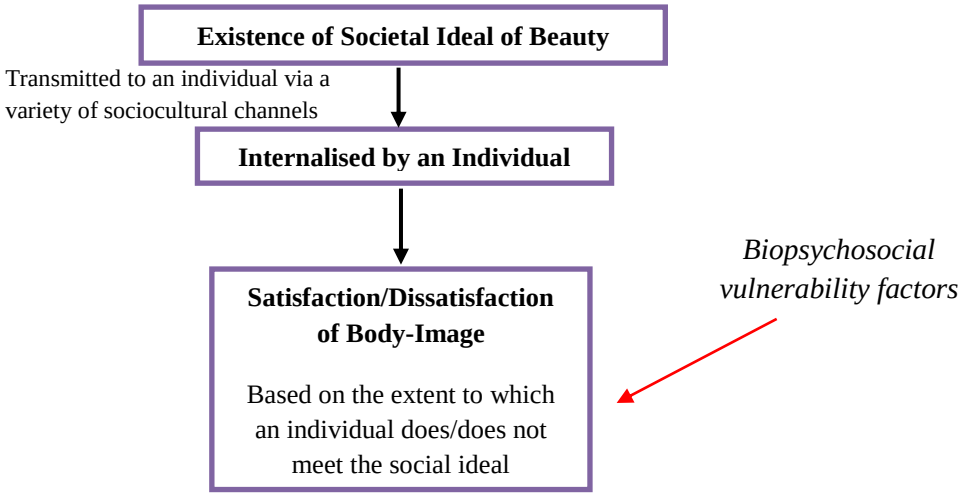
Within the empiricial paper, the End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ) was used to measure treatment adherence, however, it was altered for the study. The adaption of the ESRD-AQ reduced potential questionnaire burden for participants, given that the original questionnaire included 46 items and was estimated to take up to 40 minutes

to complete. Although the reduction of items to 9 questions allowed measurement of adherence, as these were the only items that generated a value from the answer, allowing comparison to results of other studies, it is plausible that important qualitative information may have been lost. Some of the items which were omitted from the study included questions such as "how important do you think it is to attend your HD appointments?" could have provided important information about participant perspectives of their treatment, which would have allowed a more in depth understand of adherence for the population. Future research should consider the administration of the full measure, which could allow attitudes to treatment to be compared to anxiety, depression and attachment styles. However, the burden on participants should still be considered.

The Sociocultural Model of body-image is represented in Figure 1. It is a conceptual framework for understanding and investigating the development of body-image dissatisfaction (Cash & Smolak, 2011). The model describes clearly the process by which an individual may go through in the development of positive or negative body-image. The social ideals of beauty are developed culturally and transmitted to an individual through a number of different means, but most commonly through the media. Although the model has been primarily applied in relation to weight and shape, it can be equally applied to other features, such as height, skin colour, skin clarity, eyes or many other attributes (Cash & Smolak, 2011). Within western society, newspapers, magazines and the internet idealise weight, size and appearance for men and women and rarely promote appearances that are anything other than 'perfect.' In the same way, the knowledge and awareness of ESRD and the consequential treatments are rarely publicised, meaning the bodily changes a person experiences are rarely recognise by anyone other than those who receive treatment and those closest to individuals receiving treatments, as well as renal professionals. Therefore, patients find themselves covering their bodies by carefully selecting their clothing to hide these

features (Beer, 1995). The Kidney Health Report (2013) outlines the growing need for awareness of kidney disease across the general public, mainly to prevent kidney problems and raise awareness of the need for kidney transplant donors. However, increasing awareness of treatments would also be a positive step towards making those receiving treatment feel more comfortable about their appearance, by making the bodily features of ESRD treatments more recognisable and accepted by the general public.

Figure 1. *Sociocultural Model of Body-Image (Cash & Smolak, 2011)*



It is important to recognise that the model highlights the importance of how social ideals of body-image are culturally specific. The literature review includes research papers from a number of different cultural backgrounds, including studies that have taken place in the UK, USA, Turkey, Iran, Israel and Thailand. Each culture may present with their own ideals of body-image, meaning that the extent to which patients experience BID may vary culturally, although research in ESRD and body-image is yet to explore these possible differences. For instance, the populations in Turkey and Iran are predominately Muslim. Research exploring the differences in body-image in Muslim and Non-Muslim women has suggested that the strength of a Muslim women's religious faith was correlated with less body-dissatisfaction, body-self objectification and dietary restraint, compared to Non-Muslim

women, mediated by factors such as modest clothing and a reduction in media consumption (Mussap, 2009). Additionally, an exploration into body-image which compares participants from the USA to Rural Thailand, illustrated significant differences in body image ideals in men and women cross-culturally (Sharps, Price-Sharps & Hanson, 2001). Therefore, it is important to consider the cultural differences when exploring body-image and should be considered in future ESRD research.

Importantly, the sociocultural model of body-image recognises that a number of biological, social and psychological factors moderate the relationship between cultural ideals and the development of body-image dissatisfaction, meaning that certain individuals may be more vulnerable to the development of BID than others, who may be more likely to reject social expectations (Cash & Smolack, 2011). For example, an individual with low self-esteem may be more likely to develop body-image dissatisfaction. The literature review highlighted the relationship that exists between individuals with body-image dissatisfaction in the ESRD population and mental health difficulties, such as anxiety and depression. The causality of this relationship is unclear, but it is reasonable to imagine that those patients who experience anxiety and depression could potentially be more vulnerable to the development of BID. The findings from the empirical paper also highlighted the importance of considering psychological factors, such as depression and attachment, within the ESRD.

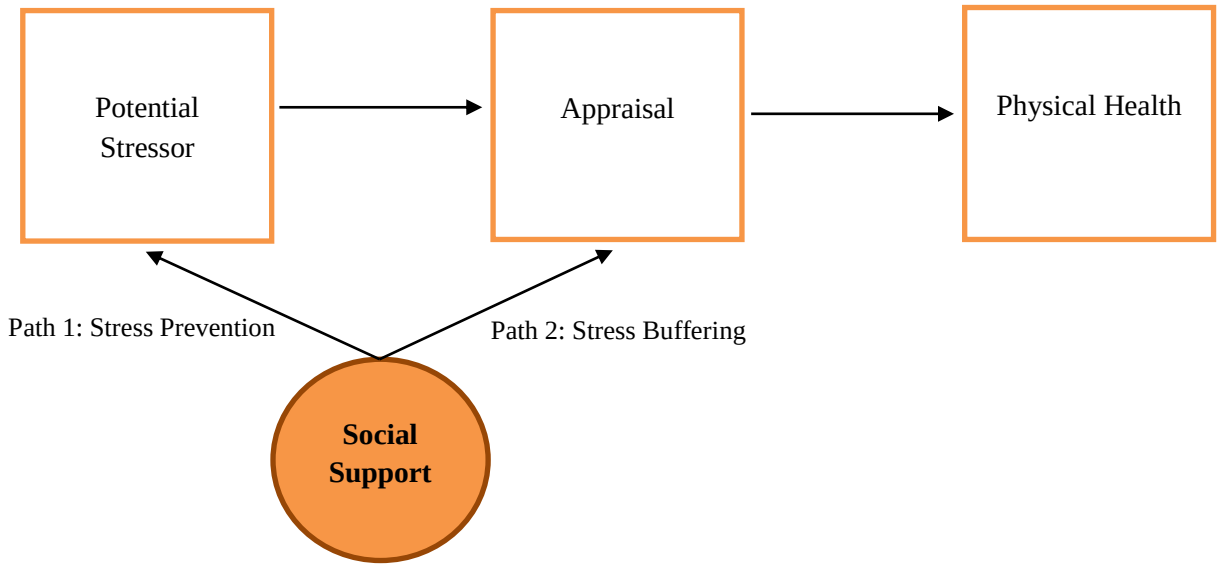
Research on the area of BID has begun to draw links between the roles of attachment styles in the development of BID. A study by Cash, Theriault and Annis (2004) identified that for both men and women, features of insecure attachment style, such as preoccupied attachment, are more likely to be associated with BID. Furthermore, in line with the Socialcultural Model for body-image, adults with anxious attachment styles are more likely to internalise media influences, which in turn is associated with the development of BID

(Cheng & Mallinckrodt, 2009). Thus, ESRD patients who present with features of insecure attachment may be more vulnerable to the development of BID, which should be explored within future research.

Given the findings for attachment, identified in renal treatment in chapter two, and the possible influences of attachment on BID, noticeable links can be identified from both papers. An individual's attachment style influences the way in which a person is able or motivated to develop and maintain social relationships and therefore can influence the way in which an individual is able to access and make use of social support. In a variety of medical settings, social support is considered to be an important factor in recovery from illness, injury and health maintenance (Di Matteo, 2004). A meta-analysis by DiMatteo (2004) which reviewed 122 studies on treatment adherence in chronic health conditions identified a significant relationship between adherence and practical, emotional and unidimensional social support. More specifically within ESRD, social support from family, special persons and friends has been positively associated with increased compliance to treatment, as well as decreases in depression and improved quality of life (Patel, Peterson & Kimmel, 2005). However, the mechanisms by which social support exerts such a positive effect is less clearly understood (Patel et al., 2005).

Models of social support, which have been considered within physical health, most commonly consider the role of social support in stress-related processes, including models of stress buffering and stress prevention, depicted in Figure 2.

Figure 2. *Main pathways involved in stress-related models of social support (Uchino, 2004).*



According to the stress prevention pathway, social support intervenes at the time in which a potential stressor presents. It is beneficial as the network of individuals providing the support delivers the resources to avoid or reduce our exposure to some types of negative life events, decreasing the number of stressors an individual may experience (Uchino, 2004). Within the appraisal phase, according to the buffering model, social support is beneficial as it decreases the negative effects of stress, mentally and physically, by reducing the intensity of the stress response through social support and facilitates coping (Uchino, 2004). However, an important factor to consider within the model is individual personality characteristics which can influence whether an individual seeks support in the first place, or benefits from social intervention. An example of this is an individual who may present as hostile or is mistrusting of others (Uchino, 2004), such as those who present with features of dismissive or fearful attachments. Although the findings from chapter two did not provide definitive evidence for the role of attachment in predicting variance in treatment adherence, a correlational relationship was identified between adherence and traits of insecure-fearful attachment. The results of the study identified that attachment appeared to predict the same variance identified by a patient's age and depressive symptoms, but did not independently predict variance in

treatment adherence. The mechanism by which insecure attachment may influence poor adherence in ESRD remains unclear, but it is plausible to consider that insecure-attachment may act as a potential barrier to accessing social support. Future research should consider whether attachment style plays a mediating role between social support and adherence to treatment in ESRD.

When considering the role of social support in ESRD, it is important to consider the impact on those closest to the patient. Previous research has considered the disruptive influence of haemodialysis and peritoneal dialysis on family life, as well as the greater amount of physical support required if some patients become frail and lose functional independence as ESRD progresses (Lowe, Smith, Burns & Jones, 2008). However, some people closest to the patient may also become a living kidney donor. Research has considered the psychological impacts of kidney donation for living donors (Wiedebusch, Reiermann, Steinke, Muthny, Pavenstaedt et al., 2009). However, there is less awareness of how donating a kidney may impact on body-image. Initial findings suggest that the impact is less prevalent for donors than recipients (Clemens, Thiessen-Philbrook, Parikh, Yang, Karley et al., 2006). However, some donors were reported to have felt less attractive to their partner, to be dissatisfied with the size and position of their scar and reported a reduction in their self-esteem. More research on the impact of BID for donors is required.

Clinical Implications

Both the literature review and the empirical paper highlight the psychological factors involved in the treatment process and treatment outcomes of ESRD. Health clinical psychology is a relatively new discipline within the field of renal medicine and official guidance and practices are predominately medically focussed. Despite the interconnection between mental and physical health, the way in which nurse training is facilitated within the

UK means that often, those whose training is focussed on physical health have little professional exposure to mental health care, and vice versa (Chesnaye & Kemp, 2016). Consequently, within the field of physical health conditions, this can leave nurses feeling hesitant to deal with people who present with psychological needs (Chesnaye & Kemp, 2016). Therefore, within clinical practice, training is required for medical staff to support them to understand and become familiar with features of psychological difficulties which may present within the population and to build confidence in professionals to be able to recognise and support patients with comorbid mental health difficulties. This can be provided by clinical psychologists, as part of their role when working within physical health is to train multiciplinary staff in psychological factors and ways of working with patients with long term conditions.

Within both papers, the impact of anxiety and depression was evident in the development of BID for patients, as well as the role of depression in adhering to treatment. Despite the role of mental health in treatment outcomes, currently, the National Institute for Health and Care Excellence (NICE) does not provide specific guidance for screening or intervention within ESRD (NICE, 2014). The guidelines refer to the importance of making patients aware of access to psychological support, but is yet to provide direction on what evidence based practices should be delivered. Given the impact of mental health on treatment outcomes, psychological distress should be routinely screened for within services, including measurement of anxiety and depression.

In comparison to previous studies conducted within the renal dialysis population, the rate of depression within this population was relatively lower, on average. One possibility for this difference could be that patients experiencing higher rates of depression were not captured during sampling. In order to ensure any potential risk of patients safety was

managed, the researchers proposed that any patient who met moderate or severe rates of clinical depression or anxiety, as identified by the psychometric measures, would be offered a referral to the renal psychological therapies service or that their GP would be notified, with participant permission. This was reported in the participant and nursing information sheets. Research suggests that factors such as social stigma, fears of treatment and experiencing emotion, possible risks and reluctance to self-disclose can result in avoidance of psychological intervention (Vogel, Wester & Larson, 2007). Therefore, the potential of a referral or feedback of a participant's psychometric measurements may have potentially discouraged participation in the study and future research should consider this potential barrier, alongside ensuring possible risks are safeguarded.

Although the majority of participants scored relatively low on the measure for depression, from visual inspection of the correlation scatter plots and raw data, a number of participants scored within the clinical range for depression and one participant in particular was considered to be a potential outlier. Where an outlier is not the result of a mistake whilst taking measurement or an administrative error, it is possible that the result is a legitimate data value, representing a natural variability in the data (Utts & Heckard, 2006). Outliers can be considered as evidence of influence of an unmeasured variable, rather than a sign that the data point is somehow erroneous. However, it is important to know whether a single point is especially influential in an analysis. Within this case, the participant scored particularly high on depression and reported high rates of non-adherence. This could be explained by the influence of a number of different unmeasured variables, such as comorbid physical health problems causing added complications to adherence or further mental health difficulties in addition to depression. Although it is not possible to anticipate all influential variables, future research should consider a broader range of exclusion criterion in order to minimise outlier influence. The potential impact of additional variables should also be considered when

developing appropriate interventions. A psychological formulation, utilising the role of renal clinical psychology, would be particularly beneficial for these patients in order to ensure that all influencing factors are considered when supporting them to manage their treatment.

In addition to mental health measurement, measurement of BID should also be considered, making careful consideration of what BID measurement tools are appropriate for the client group. Additionally, it is important to incorporate psychological disciplines into the multi-disciplinary team, particularly when patients are struggling to adhere to their treatment. Offering a psychological formulation of non-adherence, which considers attachment styles with caution, could contribute significantly to developing a care plan that supports the team to understand the best ways to interact with a patient and work towards better treatment outcomes, taking into account an individual's characteristics and previous history.

Currently, there are a limited number of randomised control trials (RCT) which have been conducted to explore the usefulness of psychological interventions in improving mental health outcomes for patients with ESRD. However, although in its infancy, Cognitive-Behavioural Therapy (CBT) has shown promising results for ESRD patients in an individual setting, as well as within group interventions. Duarte, Miyazaki, Blay and Session (2009) provided a group of 41 haemodialysis patients who presented with major depression with 12 weekly sessions of group-based CBT. When compared to a 'treatment as usual' group, the intervention group experienced a significant reduction in depressive symptoms, as well as improvements in quality of life which accounted for burden of renal disease, sleep, quality of social interaction and overall health (Duarte et al., 2009). This provides good evidence for the usefulness of CBT as an intervention. Currently, a number of other RCT's are in process across the UK, such as comparing the usefulness of CBT in comparison to pharmacological interventions. Additionally, evidence has begun to illustrate the usefulness of Acceptance and

Commitment Therapy as an intervention for depression in ESRD (Fledderus, Bohlmeijer, Pieterse & Schreurs, 2012).

Furthermore, evidence also suggests that CBT is useful in improving treatment adherence. Cukor, Ver Halen, Asher, Coplan, Weedon et al., (2014) completed a RCT which not only represented the usefulness of CBT for the treatment of depression and improvements in quality of life, but also illustrated improvements in interdialytic weight gaining, suggesting that patients were more likely to adhere to fluid restrictions. It is important to consider, however, that given the relationship identified between traits of insecure-fearful attachment and poor ESRD treatment adherence, patients with fearful attachment styles may be more likely to resist social support and therefore may find accessing psychosocial interventions challenging. With specific consideration to fearful-attachment styles, as depicted from the results of the empirical paper, research suggests that patients who present with fearful-attachments have difficulty developing a working alliance with the clinician in the initial stages of therapy, which limits the progress of the intervention (Reis & Grenyer, 2004). It is therefore important to consider that ESRD patients who present with these features are provided with longer periods of therapy to allow for the opportunity to build a therapeutic relationship in order to maximise the likelihood of good treatment outcomes. However, this should be considered with caution, as the results also suggested that insecure-attachment did not independently predict variance in adherence, over and above age and depression.

As BID research within the ESRD population is still a relatively new area, there is currently no evidence on what interventions are useful for this client group. However, given that patients with BID or who present with disfigurement following an accident or surgery often present with social anxiety, it is reasonable to consider CBT as a possible intervention. A systematic review of interventions for body-image and disfigurement by Rumsey and

Harcourt (2004) identified CBT and social skills training as useful interventions in reducing psychological distress associated with negative body-image. Additionally, promoting self-compassion has also been associated with improvements in body-image. Albertson, Neff and Dill-Shackleford (2015) provided a brief compassion focussed intervention for women with BID, focussed around mindfulness based practices, and found a significant reduction in BID following the intervention.

Although there are no current guidelines within the UK for evidence based interventions, research suggests a variety of psychological interventions are beneficial in the treatment of depression, improvements in adherence and treatment of BID which should be accessible to patients within renal services. Over recent decades, the role of psychology within medical settings has become more accepted and its usefulness is increasingly recognised. In 2002 the British Renal Society (BRS) recommended that one clinical psychologist should be in post for every 1000 renal patients, increasing to one clinical psychologists to every 500 patients, if an appropriate social work and counselling service is not accessible (BRS, 2002). This illustrates the increasing awareness of the importance of incorporating the discipline of clinical psychology into renal services. As well as facilitating a range of psychological therapies, such as the aforementioned interventions, the role of a clinical psychologist should also include training and consultation for other healthcare professionals, to increase positive treatment outcomes for renal patients.

Reflections

Prior to selecting my thesis topic, I had very little experience working in the field of health clinical psychology. Therefore, I have found myself asking the question, why did I choose this topic? Over recent years, health clinical psychology has begun to be recognised as an important and necessary resource within the field of physical health conditions. This is

particularly the case in renal medicine, which is a relatively novel area of psychology. The thought of getting involved in a project that was totally new and unique was an exciting one, and coupled with the clear enthusiasm and passion from the renal clinical psychologists working within the region, my decision was made. However, the interest in renal psychology stemmed before that, when I had to opportunity to meet some renal service users during a teaching session, who told their story of coping with ESRD and the psychological impact of their condition. I was struck by the intensity of their treatment and how challenging they had found adjusting to life on dialysis, particularly adjusting to the bodily changes they had experienced. I was completely naïve to the processes of renal failure and treatment, and inspired by the challenges that the service users had overcome. This steered my thought process towards the area of renal psychology.

Within the initial stages of developing the ideas for my thesis, I remember feeling overwhelmed by the amount of research possibilities there were to consider. There was still so much unknown about the psychological factors within ESRD, which was both exciting and daunting. I considered the themes that had developed from previous research within the local area and was drawn to exploring the implications of body-image for renal patients. This was an interest that developed from personal experiences of the impact of body-image and led me to pursue a review of the literature. For the empirical paper, I had a sense that I wanted to "do something worthwhile". After consultation with the renal team, it was clear that adherence to treatment was a priority within services and therefore I was led to this topic. I proposed my project to the local teams and was asked to present my proposal during a team meeting. Looking back over the process of completing the thesis, I consider this to be the first significant hurdle. I was very aware that introducing a psychological model into a medical framework can be a challenging experience and I felt my anxiety begin to increase as I was determined to 'fly the flag' for psychology. However, I completed the presentation and I was

over the first hurdle with support from the renal teams to proceed with applying for ethical approval for the study.

The process of data collection gave me the opportunity to travel the length and breadth of North Wales, seeing some wonderful sights along the way. However, as I was conducting the research in Wales, I was very aware of the fact that I was not a Welsh speaker and therefore, was unable to converse with participants in Welsh. I noticed myself feeling guilty about this, as I was aware that I was not facilitating some patients with the opportunity to express themselves in their first language. With this in mind, I felt content with my choice to proceed with a quantitative piece of research, as I feel that language barriers may have presented difficulties when analysing transcripts from a qualitative study.

As the process of data collection began, I quickly came to realise that, despite the study being designed for participants to be able to complete their questionnaires independently, the majority of patients wanted the opportunity to complete the questionnaire collaboratively and tell their story whilst doing so. I was privileged to have the opportunity to hear about people's lives and experiences on dialysis and I found myself accumulating hundreds of ideas for future research based on what was important to the patients receiving treatment. Throughout the completion of the questionnaires, I came to realise the strength of the relationships that had developed between service users. Several participants described 'rushing' to dialysis to try to get a seat next to their friend and, despite wishing they did not need to attend dialysis appointments, they looked forward to seeing each other. They spoke of the loss they felt when fellow patients who they had grown fond of had passed away and how this had affected them. In contrast to this, I observed how other patients wanted very much to be left alone during their treatments, having barely any interaction between other patients or

clinical staff. This again made me reflect on the processes of attachment and considered how attachment styles may impact upon the social support patients' access from one another.

As I met the participants and heard their stories during completion of their questionnaires, I began to notice that the 45 minutes I had estimated for each participant had quickly developed into 2 hours, as I felt compelled to allow each participant the opportunity to tell their story and have someone listen to it. The majority of patients were a similar age to my grandparents. I found myself thinking "if this was my Nan, I'd want someone to listen" and therefore, at times, I found balancing the roles between researcher, clinician and simply a person with a listening ear, difficult. However, participants commented on how much they had enjoyed participating in the study and the opportunity to engage in conversation and I often found myself feeling satisfied that each participant had benefitted from taking part.

Throughout the process of data collection, I spent long periods of time on the wards at patients' bedsides, often accumulating to 12 hour days. I found myself becoming more aware of the processes of the ward environment. I noticed the relationships that had developed between the staff and patients, and the care they had for one another. Unfortunately, whilst in the process of data collection, a number of patients had recently been moved to intensive care or sadly, had passed away. The impact of these losses and the concern shown by both patients and staff was warming. However, I found myself struck by the fragility of life. I began making more time for my family and friends, particularly my grandparents, rather than spending every evening and weekend working. Upon reflection, completing the thesis has offered some wonderful opportunities for professional development, but unexpectedly also offered the opportunity for personal growth.

Conclusions

Both chapters offer important findings on the psychological processes within ESRD treatments, and contribute to the theoretical understanding of ESRD. Additionally, the papers offer significant findings which should be considered within clinical practice, as well as key areas for future research. Furthermore, the process has led to important professional and personal reflections. The aim of this research was to explore areas of renal psychology that are new, unique and will assist in shaping renal services. I hope that this research will contribute towards achieving these aims and will assist with improving patient care in the future.

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Paper 1: Literature Review

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Paper 3: Contributions to Theory and Practice

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