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Exploring Loneliness and Connectedness amongst Service Users in Acute Adult Mental Health Inpatient Care

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Exploring Loneliness and Connectedness amongst Service Users in
Acute Adult Mental Health Inpatient Care

David Oakley

June 2017

This thesis is submitted in partial fulfilment of the regulations for the Doctorate in Clinical
Psychology

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Section 1

Thesis Abstract

This thesis concerns exploring and understanding loneliness and connectedness amongst service users in acute adult mental health inpatient care, through a qualitative study using grounded theory.

The empirical study used a constructivist grounded theory approach to explore the subjective experiences of loneliness and connectedness for service users both immediately before and during an admission to an acute adult mental health inpatient unit. Six service users with a diverse array of psychiatric symptoms were interviewed. Their constructions of how they experienced loneliness and social connectedness were coded with a focus upon identifying actions and processes. Three major categories emerged: (1) factors changing connectedness, (2) responses to changing connectedness and emerging processes, and (3) responding to inpatient care. The small sample size limits the generalisability of these findings. These categories may help identify valuable social processes to consider in acute care, and support further investigations in this area.

A narrative literature review evaluated the state of research regarding the subjective experience of loneliness and an area relevant to acute care, the onset of psychosis. The review identified that research has begun to explore whether loneliness may directly or indirectly influence the onset of psychosis, but is currently limited both by the cross-sectional nature of studies, and a lack of understanding of how the construct of loneliness might be different for people with psychosis.

A need for further research across more diverse populations is highlighted in a third paper, along with other research and clinical implications.

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Acknowledgements

I would like to acknowledge and thank the service users who engaged so openly and bravely during a very difficult period of their lives. This thesis exists as a vehicle for their voices to be heard. I would also like to thank the service users who I met during my own difficulties, your voices and experiences shaped this work as much as my own.

I would like to thank all the staff working at the Inpatient Unit we visited to carry out the research project. Their commitment to caring, whatever the circumstances might be, is an example to all.

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I would like to thank my training cohort for allowing the past three years to be a team effort.

I would like to thank my parents for keeping me alive.

Lastly, I would like to thank all the people who are connected to me. You are all in at least some way, responsible for this project, and most of you will never have even met me.

Section 2: Literature Review

Loneliness and the Onset of Psychosis: A Narrative Review

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Loneliness and the Onset of Psychosis: A Narrative Review

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Abstract

Whilst an association between loneliness and psychosis has now been established by recent research, the nature of this association remains unclear. A narrative literature review was conducted, using a systematic search strategy, to explore what potential mechanisms for the role of loneliness in the onset of psychosis may exist. A total of 20 studies were identified that highlight a diverse array of potential roles for loneliness in the onset of psychosis. These were organised into five conceptual categories: (1) The construct of loneliness, (2) Social networks and support, (3) Early adversity, (4) Loneliness and Paranoia, and (5) Isolation and the Social Deafferentation Hypothesis. Firm conclusions cannot be drawn at this time due to the cross-sectional nature of most of the data, and a lack of clarity regarding the concept and measurement of loneliness for people with psychosis. Suggestions for future research to resolve these concerns, and spur research capable of improving clinical outcomes for early onset psychosis are discussed.

Key Words: Loneliness, Psychosis, Narrative, Isolation, Paranoia, Adversity

Loneliness and the Onset of Psychosis: A Narrative Review

Mental health services have increasingly adopted a recovery-based approach, where recovery is informed by the subjective experience of service users (HM Government, 2009; Leamy, Bird, Le Boutillier, Williams, & Slade, 2011). This has spurred research into the subjective experience of mental health, and this has included the experience of loneliness (Cacioppo, Grippo, London, Goossens, & Cacioppo, 2015). A recent meta-analysis (Michalska da Rocha, Rhodes, Vasilopoulou, & Hutton, 2017) reviewing this growing field of research found a moderate association between psychosis and loneliness ($k= 13$, $N= 15\ 647$, $r= .32$, 95% CI 0.20, 0.44). However, the nature of this association remains unclear due to the cross-sectional nature of much of the research to date (Michalska da Rocha et al., 2017). With the increasing use of early intervention teams in the treatment of psychosis, and with limited efficacy for psychosocial interventions used by these services (Marshall & Rathbone, 2011), there is a need for greater understanding of the specific role loneliness may play in the onset of psychosis.

Defining Loneliness

Psychiatrist Frieda Fromm-Reichmann is widely attributed as first raising loneliness as an important topic of study in relation to mental health (Fromm-Reichmann, 1959). Loneliness had been considered a part of depression, (Young, 1982) but a significant body of research has now shown loneliness to be a distinct construct (Cacioppo, Hawkley, & Thisted, 2010; Cacioppo, Hughes, Waite, Hawkley, & Thisted, 2006; Heinrich & Gullone, 2006; VanderWeele, Hawkley, Thisted, & Cacioppo, 2011; Weeks, Michela, Peplau, & Bragg, 1980). Researchers have developed a theoretical and empirical basis for quantifying and measuring loneliness (Russell, Peplau, & Cutrona, 1980; Russell, Peplau, & Ferguson, 1978; Weiss, 1973). The common working definition adopted in research is of “the discrepancy

between the preferred and actual social relations of an individual” (Peplau & Perlman, 1982). By focusing upon the discrepancy between what is experienced and what is desired socially, loneliness can be separated from being alone. This separation is important, as under certain circumstances time spent alone has been linked to the potentially positive state of solitude (Storr, 1988).

Whilst the definition of loneliness refers to the single idea of discrepancy, and the current primary instrument of measurement, the UCLA Loneliness Scale (Version 3) is presented by its author as a unidimensional scale (Russell, 1996), more recent research into loneliness suggests that it should be considered a multidimensional construct (Cacioppo et al., 2015; Hawkley, Browne, & Cacioppo, 2005; Hawkley, Gu, Luo, & Cacioppo, 2012). This approach has been grounded in theories of multidimensional social (Dunbar, 2014; Weiss, 1973) and attentional (Hall, 1963; Ortigue, Megevand, Perren, Landis, & Blanke, 2006) space, and suggests three different types of loneliness: intimate, relational and collective (Cacioppo et al., 2015). Respectively, these concern the feeling of loss or absence for: an intimate loved one, quality friendships and family relationships, and social identity and connection to larger social networks. In more recent studies reviewing the UCLA Loneliness Scale as a potentially multidimensional scale, a similar three-factor structure has been shown amongst various groups in the general population, including young adults (Hawkley et al., 2005), older adults (Hawkley et al., 2005), adults and older adults in China (Hawkley et al., 2012), and adolescents in the UK (Shevlin, Murphy, & Murphy, 2015).

Studies are beginning to explore this three-factor structure amongst clinical and at-risk populations, and the nature of measuring loneliness in studies relating to the onset of psychosis will be included in this review. When considering the construct of loneliness in relation to psychosis however, a further important question should be considered. As an example, in one of the many papers considered for this review, loneliness was measured by

asking “How alone do you feel in your life?” (Giacco, Palumbo, Strappelli, Catapano, & Priebe, 2016). This question may be viable in surveys of the general population, but for people beginning to or actually experiencing phenomena such as hearing voices, the concept of “feeling alone” may have a very different meaning. Investigating how elements of psychosis are themselves experienced in the frame of reference of loneliness and social connection would appear important, as this may mean that adaptations to existing measures of loneliness are needed for this population.

Loneliness and Psychosis

Psychosis refers to “a mental health problem that causes people to perceive or interpret things differently from those around them.”(NHS Choices, 2017). Symptoms are usually distinguished as either positive symptoms where new behaviours not experienced previously emerge (e.g. hallucinations and delusions) or negative symptoms where existing behaviours are reduced (e.g. anhedonia, social withdrawal, changes in emotional responses and impaired attention).

Whilst a consensus is growing for the association between loneliness and psychosis (Michalska da Rocha et al., 2017), the potential role loneliness might play in the onset of psychosis is not clear. To assist in this endeavour, this narrative review aims to clarify the conceptual basis of the role loneliness may have in the onset of psychosis, through reviewing the available evidence concerning the relationship of loneliness and psychosis. To provide a workable structure for this endeavour, we have identified four areas of existing research in psychosis where loneliness may play a role.

Social Support and Social Networks

A 2013 systematic review (Gayer-Anderson & Morgan, 2013) found reduced social networks and support pre-date the onset of psychosis. This review considered 38 total papers and highlighted the presence of fewer close friends in groups either before or at the onset of psychosis. This finding was put forward tentatively due to the heterogeneity of the studies available. The authors proposed several potential mechanisms for this effect (Cassel, 1976; Cobb, 1976; Cohen & Wills, 1985; Hodges, Byrne, Grant, & Johnstone, 1999) although the role of loneliness was not specifically one of them. Understanding loneliness in this context may need to consider if the subjective experience of loneliness is different for people at risk of psychosis, and whether this experience has a role in the reduction of social networks and appraisals of sources of support.

Early Adversity

There is a significant amount of existing research into the relationship between early adversity (including trauma such as childhood sexual abuse (CSA) and intimate partner violence (IPV) and the onset of psychosis (see review, Varese et al., 2012). In focusing in on potential mechanisms, inquiry has centred upon the interaction between environment and cognition (Bentall & Fernyhough, 2008). An analysis of data from the 2007 Adult Psychiatric Morbidity survey also found evidence that specific adverse experiences may be solely correlated with specific symptoms of psychosis (Bentall, Wickham, Shevlin, & Varese, 2012). Whilst these relationships are established, loneliness may be a variable worthy of investigation when it comes to looking at the processes that may be involved in this association.

The Role of Isolation

Isolation, whilst not a synonym of loneliness, is one of the three factors identified in the UCLA Loneliness Scale (Hawkley et al., 2005, 2012; Shevlin, Murphy, et al., 2015). The social deafferentation (SDA) hypothesis (Hoffman, 2007) predicts that positive symptoms of psychosis grow as a response to a sensory starved, socially isolating environment. This proposed hypothesis is based upon several observations, with a key part of its rationale being the association seen between sensory deprivation and hallucinations in conditions such as Charles Bonnet Syndrome (Menon, Rahman, Menon, & Dutton, 2003). The direct role of isolation in this hypothesis provides a possible framework for a causal role of loneliness in the development of psychosis. However, further research is required to test this hypothesis.

Paranoia and Cognitive Bias

A proposed mechanism from loneliness research in the general population suggests a “loneliness loop” (Hawkley & Cacioppo, 2010) of developed cognitive biases and self-fulfilling prophecies initiated by a state of loneliness. The role of cognitive bias in the development of persecutory delusions is well established (Freeman et al., 2005; Freeman, Garety, Kuipers, Fowler, & Bebbington, 2002; Freeman & Garety, 2014), such as the “jump to conclusions” bias (Dudley, John, Young, & Over, 1997; Garety, Hemsley, & Wessely, 1991; John & Dodgson, 1994). Therefore, it would appear valid for studies to consider exploring whether these theories overlap, connecting loneliness and paranoia. Reviewing existing research efforts considering loneliness and paranoia together will be a consideration for this paper.

Overall, there is clearly a significant clinical need to develop support options for people experiencing psychosis that meet their subjective recovery goals. An intervention aimed at

increasing social connections, if done incorrectly, may potentially heighten feelings of loneliness, and reinforce the processes behind it. Therefore, it is critical that efforts to focus research in this area are made. This review will focus on evaluating research into loneliness and the onset of psychosis, with the aim of establishing how much progress has been made to date towards this important goal.

Method

Search Strategy

To optimize clarity this narrative review will be based upon a systematic search (Ferrari, 2015; Green, Johnson, & Adams, 2001). We searched a wide variety of complete versions of electronic databases (Web of Science, Science Direct, PubMed, ProQuest and PsycInfo), and these were searched from the database start dates, to April 2017. We used a search term based upon a recent loneliness and psychosis meta-analysis (Michalska da Rocha et al., 2017), adjusted to work with the databases chosen: (psychosis or psychoses or “thought disorder” or schiz* or halluc* or paran* or delus* or psychotic) AND (lonel*). Hand searches of additional references highlighted by review articles and citations also took place.

Screening was conducted by the lead author.

Inclusion and Exclusion Criteria

We employed three basic criteria for study inclusion. These were (1) that the study must focus upon the role of the subjective experience of loneliness in some form, whether by a validated quantitative measure, or through an established qualitative methodology where loneliness was explored directly (2) that participants were present in the study with symptoms of psychosis, whether through validated diagnosis or a validated measure of symptoms, and (3) the study considered loneliness in regards to the aetiology of psychosis. We did not

automatically exclude samples where the experiences of people with psychosis were pooled with those of people with other diagnoses or experiences, although this was noted.

Commentary articles and single case studies were excluded. We also did not automatically exclude studies from different countries, on the basis that they included (1) a valid translation into English (due to the language ability of the reviewer) and (2) any measures used were adequately validated for the language and culture in question.

Assessing Study Quality

Study quality was assessed using PRISMA (Moher et al., 2009) checklists to aid in the evaluation of the literature. Whilst some studies we reviewed would have been excluded in a systematic review for their sample size or not including a control group for comparisons, they were kept for the purposes of this narrative review, with study limitations reported.

Figure 1 below provides a summary of the search process using a PRISMA (Moher et al., 2009) flow diagram.

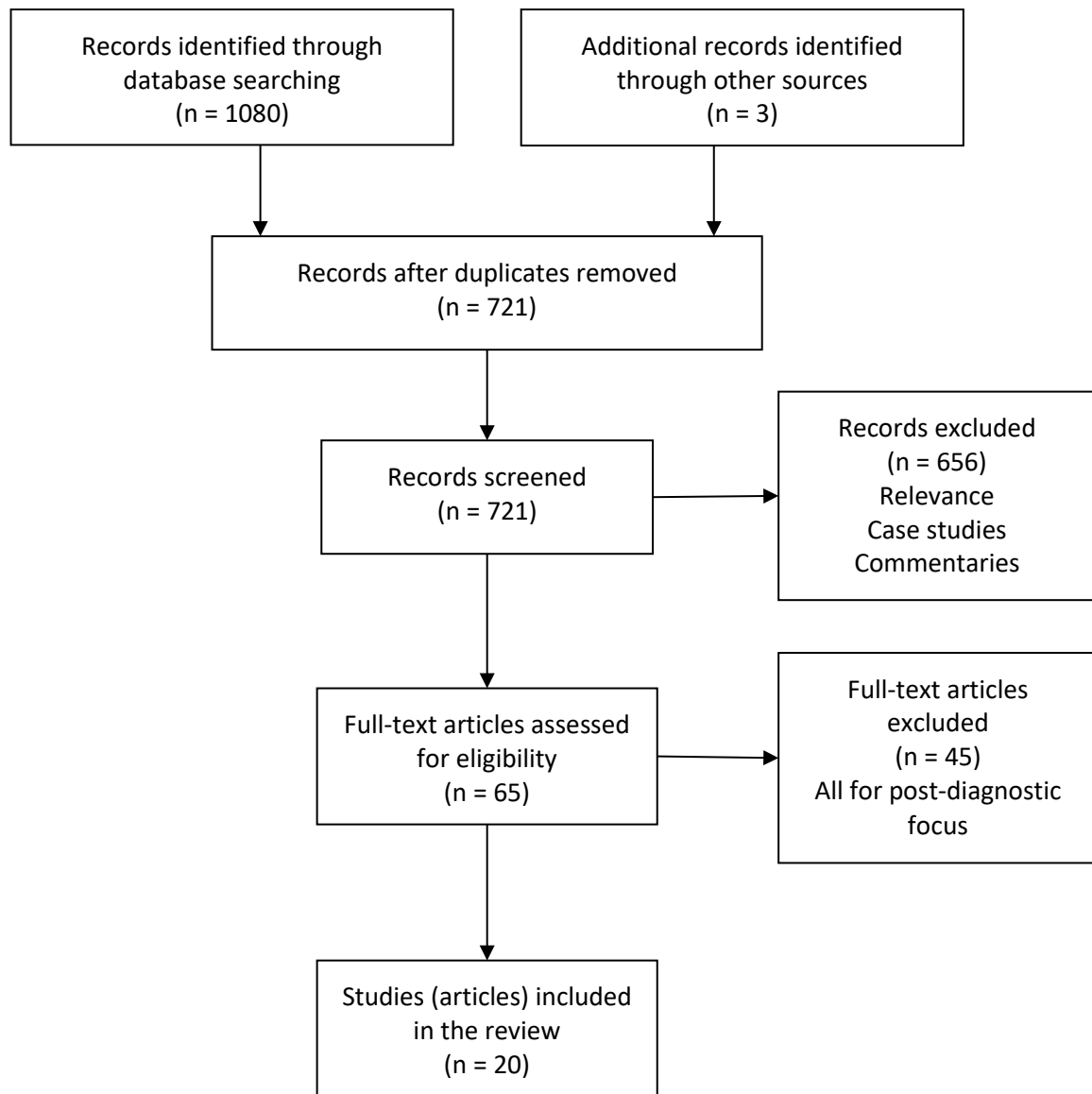


Figure 1 Flow Diagram of Study Selection Process

Results

Search Results

Initial searching returned 1083 results, of which 362 were duplicates. An initial screening of the remaining 721 results took place, with titles and abstracts checked against the inclusion/exclusion criteria. If any ambiguity was present in the abstract, the rest of the paper was checked. This process reduced the number of results to 65 (656 papers excluded). An

in-depth review of these papers followed, with 45 further papers removed due to their focus on loneliness as a factor for people already living with a psychosis related diagnosis. This left 20 remaining papers for review. These papers are summarised in Table 1.

Table 1 Summary Table for Papers Selected for Review

Study	Country	Design	Sample Size & Characteristics	Psychosis Measure	Loneliness Measure	Main Finding	Limitations
Badcock et al., 2016	Australia	Cross-sectional	551 (Students, 170M/381F, Mean Age 20.6 (5.53)).	Wisconsin Schizotypy Scales – Brief	UCLA Loneliness Scale (3 Factors)	Factor analysis showed loneliness distinct from perceptual aberrations and anhedonia once general psychopathology factor accounted for.	Majority female student non-clinical sample may not be representative, only measured two specific elements of schizotypy. Self-report.
Boyda, McFeeters & Shevlin, 2015	Northern Ireland	Cross-sectional	7403 (General UK Population, 43%M/57%F, Mean Age 51 (18.5)).	Psychosis Screening Questionnaire	Single question, four point Likert Scale.	Loneliness mediated an observed relationship between psychosis and intimate partner violence.	Cross-sectional design cannot show causality, single item measure of loneliness, self-report data from general population sample.
Gao et al., 2017	USA	Cross-sectional	10,760 (USA population genotype database, 6376M/4384F, Mean Age 67.2 (10.3)).	Existing genetic correlation data	3 question Leave Behind Questionnaire	Weak genetic coheritability of loneliness and schizophrenia.	General population sample based on genotype data without knowledge of actual psychosis being present.
Gevonden et al., 2014	Netherlands	Imaging Study, Between groups & Associations	38 (19 with Hearing Impairment and 19 Healthy Controls, 6M/32F, Mean Ages 25.1 (3) and 26 (3) respectively).	CAPE	UCLA Loneliness Scale (1 Factor)	Young adults with hearing impairment, who reported as experiencing more loneliness than controls, showed greater dopamine sensitivity when administered amphetamine.	Conclusions based on existing dopamine hypothesis for psychosis link. Female skewed sample.

Study	Country	Design	Sample Size & Characteristics	Psychosis Measure	Loneliness Measure	Main Finding	Limitations
Jaya et al., 2017	USA	Cross-sectional	766 (Pooled from four samples recruited online, 94M/195F, 83M/72F, 89M/62F, 73M/98F, Mean Ages 37.61 (12.77), 36.5 (11.62), 34.07 (11.39), 37.06 (12.65))	CAPE	3 Items from UCLA Loneliness Scale	Strong association between loneliness and positive symptoms, network analysis showed direct link between loneliness and paranoia.	Cross sectional sample from self-reporting internet volunteers may not be reliable, and despite network analysis, not necessarily causal.
Jaya et al., 2016	USA	Cross-sectional	2350 (Pooled from online recruited samples from USA, Germany and Indonesia. 62.2% Male. Mean Age 32.53 (11.38)).	CAPE	UCLA Loneliness Scale (1 Factor)	Loneliness mediated relationship between social adversity and negative psychosis symptoms.	Cross sectional sample from self-reporting internet volunteers may not be reliable. Cross-sectional design does not show causation.
Lamster, Nittel et al., 2017	Germany	Between groups	60 (Students recruited into three conditions, high loneliness, low loneliness, and controls. 37M/23F, Mean Age 33 (14.4))	CAPE, Paranoia Checklist	One question loneliness on ten point Likert Scale	State paranoia increased and reduced in line with increased or reduced loneliness, moderated by psychosis proneness.	Small sample.
Lamster, Lincoln et al., 2017	Germany	Cross-sectional	65 (Online sample self-reporting as having symptoms of psychosis, 43.1% Male, Mean Age 40.49 (12.61)).	Paranoia Checklist	UCLA Loneliness Scale (1 Factor)	Observed association between loneliness and paranoia, mediated by negative schema towards others.	Very small sample for cross-sectional design. Recruited online so may not be reliable. Cannot show causality.

Study	Country	Design	Sample Size & Characteristics	Psychosis Measure	Loneliness Measure	Main Finding	Limitations
Lim et al., 2016	USA	Cross-sectional	1010 (General population, 75.9% Female, Age Range 18-87).	Green et al. Paranoid Thoughts Scale	UCLA Loneliness Scale (1 Factor)	Loneliness observed as potential predictor of future states of social anxiety, paranoia and depression.	Sample predominantly female and highly educated limiting generalisability. Self-report.
Meltzer et al., 2013	UK	Cross-sectional	7461 (General population, of those reporting as lonely 18%M/22.7%F, Age Range 16 – 75+).	SCAN interview	One question from Social Functioning Questionnaire	Included observed association between loneliness and psychosis, an association that was not affected by levels of social support and participation.	Cross-sectional design cannot show causality.
Michael & Park, 2016	USA	Between groups	40 (25 recently diagnosed with psychosis, 15 controls, 24M/16F, Mean Ages 44.44 (9.06) and 44.93 (7.56)).	Pinocchio Illusion task used to illicit anomalous experience	UCLA Loneliness Scale (1 Factor)	Suggests social isolation related to increased susceptibility to anomalous experience.	Measurement is of loneliness and not social isolation, undermining rationale raised (social differentiation hypothesis). Small sample. Included in review primarily as effort to use experimental techniques rather than reliable data.
Murphy, Murphy & Shevlin, 2015	Northern Ireland	Cross-sectional	785 (School children, 345M/440F, Mean Age 16.2 (1.06)).	Adolescent Psychotic-Like Symptom Screener	UCLA Loneliness Scale (1 Factor)	Observed association between experiences of threat and subordination, with risk of psychosis, moderated by levels of peer victimization, with loneliness mediating that moderator.	Psychosis risk is measured through screening instrument so is measuring risk rather than actual presence of psychosis.

Study	Country	Design	Sample Size & Characteristics	Psychosis Measure	Loneliness Measure	Main Finding	Limitations
Riggio & Kwong, 2011	USA	Cross-sectional	179 (Students, 50M/112F, Mean Age 20.9 (3.4)).	Paranoia Checklist	UCLA Loneliness Scale (1 Factor)	Observed relationships between loneliness, parental relationships and paranoia, with subsequent inferences regarding role of attachment.	Predominantly female student sample may not be representative limiting generalisability. Cross-sectional design cannot show causality.
Riggio & Kwong, 2009	USA	Cross-sectional	182 (Students, 51M/131F, Mean Age 21.1 (3.7)).	Paranoia Checklist	UCLA Loneliness Scale (1 Factor)	Social skills and paranoia independently predicted increased loneliness.	Predominantly female student sample may not be representative limiting generalisability. Cross-sectional design cannot show causality.
Robustelli et al., 2017	USA	Cross-sectional	85 (44 recruited as at risk of psychosis, 41 controls, 41M/44F, Mean Ages 19.17 (1.73) and 19.20 (2.56)).	Structured Interview for Prodromal Syndromes	UCLA Loneliness Scale (1 Factor)	Less close friends, social network diversity, perceived social support, relationship quality, and greater loneliness in at risk group.	Small sample and cross-sectional design prevent causality being shown. In this case, this means study cannot show if objective social measures resulted from or increased risk of difficulties.
Shevlin, McElroy & Murphy, 2015	Northern Ireland	Cross-sectional	7403 (UK population, 3197M/4206F, Mean Age 51.12 (18.59)).	Psychosis Screening Questionnaire, SCAN Interview	Single question from Social Functioning Questionnaire, four point Likert scale	Loneliness mediated relationship in sample between childhood abuse and a number of psychiatric diagnoses including psychosis-related conditions.	Self-reporting cross sectional data prevents showing causality and limits generalisability. Frequency and severity of childhood abuse experiences not accounted for, which other studies suggest is important factor.

Study	Country	Design	Sample Size & Characteristics	Psychosis Measure	Loneliness Measure	Main Finding	Limitations
Smailes, Meins & Fernyhough, 2014.	UK	Between groups	54 (Students split into three groups of neutral, loneliness and negative mood following induction, 9M/45F, Mean Age 22.08 (5.9)).	Measurement of external misattributions on a reality discrimination task	UCLA Loneliness Scale (1 Factor)	Greater number of external misattributions for negative affect and loneliness. Suggested that loneliness was unlikely to have played role beyond negative affect.	Reliability of loneliness induction unknown. Almost entirely female sample of students not representative of general population.
Sündermann et al., 2014	UK	Cross-sectional	38 (recently diagnosed first episode psychosis, 23M/15F, Mean Age 32.3 (9.6)).	Scale for Assessment of Positive Symptoms, Scale for Assessment of Negative Symptoms	Single question asking for number of days feeling loneliness in past week	Number of lonely days associated with number of psychosis symptoms. Anxiety observed to mediate relationship between loneliness and paranoia.	Small cross section taken from one specific area in London, UK, greatly limiting generalisability. Measure of loneliness open to interpretation.
Trémeau et al., 2016	USA	Cross-sectional	87 diagnosed with psychosis-related disorder and 58 healthy controls (Patient Group 78% Male, Mean Age 29.6 (10.95)).	Existing diagnosis	UCLA Loneliness Scale (1 Factor)	Whilst a study using diagnosed participants, this study is included due to contrary finding that loneliness and paranoia were not related. Loneliness also predicted subjective but not objective social cognitive measures.	Study screened out any evidence of low mood in control group that may have skewed sample for comparisons. Cross-sectional nature limits generalisability and does not show causality.
Van der Werf et al., 2010	Netherlands	Longitudinal	1823 at baseline measurement (Community sample, 50.2% Male, 46.3% (13.9)).	Paranoid Ideation and Psychoticism subscales of Symptom Checklist 90 Revised	de Jong Gierveld Loneliness Scale (1 Factor)	Observed greater level of urbanicity in participants' environment associated with risk for psychosis. Loneliness and social isolation associated with psychosis risk.	Community sample recruited to consider hearing impairment presence, so sample not truly representative of general population.

Descriptive Features of Search Results

Of the 20 papers included in this review, 14 had cross sectional designs. Sample sizes ranged from 38 to 10760, with a total of three studies possibly limited by sample sizes of less than 100. Five studies involved laboratory-based procedures, three of which used a loneliness induction to allow comparisons of participant groups differing in their state loneliness on a variety of tasks. Sample sizes varied between 38 and 60. The remaining study was longitudinal, with 1823 people measured at baseline, six years, and 12 years, for several objective and self-report measures. Whilst this review is focussed on the onset of psychosis, this longitudinal study measured the emergence of symptoms of psychosis, rather than tracking a group following a psychosis related diagnosis.

These 20 studies included samples of clinical groups identified by as experiencing symptoms of psychosis by diagnosis or self-report questionnaires (N= 7), students and schoolchildren (N= 6), and surveys of the general population (N= 7). Samples came from a range of countries including France, Germany, the Netherlands, the United Kingdom, and the USA. Sample mean ages varied from 16.2 (SD= 1.06) to 71.55 (SD= 5.71). The diverse age ranges represented have the potential to introduce different mechanisms of loneliness, and this should be kept in mind throughout this review. For example, Erikson's work regarding the stages of life (Erikson & Erikson, 1997) would suggest the possibilities of different sources of loneliness across the lifespan.

Measuring Loneliness

Whilst as described, there is evidence for loneliness to be considered a multidimensional construct (Cacioppo et al., 2015), only one study (Badcock, Barkus, Cohen, Bucks, & Badcock, 2016) conducted their analysis with the three-factor structure identified by

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Hawkley, Browne and Cacioppo (Hawkley et al., 2005) from using the UCLA Loneliness Scale. This study showed a good fit for the three-factor structure for loneliness using the UCLA scale (RMSEA= 0.08, 95% CI [0.08, 0.09]). Ten other studies utilized the UCLA Loneliness Scale as a unidimensional construct, and the possibility remains that this data could be revisited to consider a three-factor structure.

Six studies used either a single question or up to three questions to measure loneliness. Whilst this is a common practice for some of the large-scale surveys included in the literature, consideration needs to be given for the lack of evidence and understanding we have for the experience of loneliness in psychosis, and this may limit the reliability of the findings for these studies. Additionally, some single questions may be at risk of conflating loneliness and social isolation, factors that are established as separate constructs (Cacioppo et al., 2010; Cacioppo et al., 2015; Peplau & Perlman, 1982).

The Construct of Loneliness for People with Psychosis

We found two recent studies that have implications for the construct of loneliness in relation to psychosis. The first of these was the previously mentioned study that included the three-factor approach of the UCLA Loneliness Scale (Badcock et al., 2016). This cross-sectional study compared loneliness scores with a negative symptom (social anhedonia) and a positive symptom (perceptual aberrations) amongst a non-clinical student sample ($N= 551$), primarily to see if both loneliness and schizotypy persisted as independent factors in a model containing a general psychopathological factor. When the shared variance with the general psychopathology factor was removed, any correlations between the constructs of loneliness and schizotypy were no longer present, suggesting their independence from each other. One other study exploring the heritability of loneliness (Gao et al., 2016) found strong genetic coheritability between loneliness and a measure of neuroticism, but only very weak evidence

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of coheritability between loneliness and schizophrenia. As a single exploratory study into the genetics of loneliness it is too early for any conclusions to be drawn from this area.

We identified a key need for research into loneliness and psychosis to explore the subjective experience of positive symptoms such as auditory and visual hallucination in terms of whether people feel a sense of connection to these phenomena themselves. Whilst this potentially would require a change in how loneliness is measured amongst people with psychosis, it also may have implications for developing therapeutic approaches based upon engaging with and changing the relationship people have with their hallucinations (e.g. Leff, Williams, Huckvale, Arbuthnot, & Leff, 2014). Of specific relevance to the onset of psychosis, the presence of loneliness ahead of the emergence of hallucinations, hallucinations that may produce their own feelings of connection, may be a potential relationship to explore. As of the time of this review, no research was found considering this phenomenon, and this presents a clear gap in the literature worthy of note.

Social Networks and Support

Whilst the previously described systematic review looking into the role of social networks and support in at-risk and early onset populations identified 38 studies, only one paper directly measuring loneliness in relation to social networks and support for people at-risk of psychosis was found (Robustelli, Newberry, Whisman, & Mittal, 2017). Comparing 44 young adults considered at high risk of psychosis with 41 healthy controls, their findings of fewer close friends, lower perceived support and less diverse social networks in the high risk group were in keeping with the prior systematic review (Gayer-Anderson & Morgan, 2013). More loneliness was also seen in the high-risk group ($t= 7.26, p<0.001, d= 1.63$), and loneliness was associated with having fewer close friends for the high-risk group ($B= -3.94, SE=.87; p<0.001$). The sample size was small however, and this increases the chances of variability

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playing a role in the large effect size recorded for the loneliness finding. The exclusion of potential control group participants based on the presence of any of a wide range of mental health difficulties including mood and anxiety may have introduced a further source of bias.

The antonym to social support, social defeat, has long been hypothesized as a mechanism for the onset of psychosis, through social isolation resulting in an increased sensitivity or activity in the mesolimbic dopamine system (Selten & Cantor-Graae, 2005) We found one study that explored the possible role of loneliness in this relationship (Gevonden et al., 2014), where a group of young adults with selective hearing impairment and reporting more loneliness and social defeat were more sensitive to dopamine than healthy controls. Unfortunately, the small experimental group ($N=19$) were a female skewed sample who also had a higher incidence of cannabis use than controls.

A further study utilizing the Adult Psychiatric Morbidity Survey in England 2007 data set (Meltzer et al., 2013) was found to include observed correlations between self-reports of loneliness and psychosis in the general population ($OR = 5.80$, $95\% CI = 2.62-12.84$). Of interest to this review, when entering measures of social participation and perceived social support into their model, no significant change in loneliness was observed. This may support findings from general loneliness research suggesting interventions increasing opportunities for social participation, without also providing an intervention regarding social cognition, lack efficacy (Masi, Chen, Hawkley, & Cacioppo, 2011). In regards to the onset of psychosis, this may also support a focus on cognitive appraisals and bias when considering loneliness. More studies investigating at-risk groups are needed before drawing any firmer conclusions.

Early Adversity

We identified four studies that investigated the relationship of adversity and psychosis with loneliness (Boyda, McFeeters, & Shevlin, 2015; Jaya, Ascone, & Lincoln, 2016; Murphy,

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Murphy, & Shevlin, 2015; Shevlin, McElroy, & Murphy, 2015). These were all large ($N=785$ to $N=7403$) cross-sectional surveys gathering information through self-report from general populations rather than specific clinical groups. Loneliness was found to mediate the relationship between intimate partner violence and psychosis (Boyda et al., 2015), and childhood abuse and psychosis ($OR = 2.57$, $95\% CI = 2.26-2.94$) (Shevlin, McElroy, et al., 2015). Loneliness was also found to play a role moderating ($\beta = 0.16$ ($SE = 0.04$); $p < 0.001$) the effect of peer victimization in the relationship between bullying and psychosis, through a moderated mediation model (Murphy et al., 2015).

A further online study found loneliness as mediating the link between adversity and negative symptoms of psychosis only, with depression accounting for the relationship between loneliness and positive symptoms in their model (Jaya et al., 2016). This study included a wider range of factors such as social rank and negative schema, and this highlights the difficulty currently in understanding the relationship between loneliness and psychosis when so many different variables may be involved.

There appears to be preliminary data suggesting that loneliness may have a role in the relationship between adversity and psychosis, however, it is difficult to draw actual practical applied conclusions from data sets only looking at elements of the picture through a cross-sectional lens. However, the positive findings to date should justify the investment of resources looking more closely at these potential mechanisms.

Loneliness and Paranoia

Two recent studies found evidence for a relationship between anxiety and loneliness in the onset of paranoia, in both first-episode (Sündermann, Onwumere, Kane, Morgan, & Kuipers, 2014) and non-clinical (Lim, Rodebaugh, Zyphur, & Gleeson, 2016) samples. In the clinical sample, anxiety (measured after induction through watching anxiety inducing pictures) was

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observed to mediate the association between loneliness and paranoia ($ab = 0.43$, $z = 3.5$, $p < 0.001$) in a cross-section of 37 people with first-episode psychosis. The small sample in this study limits the value of this result. The diverse (ages 18-87, $N=1010$) non-clinical sample was measured at three points over a six-month period, and loneliness was found to predict social anxiety, paranoia, and depression, with social anxiety seen as the sole predictor of loneliness in the model. Studies with a diverse range of ages may potentially be troublesome when considering loneliness, as discussed in the introduction. Whilst there are hints for considering anxiety and loneliness together when looking at psychosis, further research is needed.

Other individual studies have found negative schemas (Lamster, Lincoln, Nittel, Rief, & Mehl, 2017) and depression (Jaya, Hillmann, Reininger, Gollwitzer, & Lincoln, 2017) to mediate the relationship between loneliness and paranoia. The role of social skills has also been linked to paranoia and loneliness (Riggio & Kwong, 2009), as have difficulties in relationships with parents (Riggio & Wing Yee Kwong, 2011), an area already connected to psychosis (de Sousa, Varese, Sellwood, & Bentall, 2014). The study that observed depression as a mediator for the loneliness and paranoia relationship also conducted a network analysis, which suggested a unique direct connection between loneliness and paranoia that was not seen with other measured symptoms such as hallucinations (Jaya et al., 2017).

Of particular note, a recent study included a rare attempt to explore loneliness experimentally, in relation to paranoia (Lamster, Nittel, Rief, Mehl, & Lincoln, 2017). Utilizing a false-feedback paradigm to induce feelings of either high, low or neutral loneliness ($N=60$, split into three groups), changes in state paranoia were measured. There was positive evidence for the use of this methodology with significant changes in levels of loneliness as predicted, but whilst state paranoia fell in the low loneliness group, no significant change was observed in the high loneliness group. Whilst this investigation did

not find an increase in paranoia in the high loneliness group, the small sample used in the study may have played a role, and further research with this methodology appears justified.

We did find one study however, that disagreed with the majority of articles linking loneliness and paranoia (Trémeau, Antonius, Malaspina, Goff, & Javitt, 2016). This USA based investigation compared a group of 87 people with a mixture of schizophrenia and schizoaffective disorder diagnoses, living in a mixture of settings including inpatient wards, with a group of 58 healthy controls. They did not observe an association between loneliness and paranoia in their sample. They measured participants with both formal objective measures, and self-report subjective measures of social cognition. They found evidence of impaired social cognition on the items of self-report only, with no significant impairment found on objective measures. The authors excluded the self-reports of social cognition as less reliable than the objective measures, and therefore, concluded that social cognition was not associated with loneliness in a schizophrenia/schizoaffective sample, despite the clear links that exist in the general population (Hawkley & Cacioppo, 2010). However, a potentially significant methodological issue was found. All potential participants with a schizophrenia or schizoaffective diagnosis were screened for depression and excluded on that basis, which may make this sample unrepresentative. Estimates suggest a 50% comorbid depression rate in the schizophrenia population (Buckley, Miller, Lehrer, & Castle, 2009), and elements of mood disorders are important features in schizoaffective diagnoses (Abrams, Rojas, & Arciniegas, 2008). This conclusion also ignores existing evidence for the role of mood in positive symptoms of psychosis (Freeman et al., 2005; Morrison, 2001; Smailes, Meins, & Fernyhough, 2014).

However, it would be fair to summarize that current research into loneliness and paranoia would suggest considering loneliness as part of a model (including at least mood

and anxiety) increasing the likelihood of paranoia, rather than as an independent causal factor.

Isolation and the Social Deafferentation Hypothesis

A study in the previous section observing depression as mediating a relationship between loneliness and paranoia (Jaya et al., 2017) also reported indirect effects for other positive symptoms such as hallucinations. As this connection was indirect, the study authors did not link this particular finding to the social deafferentation hypothesis (Hoffman, 2007), which connects the presence of hallucinations directly to a shortage of normalized social interaction. A similar conclusion was reached in an earlier non-clinical study ($N=54$) that experimentally induced either negative mood, loneliness, or a neutral state and then compared performance on a reality discrimination task (Smailes et al., 2014). Whilst loneliness did increase the number of false alarms reported by participants, this effect was lower than that of the negative mood induction. This result suggested that subjective experience of loneliness does not fit the social deafferentation hypothesis, but the authors suggested that a measure of objective isolation may produce a different result.

Following that idea, an experimental approach ($N=40$) comparing susceptibility to bodily aberrations and exteroception with social isolation, reported finding associations between these factors (Michael & Park, 2016). However, there is a lack of clarity in their distinctions between isolation and loneliness. The single measure used for those factors was the overall score of the UCLA Loneliness Scale (Russell, 1996), for which studies have suggested isolation is just one of three factors present (Hawkley et al., 2005, 2012; Shevlin, Murphy, et al., 2015).

Whilst not specific to psychosis, a link between separate measures of loneliness and social isolation has been found with hallucinations amongst people with Alzheimer's disease

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(El Haj, Jardri, Larøi, & Antoine, 2016). Whilst there could be several factors involved in that relationship not found in psychosis, it is a study providing support for the social deafferentation hypothesis in principal.

A single study was found that looked at the role of living environment in connection with loneliness, social isolation and psychosis (van der Werf, van Winkel, van Boxtel, & van Os, 2010). This longitudinal investigation of a large group of adults with hearing impairment ($N=1823$), found associations between all factors, but in particular, between the urbanicity of the environment and psychosis risk, that could not be explained by levels of loneliness or isolation. This study may suggest that when looking at isolation, it is worthwhile to consider the nature of the environment surrounding the isolated individual.

Research into isolation does not currently provide support for the social deafferentation hypothesis, but it may suggest that the subjective experience of loneliness is different to that of objective isolation and sensory deprivation amongst people with psychosis. Whilst a connection was found between hallucinations and loneliness in an Alzheimer's sample (El Haj et al., 2016), it is unknown if this would translate to psychosis, or be a product of much higher mean age of that sample ($M= 71.55$, $SD= 5.71$).

General Criticisms and Research Limitations

The dominance of cross-sectional designs, diverse age groups, and small sample sizes significantly restricts drawing meaningful conclusions from literature at this time. Closer examination of the studies also revealed potential bias in the formation of control groups (where present). There was very little evidence of considering a more active control group, such as one with loneliness but without psychosis, allowing for greater isolation of psychosis as the variable of difference, and getting to grips with a key question mostly ignored: what makes loneliness *different* for people in the onset of psychosis.

When considering what is different about loneliness for people with psychosis, the consideration of measurement also places significant limitations on research to date. Whilst one recent study (Badcock et al., 2016) provides an excellent example for research to follow through keeping loneliness as a three dimensional construct in their analysis, this approach was missing in the remaining 95% of the literature we reviewed. The usage of single-question measures in many of the studies included may be of particular concern, when we may not be able assume that loneliness as a construct is the same for people with psychosis as it is in the general population.

Discussion

Overall, the cross-sectional nature of current research represents the potential of studying loneliness and the onset of psychosis, rather than allowing for significant conclusions to be drawn. Some very recent attempts at developing laboratory methods for studying the potentially causal role of loneliness should be encouraged, and critically, replicated with more representative samples when possible, for more concrete inferences to be made. These studies (e.g. Lamster, Nittel, et al., 2017) did show validity in their method of inducing states of loneliness, justifying their use with more at-risk groups.

Whilst we highlighted some areas of existing psychosis research to focus upon for looking at the role of loneliness, there are recent studies looking at potential links where loneliness might also be considered. For example, the role of attachment is directly being investigated in relation to a key area of this paper, paranoia (Sitko, Varese, Sellwood, Hammond, & Bentall, 2016). Considerable research into environmental factors is also progressing (Wickham, Taylor, Shevlin, & Bentall, 2014). It is hoped that researchers in other fields of psychosis can recognize the possible links of their work to the subjective experiences of loneliness raised here.

A limitation of this review is that whilst we focused upon research directly referring to loneliness by name. Other studies may exist containing concepts that overlap or form part of the construct of loneliness in psychosis. This was difficult to avoid when considering that the construct of loneliness in psychosis itself requires further definition through research.

We would again however, highlight the idea of considering how phenomena such as hallucinations may themselves affect how a person feels connected to other people, and perhaps create its own internal sense of connection. Recent qualitative research looking at individuals living in the community after an inpatient admission for psychosis, describes an active process of “deselection” (Andersson, Denhov, Bülow, & Topor, 2015) where participants reported choosing to shrink their social networks out of dissatisfaction with their social relationships. How might this be in part affected by the presence of heard voices, or perhaps the experience of telepathic communication sometimes reported by people with psychosis?

Conclusion

The important need for better psychosocial and engagement interventions that work in early intervention services was highlighted at the start of this review (Marshall & Rathbone, 2011). Currently, the quality and scope of research into the role of loneliness in the onset of psychosis does not offer enough practical information to aid service development, beyond highlighting that loneliness is likely to be present. That should not denigrate what research there is however, and this review has highlighted studies that show a rationale for looking closer at loneliness in the onset of psychosis. There is a need to establish how the experience of loneliness may be different compared to loneliness felt in non-clinical and other clinical populations to ensure that research in this area is evaluating the phenomenon it sets out to.

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Section 3: Empirical Paper

Exploring and Understanding Loneliness and Connectedness amongst Service Users in Acute Adult Mental Health Inpatient Care: A qualitative study using Grounded Theory

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**Exploring and Understanding Loneliness and Connectedness
amongst Service Users in Acute Adult Mental Health Inpatient
Care: A qualitative study using Grounded Theory**

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Abstract

This novel investigation used a constructivist grounded theory approach to explore the subjective experiences of loneliness and connectedness for service users both immediately before and during an admission to an acute adult mental health inpatient unit. Six service users with a diverse array of psychiatric symptoms were interviewed. Their constructions of how they experienced loneliness and social connectedness were coded with a focus upon identifying actions and processes. Three major categories emerged: (1) factors changing connectedness, (2) responses to changing connectedness and emerging processes, and (3) responding to inpatient care. The small sample size limits the generalisability of these findings. These categories may help identify valuable social processes to consider in acute care, and support further investigations in this area.

Key Words: Loneliness, Connectedness, Inpatient, Grounded Theory, Acute

Exploring and Understanding Loneliness and Connectedness amongst Service Users in Acute Adult Mental Health Inpatient Care: A qualitative study using Grounded Theory

The importance of the subjective experience of recovery (HM Government, 2009; Leamy, Bird, Le Boutillier, Williams, & Slade, 2011), has increased interest in studying subjective factors such as loneliness. A 2015 summary (Cacioppo, Grippo, London, Goossens, & Cacioppo, 2015) reviewed a variety of potential impacts for loneliness and reduced social connection on mental and physical health. They highlighted a recent meta-analysis that found an increase in mortality (amongst the general population) for social isolation (29% increase), loneliness (26% increase) and living alone (32% increase) (Holt-Lunstad, Smith, Baker, Harris, & Stephenson, 2015). Existing explorations of inpatient experiences in acute adult mental health settings have stressed the importance of relationships in determining the nature of those experiences (Gilburt, Rose, & Slade, 2008; Wyder, Bland, Blythe, Matarasso, & Crompton, 2015; Wyder, Bland, & Crompton, 2013). To date there has been no research looking at both the subjective experiences of loneliness and perceived social connectedness for adults in acute mental health inpatient services.

The concept of loneliness as a psychological construct first appeared in the writings of psychiatrist Frieda Fromm-Reichmann (Fromm-Reichmann, 1959). Since that work, loneliness as a concept, considered at one point as a feature of depression (Young, 1982), is now seen as a distinct psychological construct (Cacioppo, Hawkley, & Thisted, 2010; Cacioppo, Hughes, Waite, Hawkley, & Thisted, 2006; Heinrich & Gullone, 2006). The common working definition used within this field of research conceptualises loneliness as the discrepancy between the preferred and actual social relations of an individual (Peplau & Perlman, 1982). That discrepancy may potentially lead to the individual feeling alone, distressed and isolated, even when amongst other people (Cacioppo Fowler, & Christakis,

2009; Cacioppo & Cacioppo, 2013; Weiss, 1973). This discrepancy concept separates loneliness from the idea of solitude, a possibly positive state of being alone (Storr, 1988). More recent research suggests loneliness can be measured as a construct of three dimensions of close/intimate, relational, and collective connections (Hawkley, Browne, & Cacioppo, 2005; Hawkley, Gu, Luo, & Cacioppo, 2012; Hawkley & Cacioppo, 2010). Research considering loneliness as a multidimensional construct in clinical populations is just beginning to appear (e.g. Badcock, Barkus, Cohen, Bucks, & Badcock, 2016).

If an individual's sense of connectedness and loneliness played an important role leading to their admission, then their sudden change in environment might also change the nature of those factors. These potential effects may be significant for clinical outcomes. None of these interactions has been studied to date amongst an adult inpatient mental health unit population.

Studying a clinical population ethically also requires a meaningful link to improving outcomes for that population. A recent review of interventions targeting loneliness (Masi, Chen, Hawkley, & Cacioppo, 2011) highlighted a far larger effect size for working with social cognitions (mean effect size = -.598), compared to enhancing social support (mean effect size = -.162), and increasing opportunities for social interactions (mean effect size = -.062). This finding highlights the importance of increasing our understanding of the social cognitive functioning of people engaged with mental health services.

The aim of this study is to explore experiences of loneliness and connectedness for service users admitted to an acute mental health inpatient unit, using semi-structured interviews based upon a constructivist grounded theory approach (Charmaz, 2014). This method focuses on identifying meaningful actions and processes that are anchored in the way service users construct their sense of their own experiences. In addition, through using this methodology

with an acute inpatient population, without focusing on a specific psychiatric diagnosis, the feasibility of that approach can also be evaluated.

Method

Participants

Six participants were recruited from an Acute Adult Psychiatric Inpatient Unit in the United Kingdom. All participants had been present at the unit for at least two weeks. Participation required the ability to describe and reflect upon memories of their recent experiences, and so people with significant memory impairments, significant thought disorder, or at clear risk of re-experiencing trauma during the interview were not recruited. Specific diagnoses were otherwise not grounds for exclusion, with the homogeneity of the sample based on a need for and engagement with acute inpatient care rather than a specific diagnostic category. For this report, we did not interview adults post-retirement age, being mindful of research into the experience of different life stages (Erikson & Erikson, 1997) and how that might affect loneliness and connection.

Of the six participants, four were male and two were female. Their ages ranged from 20 to 48 years old ($M = 30.34$, $SD = 9.91$). All six participants were Caucasian in ethnicity and were born in the UK. In keeping with the transdiagnostic nature of the study, participants had a range of diagnoses and experiences including psychosis, depression, anxiety, trauma, disordered eating and self-harm.

Procedure

Ethical approval was granted both by the Research Ethics Committee of Bangor University, and the local NHS Research Ethics Committee and the R&D department for the NHS organisation involved (see appendix, 1.1 to 1.5). Service users were initially approached

by the care team at the unit, and provided with detailed information with which to decide on whether to take part in the study, with formal written consent given.

Interviews were conducted with service users lasting between 30 and 80 minutes, with interviews taking place in a quiet room off the ward. An initial interview schedule (see appendix 3.1) provided a barebones pathway to the discussion, beginning with the experiences before admission. Open questions about different periods were used to initiate discussion, such as, “what can you tell me about your life in the weeks leading up to coming here?”. This allowed the interviewees to shape the discussion to follow their own conceptual understandings and language regarding their experience. The interviewer provided summaries using the participant’s own language, and validation where appropriate, appreciating that the interviewer and interviewee work together as the interview progresses to construct meaning (Charmaz, 2014). Follow up probes were used where appropriate bring loneliness and connectedness into focus, such as, “So when someone was there in proximity... how did that affect your sense of being connected to people?”. Interviews were recorded with consent, anonymised, and transcribed line by line for analysis (for example transcript, see appendix 4.1).

Analysis

Initial coding of responses was completed line by line, using gerunds to preserve the sense of action in the data (Charmaz, 2000, 2014). Preserving this behavioural element of participant descriptions allowed consideration for function, providing a mechanism for exploring common experience across diagnostic categories. Focused coding then followed (see appendix 4.2 for excerpt), with focused codes informed by existing data and reflections. Categories were identified as they emerged, allowing for a ground-up process of generation.

The study utilised a grounded methodology (Glaser & Strauss, 1967) based upon the modified, constructivist approach of Kathy Charmaz (2014). Grounded theory has an

established basis for the qualitative exploration of phenomena that do not have an existing evidence base (Pidgeon, 1996). The adapted, constructivist approach was chosen due to its focus on identifying actions and processes that emerge from the data rather than general themes, whilst also allowing interpretation to consider the personal constructions of the individual participants (Charmaz, 2000, 2014). Appreciating different ways of constructing similar concepts was considered important due to our study looking at ideas such as connectedness across different diagnoses and experiences. A focus on identifying actions and processes rather than general themes was also considered suitable as it would help distinguish between different periods during the pathway through acute inpatient care.

Grounded theory as originally conceived (Glaser & Strauss, 1967) is an iterative process, where reflections and analysis occurs alongside data gathering, and this analysis informs and shapes data gathering as it proceeds. Due to the need to opportunistically recruit service users at an inpatient unit whose discharge may occur at short notice, a fully iterative process of complete analysis between interviews was not possible. However, in those instances memos were written reflecting on the previous interview and these influenced the subsequent interview. The interview schedule evolved over time to include concepts already identified through reflections and analysis.

Constructivist grounded theory also provides a framework for considering the constructions of the researcher involved (Charmaz, 2014), and this was utilised as the primary researcher had prior experience as an inpatient in an acute mental health setting. Incorporating lived experience of researchers into qualitative study design can be a strength when exploring service user viewpoints (Gilburt et al., 2008). To understand and control how the lived experience of the researcher might influence the analysis, the primary researcher was interviewed by another member of the research team, with responses coded using the established procedure.

Clear guidelines to promote validity in grounded theory research were followed (Charmaz, 2014). Coding and analysis were completed by the primary researcher, and then reviewed by another member of the research team, with agreement required for codes to be considered valid.

Results

Focused codes were reviewed to identify initial categories that were relevant to loneliness and social connection (see appendix 4.3). Of these initial categories, 18 were present in at least half of the interviews. Emerging from these categories were three major groupings of data: (1) Factors changing connectedness, (2) Responses to changing connectedness and emerging processes, and (3) Responding to Inpatient care. The first two groupings were observed across all the participants (through different mixes of subcategories), and emerged in the period leading up to admission. These two categories persisted whilst receiving inpatient care for differing periods of time for different participants, and we identified one further category that emerged for the sample during their inpatient admission.

In the sections below, excerpts from transcripts are included, with pseudonyms are used to protect confidentiality of participants.

Factors Changing Connectedness

Six subcategories were identified of experiences that altered the sense of connection that participants had with either an intimate partner or confidant, their family and friends, or wider communities and society. Additionally, where phenomena involving differences in perception such as auditory hallucinations were present, participants also reflected on their sense of connection and loneliness when those phenomena were occurring.

1. Feeling alienated. The construction of the concept of alienation emerging in the data referred to feelings of difference, detachment, or estrangement across all levels of connection. Alienation did not refer to proximity, being felt whether alone or in the company of others. Kevin described this directly as,

I've got good friends I've got well I haven't got a massive family but I've got a family around me but...it just doesn't feel like that anymore it just doesn't feel like it.

Kevin also described his subjective experience of alienation when walking down a public street, describing his sense of lack of connection on a societal/community level,

It's horrible...it's like black it's like you are looking down a parallel tunnel and there is just nothing around you anymore.

A different service user, Fred, experienced a sense of alienation from his friends due to these friends being cut off from his way of perceiving the world at that time,

...I was doing great things changing the world with the power of my mind and then my friend would come round and tell me that I've been ignoring him... they... were talking in a way that didn't acknowledge any telepathic knowledge or telepathic understanding or that I'd ever engaged in any telepathic communication with any of them.

2. Experiencing loss. Loss, whether due to deaths of family and friends, relationship break-ups, geographical moves cutting off social networks, or lost employment featured for all the service users taking part. For all types of loss, the degrading of social networks and support were experienced. Burt described the loss of his partner,

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Well my girlfriend was with me she stopped me going out sometimes yeah...but when she went I had nothing left and it just felt like lost and the only thing I liked to do was drink and keep my mind off it.

Kevin described his experience of leaving the Army and his sense of loss regarding no longer being part of a close group,

So that was a really big difference...you got used to a sense of being surrounded by people all the time and always feeling connected to people and then suddenly... nothing.

3. Family conflict. Whether as a causal factor or resulting from difficult experiences, changes in family connections were felt across our sample. For one service user, Elsa, whose mother was her primary contact and source of support,

I know my relationship with my Mum was very err stressful when I had that tough time... cause she basically you know she could see me wasting away basically.

For Kevin, a breakdown in his relationship with his brother preceded his current experiences,

Well with my brother I don't feel connected...when we grew up we were like that [makes a gesture indicating they were very close] ... but I haven't felt connected to him for a while.

4. Wanting belonging. Some of the participants expressed a wish to get back to an earlier time when they had been part of a small community or team of people, either in work or education, often with a sense of having defined roles. For these service users, they described

finding it hard to figure out the intentions of others and make connections when not in those environments, as Kevin described,

...Yeah in terms of trying to figure people out understanding their wavelength sort of thing cause everyone's different when you are out but in there you are all similar you all know what you are doing you all know who you are but once you are out it's completely different.

5. Feeling rejected. Feelings of rejection separated themselves from other constructed ideas primarily through either a sense of relationships being ended by the other party, or from feeling a lack of reciprocity in continuing relationships, as described by one service user, Martha, in regards to her connection on a friends/relational level,

Yeah because nobody comes round... like I go out other people's houses but nobody comes round.

6. Feeling alone. Whilst detailed engagement with the concept of loneliness did not happen often in the interviews conducted, some descriptions of feeling alone did surface. These were particularly present when service users were reflecting insightfully, such as Fred describing a desire for close/intimate connection,

Err yes I felt very alone and lonely as well... but err I felt... people that I care about talking to me telepathically and telling me they love me and they cared about me but none of that even if telepathy existed none of that makes up for a cuddle and a kiss and having someone to share a bed with.

Responding to Changing Connections and Emerging Processes

Whilst the factors changing connection primarily answer the main question of how service users in acute care construct their sense of loneliness and connectedness, our interviews

also highlighted a number additional actions and processes that appear related to the changing connectedness.

1. Responding to changing connections. When examining the data, several different actions emerged that all involved a functional element of avoiding or distancing oneself from existing or possible future connections. For some, this meant actively *seeking isolation* from other people, as Kevin described,

...and when I wasn't in work I was literally just in my room and I would close the door and I'd just lock myself like I am today I just close the curtains around.

Others described choosing to pursue *living in an internal world* even when in the company of friends, such as Fred,

... music was something I perceived in a very powerful way I perceived of being able to talk via music... but what that led to was a situation where I would go out with my friends and rather than err engage with them socially I would sit in the corner with my headphones on and listen to music.

All the service users taking part expressed efforts for *avoiding thoughts and feelings*, and this may have affected their ability to make more open and deeper connections with people. It also sometimes involved *hiding pain* from others, such a Burt describing,

I never talk about any of my problems really... I'd just be trying to make out it was a big laugh but it was actually a problem yeah.

Most people interviewed also described experiences where they felt they were *shutting down* in terms of their overall functioning, their energy, and their capacity for feeling. Awareness of this concept was particularly high around the time of admission to the acute

service, and in some cases service users felt their medication was increasing this feeling, and making it harder to engage in social activities, such as Fred,

Since I was put on the Olanzapine I I've been very tired so I was sleeping a lot... I initially said I want to do all the therapies but I've been err missing therapies because I've just been too tired.

2. Emerging processes. Potential processes that may be involved in the presence and maintenance of the factors changing connection and their responses were identified. These processes emerged from descriptions participants made of their thoughts, feelings and reasoning regarding the avoidance-based changes that occurred in their lives.

Many service users made references to feelings of shame, self-blaming, and low self-esteem as being associated with their changing circumstances, such as Elsa describing,

I would you know if I saw people I would basically turn round cause I didn't want them to look at me the way... the way that I was...cause my I I I couldn't even look at myself

Experiences of threat were the most frequently coded constructions in our data, and were described as impacting their experiences before admission, their experience of the admission itself, and their thoughts of the future. Edgar described this,

I wasn't feeling too good at all to be honest with you scared to go out... hearing voices you know don't go out and this and that you know it was an awful experience yeah

References to either a lack of, or choosing to give up control occurred both before and particularly after admission. Kevin described this feeling in the time leading up to admission,

it's been over the past six months really that I've just sort of self-destructed... I've literally just torn everything apart like not my own way... I didn't want do it like that but it just happened and it was horrible.

Elsa described how giving up control to staff after admission was difficult for her,

and it's quite daunting that you've actually gotta... erm put your medical needs in their hands... quite hard... in that I'm not in control you know.

Feelings both of being trapped and a sense of powerlessness were also common in their experience before admission, and in expressions of low confidence in their ability to reconnect with other people and communities in the future. Edgar summed these feelings up,

well I don't know... whenever I seem to go out I become unwell... that's the problem yeah... it just hurts somehow you know.

Responding to Inpatient Care

One main category relating to loneliness and connectedness emerged in descriptions of experience only after admission. This was a sense service users had of *opening up*. This process was experienced differently within our sample. For some, *opening up* was an involuntary process, and felt intrusive, particularly in the first few days after admission. Kevin found it difficult,

Cause there are so many people and obviously they check on you every fifteen minutes and stuff like that so there's always something going on round and trying to adjust to

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that is... hectic... when I'm by myself that's my little bubble yeah and there's people like trying to get involved in my bubble and it just it wasn't... it wasn't nice.

However, for some of our participants, over time their sense of *opening up* began involving feeling connected with staff and other service users on the unit, such as Fred,

(Regarding the Nurses and Health Care Assistants) ... it's just it's nice to see people coming in and smiling and being friendly all the time and checking it's almost... it's nice I mean I feel a little bit of mothering going on sometimes which is something an emotion that I have... not really experience very much... my Mum died when I was quite young.

In the case of connections with other service users, *opening up* was helped by identifying common experience, as Burt described,

It's easier to talk to somebody who goes through the similar than it is to talk to somebody who doesn't (know) anything about it.

The construction of *opening up* was considered to be temporary. Whilst service users had hopes for being more connected socially after being discharged, they had little confidence in that happening. Negative beliefs (and possibly accurate appraisals) of their opportunities once back in the community appeared to drive this low confidence, as Fred described,

I'd like a more forgiving environment I'd like err people become friends quickly here the nurses they talk to you like they've known you for years... err but... that is not reality... reality life is a very fast pace we're living in a very fast paced world with huge expectations... of course there are things that I'd like to see but I'd be a fool to believe that is going to happen.

Discussion

This study identified a set of social experiences that changed the sense of connectedness for people in our sample (feeling alienated, experiencing loss, wanting belonging, feeling alone, family conflict, and feeling rejected). In addition, well defined actions (seeking isolation, avoiding thoughts and feelings, living in an internal world, and shutting down) and processes (experiencing threat, shame, changes in control, feeling trapped, and feeling powerless) also emerged that service users felt contributed to their need for acute care, and were linked to changes in their sense of connectedness. These factors were found across a group diverse in diagnoses, validating the use of an action and process orientated qualitative methodology in this context (Charmaz, 2014). These categories also included examples of connection operating on different levels (e.g. close/intimate, relational, and collective) of social connection, providing additional evidence for conceptualizing loneliness as a multidimensional construct (Cacioppo et al., 2015; Hawkey et al., 2005, 2012).

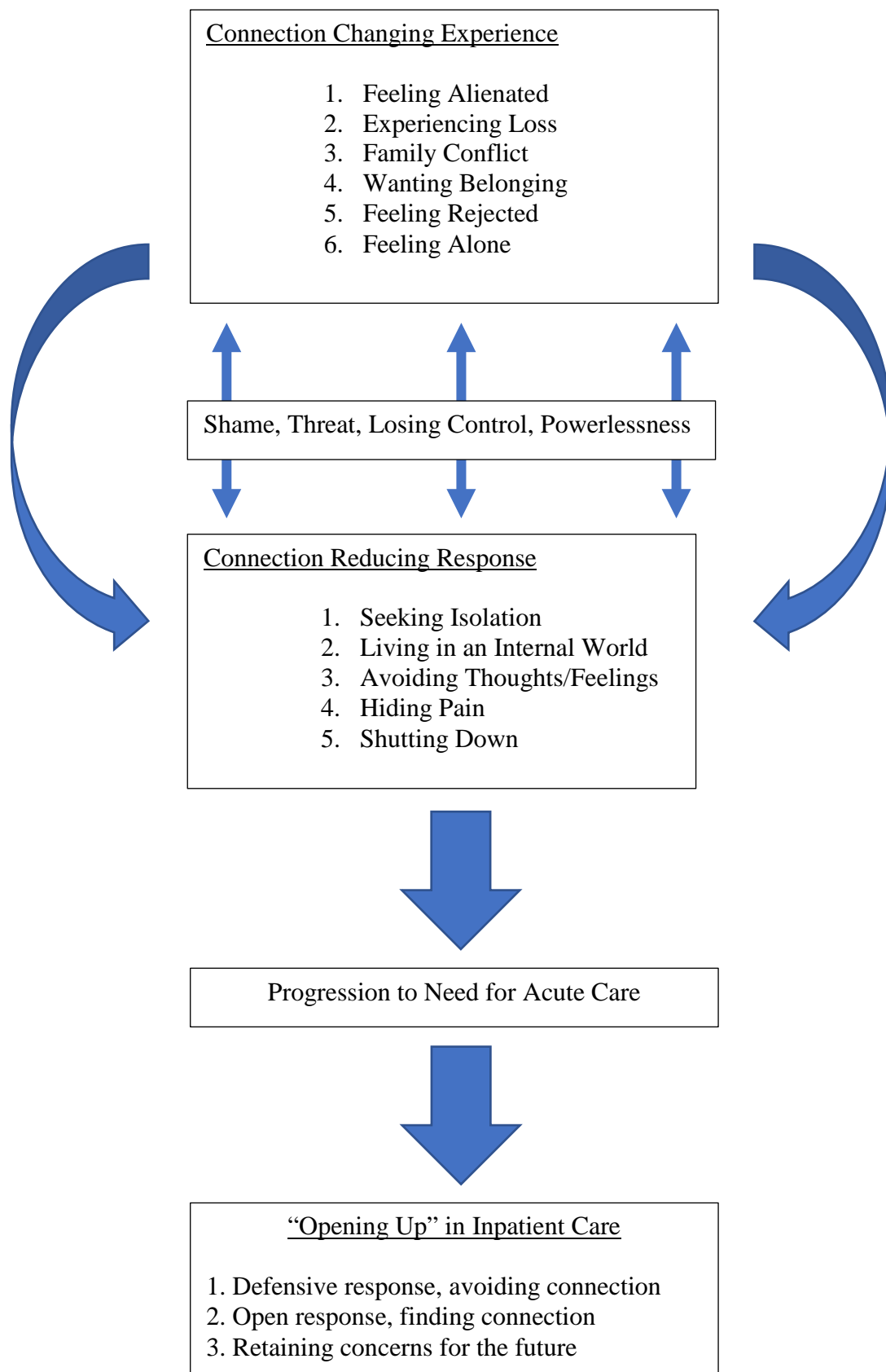
Service users participated in the study effectively and without distress, whilst still receiving acute inpatient care, indicating that acute inpatient status should not exclude people from taking part in research. Research is starting to increase in the United Kingdom into the development of psychological services in acute care (Araci & Clarke, 2016; Curran, Lawson, Houghton, & Gournay, 2007; Durrant, Clarke, Tolland, & Wilson, 2007; Kerfoot, Bamford, & Jones, 2012). To support these research efforts, investigations into psychological factors that include looking at how they are experienced by people entering a stage of a need for acute care, rather than just in community mental health or general population settings, would appear important. This study has identified that elements from the social part of the biopsychosocial model may be a viable area of focus.

Limitations

The limited exploratory scope of the project (N= 6) and its recruitment of service users from a single mental health unit restricts the generalizability of our findings. Our sample, whilst diverse in experience and diagnosis, was also ethnically and culturally homogenous. Additionally, while we successfully employed the methodology of grounded theory, it is not certain that we have reached the point of saturation at which point an inferred theory could be constructed. We may not be that far away from at least a hypothesized model however, with the presence of precipitating events, cognitive and behavioural responses, and possible processes that may be mediating or moderating observed relationships. The constructivist grounded theory approach prioritizes the saturation of categories rather than the saturation of data (Charmaz, 2014), and with a large number of subcategories identified we may be underestimating our findings.

A possible structure for a model summarising our findings is shown in figure 1, to illustrate the current position based upon our research to date. The potential for a “loop” effect of experience and response as shown in our theory, driven by cognitive and physical processing of factors such as threat and shame, is not dissimilar from similar models that refer to social processes such as the “loneliness loop” (Hawkley & Cacioppo, 2010). Areas in the proposed model that are not defined, such as the progression from connection loss to a need for acute care, could be hypothesised to involve the lack of access to normalising thoughts of behaviours of others, as suggested by similar theories such as models for paranoia (Freeman, Garety, Kuipers, Fowler, & Bebbington, 2002). We hope the model below may aid future research to identify people at risk of needing acute care in the future, allowing for earlier interventions avoiding admission, together with possible targets for community based work to improve connectedness for the general population.

Figure 1: Role of Connection in the Journey through Acute AMH Inpatient Care



Future Directions

With the importance of directing research involving service user participation towards improvement in care, we believe our findings have potential for use in clinical settings. We have identified a grouping of social factors that may indicate a greater risk of need for acute care, a set of responding behaviours that may provide a pathway for this need to grow, and processes that may mediate these factors. Consideration of these groupings for services engaging with vulnerable people (particularly perhaps in primary care settings) may provide a way of highlighting individuals needing additional support.

In addition to future research investigating these factors further with this population, repeating this exploratory approach with older adults that may have a different social perspective on loneliness and connection should be a priority, as should explorations with groups representing greater ethnic and cultural diversity.

Conclusion

Utilizing a constructivist grounded theory methodology to explore social factors affecting and resulting from social connection and loneliness for those in need of acute care may be a fruitful area of research that has a short path to practical and beneficial clinical advancements. This research also has the potential to help existing efforts (e.g. Gilbert et al., 2008) to have the voices of service users in acute care listened to and incorporated into meaningful service improvement.

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Section 4

Contributions to Theory and Clinical Practice

Summary of Findings

The empirical study provided a first investigation into how the subjective experiences of loneliness and social connectedness are constructed by service users attending an acute adult mental health inpatient unit, both before and during their admission. It highlighted a grouping of experiences that changed the sense of connectedness for participants (feeling alienated, experiencing loss, wanting belonging, feeling alone, family conflict, and feeling rejected). It also found avoidant responses (seeking isolation, avoiding thoughts and feelings, living in an internal world, and shutting down) and processes (experiencing threat, shame, changes in control, feeling trapped, and feeling powerless) that occurred following this changing sense of connectedness. From experiences following admission, a process of “opening up” was also identified, as participants found themselves coming into contact with staff and other service users. These factors were found across a group diverse in diagnoses. Limitations in the sample size (N=6) and recruitment occurring in a single inpatient unit, inhibit the generalisability of these findings, requiring further research to confirm these results.

The literature review gave an overview of research investigating the role of the subjective experience of loneliness in relation to the onset of psychosis. This review highlighted that whilst recent studies are beginning to suggest possible ways that loneliness might influence the onset of psychosis, either directly or indirectly, the cross-sectional nature of this research limits the ability to draw practical conclusions that may inform clinical practice. The review also highlighted significant concerns regarding current assumptions being made when measuring loneliness for people either at risk of or experiencing psychosis, due to the

lack of any research considering whether phenomena such as auditory hallucinations themselves change the experience of feeling alone or being connected to others.

Implications for Future Research and Theory Development

Expanding upon the Empirical Study

The nature of the empirical study as a first exploration into the subjective experience of loneliness and connectedness for people in acute mental health inpatient care, together with the observed limitations for generalisability from a relatively smaller sample (N=6) and single geographical location, raises the need for the extension and attempted replication of this research. Considering the difficulties found in reproducing studies in psychology (Open Science Collaboration, 2015), this would appear a basic, first step in building on our preliminary findings.

Whilst the empirical study could synthesise data into coherent categories with a reasonably diverse sample, it was not believed that saturation was reached. The range of experiences and mental health phenomena typically found on an acute inpatient unit stretches beyond that represented in our sample. In particular, whilst inpatient care is considered a last resort for Borderline Personality Disorder (BPD) (National Institute for Health and Clinical Excellence, 2009), we did not interview anyone with that diagnosis. Considering the attachment basis of BPD, this may be a group with additional experiences of loneliness and connection to be considered.

A reason why people with personality disorders did not make it into our sample to date was the high incidence of trauma in this group, and currently our protocol is designed to avoid re-traumatising people, particularly during an inpatient stay. However, this does mean that personality disorders, in addition to both thought disorder and organic conditions affecting

memory such as Alzheimer's Disease are not included in our range of loneliness experiences. Developing alternative methods to help explore these groups should be considered, as they all have valuable perspectives to be expressed.

Continuing research using our established methodology should also be considered for older adults specifically, as a group where loneliness has been raised as a major concern (Office for National Statistics, 2015). We have begun this interviewing older adults as an extension of our current study, and whilst research is ongoing, we have already begun to detect additional elements regarding connectedness. Specifically, the importance of family and the quality of connections to family is appearing with greater prominence.

The empirical study to date has also only interviewed people of one ethnicity, in a region with a far lower amount of ethnic diversity compared to other areas of the UK. The setting was also not close to a significant urban centre. Further research to expand upon how factors of ethnicity, urbanicity and similar considerations such as the experience of also immigrating from another culture is needed.

Our study also only looked at the perspectives of service users. Whilst this is arguably the most important point of view, when considering an acute inpatient environment, the potential for meaningful insights to also come from staff working at the unit is significant. Other points of view to consider would also be the perspectives of other people in the service user's social networks, such as friends and family. The possibility of considering not just the perspectives these groups have of a relevant service user, but their own sense of loneliness and connection should also be explored.

Theory Development from the Empirical Study

Whilst saturation was not reached and grounded theory was not proposed, the formulation-based nature of the categories identified provide several variables (as listed in the summary of

findings) that fit into a model of precipitating event/experience, avoidant coping mechanism, and perpetuating processes. A positive next step to further investigate the identified categories would be the utilisation of a longitudinal design in community mental health settings. Whether through measuring a specific experience such as feelings of alienation, or through composite measurement of the categories identified, over six month intervals, correlations with the incidence of inpatient admissions over a set time frame could be made. This would provide preliminary data regarding the predictive value of the findings from the empirical study, a key step towards moving to meaningful clinical applications of the research.

Wider Research Implications Arising from the Empirical Study

An emerging cognitive model for the link between loneliness and mental health difficulties is that of a “loneliness loop” (Hawkley & Cacioppo, 2010). This theory predicts that perceived social isolation produces a threat response, increasing hypervigilance for social threats in the environment. This hypervigilance is then hypothesised to lead to the production of multiple negative cognitive biases regarding social connections, that then work to create self-fulfilling prophecies predicting that attempts to make connections will fail, maintaining a state of loneliness and disconnection. There are some parallels for the loneliness loop that can be drawn with theories in psychosis, such as the cognitive model of persecutory delusions (Freeman et al., 2005; Freeman, Garety, Kuipers, Fowler, & Bebbington, 2002; Freeman & Garety, 2014), that also identify the relationship between threat and the emergence of cognitive biases.

Categories emerging in our study, when considering the theory of the loneliness loop after our analysis was completed, do appear in keeping with this theory. Experiences of threat were the most commonly recorded data. Feelings of powerlessness, and of feeling trapped were also prevalent. Predictions regarding the future were negative, even for service users who had positive experiences of connection during their time as an inpatient, creating an impression

of learned helplessness (Seligman & Maier, 1967). Therefore, it seems reasonable to suggest that attempts to formally, and possibly quantitatively explore the proposed loneliness loop model amongst acute mental health populations may be a worthy goal.

Going beyond the Empirical Study

A 2009 study (Cacioppo, Fowler, & Christakis, 2009) that explored the data from the longitudinal Framingham studies of coronary heart disease (particularly the Framingham offspring study, (Kannel, Feinleib, McNamara, Garrison, & Castelli, 1979), investigated how loneliness might arise in social networks. Their findings suggested that loneliness tended to occur in social clusters and that it would be disproportionately represented amongst those at the periphery of social groups. The authors of the study went further to put forth an interpretation of their data that might have wide-ranging implications for mental health care: that loneliness might spread through social networks as a contagious process. Considering these findings in the context of how people experience the path leading to an inpatient admission and what follows afterwards, might provide an opportunity to improve our systemic understanding of acute mental health difficulties. The potential for people to have been relatively isolated at the edges of their social groups, and then suddenly move to a different environment, with a different social group with the potential to affect their mental health both positively or negatively, appears important to explore. A further feature of the “loneliness spreads” study (Cacioppo et al., 2009) was to note how connections up to three degrees of separation might also be influencing loneliness, even from people with whom we do not have direct contact. Therefore, it is possible that many possible sources influence change in a person’s life when they become an inpatient, many of which may not be easily noticed. Understanding how these factors are experienced and how they might affect loneliness and

connection, may help inform both our conception of how people come to require acute care, and how the structure of acute care may help or harm recovery.

Future research informed by the idea of spreading loneliness and social network effects, may be more complex, but worthwhile. This hypothesis might predict, for example, that loneliness would increase for staff working in acute care, and that could be a very important topic to research. Mapping social networks in a local community, particularly for areas already associated with mental health difficulty incidence based on demographic factors (research currently in progress at Bangor University), could provide a platform for developing theories on a community psychology level.

Expanding upon the Literature Review

Whilst the reported review already describes the most pertinent findings for future research as a feature of its narrative structure, an earlier draft of this document featured a wider scope, including experiences of loneliness in psychosis after diagnosis. A further paper exploring the experience of loneliness after diagnosis may be equally important, and a highlight may be a feature not discussed in the onset of psychosis: stigma. The role of self-stigma and external discrimination in the negative symptoms of psychosis (rather than the predominantly positive symptom focus of the onset paper) and their possible relationship with loneliness are worth exploring, with specific studies already identified (Campellone, Caponigro, & Kring, 2014; Cavelti, Rüsch, & Vauth, 2014; Świtaj, Grygiel, Anczewska, & Wciórka, 2014).

Implications for Clinical Practice

The existing papers emphasised reporting implications for clinical practice, but some room exists to expand on these ideas, as well as additional insights from data that was not specifically reported as it was not specific to loneliness and social connection.

Reference was made in the empirical paper regarding the use of findings in primary care. With the current environment of restricted NHS budgets, efforts to reduce inpatient admissions are commonplace across the UK. The ability to engage with people at an earlier stage and provide effective support is a primary means of achieving this aim. However, an approach grounded in the traditional medical model of mental health, may struggle to detect sufficient symptom strength in the early stages of mental health difficulty. By identifying potential social factors, particularly in terms of life events, that may be predictive of an increased risk for the need of acute care, earlier detection and support could be possible. Understanding the underlying processes may also help in decision making in stepped care modelled services regarding the appropriate level of care.

The views of service users towards staff was also an important finding that may have implications for clinical practice, and there was not room to explore this fully in the empirical paper. We were struck by the universally positive expressions of admiration and gratitude towards nursing and care assistant staff on the wards by all the people we have interviewed to date. However, discussing this amongst the research team, it was raised that these opinions did not fit anecdotally with the opinions often expressed after discharge when engaging with community services, around their experiences with staff during an inpatient admission. Whilst this needs further exploration, one working hypothesis we identified was the potential for people receiving acute care to have backgrounds that may contain what can be conceptualised as attachment difficulties, particularly in terms of growing up in invalidating or neglectful environments. This has important clinical implications if borne out by further research for raising awareness of attachment related behaviour and interpersonal relating on acute wards, both in improving care, but also in supporting staff. Whilst attachment is a feature typically prioritised in inpatient environments for adolescents, based on approaches such as DBT

(Linehan, 1993), awareness of attachment in adult settings is less common in the experience of the research team.

Personal Experience

The generation of the ideas for this project were based upon my own personal experiences of acute inpatient mental health care over a decade ago. These experiences were very positive, and analysis of my own interview produced codes not replicated in our sample. A code was striking in its absence from our sample, that of *finding belonging*. In my own experience, I found myself connecting with a sense of community in the unit that I attended, in a way that I had not experienced previously in my life. At the unit, I attended, a full routine of daily activities was compulsory, and this also created a working behaviourally activating environment. The biggest change I experienced because of these factors was a shifting out of what had been a very egocentric experience of the world, much like the *living in an internal world* found in our sample. I stopped thinking of other people with the predictions that might be described in the loneliness loop (Hawkey & Cacioppo, 2010), and this created the opportunity to experience events that changed my sense of connection in a positive, connective manner.

I am providing this information here primarily to help illustrate my own constructions of acute care, and to provide the opportunity for the reader to consider how they may have influenced this thesis. If the most important experience for me was *finding belonging*, consider as well the fact that for most people in acute care, *wanting belonging* is the code more likely to appear. Add to that the likelihood of *feeling powerless and feeling trapped*. I hope this avenue of research grows.

Reflecting on Completing My Thesis

In reflecting on what I have learnt from carrying out this piece of research, it was only right at the end of the process, a few days before having these words bound, that I realised what the lesson was. Whilst throughout the process, my focus had been on the clinical aspects of loneliness and connectedness, the realisation that connection has an important role in everything we do became apparent. The biggest difficulty I encountered academically had been in reigning in and focusing this work, with so many possible directions to explore in regards to the role of connection, this was particularly hard to do. What became apparent was that trying to resolve and focus multiple concepts in your own *internal world* is likely always going to be doomed to failure. It was not in my internal world where I found the experiences that changed the trajectory of my life, it was in other people. Likewise, where we find focus in our research is not in the endless frontiers of our own thinking, but collaboration, and frankly, help from our colleagues.

A recent talk I attended at a conference regarding the application of psychology in acute care had an important point: physics tells us that the natural state of any system is not order, it is chaos. As communities, we work collaboratively to create structure and order. Without connectedness, there is only chaos. I know what that chaos is like when it is in your own mind, and you are lost there without any hope of escape that you can see. I hope this thesis helps provide one small step towards helping the thousands of people in the UK who are still trapped there.

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Word Count Statement for Thesis:

Literature Review Text: 6583

Literature Review Abstract: 159

Literature Review References 1804

Empirical Paper Text: 4466

Empirical Paper Abstract: 120

Empirical Paper References: 714

Research and Clinical Directions Text: 2649

Research and Clinical Directions References: 365

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)
Loneliness and Connection in Acute Adult Mental Health Inpatient Care

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 lead investigator is a Trainee Clinical Psychologist, and the project will form the basis for their thesis, to be submitted for the Clinical Psychology Doctorate (DClinPsy).

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

DRAFT

Integrated Research Application System
Application Form for Research involving qualitative methods only



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 familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Loneliness and Connection in Acute Adult Mental Health Inpatient Care

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

REC Name:
Wales REC 5

REC Reference Number:
16/WA/0328

Submission date:
04/10/2016

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:
Exploring and Understanding Loneliness and Connectedness amongst Service Users in Acute Adult Mental Health Inpatient Care: A qualitative study using Grounded Theory.

A2-1. Educational projects

Name and contact details of student(s):

Student 1	
	Title Forename/Initials Surname Mr David Oakley
Address	9 Glyn Garth Court Menai Bridge
Post Code	LL59 5PB
E-mail	psp4e6@bangor.ac.uk
Telephone	07801553279
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 Mike Jackson
Address	North Wales Clinical Psychology Programme School of Psychology, Bangor University Bangor, Gwynedd
Post Code	LL57 2DG
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Fax	

Academic supervisor 2

Title	Forename/Initials Surname
	Dr Alison Firth
Address	Hergest Unit, Ysbyty Gwynedd Bangor, Gwynedd
Post Code	LL57 2PW
E-mail	Alison.Firth@wales.nhs.uk
Telephone	01248363460
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 Mr David Oakley	<input checked="" type="checkbox"/> Dr Mike Jackson <input checked="" type="checkbox"/> Dr Alison Firth

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
	Mr David A Oakley
Post	Trainee Clinical Psychologist
Qualifications	BSc (Hons) Psychology MSc Research Methods in Cognitive Neuropsychology
ORCID ID	
Employer	Betsi Cadwaladr University Health Board
Work Address	North Wales Clinical Psychology Programme School of Psychology, Bangor University Bangor, Gwynedd
Post Code	LL57 2DG
Work E-mail	psp4e6@bangor.ac.uk
* Personal E-mail	
Work Telephone	07801553279
* 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 Adeilad Brigantia, Penrallt Road Bangor, Gwynedd
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):

Sponsor's/protocol number:

Protocol Version: 1

Protocol Date: 01/08/2016

Funder's reference number:

Project website:

Additional reference number(s):

Ref.Number	Description	Reference Number
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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.*

There is increasing evidence that loneliness is a very significant factor affecting both mental and physical health. There is also evidence to suggest that our social connections have the potential to affect our sense of loneliness both positively and negatively.

Individuals who are admitted to an Adult Mental Health Inpatient Unit are experiencing a time of acute distress, but also find themselves in a different environment, with different people and possibly a different perspective of the world around them. There is clear potential for factors of loneliness and social connection to play a role in the difficulties that led to admission, but also to be affected by that admission.

This study aims to explore these factors, and how inpatient admission may have affected them. It will do so by giving service users the opportunity to describe their experiences of loneliness and social connection, as well as their journey through services. Using a research method called "Grounded Theory" (based on a version by Kathy Charmaz in 2006), this process will involve hour long interviews with service users, and observations of daily events in the mental health unit. The approach will also include the interpretations of the chief investigator, who is both a third year Trainee Clinical Psychologist working at the unit, and a former service user who has attended an inpatient unit in the past.

The study will aim to recruit service users who have made some steps already in their recovery and feel ready to reflect on their experiences. It is hoped that these reflections will aid our understanding of how service user difficulties are influenced by loneliness, assist inpatient service planning, and potentially provide helpful insights to aid recovery for the service users themselves.

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.

Service users at an Adult Mental Health Inpatient Unit have all experienced a period of acute difficulty that has led to their admission to the unit. For many, that admission may have been made in part to manage significant risk to their safety. Any study that proposes engaging with this group must do so with a very clear structure for ensuring that risk is not increased nor recovery interrupted. This study's structure includes:

1) Clear guidelines for recruitment that exclude approaching any service user within their first two weeks attending the unit. In addition to ensuring that the work of the inpatient unit in that early period is not affected, this period also

ensures time for any service user to become acclimated to their surroundings.

2) Even after a two week period, many service users may still be experiencing significant difficulties, feel unsettled, or may still be in the process of adjusting to changing medications. A recruitment procedure independent of the Trainee Clinical Psychologist, led by the Clinical Psychologist at the unit in consultation with other key workers, will only look to approach those who have made progress and who are ready and able to take part. The study involves interviews where the purpose is to give service users an opportunity to reflect upon their experiences, and only those who have reached a stage of being ready to do that will be approached. It is hoped that the interview experience may potentially be a positive experience in a person's recovery.

3) Contact with service users will only take place at the Unit, following the robust procedures already in place at that unit for managing risk and promoting well being. The Trainee Clinical Psychologist will also be on placement at the unit during the research project period, and will be fully trained and up to date on all procedures and practice.

4) Availability of key workers known to service users participating in the study will always be arranged in advance. This is so that any service user taking part in an interview, has the opportunity for further one-to-one support independent of the research team, immediately after the interview is completed. This will allow for further discussion by the service user of any thoughts or emotions raised by the interview. This supported process will help any new insights be understood in a helpful and adaptive way, as well as give staff an opportunity to assess the well being of the service user concerned.

5) Capacity will be assessed by Dr Alison Firth (Clinical Psychologist working at the Unit) before any service user is approached to introduce the study. Capacity to both give informed consent, and to continue taking part in the study throughout its duration, will be constantly assessed and never assumed. If there is any question or concern at any point, the study will cease and additional support from the care team provided immediately. The safety and continued recovery of service users will always take priority.

6) A clear statement explaining that study participation will have no affect on the level of care provided, or in any decisions about the service user's status at the unit, will be provided. Capacity to understand that statement will be part of the independent recruitment procedure.

7) The interview procedure itself will not directly ask any service users to discuss traumatic or distressing experiences from the past. It will raise themes of loneliness and social connection, and provide open questions for service users to explore those themes how they wish. Follow up questions may highlight particular ideas raised by the service user, but these will be crafted with sensitivity and will not be directive.

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.*

Question 1: How do service users of acute AMH inpatient care describe their sense of loneliness and connectedness, and how has this changed since becoming an inpatient?

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

Question 2: How might the experiences of loneliness and connectedness amongst participants affect their mental health?

Question 3: What processes may be present in acute AMH inpatient settings that could explain the changes in loneliness and connectedness that are observed by participants?

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

A 2015 summary (Cacioppo et al., 2015) highlighted a wide variety of potential impacts of loneliness and reduced social connection on both mental and physical health. Of particular note, they highlighted a recent meta-analysis found an overall weighted increase in mortality (amongst the general population) for social isolation (29% increase), loneliness (26% increase) and living alone (32% increase) (Holt-Lunstad, Smith, Baker, Harris, & Stephenson, 2015). These experiences are likely to occur amongst service users in Adult Mental-Health inpatient settings and are worthy of study.

Existing research into the experience of becoming an inpatient in acute adult mental health settings has stressed the importance of relationships as the critical factor in determining the nature of those experiences (Gilbert, Rose, & Slade, 2008; Wyder, Bland, & Crompton, 2013). This study will explore the role of loneliness and connection in shaping those relationships.

The concept of loneliness as a studied psychological construct was mostly absent in the first half of the 20th century, only appearing in a notable form amongst the writings of psychiatrist Frieda Fromm-Reichmann in 1959. Since that work, loneliness as a concept, considered at one point as a feature of depression (Young, 1982), has come to be seen as a distinct psychological construct (Cacioppo, Hughes, Waite, Hawkley, & Thisted, 2006; Heinrich & Gullone, 2006; Cacioppo, Hawkley, & Thisted, 2010). The current working definition used within this field of research describes loneliness as the discrepancy between the preferred and actual social relations of an individual (Peplau & Perlman, 1982). That discrepancy may potentially lead to the individual feeling alone, distressed and isolated, even when amongst other people (Cacioppo Fowler, & Christakis, 2009; Cacioppo & Cacioppo, 2013; Weiss, 1973). This focus on the discrepancy between the wished for and the realised in social relations, separates loneliness from the idea of solitude, a possibly positive state of being alone (Tillich, 1959; Storr, 1998).

The existing studies of loneliness and connectedness described so far have focused upon the general population. However, the importance of loneliness and connectedness as clinical features to be studied, understood and included in formulations has also been mentioned (Cacioppo et al. 2015), yet significant research into clinical populations has yet to materialise. Therefore, to further inform and guide attempts to bridge studying loneliness from general to clinical populations, research into social networks and systemic factors has also been considered.

A 2009 study (Cacioppo Fowler, & Christakis, 2009) that explored the data from the longitudinal Framingham studies of coronary heart disease (particularly the Framingham offspring study, Kannel, Feinleib, McNamara, Garrison, & Castelli, 1979), investigated how loneliness might arise in social networks. Their findings suggested that loneliness tended to occur in social clusters and that it would be disproportionately represented amongst those at the periphery of social groups. The authors of the study went further to put forth an interpretation of their data that might have wide-ranging implications for mental health care: that loneliness might spread through social networks as a contagious process.

Considering these findings in the context of how people experience the path leading to an inpatient admission and what follows afterwards, might provide an opportunity to improve our systemic understanding of acute mental health difficulties. The potential for people to have been relatively isolated at the edges of their social groups, and then suddenly move to a different environment, with a different social group with the potential to affect their mental health both positively or negatively, is important to explore. A further feature of the Framingham study (Cacioppo Fowler, & Christakis, 2009) was to note how less immediate connections (such as friends of your friend) might also be influencing loneliness, even from people with whom we do not have direct contact. Therefore, it is possible that many possible sources of influence change in a person's life when they become an inpatient, many of which may not be easily noticed. Understanding how these factors are experienced and how they might affect loneliness and connection, may help inform both our conception of how people come to require acute care, and how the structure of acute care may help or harm recovery. Whilst the research identifying these possibilities exists on a systemic,

networked level, this study will attempt to ground our understanding in what these actual processes are, and it will do so by exploring the points of view of the individuals experiencing them.

If an individual's sense of connectedness and loneliness played an important role leading to their admission, then a sudden and severe change in environment may have a strong effect on those factors. It is unclear in which directions these effects may work, with the potential for experiences that may either increase or decrease connectedness occurring in such an inpatient unit. Additionally, following the definitions provided above, different individuals might react to the same experiences differently. None of these interactions has been studied to date amongst an adult inpatient mental health unit population. A Welsh Government audit of residents in "Hospital and units for people with a mental illness in Wales" covering 2014-2015, reported 1,441 total patients present at the time of the audit, 661 of whom (46%) had been resident for three months or longer. With these figures in mind, any development of our understanding of the systemic factors of loneliness and connection present in mental health units will be useful for services.

Studying a clinical population ethically also requires a constant link to the possibility of meaningful interventions based on any data gathered. Some research into interventions for loneliness in community settings has taken place and a review of this research (Masi, Chen, Hawkey, & Cacioppo, 2011) highlighted some key findings. Specifically, a far larger effect size for interventions working with social cognitions was found, compared to interventions that enhanced social support, social skills and increasing opportunities for social interactions. These findings suggest that increasing access to social opportunities alone may not result in improvement for lonely, disconnected people. This suggests that not only will a person's social connection and network play a role in their experience of loneliness, but also their appraisals of others, and all the factors that might affect the accuracy of those appraisals. To understand the role of loneliness in acute mental health difficulties requires an exploration of the subjective experiences of service users, and this has influenced and guided the direction and methodology of this proposed study: to focus on subjective experience.

To begin the process of research into loneliness and connectedness amongst clinical populations, this study will begin by exploring the qualitative experiences of service users admitted to an Adult Mental Health (AMH) Inpatient unit. Their experiences of connectedness and loneliness before admission, during the admission process itself and then their time spent on the unit will be investigated following a grounded theory structure (based upon Charmaz, 2006). It is planned for data to be gathered through both observations and interviews with service users, with an appreciation for how different service users may construct their sense of loneliness and connection. The goal of this research effort will be to develop a preliminary theory to support future research into the role of loneliness and connectedness in mental health, and to support clinical practice and service provision in acute inpatient settings in the future.

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.*

Design:

This study will follow a grounded theory approach that also considers how people perceive themselves and the world around them (Charmaz 2006). This approach includes an appreciation for what the researcher may bring themselves to the interpretation of the qualitative data that is gathered. In this case, the primary researcher is a clinician who has previously been a service user in acute AMH inpatient settings, and has personal experience of the actions and processes being studied. Whilst this might be seen as a source of bias in more traditional research, in grounded theory, the insights of the researcher are made clear and accounted for in the data. In more traditional research, the bias of the researcher may be present but unidentified. It has also been suggested that "insider" researchers may be a strength in qualitative studies where their role is integrated into research design (particularly in service user led research) (Gilburt, Rose & Slade, 2008).

Grounded theory approaches provide a framework for using both multiple data sources (in this case observations and interviews), and memo writing and reflections by the researchers, in the identification of actions and processes, leading to theory generation (Charmaz, 2006). This study will begin through a process of reflection by the primary researcher on their experiences of the actions and processes present at the unit. This process will include the writing of memos and reflection by the primary researcher, who will also receive supervision from the clinical supervisor to aid in this effort. Identified actions and processes at this stage will then be referenced in the further stage of semi-structured interviews (a minimum of six and a maximum of ten). The interview stage will then allow for the subjective experiences of service users currently in acute mental health settings to draw together and both focus and differentiate the data. Data analysis will take place concurrently with data collection, and will influence and evolve subsequent data collection sessions (Charmaz, 2006).

What will happen:

The first stage of data gathering will involve the primary researcher reflecting upon their experiences working on placement at the unit. This process will not use formalised measures, but rather include written memos and reflections by the main researcher (Charmaz, 2006). No identifiable data will be recorded at this stage, but rather the researcher's own impressions of the actions occurring in the unit. Written memos will be checked by the research team during supervision to ensure no identifying information is recorded.

Following the recruitment procedures detailed later in this document, service users participating will then, if they wish, take part in a one hour interview, followed by an unhurried debrief.

The interview questions will evolve throughout the project as data is gathered. Its broad themes will include exploring different time points (before, during and after admission), and different levels of connectedness (close, wider friendship and family level, and community). Additionally, it will consider earlier observations, as well as prior qualitative research in inpatient settings (e.g. Gilbert, Rose, & Slade, 2008). Following grounded theory procedures, the interview questions will develop throughout the data gathering process, reflecting the data and insights gained as the study progresses.

A demographic questionnaire will also be provided for interview participants to complete.

Data analysis will be conducted by the investigator as the study progresses (between interview sessions) and inform future interviews.

As processes emerge, a theory responding to the research questions will be generated. Full results of the analysis will be available for all participating service users, and availability to answer and discuss these findings offered.

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.

The primary researcher is a member of the North Wales Clinical Psychology Programme People Panel, a service user and carer group that meets on a regular basis to manage and promote service user and carer participation in Clinical Psychology training. Discussions from the early planning stage onwards with members of the People Panel regarding the core themes of the research project took place. All forms to be given to service user participants in the project have been shared with the People Panel for feedback on their suitability. Following the analysis of results, the findings will be formally shared with the People Panel and discussed, and their thoughts and feedback will help to shape future research following from this project, with the potential for collaboration if possible.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

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

- 1) Service Users currently engaged as inpatients at the Hergest Unit, Ysbyty Gwynedd, who have been present at the unit for at least two weeks since their admission.
- 2) Potential participants will require sufficient language and comprehension skills to read and understand information sheets (Welsh or English) and to comprehend and respond to questions asked in English (responding in English).
- 3) Potential participants must have capacity to take an informed decision to take part in the study as their own choice. Dr Alison Firth and the team at the Hergest Unit will lead the process of assessing capacity; this will be completed in advance of any contact with the service user regarding the study.

4) Participants must be aged 18 to 39. Due to different life stages predicted by models such as Erikson & Erikson (1982), and their potential effect upon the qualitative experience of loneliness/connectedness, it was decided to concentrate on one age group at this time. It is hoped that further studies will look at different age groupings in the future.

5) Participants will need to be able to maintain their concentration and attend to the study protocol for its complete length. These factors will be evaluated by Dr Alison Firth and the team at the Hergest Unit before participation, and monitored by the trainee during participation.

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

- 1) Presence of an observed and diagnosed disorder of thought that may either make comprehension of the protocol difficult, but also risk attributions by the service user that cause them additional distress.
- 2) Presence of organic conditions such as Alzheimer's, Vascular and other dementias that might make recalling memories of recent experiences difficult and result in additional distress.
- 3) Potential participants may not take part if they have received Electro-Convulsive Therapy (ECT) treatment during or immediately before their admission, due to the effect this might have on their memory.
- 4) Presence of an episode of mania type symptoms immediately before or during their admission, due to the effect this might have on their memory.
- 5) Service users currently undergoing treatment for drug or alcohol withdrawal as part of their care will not be recruited.
- 6) If at any point during their participation in the study, a service user loses the capacity to give informed consent to continue, they will be withdrawn from the study.

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
Initial approach by Dr Alison Firth to introduce the idea of the study and whether the service user wishes to speak to the investigator.	1	0	10m	Dr Alison Firth, Clinical Psychologist. A quiet room at the Mental Health Unit.
Initial meeting with investigator to discuss the study, providing information sheets. Consent process.	1	0	15-45m	David Oakley, Trainee Clinical Psychologist. Quiet room at the Mental Health Unit.
Interview protocol	1-2	0	60m	David Oakley, Trainee Clinical Psychologist. Clinic room at the Mental Health Unit.
Debrief after interview	1	0	15-45m	David Oakley, Trainee Clinical Psychologist. Clinic room at the Mental Health Unit.

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

Participants taking part in interviews will as standard only be involved for a single, one-hour interview. Due to the

methodology of grounded theory, further interviews with previous participants are possible. In that case, the same procedure for initial recruitment would be followed, with the approach made by the care team and not the Trainee Clinical Psychologist, and the service user would receive the same assurances regarding their freedom to not take part if they wish. It is not anticipated that more than two interviews would occur for any single service user taking part.

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.

The interviews will provide the opportunity for service users taking part to explore, if they wish, their recent experiences in terms of their sense of connectedness and loneliness. As such, this exploration may raise difficult and potentially distressing feelings.

The process of identifying potential participants will be conducted by Dr Alison Firth together with the care team at the Mental Health Unit. Any person who they consider may find such feelings potentially destabilising, with the possibility of negatively impacting their recovery, will not be approached to take part. Only service users who have been at the Unit for long enough to have moved beyond the immediate crisis that initiated their admission will be approached. Where possible, participants with the potential to benefit from the opportunity to reflect on their sense of connectedness will be identified. It is hoped that the interview may help service users to process their inpatient experience and aid their eventual discharge process, although we do not have evidence to formally claim this effect at this time.

All potential participants will be given information and time to consider whether they wish to take part. The ability to refuse to answer any questions or to withdraw altogether will be made clear throughout the process, and to do so without any impact on an individuals' care. Capacity will be considered an issue to be constantly monitored, and must be present throughout the process for a service user to continue participating.

A full and unhurried debrief will be included in the interview process, with information and the opportunity for the investigator to answer any questions the service user has. It will be ensured that a member of the care team known to the service user will be available at the time of the interview for the service user whenever requested, and this care team member will always take time to talk to the service user at the end of the interview, separate from the investigator. This additional opportunity for discussion will allow room for the service user to discuss any concerns they have, and for the care team to evaluate the well being of the service user.

The safety and well being of the service user participating will always take precedence over any other factors of the study.

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:

Interviews will ask participating service users to reflect on themes such as their sense of connectedness to others, both before and during their inpatient stay. This interview process will consist of open, "soft" questions that give the service user taking part the option to explore these ideas if they wish, but without any pressure of talking about specific events if they do not wish to. This will be explained in full during the consent process.

Service users taking part will be clearly informed that they do not have to respond to any question, and can cease taking part at any point, and that this will not affect their care in any way.

The investigator will be a third year Clinical Psychology Trainee with experience talking to service users about potentially difficult and sensitive topics, and doing so in a confidential and considerate way. Supervision will be provided on a regular basis by Dr Alison Firth, Clinical Psychologist at the Mental Health Unit in question.

Information on confidentiality will be clearly explained and observed, as detailed in the confidentiality section of this form.

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

Service users taking part will have an opportunity to reflect upon their recent experiences in a safe environment, in a way that may help to promote the development of insight that may be beneficial to their recovery. Opportunity to reflect upon the session with staff members outside of the research team that are involved with their care, will be assured.

Information regarding research into loneliness and connectedness that may be of benefit will be provided throughout the study, and this psycho educative material may also benefit their recovery.

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

No additional risks are anticipated for the researchers themselves. The Trainee Clinical Psychologist will be working on placement at the Mental Health Unit already for the duration of the study, and receiving relevant training and support

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).

Dr Alison Firth, Clinical Psychologist and permanent staff member of the care team at the Hergest Unit, will identify potential participants from service users currently at the Hergest Unit. This process will involve Dr Firth evaluating suitability based upon the established inclusion/exclusion criteria, which focus upon the safety and well-being of any potential participant. To do this effectively, in addition to her own knowledge of the service user, Dr Firth may also discuss potential involvement with other members of the care team who are directly involved with the care of that individual.

The file kept by the service for the service user may be referred to, but only by the care team members directly involved, who would have access to review such information in their role delivering care. Part of the recruitment criteria will be the clinical judgement of Dr Firth and the care team for a service user to be comfortable in participating, and that judgement requires knowledge and familiarity with the potential participant. Therefore, access to a file by the care team would only be to further review and check information for a service user already identified as a potential participant, as an additional layer of safety.

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:

Participants will only be identified by Dr Alison Firth, Clinical Psychologist and member of the care team at the Hergest Unit. As detailed in A27-1, service user records may be referred to by Dr Firth in discussion with members of the care team directly involved with that service user, to further assess suitability and safety to participate for an already identified individual. This would only be done for service users already identified as possible participants, and mass screening/identification by records first will not be carried out.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

Yes No

A27-5. Has prior consent been obtained or will it be obtained for access to identifiable personal information?

Yes No

If Yes, please give details below.

The identifiable personal information involved in the study will be some of the qualitative data provided by the participant, and their contact and demographic data. All of this data will be requested during contact with the participant, and no attempts will be made to obtain access to such data from other sources.

Specific, detailed information regarding the request and recording of identifiable personal information will be provided before participation, allowing for the potential participant to make a decision regarding giving informed, written consent, required to take part in the study.

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?

Dr Alison Firth, Clinical Psychologist working at the Hergest Unit, will first approach potential participants to discuss potential participation. This will be done at a suitable time of day, when the service user is not busy, and comfortable with being approached. This initial approach would only be a short discussion to gauge potential interest, if interested, Dr Firth would then arrange a time to introduce the participant to the Chief Investigator for a more detailed introduction, and for discussing consent.

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.

David Oakley, Chief Investigator and Trainee Clinical Psychologist, will be introduced to a potential participant, once they have already indicated to Dr Alison Firth that they wish to take part.

A written information sheet will be provided in either Welsh or English as preferred by the service user. This can be read out loud if the service user prefers (if in Welsh then assistance from a Welsh speaking member of the care team will be sought, their availability checked in advance).

An unhurried discussion and clarification of the elements of participation in the study will then take place. This discussion will occur to both allow the potential participant have any further questions answered, and to also allow the Chief Investigator to ascertain that the study information has been understood. If the potential participant wishes for another member of the care team to attend and join this discussion than this will be facilitated, including arranging a further meeting if necessary.

If both the potential participant and the Chief Investigator are content that informed consent can be given, then it shall then be carried out using the form agreed with the Ethics committee. If there are any doubts from either party, then consent will not sought at that time. If the potential participant wishes for further time to think and to digest the information then this will be facilitated. If the potential participant chooses not to opt in to the study, they will be reassured that this will not affect their care at the Hergest Unit in any way.

If the participant opts in to the study, further reminders regarding the right of participants to withdraw their consent at any time will also be provided at intervals throughout their participation.

The capacity to consent will be evaluated throughout a person's participation in the study, and if at any stage there is evidence suggesting this is no longer present, participation in the study will cease and assistance from the care team sought immediately.

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

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?

Potential participants will be given as much time as they need at the initial meeting to ask questions and consider whether to take part. If any potential participant does not feel able to make a decision at the initial meeting, but would like further time to think about taking part, they will be given an additional 24 hours to think further.

We will request that potential participants do not discuss their possible involvement in the study with other service users. This is to avoid either influencing other service users who may yet take part in the study, or making those who have taken part feel uncomfortable, or feel under pressure to discuss their involvement.

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)

The study is based in an area of Wales with a high proportion of first language Welsh speakers. Unfortunately, due to the requirements of the Doctorate and the process of Grounded Theory, the data gatherer must be the Trainee Clinical Psychologist, David Oakley, who is not a Welsh speaker. Therefore, the interviews section of the study will be conducted in English. If, in places in the interview, the participant feels they can only convey a specific idea in Welsh rather than English, this will be possible. It will require subsequent translation by research team member Dr Alison Firth, who is a Welsh speaker. This will only be feasible for short sections of the interview. This will be explained clearly and included in the informed consent stage.

It is hoped that if the study design proves successful and once the doctorate part of the project is completed, a Welsh speaking researcher may be able to conduct interviews in Welsh. This is not in place at this time and does not form a part of this current proposal.

Due to the qualitative nature of the study, which is asking participants to talk in detail about their thoughts, feelings and experiences, being able to communicate comfortably in English will be a key part of the recruitment criteria. This will be explained clearly at the first meeting and if the potential participant does not feel they will be able to do so, then they will not take part in the study.

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 written materials, including information sheets and consent forms, will be available in both Welsh and English. They will initially be generated in English by the Trainee Clinical Psychologist David Oakley, and then translated into Welsh using BCUHB and/or University of Bangor translation services. This translation will be discussed with Dr Alison Firth, Clinical Psychologist at the Hergest Unit, a Welsh speaker, to double check consistency across languages.

As described in A33-1, there will unfortunately be limitations in the current study for participants to engage in all stages of the study in spoken Welsh. These will be clearly explained in written Welsh on the information sheets provided.

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 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:

Capacity to consent will be monitored throughout a person's participation in the study, and never assumed or taken for granted once written consent is given. Any concerns that the Trainee Clinical Psychologist David Oakley has will cause the current participation session to cease, and will be reported to Dr Alison Firth, Clinical Psychologist at the Hergest Unit immediately, with the focus being on that individual's safety and well-being rather than their involvement in the study. The evaluation of whether that individual is able to continue in the study would be a decision made by consultation between the service user and Dr Alison Firth.

Any concerns are expected to result in withdrawing the participant from the study, as their safety and well-being will always take priority. Their participation and data produced will not be withdrawn from the study, so as not to invalidate their contribution. However, we will in such cases seek to contact the service users in the future if they consented to be contacted, and again present them with the option to decide on whether they wish their data to remain or be withdrawn.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

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:

All participants will be allocated a unique alphanumerical identifying code. All experimental materials will only use this code for identification and no other personal details will be recorded on materials for this purpose.

One document matching names to ID codes will exist and will be kept in a locked cabinet in the pass code secured office of Dr Alison Firth, Clinical Psychologist working at the research site. This document will be kept separately from

other materials produced by the study.

University and personal computers will only be used for the writing of the Doctoral thesis, and this will be done using already analysed, anonymous data. No identifying information will be involved in that task. The anonymous data will be kept on encrypted USB sticks and not transferred to computer hard drives.

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.*

All participants will be allocated a unique alphanumeric identifying code. All experimental materials will only use this code for identification and no other personal details will be recorded on materials for this purpose.

One document matching names to ID codes will exist and will be kept in a locked cabinet in the pass code secured office of Dr Alison Firth, Clinical Psychologist working at the research site. This document will be kept separately from other materials produced by the study.

All personal data will be kept at the NHS site of origin and will be maintained following existing NHS guidelines for information governance. The only possible circumstance for breaking confidentiality under those guidelines (clear threat of harm to self or others) will be explained during the process of obtaining written consent to participate, and included in the consent form. This process if occurring, would follow established NHS procedures.

Anonymous data used for publication, including quotations, will be attributed to single name pseudonyms with no connection to the participant. No possible identifiers will be included in any such data, and if a quote is not able to be anonymised, it will not be used for publication.

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 will have access to the personal data generated by service users participating in the study, and that data will be kept separate from other records for those service users also held at the Hergest Unit as part of their care.

Access to personal data generated by the study, by members of the direct care team who are not part of the research team, would only occur if requested (and formally consented to) by the service user themselves after the interview, if the service user felt it would be of benefit to their care. This would only be at the initiation of the service user, as any suggestion from the research team may create a sense of obligation to do so.

The only other possible reason for access to personal data by the direct care team would be in response to an immediate threat of harm to self or others indicated by the service user during their participation. This would initiate established NHS procedures as detailed in A38.

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

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined. Participants being interviewed will be paid £10 as compensation for their time spent taking part in the study.

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

If 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.

The study is a qualitative exploration and not a clinical trial. The structure of Grounded Theory also requires constant review and reformulation of the structure and questions asked in interviews, and therefore, the registering of initial methods would not accurately reflect the study.

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)

Trainee Clinical Psychologist David Oakley will also produce a Doctoral Thesis in Clinical Psychology based upon the data from the study.

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.

All service users taking part will be given the opportunity to register to receive a document summary for the study, with the further opportunity to offer feedback on the findings if they wish by post/email (their preference).

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 research project was developed in collaboration with Dr Mike Jackson, Research Director for the North Wales Clinical Psychology Programme (NWCPP). A completed proposal document including design and statistical review procedures was then reviewed independently of the research team, by Dr Chris Saville, Research Tutor for NWCPP, and approved. This review included consideration of both the methodological rigour and feasibility of the proposed research project.

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.

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: 10
 Total international sample size (including UK): 10
 Total in European Economic Area: 10

Further details:

The proposed qualitative methodology of Grounded Theory (following the guidelines of Charmaz, 2006) does not

propose a set sample size to be recruited, rather that data gathering should continue until a theory is generated for the area of study.

This approach will initially be followed. However, due to the scheduling requirements of the Clinical Psychology Doctorate programme, a maximum of ten participants will be recruited initially and their data will form the basis of the doctoral thesis produced. After the doctoral thesis has been produced, recruitment will then continue if needed to aid theory generation, throughout the remaining period of 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.*

Following the well established guidelines of Kathy Charmaz (2006) for Grounded Theory projects, no set sample size is calculated, rather data is gathered until theory generation is possible.

As detailed in section A59, a limit on interview recruitment to ten has been set for the generation of a doctoral thesis, and this figure was a feasibility decision based on input from an experienced doctoral thesis supervisor. Following Grounded Theory guidelines, if theory generation is possible with fewer than ten participants, then recruitment will end at that point.

If further recruitment is required to further develop theory following the submission of the doctoral thesis, this will occur within the rest of the proposed study period (up until October 2017).

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.

The qualitative analysis will follow guidelines established for grounded theory (Charmaz 2006), including the categorisation and coding of data. It is expected that quite different conceptualisations of loneliness and connectedness may present, based upon other factors such as the relative internalising or externalising the individual does to understand their own experiences. This will require careful interpretation beyond identifying themes (such as in a thematic analysis). Criticisms of qualitative research in that it fails to develop interpretation at a sophisticated level (see Hefferon & Gil-Rodriguez, 2011) will be considered when analysing the data.

Grounded Theory coding following the guidelines of Charmaz (2006) begins with open coding, focused upon identifying actions, rather than topics and themes. Through further analysis of these actions, processes should emerge that can then form the basis of a possible grounded theory for the topic.

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
Post
Qualifications
Employer
Work Address
Post Code
Telephone
Fax
Mobile
Work Email

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: Non-Commercial

If Other, please specify:

Contact person

Name of organisation Bangor University
 Given name Hefin
 Family name Francis
 Address School of Psychology
 Town/city Adeilad Brigantia, Penrallt Road
 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 Nefyn Williams
Organisation	Betsi Cadwaladr University Health Board
Address	Clinical Academic Office
	Ysbyty Gwynedd
	Bangor, Gwynedd
Post Code	LL57 2PW
Work Email	nefyn.williams@bangor.ac.uk
Telephone	01248384877
Fax	
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: 01/09/2016

Planned end date: 02/10/2017

Total duration:

Years: 1 Months: 1 Days: 2

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

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 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 indemnity scheme will apply

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)

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.

- 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.

DRAFT

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 Mr David Oakley on 04/10/2016 13:17.

Job Title/Post: Trainee Clinical Psychologist
Organisation: BCUHB
Email: psp4e6@bangor.ac.uk

DRAFT

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 04/10/2016 14:06.

Job Title/Post: School Manager for Psychology
Organisation: Bangor University
Email: h.franis@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 Alison Firth on 04/10/2016 12:58.

Job Title/Post: Clinical Psychologist
Organisation: BCUHB
Email: alison.firth@wales.nhs.uk

Academic supervisor 2

This section was signed electronically by Dr Mike Jackson on 04/10/2016 13:48.

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

DRAFT

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)
Loneliness and Connection in Acute Adult Mental Health Inpatient Care

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 lead investigator is a Trainee Clinical Psychologist, and the project will form the basis for their thesis, to be submitted for the Clinical Psychology Doctorate (DClinPsy).

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

DRAFT

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs). The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

Title Forename/Initials Surname
Mr David A Oakley

Work Address North Wales Clinical Psychology Programme
School of Psychology, Bangor University
Bangor, Gwynedd

PostCode LL57 2DG

Email psp4e6@bangor.ac.uk

Telephone 07801553279

Fax

For guidance on this section of the form refer to the guidance

Full title of study:	Exploring and Understanding Loneliness and Connectedness amongst Service Users in Acute Adult Mental Health Inpatient Care: A qualitative study using Grounded Theory.
Lead sponsor:	Bangor University
Name of REC:	Wales REC:5
REC reference number:	16/WA/0328

Additional reference number(s):

Ref.Number Description	Reference Number

Name of lead R&D office:	Betsi Cadwaladr University Health Board
Date study commenced:	16th December 2016
Protocol reference (if applicable), current version and date:	Updated to Version 2, 25/1/2017
Amendment number and date:	Amendment 1.0, Date 27/1/2017

Type of amendment

(a) Amendment to information previously given in IRAS

Yes No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

Yes No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

New Protocol version 2 (25/1/2017) now uploaded to IRAS.

Only one change:

Participant age range in the inclusion criteria has had the upper limit (was 39 years of age) removed. Since recruitment started, it became apparent that a majority of service users at our recruitment site were over 39 years of age. Therefore, to both aid recruitment, but also to keep the sample representative of the inpatient population at the site, we are proposing to remove the upper age limit.

All other criteria that exist to protect service users remain the same, and these criteria already include reference to the presence of cognitive/biological factors such as dementia.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

Yes No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

Yes No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.

If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

Only one change:

Participant age range in the inclusion criteria has had the upper limit (was 39 years of age) removed. Since recruitment started, it became apparent that a majority of service users at our recruitment site were over 39 years of age. Therefore, to both aid recruitment, but also to keep the sample representative of the inpatient population at the site, we are proposing to remove the upper age limit.

All other criteria that exist to protect service users will remain the same, and these criteria already include reference to the presence of cognitive/biological factors such as dementia.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

Document	Version	Date
Study Protocol	2	25/01/2017

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Mr David Oakley on 27/01/2017 13:51.

Job Title/Post: Trainee Clinical Psychologist
Organisation: BCUHB
Email: psp4e6@bangor.ac.uk

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Mr Hefin Francis on 30/01/2017 15:56.

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

Appendix 1.2 Study Protocol

**Exploring and Understanding Loneliness and Connectedness amongst Service Users in
Acute Adult Mental Health Inpatient Care: A Qualitative Study using Grounded Theory.**

Chief Investigator: David Oakley (Trainee Clinical Psychologist)

Academic Supervisor: Dr Mike Jackson (Consultant Clinical Psychologist)

Clinical Supervisor: Dr Alison Firth (Clinical Psychologist at Hergest Unit, Ysbyty Gwynedd)

IRAS ID: 211238.

University of Bangor, BCUHB

Exploring and Understanding Loneliness and Connectedness amongst Service Users in Acute Adult Mental Health Inpatient Care: A Qualitative Study using Grounded Theory.

IRAS ID: 211238. Study Protocol Version 2. 25/1/2017

1. Project Title

Exploring and Understanding Loneliness and Connectedness amongst Service Users in Acute Adult Mental Health Inpatient Care: A Qualitative Study using Grounded Theory.

2. Supervision

2.1 Academic/Research Supervisor: Dr Mike Jackson.

The academic/research supervisor has agreed to support the project in regards to the following areas:

- 1) Developing the research idea, design, method and protocol of the study.
- 2) Supporting the trainee in successfully navigating all require ethical and school approval procedures for the study to take place.
- 3) Monitoring and supporting overall trainee progress and in fulfilling NWCPP requirements.
- 4) Supporting the trainee in analysing data and producing written reports resulting from the study.

2.2 Clinical/Site Supervisor: Dr Alison Firth

The clinical/site supervisor has agreed to support the project in regards to the following areas:

- 1) Supporting the trainee in liaising with the relevant clinical service, different healthcare professionals that work within that service, and any other affiliated bodies.
- 2) To provide clinical supervision at the research site to support interactions between the trainee and both staff and service users.
- 3) To provide oversight in assessing capacity of service users to take part in the study, as well as provide an initial introduction of the study and the trainee to potential study recruits.
- 4) To support the trainee in assessing and dealing with any unforeseen circumstance that occurs at the research site.
- 5) To support the trainee in seeking the required NHS Ethics and R&D approval in areas relevant to the clinical service.

3. Background

A 2015 summary (Cacioppo et al., 2015) highlighted a wide variety of potential impacts of loneliness and reduced social connection on both mental and physical health. Of particular note, they highlighted a recent meta-analysis that found an overall weighted increase in mortality (amongst the general population) for social isolation (29% increase), loneliness (26% increase) and living alone (32% increase) (Holt-Lunstad, Smith, Baker, Harris, & Stephenson, 2015). The likelihood of these possible experiences occurring amongst service users engaging with Adult Mental Health services, particularly in acute, inpatient settings would appear high, and worthy of further study. Existing research into the experience of becoming an inpatient in acute adult mental health settings has stressed the importance of relationships as the critical factor in determining the nature of those experiences (Gilbert, Rose, & Slade, 2008; Wyder, Bland, &

Crompton, 2013). Therefore, the role of loneliness and connection in shaping those relationships would also appear consistent with the current research picture for inpatient experiences.

The concept of loneliness as a studied psychological construct was mostly absent in the first half of the 20th century, only appearing in a notable form amongst the writings of psychiatrist Frieda Fromm-Reichmann in 1959. Since that work, loneliness as a concept, considered at one point as a feature of depression (Young, 1982), has come to be seen as a distinct psychological construct (Cacioppo, Hughes, Waite, Hawkley, & Thisted, 2006; Heinrich & Gullone, 2006; Cacioppo, Hawkley, & Thisted, 2010). The current working definition used within this field of research conceptualises loneliness as the discrepancy between the preferred and actual social relations of an individual (Peplau & Perlman, 1982). That discrepancy may potentially lead to the individual feeling alone, distressed and isolated, even when amongst other people (Cacioppo Fowler, & Christakis, 2009; Cacioppo & Cacioppo, 2013; Weiss, 1973). This focus on the discrepancy between the wished for and the realised in social relations, separates loneliness from the idea of solitude, a possibly positive state of being alone (Tillich, 1959; Storr, 1998).

The existing studies of loneliness and connectedness described so far have focused upon the general population. This is understandable, as studies looking to define and differentiate loneliness as a distinct construct benefit from being able to generalise those ideas to the general population. However, the importance of loneliness and connectedness as clinical features to be studied, understood and included in formulations has also been mentioned (Cacioppo et al. 2015), yet research into clinical populations has yet to materialise in significant numbers. Therefore, to further inform and guide attempts to bridge studying loneliness from general to clinical populations, research into social networks and systemic factors has also been considered.

A 2009 study (Cacioppo Fowler, & Christakis, 2009) that explored the data from the longitudinal Framingham studies of coronary heart disease (particularly the Framingham offspring study, Kannel, Feinleib, McNamara, Garrison, & Castelli, 1979), investigated how loneliness might arise in social networks. Their findings suggested that loneliness tended to occur in social clusters and that it would be disproportionately represented amongst those at the periphery of social groups. The authors of the study went further to put forth an interpretation of their data that might have wide-ranging implications for mental health care: that loneliness might spread through social networks as a contagious process. Considering these findings in the context of how people experience the path leading to an inpatient admission and what follows afterwards, might provide an opportunity to improve our systemic understanding of acute mental health difficulties. The potential for people to have been relatively isolated at the edges of their social groups, and then suddenly move to a different environment, with a different social group with the potential to affect their mental health both positively or negatively, appears important to explore. A further feature of the Framingham study (Cacioppo Fowler, & Christakis, 2009) was to note how connections up to three degrees of separation might also be influencing loneliness, even from people with whom we do not have direct contact. Therefore, it is possible that many possible sources of influence change in a person's life when they become an inpatient, many of which may not be easily noticed. Understanding how these factors are experienced and how they might affect loneliness and connection, may help inform both our conception of how people come to require acute care, and how the structure of acute care may help or harm recovery. Whilst the research identifying these possibilities exists on a systemic, networked level, this study will attempt to ground our understanding in what these actual processes are, and it will do so by exploring the points of view of the individuals experiencing them.

If an individual's sense of connectedness and loneliness played an important role leading to their admission, then a sudden and severe change in environment may have a strong effect on those factors. It is unclear in which directions these effects may work, with the potential for experiences that may either increase or decrease connectedness occurring in such an inpatient unit. Additionally, following the definitions provided above, different individuals might react to the same experiences differently. None of these interactions has been studied to date amongst an adult inpatient mental health unit population. A Welsh Government audit of residents in "Hospital and units for people with a mental illness in Wales" covering 2014-2015, reported 1,441 total patients present at the time of the audit, 661 of whom (46%) had been resident for three months or longer. With these figures in mind, any development of our understanding of the systemic factors of loneliness and connection that may illuminate the impact of that residency, and offer guidance to increase positive long-term outcomes would appear to be of value.

Studying a clinical population ethically also requires a constant link to the possibility of meaningful interventions based on any data gathered. Some research into interventions for loneliness in community settings has taken place and a review of this research (Masi, Chen, Hawkey, & Cacioppo, 2011) highlighted some key findings. Specifically, a far larger effect size for interventions working with social cognitions was found (mean effect size = -.598), compared to interventions that enhanced social support (mean effect size = -.162), social skills (mean effect size = .017) and increasing opportunities for social interactions (mean effect size = -.062). These findings suggest that increasing access to social opportunities alone may not result in improvement for lonely, disconnected people. It is fair to hypothesise therefore, that not only will a person's social connection and network play a role in their experience of loneliness, but also their appraisals of others, and all the factors that might affect the accuracy of those appraisals. To

understand the role of loneliness in acute mental health difficulties requires an exploration of the subjective experiences of service users in addition to growing a systemic understanding, and this has influenced and guided the direction and methodology of this proposed study, to focus on subjective experience.

To begin the process of research into loneliness and connectedness amongst clinical populations, this study will begin by exploring the qualitative experiences of service users admitted to an Adult Mental Health (AMH) Inpatient unit. Their experiences of connectedness and loneliness before admission, during the admission process itself and then their time spent on the unit will be investigated following a grounded theory structure (based upon Charmaz, 2006). It is planned for data to be gathered through both observations and interviews with service users, with an appreciation for how different service users may construct their sense of loneliness and connection. The goal of this research effort will be to develop a preliminary theory to support future research into the role of loneliness and connectedness in mental health, and to support clinical practice and service provision in acute inpatient settings in the future.

4. Research Questions

Question 1: How do service users of acute AMH inpatient care construct their sense of loneliness and connectedness, and how has this changed since becoming an inpatient?

Question 2: How might the experiences of loneliness and connectedness amongst participants affect their mental health?

Question 3: What actions and processes may be present in the acute AMH inpatient settings that could explain the changes in loneliness and connectedness that are observed by participants?

4 Participant Recruitment

Dr Alison Firth, Clinical Psychologist and permanent staff member of the care team at the Hergest Unit, will identify potential participants from service users currently at the Hergest Unit. This process will involve Dr Firth evaluating suitability based upon the established inclusion/exclusion criteria, which focus upon the safety and well-being of any potential participant. To do this effectively, in addition to her own knowledge of the service user, Dr Firth may also discuss potential involvement with other members of the care team who are directly involved with the care of that individual.

Only Dr Alison Firth, Clinical Psychologist working at the Hergest Unit, will make the first approach to potential participants to discuss participation. This will be done at a suitable time of day, when the service user is not busy, and comfortable with being approached. This initial approach would only be a short discussion to gauge potential interest, if interested, Dr Firth would then arrange a time to introduce the participant to the Chief Investigator for a more detailed introduction, and for discussing consent.

6.1 Inclusion Criteria

- 1) Service Users currently engaged as inpatients at the Hergest Unit, Ysbyty Gwynedd, who have been present at the unit for at least two weeks since their admission.

- 2) Potential participants will require sufficient language and comprehension skills to read and understand information sheets (Welsh or English) and to comprehend and respond to questions asked in English (responding in English).
- 3) Potential participants must have capacity to take an informed decision to take part in the study as their own choice. Dr Alison Firth and the team at the Hergest Unit will lead the process of assessing capacity; this will be completed in advance of any contact with the service user regarding the study.
- 4) **Participants must be aged 18 and above. Whilst initially it was proposed for recruitment to concentrate upon the 18-39 age group, the proportion of service users present over the age of 39 was significant. Recruiting older adults is therefore more representative of the inpatient population, and will allow a greater number of people to take part.**
- 5) Participants will need to be able to maintain their concentration and attend to the study protocol for its complete length. These factors will be evaluated by Dr Alison Firth and the team at the Hergest Unit before participation, and monitored by the trainee during participation.

4.1 Exclusion Criteria

- 1) Presence of an observed and diagnosed disorder of thought that may either make comprehension of the protocol difficult, but also risk attributions by the service user that cause them additional distress.

- 2) Presence of organic conditions such as Alzheimer's, Vascular and other dementias that might make recalling memories of recent experiences difficult and result in additional distress.
- 3) Potential participants may not take part if they have received Electro-Convulsive Therapy (ECT) treatment during or immediately before their admission, due to the effect this might have on their memory.
- 4) Presence of an episode of mania type symptoms immediately before or during their admission, due to the effect this might have on their memory.
- 5) Service users currently undergoing treatment for drug or alcohol withdrawal as part of their care will not be recruited.
- 6) If at any point during their participation in the study, a service user loses the capacity to give informed consent to continue, they will be withdrawn from the study.

All participants will retain the right to cease their participation in the study at any stage, and have any information they have provided removed and disposed of following established guidelines. It is proposed at this time that a Tesco Voucher worth £10 is given to all participants for their time engaging in qualitative stage of the study.

5 Design and Procedures

This study will follow a grounded theory approach that also considers how people perceive themselves and the world around them (Charmaz 2006). This approach includes an appreciation for what the researcher may bring themselves to the interpretation of the qualitative data that is gathered. In this case, the primary researcher is a clinician who has previously been a service

user in acute AMH inpatient settings, and has personal experience of the actions and processes being studied. Whilst this might be seen as a source of bias in more traditional research, in grounded theory, the insights of the researcher are made clear and accounted for in the data. In more traditional research, the bias of the researcher may be present but unidentified. It has also been suggested that “insider” researchers may be a strength in qualitative studies where their role is integrated into research design (particularly in service user led research) (Gilburt, Rose & Slade, 2008).

Grounded theory approaches provide a framework for using both multiple data sources (in this case observations and interviews), and memo writing and reflections by the researchers, in the identification of actions and processes, leading to theory generation (Charmaz, 2006). This study will begin through a process of reflection by the primary researcher on their experiences of the actions and processes present at the unit. This process will include the writing of memos and reflection by the primary researcher, who will also receive supervision from the clinical supervisor to aid in this effort. Identified actions and processes at this stage will then be referenced in the further stage of semi-structured interviews (a minimum of six and a maximum of ten). The interview stage will then allow for the subjective experiences of service users currently in acute mental health settings to draw together and both focus and differentiate the data. Data analysis will take place concurrently with data collection, and will influence and evolve subsequent data collection sessions (Charmaz, 2006).

6 Measures

The first stage of data gathering will involve the primary researcher reflecting upon their experiences working on placement at the unit. This process will not use formalised measures, but rather include written memos and reflections by the main researcher (Charmaz, 2006). No identifiable data will be recorded at this stage, but rather the researcher's own impressions of the actions occurring in the unit. Written memos will be checked by the research team during supervision to ensure no identifying information is recorded.

Following the recruitment procedures detailed earlier in this document, service users participating will then, if they wish, take part in a one-hour interview, followed by an unhurried debrief.

The interview questions will evolve throughout the project as data is gathered. Its broad themes will include exploring different time points (before, during and after admission), and different levels of connectedness (close, wider friendship and family level, and community). Additionally, it will consider earlier observations, as well as prior qualitative research in inpatient settings (e.g. Gilbert, Rose, & Slade, 2008). Following grounded theory procedures, the interview questions will develop throughout the data gathering process, reflecting the data and insights gained as the study progresses.

A demographic questionnaire will also be provided for interview participants to complete.

Data analysis will be conducted by the investigator as the study progresses (between interview sessions) and inform future interviews.

As processes emerge, a theory responding to the research questions will be generated. Full results of the analysis will be available for all participating service users, and availability to answer and discuss these findings offered.

7 Data Management and Analysis

Data will be stored following University and NHS guidelines. All identifiers will be kept securely at the Hergest Unit. Anonymised data will be analysed following University guidelines for storage. Qualitative data will be processed and analysed using standard procedures for the qualitative methodology and using word processing packages.

9.1 Sample Sizes

The sample size for the study will follow established guidelines for grounded theory according to Charmaz (2006). In grounded theory the sample size is driven by the data itself and an exact figure cannot be given at this time. Due to the time constraints of the LSRP, a maximum of ten participants for this stage of the study will be recruited for the empirical paper.

9.2 Data Analysis

The qualitative analysis will follow guidelines established for grounded theory (Charmaz 2006), including the categorisation and coding of data. It is expected that quite different conceptualisations of loneliness and connectedness may present, based upon other factors such

as the relative internalising or externalising the individual does to understand their own experiences. This will require careful interpretation beyond identifying themes (such as in a thematic analysis). Criticisms of qualitative research in that it fails to develop interpretation at a sophisticated level (see Hefferon & Gil-Rodriguez, 2011) will be considered when analysing the data.

Grounded Theory coding following the guidelines of Charmaz (2006) begins with open coding, focused upon identifying actions, rather than topics and themes. Through further analysis of these actions, processes should emerge that can then form the basis of a possible grounded theory for the topic. Coding and analysis occurs concurrently with data gathering, and helps shape and form the interviews that follow.

8 Diversity

The study is centred upon and recruiting participants within a specific service, and therefore the diversity of those involved in the study will reflect the inherent level of diversity within that group, but not the diversity of the wider population.

Individuals with thought disorder, organic conditions, or experiencing an episode of mania have been excluded from participating in the study. This has unfortunately been necessary to preserve the validity of a study based on retrospective accounts of thoughts and feelings. It is hoped however, that future studies based on the findings of this project, using different methodologies, will be able to include these groups and their experiences.

The decision was taken initially to only recruit service users aged 18-39, but this has now been updated to remove the upper age limit. All service users over the age of 18 will

now be able to take part in the study, representing a wide range of different experiences across the lifespan.

9 Proposed Journals

Due to the exploratory nature of the study, more time is needed before focusing upon specific journals for publishing research findings. As the general underlying principles involve very broad themes such as connectedness, a wide range of psychological and health journals can be considered, e.g. Psychology and Psychotherapy: Theory, Research and Practice.

10 Ethical/Registration Issues

Full NHS REC ethical approval will be required, and applied for through the NHS research ethics process. The study involves service users currently experiencing acute difficulties requiring inpatient services. It is very important that any research project does not interfere with their care or increase their distress. To prevent this occurring, the study design includes the following:

- 1) A process independent of the trainee to establish capacity to take part.
- 2) An evaluation of participation, again independent of the trainee, to identify potential participants who are at a stage of their recovery where participation is not considered a significant risk to that recovery process.
- 3) No participant will be recruited within their first two weeks at the Hergest Unit when their difficulties are likely to be more acute.
- 4) The researcher conducting the study is a Trainee Clinical Psychologist with experience working with vulnerable individuals one-to-one, with a variety of

experiences including significant trauma. The Trainee also has experience prior to training as a service user themselves in inpatient settings.

- 5) A thorough debrief period will be included to help manage and interpret any difficult thoughts and feelings that have surfaced, and additional information provided. A member of the care team at the Hergest Unit will also be guaranteed to be available to talk with the service user after their participation ends, to provide additional support independent of the study.
- 6) Information presented to the care team at the Hergest Unit will assist the care team in potentially finding positive clinical benefits from the reflective process of taking part in the study that may aid recovery.
- 7) The participant retains the ability to stop taking part at any stage, and to have any information they have produced removed from the study.
- 8) A University Panel that includes service users with experiences similar to those who may be recruited in the study will be fully consulted in the creation of all materials relevant to the protocol, to ensure that they are clear, understandable and do not cause any additional distress.
- 9) If the service user wishes to have a member of staff present during their participation this will be supported, and any additional requests for information met.

R&D approval will also be sought from the local R&D unit to the research site. Before R&D and site approval is sought, a period of staff engagement and information sharing will take place to both support the study and answer any concerns raised.

11 Feedback

In addition to information and discussion during the debrief stage, contact details both digital and by post for participants to contact the research team will be provided. This will allow both for the request of study findings, but also to provide answers to any further concerns participants have regarding the study.

12 Risk Assessment

14.1 Risk to Participants

Details regarding the various measures to reduce potential distress amongst participants that might occur through discussing their experiences with loneliness have been provided in section 12. It should be noted in addition that service users would be present in an environment already strongly geared to managing risk and ensuring safety.

14.2 Risk to Researchers

No significant risks to researchers are predicted. All members of the research team are NHS employees who have attended relevant training for maintaining safety in the workplace following established guidelines.

13 Data Storage

Any data containing possible identifiers will be kept securely at the research site in a secure office requiring key card access. Anonymised data may be taken to other NHS or Bangor University sites for analysis. This anonymised data will contain participant codes, the list linking code to any identifiers will always remain at the secure research site in the secure office. Only members of the research team will have access to the data, with the only exception being the care

team at the Hergest Unit if the conditions are met to break confidentiality, as described in the agreed and signed consent form.

Personal identifiers will be retained for 6-12 months at the secure NHS site to allow for any requests by participants for their data to be removed. This data will then be destroyed following NHS guidelines developed in keeping with the data protection act. Anonymised data will be kept securely by the research team for a longer period following the data storage policy of the University. This will follow University guidelines, including the storage of the data securely at the University offices in a secured cabinet.

14 Financial Information

The only current financial cost will be the proposed £10 gift vouchers, totalling £100. No further costs are anticipated at this time.

15 Timetable

October 2016: NHS Ethics Application process.

November 2016: Completion of NHS Ethics process, R&D review process.

December 2016: Begin data gathering, analysis occurs concurrently.

March 2017: Cut-off date for data inclusion in thesis for Doctoral Program.

April 2017: Two-month break for review of thesis and submission

June 2017: Thesis submission. Review and continue data gathering if additional data will add further value to project.

September 2017: End study. Report to NHS REC on results of study.

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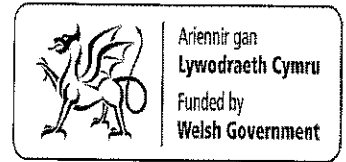
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Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service



Pwyllgor Moeseg Ymchwil Cymru 5
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27 October 2016

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Dear Mr Oakley,

Study title: **Exploring and Understanding Loneliness and Connectedness amongst Service Users in Acute Adult Mental Health Inpatient Care: A qualitative study using Grounded Theory.**
REC reference: **16/WA/0328**
IRAS project ID: **211238**

The Research Ethics Committee reviewed the above application at the meeting held on 20 October 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

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.

The Committee concluded that the research question was highly appropriate and likely to aid the understanding of how service user difficulties are influenced by loneliness, assist inpatient service planning, and potentially provide helpful insights to aid recovery for the service users themselves.

The Committee noted that the outcome measures will not be identify whether loneliness is a result of being marginalized or a factor contributing to the marginalization of patients who have mental health issues.

You confirmed that the current published literature does not provide a definitive answer on this issue; from this study's perspective, the research team will try to be open and not put leading questions but present them as concepts and give people the opportunity to talk from their own perspective; patients may have their own perceptions and may present an event that precipitated their isolation or may identify that their initial isolation led to a relationship breakdown which in turn led to distress. The aim of the study is to look at different accounts not to establish causality, and the study team is very keen not to introduce ideas around causality which were not present before the investigation. The team will explain and discuss it as a concept on 'how you connect to other people' and an exploration discrepancies between "connections we want" and "connections we have".

The Committee discussed whether the design and methodology makes use of accepted scientific principles and methods to produce reliable and valid data.

The Committee concluded that the study design robust and the proposed analysis using Grounded Theory is adequate to answer the research question.

Public Involvement

It was noted that patients and service users were involved in the design of the study; you confirmed that you discussed the study with the North Wales Clinical Psychology Programme People Panel, a service user and carer group that meets on a regular basis to manage and promote service user and carer participation in Clinical Psychology training. The core themes of the research project have been discussed and feedback has also been sought on the suitability of patient facing information.

Recruitment arrangements and access to health information; fair participant selection

The Committee discussed the recruitment method, the fairness of the inclusion and exclusion criteria, and whether any incentives or payments are made.

The Committee was satisfied that the selection of participants has taken into account the patients' clinical care. Participants will be recruited fairly and sufficient details are provided in the protocol regarding the inclusion and exclusion criteria.

A query was raised in relation to the first approach made to participants.

You clarified that potential participants will be approached with information about the study by the clinical psychologist who is part of their clinical care team.

Favourable risk benefit ratio; anticipated benefit/risks for research participants

The Committee discussed the anticipated benefits and potential risk for individual research participants, and whether the research team clearly identified them and took steps to minimise or eliminate the discomfort, and distress and enhance potential benefits.

It was noted that the clinical care team will conduct an initial eligibility assessment and only service users on whom the study will have no detrimental effect (negatively impacting their recovery) will be approached.

You added that the research team will not consider including patients who are in an acute situation.

The clinical psychologist who approaches the patients first will act as a gatekeeper and will check the suitability for the study against the eligibility criteria to ensure no harm or distressed is being caused by approaching participants who are not suitable to be included in the study. Participants will potentially benefit from the opportunity to reflect on their sense of connectedness and the interview may help service users to process their inpatient experience and aid their eventual discharge process. A full debrief will be included in the interview process, and the research team will ensure ensured that a member of the care team will be available.

The Committee was satisfied that the risks to the research participant were considered proportionate to the benefits and the balance between risk and benefit equitable. The risks and benefits have been suitably identified and highlighted in the information given to potential participants.

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, what it entails, potential risks and benefits, and whether it includes all procedures as described in the protocol.

It was noted that a Welsh language version of the participant facing documentation will be available, however, the interviews will be conducted in English only; it is not possible to translate the transcribed material as this would lose validity.

Arrangements are made to inform the GP of their participation in the study and explicit consent is sought.

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.

The Committee noted that a Welsh language translation of all patient-facing documentation will be provided to participants and queried whether a paragraph should be added to the translation to clarify that the interviews will be conducted in English and all questionnaires are in English.

You clarified that this would be discussed with the participant when the study is introduced.

Suitability of supporting information

The Committee discussed the suitability of the supporting information and noted that the questionnaire collects data on ethnicity, and queried how relevant this information is for the study as in a small this may make patients identifiable.

You clarified that it is important to collect the demographic data, but particular demographic details that would make patients identifiable will be excluded in any write-up.

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 in the next 10 days.

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
Covering letter on headed paper [Cover Letter]	-	03 October 2016
GP/consultant information sheets or letters [GP Letter V..1]	1	03 October 2016
Interview schedules or topic guides for participants [Current Topics Guide V.1]	1	03 October 2016
Non-validated questionnaire [Demographics Questions]	1	03 October 2016
Other [Debrief Sheet V.1]	1	03 October 2016
Participant consent form [Consent Form V.1]	1	03 October 2016
Participant information sheet (PIS) [Participant Information Sheet V.1]	1	03 October 2016
REC Application Form [REC_Form_04102016]		04 October 2016
Research protocol or project proposal [Study Protocol V.1]	1	03 October 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Bangor University Insurance Document]	-	18 July 2016
Other [Clinical Supervisor Dr Alison Firth Brief CV]	-	
Summary CV for Chief Investigator (CI) [D Oakley Summary CV]	-	
Summary CV for supervisor (student research) [Dr Mike Jackson Brief CV]	-	

Membership of the Committee

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

No declarations of interest were 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/0328

Please quote this number on all correspondence

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

Yours sincerely

Rossela Roberts

P

**Dr Philip Wayman White, MBChB, MRSM
Chair**

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:

Sponsor:

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Bangor
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R&D Office:

Miss Debra Slater
Clinical Academic Office
Betsi Cadwaladr University Health Board
Ysbyty Gwynedd
Bangor
Gwynedd
LL57 2PW debra.slater@wales.nhs.uk

Wales Research Ethics Committee 5

Attendance at Committee meeting on 20 October 2016

Committee Members

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>	<i>Present</i>
Dr Karen BE Addy	Clinical Psychologist	Expert	No
Dr Swapna Alexander	Consultant Physician	Expert	No
Mrs Kathryn Chester	Research Nurse	Expert	No
Ms Geraldine Jenson	Retired College Vice-Principal	Lay +	Yes
Mr Eliezer Lichtenstein	Student	Lay +	Yes
Dr Mark Gregson Lord	Consultant Pathologist	Expert	No
Dr Pamela A Martin-Forbes	WCRW Research Officer	Expert	Yes
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	No
Dr Philip W White	General Practitioner (Chairman)	Expert	Yes
Ms Sydna A Williams	Lecturer	Lay +	No

In attendance

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

Academic Supervisor:

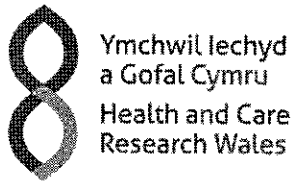
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Dr Alison Firth
Hergest Unit
Ysbyty Gwynedd
Bangor
Gwynedd
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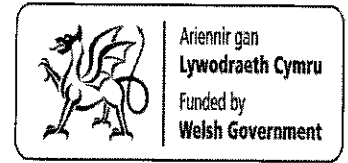
Alison.Firth@wales.nhs.uk

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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
Website : www.nres.nhs.uk

20 February 2017

Mr David A Oakley
Trainee Clinical Psychologist
Betsi Cadwaladr University Health Board
North Wales Clinical Psychology Programme
School of Psychology
Bangor University
Bangor, Gwynedd
LL57 2DG psp4e6@bangor.ac.uk

Dear Mr Oakley

Study title: Exploring and Understanding Loneliness and Connectedness amongst Service Users in Acute Adult Mental Health Inpatient Care: A qualitative study using Grounded Theory.
REC reference: 16/WA/0328
Amendment number: 01
Amendment date: 27 January 2017
IRAS project ID: 211238

The above amendment was reviewed at the meeting of the Committee held on 16 February 2017.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Committee noted that this amendment proposes to remove the age cap of inclusion criteria.

Participant age range in the inclusion criteria has had the upper limit (was 39 years of age) removed. Since recruitment started, it became apparent that a majority of service users were over 39 years of age. Therefore, to both aid recruitment, but also to keep the sample representative of the inpatient population at the site, the research team is proposing to remove the upper age limit.

All other criteria that exist to protect service users remain the same, and these criteria already include reference to the presence of cognitive/biological factors such as dementia.

The Committee does not consider that this amendment significantly alters the initial research design or methodology and decided that this amendment raises no ethical issues.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMP)	01	27 January 2017
Research protocol or project proposal [Protocol V2]	2	25 January 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

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

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

16/WA/0328:

Please quote this number on all correspondence

Yours sincerely



 Dr Philip Wayman White, MBChB, MRSM
Chair

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*

R&D Office: Miss Debra Slater
Betsi Cadwaladr University Health Board
debra.slater@wales.nhs.uk

Sponsor: Hefin Francis
Bangor University
h.francis@bangor.ac.uk

Wales Research Ethics Committee 5

Attendance at Committee meeting on 16 February 2017

Committee Members

Name	Profession	Capacity	Present
Dr Karen BE Addy	Clinical Psychologist	Expert	Yes
Dr Swapna Alexander	Consultant Physician	Expert	Yes
Mrs Kathryn Chester	Research Nurse	Expert	No
Ms Geraldine Jenson	Retired College Vice-Principal	Lay +	Yes
Mr David Rhys Jones	Retired Teacher	Lay +	Yes
Mr Eliezer Lichtenstein	Student	Lay +	Yes
Dr Mark G Lord	Consultant Pathologist	Expert	Yes
Dr Pamela A Martin-Forbes	NISCHR Research Officer	Expert	No
Dr Paul G Mullins	Reader, MRI Physicist	Lay +	No
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
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
Mr Norbert Leon Ciumageanu	RES Administrative Assistant

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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

Dr. David Oakley
Trainee Clinical Psychologist
Betsi Cadwaladr University Health Board
North Wales Clinical Psychology Programme
School of Psychology, Bangor University
Bangor, Gwynedd
LL57 2DG psp4e6@bangor.ac.uk

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

16th December 2016

Dear Dr. David Oakley

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

Study Title Loneliness and Connection in Acute Adult Mental Health Inpatient Care
IRAS reference 211238
REC reference 16/WA/0328

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 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:
IRAS Form	V5.3.2	10/11/2016
SSI Form	V5.3.2	14/11/2016
Protocol	V1	03/10/2016
Participant Information Sheet	V2	16/12/2016
Consent form	V1	03/10/2016
GP letter	V1	03/10/2016
Questionnaire - Demographic	V1	03/10/2016
Summary CV: Firth		2016
Summary CV: Jackson		2016
Summary CV: Oakley		Undated
Evidence of Insurance		Expires 31/07/2017
Risk Assessment		29/11/2016
REC favourable opinion letter		27/10/2016

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: Hefin Francis
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Academic Supervisors: Dr Mike Jackson
North Wales Clinical Psychology Programme
School of Psychology, Bangor University
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LL57 2DG mike.jackson@bangor.ac.uk

Principal Investigator: Dr Alison Firth
Hergest Unit,
Ysbyty Gwynedd
Bangor, Gwynedd
LL57 2PW Alison.Firth@wales.nhs.uk

1.4

David Oakley

From: Sion Lewis (BCUHB - Research & Development) <Sion.Lewis@wales.nhs.uk>
Sent: 21 April 2017 12:53
To: David Oakley
Cc: Alison Firth (BCUHB - Mental Health & Learning Disabilities)
Subject: 211238 - Substantial Amendment AM01 dated 27 January 2017

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

Dear Dr Oakley,

Re: Substantial Amendment AM01 dated 27 January 2017

Study Title Exploring and Understanding Loneliness and Connectedness amongst Service Users in Acute Adult Mental Health Inpatient Care: A qualitative study using Grounded Theory.
R&D reference 211238
Category A

The above amendment was reviewed by the R&D Office on the 21 April 2017 on behalf of the Internal Review Panel.

Documents reviewed:	Version	Date
Notice of Amendment Form	AM01	27/01/2017
Protocol	2	25/01/2017
REC Approval of Amendment	-	20/02/2017

The R&D Office have no objection and is able to support the amendment based on the information provided. The amendment does not affect local management approval previously given to this research and is approved to continue at Betsi Cadwaladr University Health Board (BCUHB) sites as described in the application.

As part of the regular monitoring undertaken by the Internal Review Panel you will be required to complete a short progress report. This will be requested on a 6 monthly basis. However, please contact me sooner should you need to report any particular successes or problems concerning your research. Whilst BCUHB is keen to reduce the burden of paperwork for researchers failure to produce a report may result in withdrawal of approval.

All research conducted at the BCUHB sites must comply with the Research Governance Framework for Health and Social Care in Wales (August 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.

The decision is sent to you in electronic format only – please let me know whether you will be requiring a formal letter.

On behalf of BCUHB, we would like to wish you every success with your research.

Yours sincerely


Mr Sion Lewis
Cynorthwydd Ymchwil a Datblygu/Gweinyddwr Treilon
Research & Development Assistant/Trial Administrator

Bwrdd Iechyd Prifysgol
Betsi Cadwaladr
University Health Board

Monday - Wednesday - Tel: (01745) 448687 – Ext: 8687 (Trials Administrator - Abergele)
Thursday - Friday - Tel: (01248) 384877 – Ext: 4877 (R&D Assistant - Ysbyty Gwynedd)
Email: Sion.Lewis@wales.nhs.uk

Bwrdd Iechyd Prifysgol Betsi Cadwaladr yw enw gweithredol Bwrdd Iechyd Lleol Prifysgol Betsi Cadwaladr

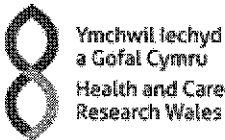
Betsi Cadwaladr University Health Board is the operational name of Betsi Cadwaladr University Local Health Board

 *Dilynwch ni ar Twitter/Follow us on Twitter: @BetsiResearch*

Today's Research; Tomorrow's Care
Ymchwil Heddiw; Gofal Yfory

We constantly strive to improve our services and value your feedback. We'd really like to hear from you and your responses will, of course, remain confidential and you won't be identified in any results. Please click on this link to leave your feedback:
www.healthandcareresearch.gov.wales/your-views/

Rydyn ni bob amser yn ymdrechu i wella ein gwasanaethau ac rydyn ni'n gwerthfawrogi'ch adborth. Fe fydden ni'n wirioneddol hoffi clywed oddi wrthyh chi ac fe fydd eich ymatebion, wrth gwrs, bob amser yn gyfrinachol ac ni fyddwn ni'n eich enwi mewn unrhyw ganlyniadau. Cliciwch ar y ddolen hon i roi'ch adborth: www.ymchwiliiechydagofal.llyw.cymru/your-views-cy



Cymraeg

Rhybudd Eboost (2010) - Bwrdd Iechyd Prifysgol Betsi Cadwaladr

Fe'ch cynghorir i ddarllen rhybydd eboost Bwrdd Iechyd Prifysgol Betsi Cadwaladr (a'i argraffu er mwyn cyfeirio ato yn y dyfodol). Gellir dod o hyd iddo yn y lleoliad canlynol
<http://www.wales.nhs.uk/sitesplus/861/tudalen/47230>

English

Betsi Cadwaladr University Health Board - Email Notice (2010)

You are advised to read (and print for future reference) the Betsi Cadwaladr University Health Board e-mail notice which can be found at this location
<http://www.wales.nhs.uk/sitesplus/861/page/47229>

Betsi Cadwaladr University Health Board is the operational name of Betsi Cadwaladr University Local Health Board



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Appendix 2.1 Participant Information Sheet V.2 16/12/16

Loneliness and Connection in Acute Adult Mental Health Inpatient Care

You have been invited to take part in a study exploring the experiences of loneliness and connection felt by service users attending an adult mental health inpatient unit. Please read the following information at your own pace, and feel free to ask any questions about the study if you would like to.

You do not have to take part in this study if you do not wish to. Whether you choose to take part or not, the level of care you receive will remain the same.

What is this study about?

This study is looking to explore how loneliness and social connection are experienced by people who have attended an adult mental health inpatient unit. It will also investigate how that experience may have changed since admission to the unit, and what may have made those changes come about.

An experience of loneliness does not have to mean being physically alone. It can also be experienced when you do not feel connected to others around you. Those possible connections can be very different. Some are close, like partners, family, close friends. Some are more distant. We can also feel more or less connected to the bigger society around us. Some connections occur face to face, and some happen through our phones, and online.

With all these different ways to connect, what research has shown to be similar is how feeling disconnected can affect us negatively. How that negative feeling might influence the need for an admission to an inpatient unit, is something that we would like to understand better. How that feeling might be lessened or increased by spending time at an inpatient unit, is something important for everyone involved to understand, and improve if possible.



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What will be required of me?

If you agree to take part, we will arrange a time for us to meet in a private, safe place at the unit, to discuss your experiences of loneliness and social connection for about one hour. At this meeting you will be asked some short questions that give you the chance to talk about your experiences, thoughts and feelings.

You will not be asked questions about any specific experiences from your past. What is discussed will only be what you feel comfortable and able to talk about. If you wish to end a topic of discussion, we will do so. You do not have to answer any particular questions or say anything you do not want to. If you would like a break at any point, we will take one.

At the end of the interview you will carry out a short questionnaire that records anonymously some details about your background, such as your age, ethnicity and education. Again, you need only complete this questionnaire if you wish to.

You will also be provided with further information about the study, and you will have the opportunity to ask any questions you have about it. You will also have the opportunity to talk to a staff member that you feel comfortable talking to, immediately after the interview if you wish. If you have further questions or concerns after the session is over, you may contact us using the details provided in your information sheet.

The interview will be recorded on a small recording device, purely to aid the research team in their analysis of the discussion. This recording will be written down soon after the interview, and the recording will then be securely deleted from the device. At no point will the device leave the Hergest Unit, and it will be kept in a locked cupboard when not in use.

If at any time, you decide you no longer wish to take part in the study, we will stop immediately. If you wish to have any information you have provided to that point removed and deleted this will be done.



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What are the risks in taking part?

Engaging with the interview may mean thinking and talking about possibly negative feelings and experiences. These may be things you sometimes try to avoid thinking about, or feeling. As a result, it is possible that some difficult feelings may surface.

You have the right to change topic or stop the interview at any time if you wish. We will make sure that a member of the care team is available to offer extra support as soon as the interview is over.

It is also possible that some thoughts and feelings you were not necessarily aware of may be brought to the surface through discussing your experiences. This may also happen in the time following the interview. If this happens, please communicate this to the care team as soon as possible so that they can give you extra support and help ensure you are safe.

The researcher will check on your welfare throughout the study. Your well-being will always be more important than the study, and we will stop if we have any concerns that it might be causing distress.

What are the benefits of this study?

There is an increasing amount of evidence linking social connection and loneliness to many areas of mental health. There is a need for greater understanding of how connection and loneliness are experienced by service users receiving inpatient care. This will help our understanding of both how people come to need inpatient care, and how inpatient care may be affecting people. It is hoped that the findings of this study will be useful for planning and running inpatient services in the future, as well as assisting those with mental health difficulties in general. It is also hoped that taking part in the study may also be a positive opportunity for service users to reflect on their experiences as an inpatient.



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What happens to the information I provide?

All information provided will be kept strictly confidential. Any personal details provided will be kept safe, secure and separate from the research data. The information you provide will be maintained for the purposes of the study only, and will not be transferred or used for anything else. Once the information is no longer required for the study it will be deleted. Only the research team and your directly involved care team will have access to your information held the Hergest unit. Any information that is used for analysis by the research team at Bangor University will have all information that might identify you removed before it leaves the Hergest Unit.

The one important exception that would lead to a break in confidentiality is if during the course of your participation, something is disclosed that would indicate that yourself or others are at risk of imminent harm. If this occurs, then then the researcher will cease the interview and share this information with your care team, so that they can provide immediate support. **It is important that you understand and agree to this possibility before you give consent.**

If after completing the study you subsequently decide to withdraw and have your results removed and deleted, you may request this using the details provided below.

Who has approved this study?

This study has been approved after a thorough review process carried out by the NHS Wales 5 Research Ethics Committee. It has also been reviewed by the local NHS Wales Research and Design centre, and has proceeded through a review by the Bangor University. The primary purpose of these reviews has been to ensure that your safety and wellbeing are safeguarded, and that the study provides a benefit to both future research and service users engaged with adult inpatient services.



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Who is conducting this study?

This study is primarily being conducted by David Oakley, a Trainee Clinical Psychologist, in part fulfilment of study towards a Doctorate in Clinical Psychology. As a Trainee Clinical Psychologist, David Oakley is both a full time employee of the Betsi Cadwaladr University Health Board and an enrolled student at Bangor University. The research study is officially sponsored by Bangor University. David Oakley is receiving supervision and support in carrying out this study from Dr Alison Firth (Clinical Psychologist at the Hergest Unit) and Dr Mike Jackson (Consultant Clinical Psychologist and Director of Research at the North Wales Clinical Psychology Programme).

To contact the research team regarding this study please use the details below:

David Oakley
North Wales Clinical Psychology Programme
School of Psychology, Bangor University
Bangor, Gwynedd
LL57 2DG
Email: psp4e6@bangor.ac.uk

Additionally, if following your participation in this study, you have concerns or a specific complaint about any element of the study, please contact:

Mr Hefin Francis
School Manager, School of Psychology
Adeilad Brigantia, Penrallt Road
Bangor, Gwynedd
LL57 2AS
Email: h.francis@bangor.ac.uk



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I agree to take part, what do I do now?

Please inform the researcher that you wish to take part, he will agree with you a mutually convenient time for the interview to take place. He will also provide a consent form for you to sign recording your agreement to take part. This form will be explained in full by the researcher, but please feel free to ask any question you have about the form. In addition, if you wish for the research team to inform your G.P about your participation in the study, please indicate this on the consent form.

If you want to have more time to decide whether to take part, please inform the researcher of this and he will arrange a time a day from now to meet once you have decided. Thank you for taking the time to read this information sheet.



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Appendix 2.2 Consent Form V.1 03/10/2016

Study: Loneliness and Connection in Acute Adult Mental Health Inpatient Care

Principal Investigator: David Oakley

Please initial box to indicate agreement

1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. I have been given a copy of the information sheet to keep. []

2. I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving any reason, without my health care or legal rights being affected. []

3. I understand that I will be providing some personal details and producing data to be accessed by the named Researchers, and Betsi Cadwaladr University Health Board, where it is relevant to my taking part in this research. I give permission for these individuals to have access to these records. I understand that my personal data will be processed and stored securely in compliance with the 1998 Data Protection Act. []

4. I would like the researchers to inform my G.P of my participation in this study, and I consent to the research team contacting my G.P for this purpose. This is optional. []

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

Name of patient

Date

Signature

Name of Researcher

Date

Signature



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If you would like to receive further information and feedback on the results of the study once it is completed, please add a contact address or email address in the space provided below if you wish. If you decide not to do so at this time, you may still contact the research team in the future to request this information, using the contact details we have provided on your information sheet.



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Appendix 2.3 Debrief Sheet V.1 03/10/16

Loneliness and Connection in Acute Adult Mental Health Inpatient Care

Thank you for participating in this study. In addition to our thanks, please accept a £10 payment for your time and effort in taking part in the study.

The aims of this study were to understand how loneliness and social connection are experienced by inpatients in an adult mental health unit, and how spending time as an inpatient may change these experiences. To achieve this, you took part in an interview, where you talked about how you feel connected to others, if and how this may or may not lead to loneliness, and how becoming an inpatient has changed this. As research in this area is still at an early stage, we do not have specific predictions of what those experiences might be, and this study is designed for the voices of people using services to be listened to and heard.

We will analyse what was said during the interview, with a focus on identifying the 'actions' that have occurred that influenced your experience. From these 'actions' we can identify 'processes', the ways in which the experience of loneliness and social connection affects us. By comparing your experiences with those of other people, we can see how people may react the same or differently to various events, thoughts and feelings. Some of those findings may help us understand how inpatient services might be affecting loneliness and social connection, and some findings may help us understand mental health better in general. Both of these areas will be of great benefit for improving services in the future.

We hope the experience of taking part in this study has been a positive one, and the information provided helpful. Your contribution is immensely valuable and appreciated, especially considering that it comes at a difficult time. Your patience and effort will hopefully benefit both the development of inpatient services, and understanding of mental health difficulties in general. Your data will be analysed in depth, but please note that it will be kept



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in an anonymised format: no details linking what you have written to your name or address will be present, and your confidentiality will remain intact throughout the process.

If you feel any discomfort or distress in the next few days following your participation in this study, please discuss this with a member of your care team. If this occurs following being discharged from the Hergest Unit, please contact your GP. If you have any additional questions regarding the details of the study, please contact the researcher through the details provided below, or if this is not possible, ask the care team to contact the researcher on your behalf.

If you would like a copy of the paper written from the results of this study, please tell the researcher and he will arrange for these to be sent to you. If you decide you would like a copy in the future, please contact the researcher using the details below.

If, for any reason, you would like to withdraw from the study and have your data removed from the results, please contact the researcher using the details below.

Contact Details:

David Oakley

North Wales Clinical Psychology Programme

School of Psychology, Bangor University

Bangor, Gwynedd

LL57 2DG

Email: psp4e6@bangor.ac.uk

If you would like to read further on the topics of loneliness and social connection, please contact us at the address above and we will be happy to provide a suitable reading list.

Thank you again for contributing to this study.

Appendix 3.1 – Example Interview Topics and Possible Questions

1) If you feel comfortable, can you tell me about how your life was in the weeks before admission?

- a. Where did you spend your time?
 - i. How did it feel to be there?
 - ii. If alone, what was that like?
- b. What people did you see?
 - i. Missing people?
 - ii. Or, what did you like/dislike about people?
 - iii. Was there a particular important relationship that changed/lost?
- c. Had this changed?
- d. How did you feel about the world outside? Connected or distant?
- e. What are your beliefs regarding how people react to you? How they see you? Do you feel confident you can make connections?

2) How did you find the admission process?

- a. It must have been a sudden change
- b. What was it like having all the staff and patients around?
- c. How did you feel the admission process went?
- d. Did it affect you in any way?

3) What is a typical day here like for you?

4) What have your experiences of interacting with others on the ward been like?

- a. Are there different types of connections/relationships? Staff vs SUs?
- b. Are there certain events that affect this? Different times of day?
- c. Are there things you find different about different people?
- d. How does it compare to how things were before you came here?
- e. How is being alone here?
- f. How is it being in groups of people? Different when staff present?
- g. Have any of these interactions changed how you think about yourself, or about other people?

5) How do you feel about the outside world?

- a. Has this changed by spending time here?
- b. How do you think you fit into the world?
- c. Has this changed since being here?

6) How do you feel about the future?

- a. What do you think will happen after being discharged?
- b. Do you have plans to see more people?
- c. Do you think it will change relationships?
- d. Are there specific relationships you would like to have?

7) Can you think of a time when you felt really connected to other people?

Appendix 4.1 Sample Transcript

<p>Appendix 4.1 Sample Transcript</p> <p>Participant: P007</p> <p>Demographics: Deleted for anonymity</p> <p>Interview:</p> <p>1) I: If you are comfortable talking about it how were things in the weeks before you came here?</p> <p>2) R: [sigh] (2) before I came here?</p> <p>3) I: Yes</p> <p>4) R: I dunno (2) ahh (2) I wasn't feeling too good at all to be honest with you scared to go out (.) hearing voices you know don't go out and this and that you know it was an awful experience yeah</p> <p>5) I: It was a very tough experience</p> <p>6) R: A very tough experience yeah</p> <p>7) I: From the sound of it it was very threatening to go out?</p> <p>8) R: Yes</p> <p>9) I: Did you feel safer at home?</p> <p>10) R: (3) I feel safer here</p> <p>11) I: Ok safer here as well (.) but in the flat you were in was it safer being in the flat than being outside?</p> <p>12) R: Erm yes yes yes I became so unwell you know I didn't feel sort of safe there</p>	<p><i>Initial Coding</i></p> <p><i>(needing time to focus)</i></p> <p><i>Taking time to engage thoughts with negative experience.</i></p> <p><i>Feeling scared to go outside.</i></p> <p><i>Experiencing voices following his sense of fear.</i></p> <p><i>Experiencing life as awful before admission.</i></p>
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Appendix 4.1 Sample Transcript

<p>either you know</p> <p>13) I: So in the end=</p> <p>14) R: =it got so much I couldn't cope with it</p> <p>15) I: It sounds like you went through a really tough time</p> <p>16) R: It was yeah</p> <p>17) I: So (.) You said before that things haven't been good for quite a long time?</p> <p>18) R: No</p> <p>19) I: So was there a sense of things changing and getting worse over the last few months?</p> <p>20) R: Well (2) this flat I've been in now I been in three years (.) it was quite alright for a while for quite a while (.) and then I became unwell once twice I became unwell now yeah (.) the first time was bad and the second time was bad (.) you know the first time it was awful you know the experience erm but between that the first and the second (.) I was doing quite well like I was managing my money going out shopping and that (.) and all of a sudden it I just became unwell again now</p> <p>21) I: So there was no sense of why it started becoming bad again?</p> <p>22) R: That I don't know no</p> <p>23) I: That's ok we're not here to figure that out we're just here to get an idea of what you went through and for you to tell your story really</p> <p>24) R: Yeah (.) Oh yeah</p> <p>25) I: Ok (.) So when things were going better a bit better what sort of things were you doing day to day?</p> <p>26) R: Well I'd wake up first thing in the morning yeah (.) make a cup of tea (.) put</p>	<p><i>Feeling safer at the Unit.</i></p> <p><i>Feeling threat internally as well as externally. Internal threat creating feeling that nowhere was safe.</i></p> <p><i>Negative experience overwhelming coping strategies.</i></p> <p><i>Experiencing difficulties over a prolonged period.</i></p> <p><i>Experiencing respite initially in new living situation.</i></p> <p><i>Becoming unwell for periods of time when life is awful.</i></p>
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Appendix 4.1 Sample Transcript

<p>the television on watch the news have a cigarette [chuckle] (.) erm then have a shave have a shower put clean clothes on (.) get my rucksack get my bag and go out and do a bit of shopping (.) sometimes I'd go (xxx) (.) make us a pack lunch make a pot of coffee take my camera with me and take photographs and walk around (local town) all day (.) but erm (.) I was doing ok but it's coming bad again now</p> <p>27) I: So when you were doing ok what was it like being out and about?</p> <p>28) R: Well I was gaining my confidence yeah</p> <p>29) I: So when you were passing people in the street how would you feel about them?</p> <p>30) R: Ok (.) yeah</p> <p>31) I: So [you didn't feel as threatened?</p> <p>32) R: [It wasn't too it wasn't too it was ok you know (.)] It wasn't the first time I'd been to (local town) I'd been before with my parents you know (.) but going on the buses between (towns) I felt quite alright (.) yeah</p> <p>33) I: That's quite good particularly getting on a bus as well as it's a slightly smaller=</p> <p>34) R: =well once I had my confidence (xxx)</p> <p>35) I: So as you said for a number of years was there a time much earlier in your life when things were different?</p> <p>36) R: Well (4) I used to work quite hard you know factories and that and that was hard as well but (2) [sigh]</p> <p>37) I: So when you were working=</p> <p>38) R: =when I was when I was err I've had some quite good times in my life you know (.) going out and working really hard during the week (.) and going out on</p>	<p><i>Experiencing periods of functioning between unwell periods.</i></p> <p><i>Not knowing why life got worse</i></p> <p><i>Following routine when feeling better.</i></p> <p><i>Going out to do activities.</i></p> <p><i>Not going out to meet other people.</i></p> <p><i>Using activity to gain confidence.</i></p> <p><i>Not feeling threat when feeling better.</i></p> <p><i>Feeling better but not too comfortable. Linking presence of parents to safety.</i></p>
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Appendix 4.1 Sample Transcript

the weekend and having a good time with friends yeah

39) I: So thinking back to that nicer time (.) so when you would go out on the weekend with friends how many friends would you see?

40) R: Just a few of us yeah

41) I: And was it a regular group of friends you had?

42) R: Yeah yeah

43) I: Had you known them quite some time or?

44) R: From work and (xxx) yeah

45) I: So it was from work?

46) R: Yeah

47) I: Ok (.) so what sort of things did you do?

48) R: (2) at that time I used to work in an abattoir (.) yeah (2) there's the main place in (local town) (2) yeah that work was hard work you know erm (.) but the money was good at the time so (.) kept me going really (.)

49) I: So (.) so you worked very hard during the week then you'd go out on the weekend?

50) R: Yeah

51) I: Going to the pub?

52) R: Yeah (.) to (another local town) and go to the student's union and discos and watch bands and that it was quite good yeah

53) I: So what sort of friendships and relationships did you have at that point?

54) R: (3) [sigh] they were ok you know (.)

Needing sense of confidence to feel safe.

*Recognising past in work as different but not easier.
Judging life as hard.*

*Feeling good from doing work.
Connecting good times to being with friends.*

Having a small circle of friends

Keeping to the same friends

Connecting to others through work.

Appendix 4.1 Sample Transcript

<p>55) I: Would you say you had close friends at all? 56) R: (3) no not really no 57) I: More going to the pub type friends go out and do stuff with? 58) R: Have a laugh yeah</p>	<p><i>Doing difficult work. Finding work hard. Acknowledging advantage of having money.</i></p>
<p>59) I: Ok (.) so has there always been a sense of meeting people and you wouldn't talk about yourself and things like that (.) you'd go out and talk about football or something like that? 60) R: We'd just have a you know (.) have a few drinks (2) and you'd smoke when you were drinking you know and have a good laugh and just (.) have a bit of fun really you know (.)</p>	<p><i>Keeping routine. Valuing social life.</i></p>
<p>61) I: So when did that change? 62) R: No err (2) it went down not long after that (.) I finished I lost me job (.) I don't know why I lost me job to this day I don't know why I lost me job (.) and it just went down from there</p>	<p><i>Not feeling certain about friends he had. Lacking a closer relationship.</i></p>
<p>63) I: It sounds as though the job was a big part of your life not just the work but the people= 64) R: =It was a horrible job the thing is the people there were quite nice that I used to work with as well you know (.) but erm (2) the people I'd associate with were you know I used to smoke cannabis and that (.) I used to get drunk three or four pints at the weekend that'd do me you know (.) but erm after a while things just started going downhill a bit</p>	<p><i>Socialising on fun level but not deeper. Involving substance use in socialising to have fun.</i></p>
<p>65) I: Did you= 66) R: =I carried on working after then not long after (.) I did more factory working in (local town) and erm (.) I didn't like it at all I wasn't feeling very well at all to be honest with you</p>	

Appendix 4.1 Sample Transcript

- 67) I: So when you left the abattoir did you lose touch with the friends that you had there? Or did you still see them?
- 68) R: I don't see them no (.) I do see one or two but I don't say much too them (.)
Hi (.) that sort of thing you know (.)
- 69) I: So when you went to the factory job how were the other people there?
- 70) R: In (name of company)?
- 71) I: Were they a bit different?
- 72) R: (2) err they were all right yeah (.)
- 73) I: But it sounds as though you weren't able to get on with them the same as you did with the people from the abattoir?
- 74) R: (3) I can't answer that one really [laughs]
- 75) I: So the sound of it you ended up not working and your day to day life became quite solitary?
- 76) R: Yes (.) stuck on my own that sort of thing
- 77) I: So one of the parts of this research is people's sense of loneliness (.) so if I said the word loneliness how would you (.) was that something you experienced?
- 78) R: (2) yeah (2) I just (.) I just get quite paranoid of people like you know (.) its just you keep people away a bit (.) cause it's hard to trust people that you don't know (.) you can have a chat or have a laugh but you know (.) how how who are these people? That's how I feel that's the way I've been (.) for three years like you know (2)
- 79) I: So when you are in the workplace you got to trust people a bit so you could get on with them at the weekend?

- Losing job.
Not understanding job lost/why life changed.
Losing job/losing connection starting downward trajectory.*
- Valuing social element of job despite disliking the work.*
- Substance use defining social circle.*
- Feeling less satisfied with work and social life over time.*
- Trying to keep working but feeling self as going downhill.
Experiencing downward pull.*
- Losing contact/connection to social circle once job link broken.*
- Not recalling life as things were getting worse.*

Appendix 4.1 Sample Transcript

<p>80) R: Yeah erm erm (.) yes in a way yes yeah</p> <p>81) I: But then without that when you were on your own was it difficult to trust people?</p> <p>82) R: (2) It's hard yeah it's just the way I am you know (2) I'm not like that with everyone you know (.) but at the end of the day (2) people take advantage sort of thing you know</p> <p>83) I: So you said you are not like that with everyone (.) are there some types of people that you find it easier to get on with?</p> <p>84) R: (3) My mother and father like you know erm (4) I get on with a few people you know but I don't I the people they drifted away from me sort of thing (.) I don't see many of them any more like you know</p> <p>85) I: You said it's easier to get on with your family and you said your parents=</p> <p>86) R: =yeah they're always there when I want them you know</p> <p>87) I: So what's different about your parents?</p> <p>88) R: I don't know I just get on with them quite well like you know</p> <p>89) I: When you are with your parents does it make you feel different?</p> <p>90) R: Yeah (.) Well I spent a lot of time with them when I was younger you know (.) the time was quite lonely in my life</p> <p>91) I: Were there things that you would like to be different?</p> <p>92) R: I'm sorry I can't answer you</p> <p>93) I: It's ok you don't have to answer (.) It sounds as though from what you've said that (.) the loneliness (.) the being able to spend time with them and connect with them is something that you have found difficult most of your life</p>	<p><i>Feeling stuck in feeling alone.</i></p>
<p>83) I: So you said you are not like that with everyone (.) are there some types of people that you find it easier to get on with?</p> <p>84) R: (3) My mother and father like you know erm (4) I get on with a few people you know but I don't I the people they drifted away from me sort of thing (.) I don't see many of them any more like you know</p> <p>85) I: You said it's easier to get on with your family and you said your parents=</p> <p>86) R: =yeah they're always there when I want them you know</p> <p>87) I: So what's different about your parents?</p> <p>88) R: I don't know I just get on with them quite well like you know</p> <p>89) I: When you are with your parents does it make you feel different?</p> <p>90) R: Yeah (.) Well I spent a lot of time with them when I was younger you know (.) the time was quite lonely in my life</p> <p>91) I: Were there things that you would like to be different?</p> <p>92) R: I'm sorry I can't answer you</p> <p>93) I: It's ok you don't have to answer (.) It sounds as though from what you've said that (.) the loneliness (.) the being able to spend time with them and connect with them is something that you have found difficult most of your life</p>	<p><i>Feeling afraid of others. Not feeling able to trust others. Pushing others away to feel safe. Appraising strangers as threatening/unsafe by default. Feeling weight of being on watch for threat over time.</i></p>
<p>88) R: I don't know I just get on with them quite well like you know</p> <p>89) I: When you are with your parents does it make you feel different?</p> <p>90) R: Yeah (.) Well I spent a lot of time with them when I was younger you know (.) the time was quite lonely in my life</p> <p>91) I: Were there things that you would like to be different?</p> <p>92) R: I'm sorry I can't answer you</p> <p>93) I: It's ok you don't have to answer (.) It sounds as though from what you've said that (.) the loneliness (.) the being able to spend time with them and connect with them is something that you have found difficult most of your life</p>	<p><i>Recognising some people are not a threat. Being taken advantage of/hurt in the past. Making sure the hurt doesn't happen again.</i></p>
<p>92) R: I'm sorry I can't answer you</p> <p>93) I: It's ok you don't have to answer (.) It sounds as though from what you've said that (.) the loneliness (.) the being able to spend time with them and connect with them is something that you have found difficult most of your life</p>	<p><i>Feeling parents are safe. Seeing others as withdrawing from him. Trusting in parents to support when needed.</i></p>

Appendix 4.1 Sample Transcript

<p>94) R: Yeah</p> <p>95) I: Ok (.) Erm (2) So if I can ask a couple more questions and then we'll move on to how you have been since you have been here</p> <p>96) R: Ok</p> <p>97) I: Erm I suppose one thing is (.) and again you don't have to answer these questions (.) is (.) if you were sort of walking down the street and you came across someone you hadn't met before (.) how do you think they see you? What do you think people see when they see you?</p> <p>98) R: (2) How do I feel about it?</p> <p>99) I: Well that but also just a sense of what (.) sometimes we see people and we think about what they might be thinking about us (.)</p> <p>100) R: (2) No I don't think</p> <p>101) I: Do you have a feeling?</p> <p>102) R: I used to yeah you know (.) I used to get quite nervous and like (.) I don't feel so bad now but (.) you know some friends I don't see much of (.) there's not many I have in a way (2)</p> <p>103) I: It sounds like you get nervous that it's a reaction you have (.) So what is your confidence like about going into situations where there are people you don't know and your ability to get on with people?</p> <p>104) R: Can you ask that question sorry</p> <p>105) I: You want me to ask it again?</p> <p>106) R: Yes</p> <p>107) I: What is your confidence about your ability to get on with other people (.) so if you went into a group of people you didn't know about your ability to fit in or</p>	<p><i>Not knowing why parents feel safe.</i></p> <p><i>Describing proximity with parents. Feeling lonely despite proximity of parents.</i></p> <p><i>Not wanting to talk about parents further.</i></p> <p><i>Not thinking about what others might be thinking.</i></p>
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Appendix 4.1 Sample Transcript

<p>make conversation?</p> <p>108) R: I don't know (.) it depends what kind of people I think they are you know looking at them yeah (.) if I saw people with tattoos on them and skinheads and that like no (.) a bunch of them I'd think god you know you know (.) I know it's not a good thing to say like that in that respect but it's different people (2) you know I'm just saying that it's not like</p> <p>109) I: Its ok that's just a feeling you have we all have different feelings when we see different people (.) particularly when we see people who aren't similar to us people who are different then people can feel quite anxious</p> <p>[this was normalising a bit to keep P007 open and engaged rather than relevant to the interview]</p> <p>110) R: Yeah</p> <p>111) I: Ok so we'll move onto coming here (.) so the actual process of coming here (.) how was that for you?</p> <p>112) R: Why did I come here?</p> <p>113) I: Well just that whole process=</p> <p>114) R: =Well I'm informal yeah (.) but I spoke to my consultant on Tuesday and I can stay until I feel well enough really and that I don't feel well at the moment (.) I don't want to go back and relapse again (.) I don't know</p> <p>115) I: You were quite isolated before you came here=</p> <p>116) R: =Yeah</p> <p>117) I: So suddenly arriving here with all the noise and all the people (.) what was that like?</p> <p>118) R: Here?</p>	<p><i>Feeling anxious around others in the past. Feeling loss of friends/connections over time.</i></p> <p><i>Looking out for surface signs of threat in others. Fearing people who are different.</i></p>
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Appendix 4.1 Sample Transcript

<p>119) I: When you first arrived= 120) R: =ohhh it wasn't very nice at all you know (.) I was put in a small room because I was put in a dormitory but I had to move to a small room erm (.) and I was I just I dunno I just couldn't be in the room (.) I was on my own you know and the nurses helping me they're good here yeah (.) erm I couldn't sleep at night it was not a good experience yeah 121) I: Well it must have been very tough as you were in this much smaller quiet world and it's quite loud here= 122) R: = well no I probably would have been worse in a dormitory actually (.) it's nice to have your own little room you know I had me little room (.) but I didn't sleep for three or four days a long day and a long night (.) it was a horrible experience you know (.) horrible 123) I: What other feelings did you have in the first few days? 124) R: (4) I dunno 125) I: Sometimes people come here and in the first few days with the noise and other people they feel quite threatened? 126) R: No well I could hear people talking (.) and I feel like they were talking about me but they weren't like you know (.) things like that yeah they weren't but it was just how ill I was at the time 127) I: So there was a sense of sitting or lying there and were you listening to the noise on the ward and people talking? 128) R: Yeah (.) Not staff you know (.) people (.) I dunno (2) it was just a bad feeling you know 129) I: You said the staff were quite helpful (.) those first few days what did they do to help? 130) R: Well they'd keep asking me if I wanted to eat you know I wasn't eating you</p>	<p><i>Wanting to stay on the ward. Not wanting to back out and by himself.</i></p> <p><i>Feeling uncomfortable and not wanting to be in room on ward after arriving. Noting being alone in room on ward. Feeling helped by nurses. Not being able to sleep to begin with on ward.</i></p> <p><i>Having own space increased sense of safety to begin with on ward. Not sleeping, not being able to get away. First few days on ward feeling horrible.</i></p>
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Appendix 4.1 Sample Transcript

<p>know (.) I wasn't doing anything really</p> <p>131) I: It sounds like you were surviving</p> <p>132) R: Making it through yeah</p> <p>133) I: Were there times when you wanted the nurses to be there more or were there times when you wanted them to leave you alone?</p> <p>134) R: To be quite honest with you I don't remember [chuckle]</p> <p>135) I: Ok that's fine (.) You have a rough feeling of the first few days being very difficult=</p> <p>136) R: =yes</p> <p>137) I: Of there being a big change=</p> <p>138) R: =yes</p> <p>139) I: Erm so after those first few days what started to change?</p> <p>140) R: (2) erm I came out of my room the small room into a dormitory (.) I didn't smoke for a few days I didn't smoke (xxx) (.) I feel like I couldn't have a smoke for some reason I don't know why (.) and erm I had a smoke and felt better (.) and gradually things started to get better and better and better you know</p> <p>141) I: So that feeling of things getting better (.) what were the changes for you?</p> <p>142) R: (2) Yes I started to eat a little better (.) started to have a shave cause I grew a beard sort of thing I don't grow a beard myself doesn't look right [laughs] for me anyway (.) so erm</p> <p>143) I: You said before when things were better you'd get up in the morning and have a shave=</p> <p>144) R: =yeah I shaved I started gradually got better and better I am a little bit</p>	<p><i>Listening out for people talking about him. Recognising reality and feelings were different.</i></p> <p><i>Not attributing hearing others to specific people but to bad feeling.</i></p> <p><i>Not eating after arriving on ward. Shutting down and not doing anything</i></p> <p><i>Just surviving</i></p> <p><i>Not remembering early days on ward clearly.</i></p> <p><i>Stopping smoking as part of shutting down.</i></p>
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Appendix 4.1 Sample Transcript

better now you know (.)

145) I: I imagine in those first few days you probably wouldn't be able to sit here and talk like this?

146) R: No (.) I probably couldn't have sit down for more than five minutes

147) I: Would you feel very restless?

148) R: Yeah I'd be pacing around you know (.) I couldn't settle where I was and I couldn't sleep and I couldn't lie down long (.) you know

149) I: Were there any thoughts going through your head then or things you would keep thinking about?

150) R: (2) no (.) I dunno

151) I: That's ok (.) You said also you were in your own room and then you moved to the dormitory (.) so how have you found the other patients here?

152) R: Ok (.)

153) I: So moving into the dormitory that is quite different as well?

154) R: Well I don't as far as I know I had I had to move cause there was somebody who had to come into my room (.) so I came out and I was again a bit better and I moved on to the dormitory and I am a little bit better now you know and erm (.) when I first came in my Mum and Dad got upset you know (.) you know erm I was just a state really (.)

155) I: So when you are in the dormitory how are the other people?

156) R: Yeah they're ok yeah

157) I: Do you talk to them?

158) R: Yeah I did I talked to a few of them yeah (.) one he didn't say much he's

*Moving into room with other people.
Reconnecting with activities.*

*Regaining appetite.
Beginning to self-care.*

Feeling better bit by bit.

Noticing change. Feeling calmer.

Feeling restless and finding no relief when initially admitted.

Not remembering specific thoughts (only memory of anxiety)

Feeling ok about other inpatients (not giving opinions?)

Appendix 4.1 Sample Transcript

<p>quite quiet like you know (.)</p>	<p><i>Repeating statement of being a bit better.</i></p>
<p>159) I: Is that something (.) do you like that someone is not too loud?</p>	<p><i>Recognising emotional effect on parents but not on self.</i></p>
<p>160) R: Yeah he eats crisps sometimes in the evening yeah [makes crunching noise] and I say to myself hmm and one packet goes and next minute [makes crunching noise] another packet and then [crunching noise] another packet ohh you know it drives me mad sometimes but it's nice all the same</p>	<p><i>Not giving opinions</i></p>
<p>161) I: Have you had the opportunity to have conversations with the other patients?</p>	<p><i>Not giving opinions</i></p>
<p>162) R: Yeah yeah</p>	<p><i>Talking with others in room.</i></p>
<p>163) I: Is it different talking to the patients here than it is talking to people outside of here?</p>	<p><i>Talking with others in room.</i></p>
<p>164) R: (3) Well I when I was quite well you know I used to have a chat with the elderly people you know at the bus stop and things you know (2) erm like I said it's hard to err talk to people you don't know really (.) it's a bit different here you know I don't know why but it is a little bit different here (2) I know a few faces here for years yeah (.) and some I haven't seen for a few years you know</p>	<p><i>Difficulty tolerating noises/actions of others.</i></p> <p><i>Recognising some value in someone else being there?</i></p>
<p>165) I: Sometimes people find it easier to talk to people here than [outside</p>	<p><i>Recognising some value in someone else being there?</i></p>
<p>166) R: [outside yeah</p>	<p><i>Recognising some value in someone else being there?</i></p>
<p>167) I: Do you have any idea why that might be?</p>	<p><i>Recognising some value in someone else being there?</i></p>
<p>168) R: I dunno (2) people got problems themselves you know?</p>	<p><i>Recognising some value in someone else being there?</i></p>
<p>169) I: OK (.) Have you had any chance to do the activities here?</p>	<p><i>Recognising some value in someone else being there?</i></p>
<p>170) R: I started to do some art work but art therapy but the lady who was organising it I only done it once but she's been off for some reason (.) I started doing a bit of the old weights training and a bit (.) I'm not sure when maybe Friday for Art Therapy</p>	<p><i>Perhaps seeing elderly people as less threatening.</i></p> <p><i>Finding it hard to connect with strangers.</i></p> <p><i>Experiencing interacting with others as different on the ward.</i></p>

Appendix 4.1 Sample Transcript

171) I: How did you find that?

172) R: Ok I found that good fun (.) I done it for years you know

173) I: And how about the art work?

174) R: I like the art therapy I think for those two are the only things I like doing really (.) I made one of those certain things that make noises (.) with the door (.) you buy them and you cover them up (.)

175) I: Is that something you wouldn't do outside?

176) R: I started doing weight training but I left and I don't know why I left (.) problems started to come again (.)

177) I: You said that you quite like taking pictures

178) R: Photographs yeah

179) I: Before you liked photography so the art was something you [quite liked?

180) R: [exactly yeah (.) I like taking photos and I got three cameras yeah (.) they all were given to me by my parents (.) they're quite complicated ones quite complicated to use but it's a nice thing to do you know it's nice trying to make a good picture like you know?

181) I: Is that something if you feel better you'd like to go back to doing when you leave?

182) R: yeah yeah

183) I: How do you feel about the future? You've said quite clearly that you're not ready at the moment you need more time=

184) R: I do I do yeah

185) I: That's understandable (.) Have you had any thoughts about things that

Recognising the problems in others on the ward. (thinking about thoughts of others unlike outside the ward).

Engaging with art and physical therapies.

Enjoying activities. Reconnecting with old activities.

Enjoying making something.

Experiencing loss of activities and not knowing why when things were bad.

*Engaging with being creative.
Receiving support from parents financially.*

Appendix 4.1 Sample Transcript

<p>you'd like to do?</p> <p>186) R: When I leave here?</p> <p>187) I: Yeah</p> <p>188) R: (2) [sigh] I don't know you know</p> <p>189) I: Is it difficult to see past leaving here at the moment?</p> <p>190) R: It's difficult to see it yeah</p> <p>191) I: I suppose one of the things being here is having the opportunity to have more people around=</p> <p>192) R: =yes</p> <p>193) I: So compared to how life was before you came here=</p> <p>194) R: =well I don't know (.) whenever I seem to go out I become unwell (.) that's the problem yeah (.) it just hurts somehow you know</p> <p>195) I: One of the things that we're looking at with the research project is whether one of the reasons it's better in here=</p> <p>196) R: =It is better in here yeah</p> <p>197) I: Is part of the reason it is better in here to do with all the other people that are here?</p> <p>198) R: Its well yeah I get on quite well with people here</p> <p>199) I: So when we've talked about (.) and its not a nice feeling (.) but that feeling of loneliness (.) has that been changed by being in here?</p> <p>200) R: Yes it has yeah it has yeah (.) you know erm (.) in my thoughts coming in here was oh no you know (.) but once I come here I settled down alright it's ok</p>	<p><i>Connecting a pleasurable activity to wanting to do in the future.</i></p> <p><i>Not engaging with thinking about leaving the ward.</i></p> <p><i>Not expressing sense of agency. Learning hopelessness. Experiencing loss of hope as pain.</i></p>
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Appendix 4.1 Sample Transcript

<p>here (.)</p> <p>201) I: It sounds as though you feel a bit safer</p> <p>202) R: I really do yeah (2) well I feel safer you know and (.) I can do things nice things you know (.) without having to be stuck in a rut and worry and problems like I have been (.)</p> <p>203) I: And when you are by yourself=</p> <p>204) =yeah</p> <p>205) I: I know you said it's difficult to look past leaving here (.) what sort of things might help?</p> <p>206) R: I don't know (.)</p> <p>207) I: Would living somewhere different help?</p> <p>208) R: Probably could be yeah</p> <p>209) I: Would being able to see more people help?</p> <p>210) R: Well umm (2) it's a nice flat you know it's a nice place that area but whenever I seem to go out I get unwell (.) I just I dunno (2)</p> <p>211) I: Are there any activities or things that happen on the ward that you don't like?</p> <p>212) R: Erm I don't mind taking part in things (.) I've started doing a bit of gardening work where the ward is (.) I started doing that cause I started going to ward rounds and seeing my parents you know I wish I could just stay carrying on (xxx)</p> <p>213) I: How do you find the ward rounds?</p> <p>214) R: Ok (.) easy going (.) I used to go to ward rounds years ago and I'd feel quite nervous (.) but there's only about two or three of us now and I feel quite</p>	<p><i>Judging being on ward as better than his life outside.</i></p> <p><i>Feeling safe enough to engage with others in ward environment.</i></p> <p><i>Feeling change from being on ward. Feeling settled in ward environment.</i></p> <p><i>Feeling safer on the ward. Enjoying activities. Being free from sense of responsibilities from outside (being cared for).</i></p> <p><i>Not really engaging with ideas for future.</i></p>
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Appendix 4.1 Sample Transcript

<p>comfortable with it (.)</p> <p>215) I: So actually having less people on the ward round makes it easier?</p> <p>216) R: Well there's a Doctor and Nurse so it's not so bad</p> <p>217) I: So when it used to be a room of people that was quite daunting?</p> <p>218) R: Yeah (.) Yeah they'd have err a Consultant a couple of nurses a couple of Doctors OT you know it's just [chuckle]</p> <p>219) I: So just to finish then (.) Just one more question really (.) Can you think of a time in your life when you did feel as though you felt connected to other people?</p> <p>220) R: The one time was when I was working in the abattoir</p> <p>221) I: OK</p> <p>222) R: I used to get quite a I used to sleep quite well you know you'd have a few smokes it was quite a few years ago you know (.) I'd go to bed late at night I used to get up at six in the morning and go to work (.) work hard (.) sometimes I wouldn't go home I'd be at a friend's house till midnight and then I'd continue on into the weekend (.) wake up Saturday Morning and have a Saturday night and a Sunday night and then back to work again</p> <p>223) I: So you wouldn't have much time just by yourself thinking=</p> <p>224) R: =I'd just constantly doing things yeah</p> <p>225) I: I know it's difficult to see it at the moment but is that some kind of life of having the job and having the friends something you would like to get back if you could I understand it's hard right now</p> <p>226) R: I don't know if I could do it now I've lost my confidence to be honest with you (2)</p> <p>227) I: So that confidence in being able to spend time with other people and do</p>	<p><i>Seeing relapse as inevitable.</i></p> <p><i>Liking ward environment and wanting to stay. Not wanting to go back to life outside.</i></p> <p><i>Finding small groups easier to interact with, feeling less threatened.</i></p> <p><i>Identifying feeling of being connected with being in job with social circle.</i></p> <p><i>Having a routine. Using substances to help. Just living in present and enjoying weekends.</i></p>
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Appendix 4.1 Sample Transcript

things?

228) R: Yeah (.) I don't know if I could work like that again I couldn't take a full time job again like that no yeah (.) I can't sleep properly that's one thing

229) I: What do you think would go wrong?

230) R: I don't know (.) it just wouldn't be the same (.) too many problems I have here now

231) I: All the bad things make it feel like it'd be too much?

232) R: I dunno (.) it's just how I feel you know (2)

233) I: And how you feel is what we are here to find out

234) R: Well it's nice to have someone you can talk to you know

235) I: Well thank you very much you've been quite open and talking about difficult things and periods you'd rather not think about (.) we do really appreciate the time you've spent talking about that thank you very much

236) R: Ok

[end of interview]

Keeping busy, needing momentum.

Feeling sense of having lost confidence, lost strength.

*No longer feeling able to work and engage with others.
Experiencing lack of sleep as disablement.*

Feeling overwhelmed by problems. Not believing in ability to have effective recovery.

Living according to feelings.

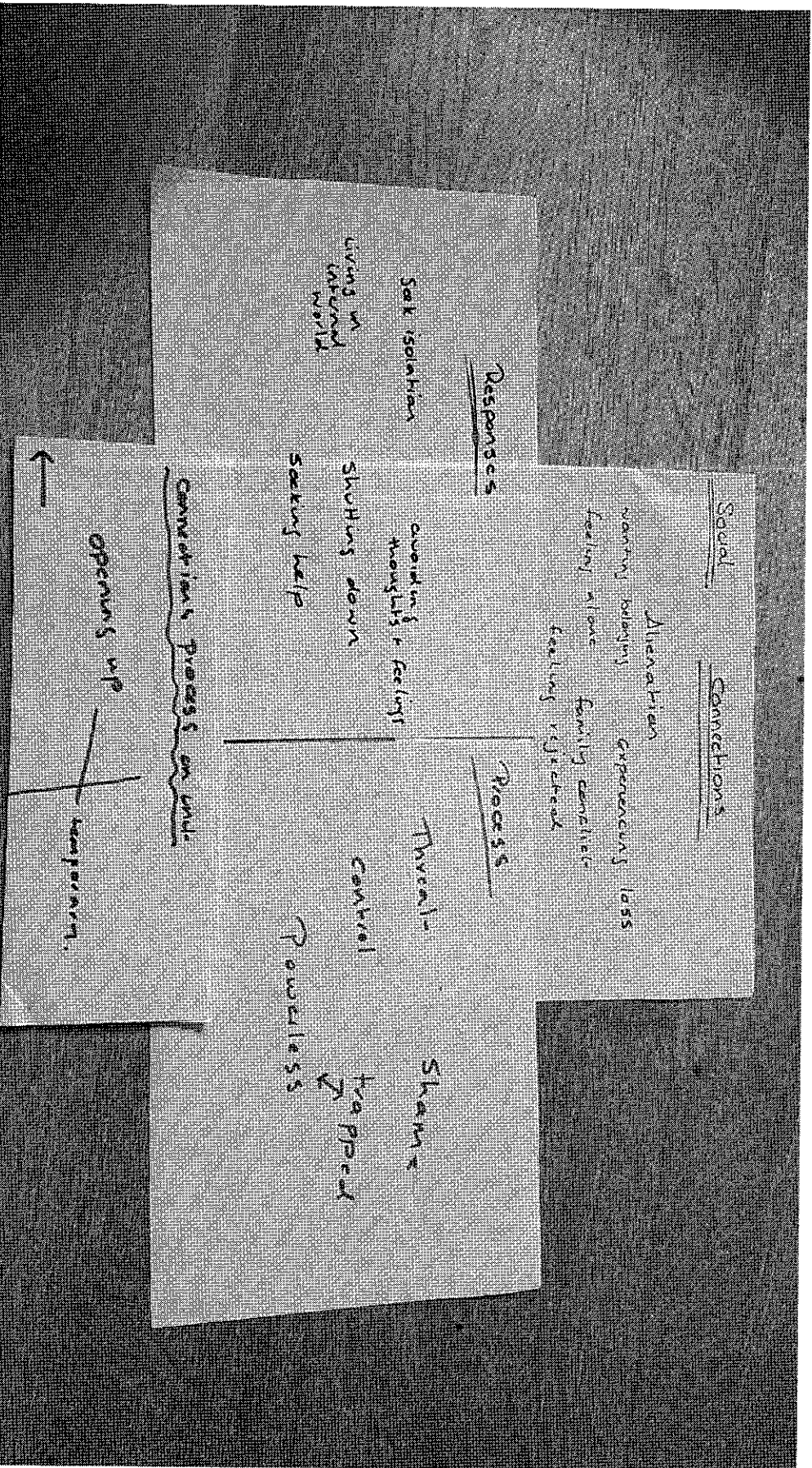
Appreciating being listened to.

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Appendix 4.2 Coding Excerpt

P004

Activity	1	2	3	4	5	6	7	8	9	10
Admin. Support	1	2	3	4	5	6	7	8	9	10
Accounting	1	2	3	4	5	6	7	8	9	10
Business Development	1	2	3	4	5	6	7	8	9	10
Customer Support	1	2	3	4	5	6	7	8	9	10
Finance	1	2	3	4	5	6	7	8	9	10
Human Resources	1	2	3	4	5	6	7	8	9	10
Information Technology	1	2	3	4	5	6	7	8	9	10
Legal	1	2	3	4	5	6	7	8	9	10
Marketing	1	2	3	4	5	6	7	8	9	10
Operations	1	2	3	4	5	6	7	8	9	10
Product Development	1	2	3	4	5	6	7	8	9	10
Project Management	1	2	3	4	5	6	7	8	9	10
Quality Assurance	1	2	3	4	5	6	7	8	9	10
Research & Development	1	2	3	4	5	6	7	8	9	10
Sales	1	2	3	4	5	6	7	8	9	10
Systems Administration	1	2	3	4	5	6	7	8	9	10
Training	1	2	3	4	5	6	7	8	9	10
Writing	1	2	3	4	5	6	7	8	9	10



Appendix 4.3 Picture of Groupings

