A Systematic Review of Older Adult Anxiety Measures and the Clinical Effectiveness of Group Psychoeducational CBT for Mixed Anxiety and Depression in Older Adults

Submitted by

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Declaration

This thesis is submitted for the degree of Doctorate in Clinical Psychology at the University of Sheffield. It has not been submitted for any other qualification or to any other academic institution.

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Research report without references	8,800
Appendices	4,715
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Abstract

The Psychometric Properties of Older Adult Self-Report Anxiety Measures: A Systematic Review

Appropriate anxiety assessment for older adults is based on validated measurement. Without sound psychometric tools, accuracy of assessment is compromised. This review considers the practicality of and psychometric evidence for self-report anxiety measures designed specifically for use with older adults. Reviewing 17 articles, a total of 8 older adult anxiety measures met inclusion criteria, with the Geriatric Anxiety Inventory (Pachana, Byrne, Siddle, Koloski, Harley & Arnold, 2007) having the most evidence of sound psychometric foundations. Most of the older adult specific anxiety measures were found to be accessible for clinical use and have low practical burden. Methodological critique of the studies is discussed, as well as directions for future research.

The Clinical Effectiveness of Group Psychoeducational Cognitive Behavioural Therapy for Mixed Anxiety and Depression in Older Adults: A Feasibility Study

There is a dearth of literature in relation to group interventions that address co-morbid anxiety and depression for older adults. This research evaluates the clinical effectiveness of a manualised 6 session cognitive behavioural psychoeducational group programme for older adults using a pre-post and short term follow up design. Patients (N=34) meeting specified inclusion criteria attended a group (N=8). A battery of process and outcome measures, Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983), Clinical Outcomes in Routine Evaluation – Outcome Measure (Barkham et al., 1998) and Health of the Nation Outcome Scale 65+ (Burns et al., 1999) were completed at assessment, termination and 6 week follow up. All outcome measures

demonstrated improvement from assessment to termination and assessment to follow up comparisons. On the CORE-OM, 28% of patients reliably improved and 22% were classified as recovered at termination.

Acknowledgements

I would like to dedicate this to my Mum. She nurtured my ambition and gave me unconditional love for which I will always be grateful. I only wish she was here to share the final part of this journey with me, I know she would be proud.

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and every one of you. The shared struggles and celebrations have been central to my experience, and for that I thank you.

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SECTION ONE: LITERATURE REVIEW

The Psychometric Properties of Older Adult Self-Report Anxiety Measures: A Systematic Review

Abstract

Purpose. Appropriate assessment of anxiety for older adults is based on validated measurement. Without sound psychometric tools, accuracy of assessment is compromised. This review considers the practicality for and psychometric evidence for self-report anxiety measures designed specifically for use with older adults.

Method. Studies were extracted from PsycARTICLES, PsycINFO and PubMed using Ovid and ISI Web of Knowledge search tools. Databases were searched up until the 20th of May 2012. A total of 17 articles were reviewed.

Results. A total of 8 older adult anxiety measures met inclusion criteria, with the Geriatric Anxiety Inventory (Pachana, Byrne, Siddle, Koloski, Harley & Arnold, 2007) having the most evidence of sound psychometric foundations. All 8 measures had low practical burden, however several lacked robust investigation of their psychometric properties.

Conclusions. The current review systematically considered validation studies of older adult specific anxiety measures. The Geriatric Anxiety Inventory (Pachana, Byrne, Siddle, Koloski, Harley & Arnold, 2007) demonstrated most evidence of reliability and validity. Most of the older adult specific anxiety measures were found to be accessible for clinical use and have low practical burden. Methodological critique of the studies is discussed, as well as directions for future research.

Keywords: older adults; anxiety; assessment; self-report; psychometric; systematic review

Anxiety disorders are highly prevalent in older adults (OAs) across cultures (Bryant, Jackson, & Ames, 2008). The estimated projected risk of any anxiety disorder at the age of 75 varies from 6% in China to 36% in the USA (Kessler et al., 2007). Despite high prevalence, anxiety is still under-diagnosed and treated (Byrne & Pachana, 2011). Dennis, Boddington, & Funnell (2007) noted that OA anxiety research has not developed at the same rate as research with working age adults.

Anxiety disorders are more prevalent in OAs with chronic medical conditions and are highly co-morbid with depressive disorders (Beekman et al., 2000; Lenze et al., 2001). Mohlman (2004) stated that OAs with Generalised Anxiety Disorder (GAD) are at a significantly higher risk of a co-morbid depressive disorder and co-morbidity increases the risk of suicide (Lenze et al., 2001). Excessive worry is considered to be one of the main characteristics of GAD and features in most anxiety disorders (Brown, Antony & Barlow, 1992). Worry has been found to be a prevalent facet of anxiety for OAs, particularly in relation to health, family, and keeping independence (Wisocki, 1994). The assessment challenges faced in this field include symptoms of anxiety being confused with aspects of normal aging (Lenze & Wetherell, 2009), the high co-morbidity rate of anxiety and depression in OAs (Beekman et al., 2000) and the overlap of the somatic symptoms of medical conditions with anxiety (Kogan, Edelstein & McKee, 2000).

Self-report is an efficient aspect of anxiety assessment and is particularly appropriate to measure subjective states (James, Reynolds & Dunbar, 1994). Sound anxiety assessment for OAs is based on use of standardised measures and without psychometrically validated tools, clinical effectiveness is compromised (Hersen & Van Hasselt, 1992). The importance of psychometrically sophisticated measures of anxiety is therefore a clinical imperative (Portman, Starcevic & Beck, 2011).

The most commonly used measures of anxiety in OAs have recently undergone a systematic review (Therrien & Hunsley, 2012) which highlighted that the most commonly used measures with this population are designed, in fact, for younger people. Although some mention of OA specific measures is made, no attempt was made to review the psychometric properties of OA specific anxiety measures. The central aim of this paper is therefore to review the psychometric foundations of self-report anxiety measures (including worry), designed specifically for use with OAs. In addition to this, the practical use of these measures is discussed, including practical burden and financial implications. The term 'OAs' generally applies to those aged over 65, however, any literature suggestive of using an older population will be considered.

Method

Literature Search

Studies used in this review were extracted from PsycARTICLES, PsycINFO and PubMed using Ovid and ISI Web of Knowledge search tools. In addition to this, reference sections of articles were searched as well as citation searches for any relevant literature. Databases were searched up until the 20th of May 2012 and articles from any publication date were used. The following keywords were searched in various combinations: 'anxi*', 'outcome measure', 'assessment' 'elder*', 'psychometric', 'old*', 'late life', 'geriatric', 'aging', 'gerontology', 'validity' 'reliability'. Inclusion of articles was based on the title and abstract, full texts of articles were read if necessary. Only English publications were included. Filters were used to exclude dementia samples, child samples and research with animals. Literature was excluded if the primary focus was not considering the psychometric properties of anxiety/worry measures designed specifically for use with OAs. Figure 1 details part 1 of the literature search process.

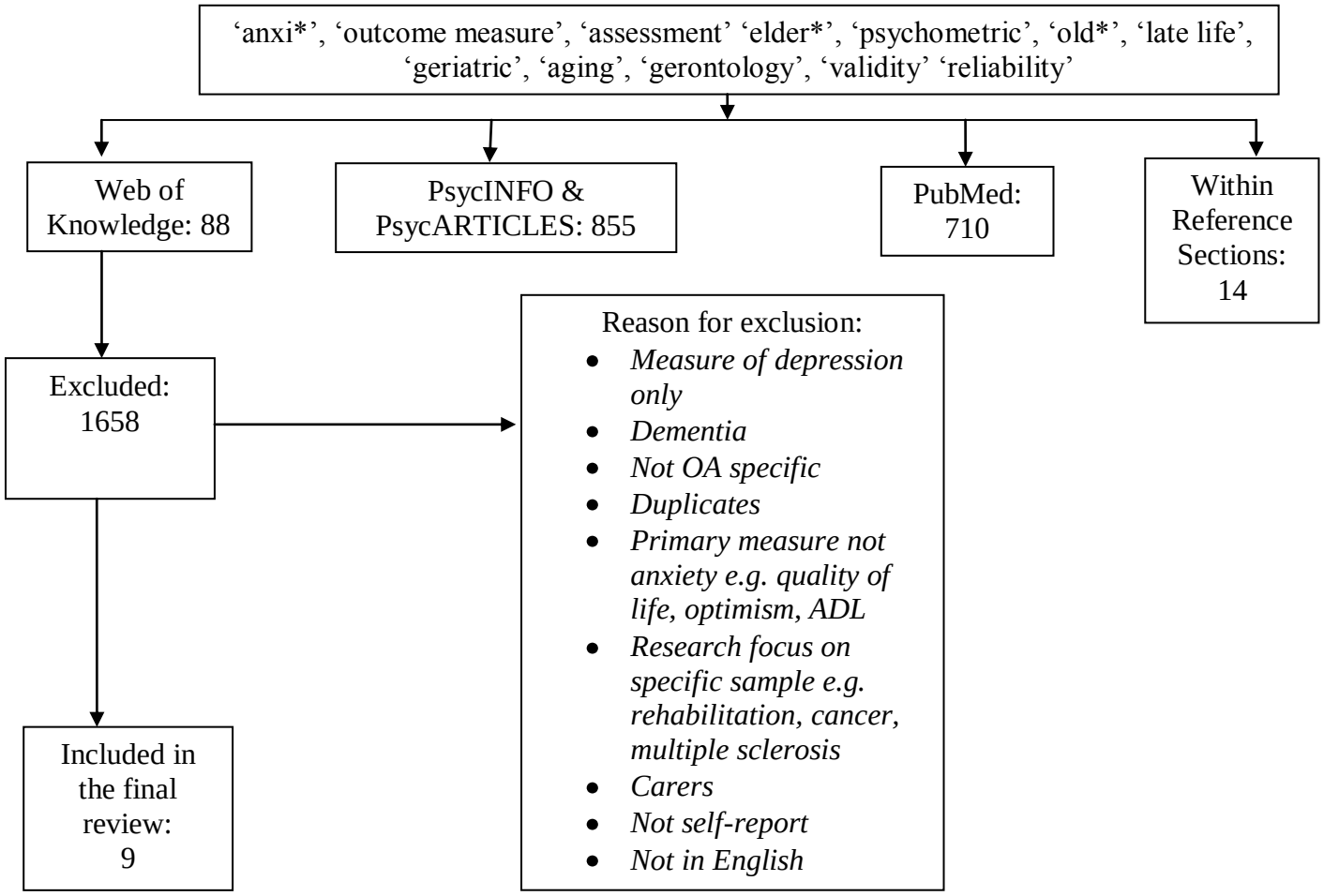

Figure 1. Flow Chart of the Literature Search Process Part 1

From this search strategy, the following anxiety measures were identified, Adult Manifest Anxiety Scale – Elderly (AMAS-E; Reynolds, Richmond & Lowe (2003) cited in Lowe & Reynolds, 2006), Geriatric Anxiety Inventory (GAI; Pachana, Byrne, Siddle, Koloski, Harley & Arnold, 2007), Geriatric Anxiety Inventory – Short Form (GAI-SF; Byrne & Pachana, 2011), Geriatric Anxiety Scale (GAS; Segal, June, Payne, Coolidge & Yochim, 2010), Geriatric Worry Scale (GWS; Diefenbach, Tolin, Meunier & Gilliam, 2009), Short Anxiety Screening Test (SAST; Sinoff, Ore, Zlotogorsky & Tamir, 1999), Worry Scale (WS; Wisocki & Handen (1983) cited in Wisocki, Handen & Morse, 1986), and the Worry Scale for Older Adults – Revised (WSOA-R; Wisocki, 1994).

Measures considering specific phobias or specific anxiety disorders (e.g. panic, agoraphobia, social) were excluded, to focus exclusively on anxiety. Further searches were conducted using the names of each of these measures; search results are detailed below.

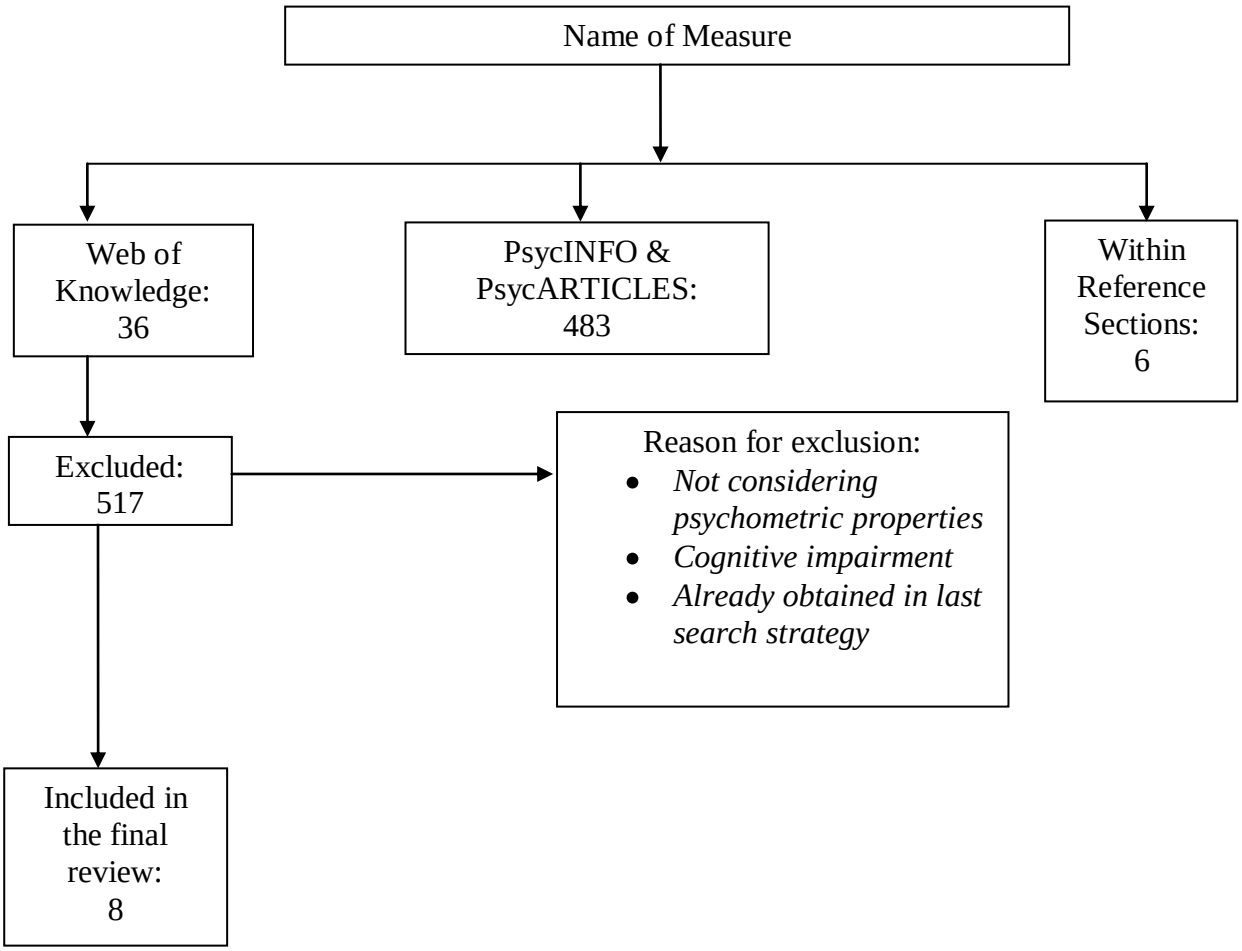

Figure 2. Flow Chart of the Literature Search Process Part 2

Definition of the Psychometric Properties Included

Psychometric properties relate to reliability and validity. Reliability is the consistency and reproducibility of a measure, and validity "whether or not a measure actually measures what it is intended to measure" (McGoey, Cowan, Rumrill & LaVogue, 2010, p. 109). Considered collectively, reliability and validity establish the

parameters of psychometric properties. Tables 1 and 2 summarise the areas of reliability and validity that are considered within this review.

Table 1.

Measures of Reliability

Criterion	Definition
Internal Consistency	Stability of scores across items that comprise the assessment e.g. measuring whether the items of a scale are measuring the same thing (indicating high consistency). An assessment is considered internally consistent when items are highly correlated with one another. This is usually measured by Cronbach's alpha. The following descriptions are used within this review based on descriptions cited in George & Mallery., (2003): $a = \geq 0.9$ (excellent); $0.9 > a = \geq 0.8$ (good); $0.8 > a = \geq 0.7$ (acceptable); $0.7 > a \geq 0.6$ (questionable); $0.6 > a \geq 0.5$ (poor); $0.5 > a$ (unacceptable)
Test-retest	Measure of stability or consistency of an assessment across separate administrations of the same assessment.
Inter-rater	Measure of two or more assessment scorers or observers. Measured by considering the correlation between the raters. This is usually not applicable with self-report measures, however, may be reported if the measure was rated by an interviewer/researcher.

Table 2.

Measures of Validity

Criterion	Definition
Construct	Extent to which an assessment accurately measures a construct or trait i.e. the degree to which operationalisations of a construct actually measure what the theory states it does. Construct validity is more than a single statistic but rather a process of information gathering to build evidence.
Convergent	Extent to which an assessment is similar to (converges on) other operationalisations that it theoretically should be similar to. High correlations are evidence of greater convergent validity.
Discriminant	Extent to which the assessment is not similar to (discriminates from) other assessments that it theoretically should not be similar to.
Sensitivity	Measure of the proportion of actual positives that are correctly identified e.g. percentage of people identified as having a condition that they do actually have.
Specificity	Proportion of negatives which are correctly identified e.g. percentage of people identified as not having a condition that they do not have.

Quality Assessment

There is no established tool to consider the quality of studies of psychometric properties of measures. Therefore, a bespoke tool was devised (Appendix A) that combined seven relevant items from the Downs and Black checklist (Downs & Black, 1998) and five areas detailed by Bot et al., (2003) that consider self-report measures. Items included were agreed between authors.

The Downs and Black checklist (1998) considers the relative strength of a study's design and has been used widely, has internal consistency, content and criterion validity (National Collaborating Centre for Methods and Tools, 2008). Results from the items in this checklist can be seen in Table 3. Bot et al., (2003) highlight the following areas as vital when considering psychometric properties of self-report measures; validity, reproducibility (reliability), responsiveness, interpretability and practical burden. This checklist has been utilised in other systematic reviews (Castelino, Abbott, McElhone, Teh, Lee-Suan, 2009). All of these areas were therefore considered when assessing the psychometric properties of OA anxiety measures (results can be seen in Tables 4 and 5). All studies and measures were scored by the first author and (4/17) were chosen at random to be rated by a second author. An intraclass correlation coefficient (ICC) was calculated to check for reliability.

Results

As detailed in Figures 1 and 2, the search process highlighted 17 studies which considered 8 anxiety measures; summaries of these studies can be seen in Table 3. Study quality varied from 3-5 for the Downs and Black (1998) checklist. Tables 4 and 5 give an overview of the practical implications and psychometric foundations of each measure, using the checklist devised by Bot et al., (2003). Psychometric foundations of the anxiety measures are considered in further detail through the discussion. Good levels of agreement were found between authors in terms of quality assessments (ICC=.708). The Downs and Black (1998) checklist was not particularly helpful to comment on study quality on this occasion, as all studies scored similarly and there was no cut-off criteria available. The criteria set by Bot et al., (2003) provided a helpful framework to consider reliability, validity and the practical use of the measures as highlighted in Tables 4 and 5.

Overview of Measures

Adult Manifest Anxiety Scale – Elderly (AMAS-E; Reynolds, Richmond & Lowe (2003) cited in Lowe & Reynolds, 2006). The AMAS-E assesses chronic, manifest anxiety and is derived from Taylor's Manifest Anxiety Scale (MAS; Taylor, 1951). The AMAS is available in three versions dependent on age group. The measure contains 44 items with a yes/no response option. Two studies were reviewed in relation to the AMAS-E (Table 3).

Geriatric Anxiety Inventory (GAI; Pachana, Byrne, Siddle, Koloski, Harley & Arnold, 2007). The GAI was designed to address some of the weaknesses in the field of OA specific anxiety measures. The 20 item measure has an agree/disagree response format. The development of the GAI was designed to measure common symptoms of anxiety, rather than diagnose anxiety disorders. The GAI items were developed using pre-existing measures of anxiety. Sixty sample items were devised that

included different facets of anxiety (e.g. fear, worry, somatic symptoms etc). These 60 items were given to healthy OAs, and clinical psychologists and psychiatrists who commented on understanding, language and redundancy. This reference group preferred the use of agree/disagree as response options. These items were then piloted on a healthy community sample and an outpatient psychogeriatric sample and 20 items were chosen based on correlations. Five studies were reviewed in relation to the GAI (Table 3).

Geriatric Anxiety Inventory (GAI-SF; Byrne & Pachana, 2011). Following on from the promising psychometric properties of the GAI, Byrne & Pachana (2011) developed a shorter 5 item version for use in geriatric medical settings. The most endorsed items of the 20 item GAI from the research described in Byrne & Pachana (2011) were used in different combinations. From this, 5 items were found to have the best ability to distinguish participants with GAD. One study was reviewed in relation to the GAI-SF (Table 3).

Geriatric Anxiety Scale (GAS; Segal, June, Payne, Coolidge & Yochim, 2010). The GAS is a 30 item measure with 4 point scale response options, varying from 0 to 75. The GAS was developed as a brief screening measure of anxiety specifically for an older population. One of the most notable strengths of the development of the GAS is that the items for the measure were devised from the full range of anxiety disorder symptoms in the Diagnostic and Statistical Manual of Mental Disorders-4th Edition (DSM-IV; American Psychiatric Association, 2000). The GAS was developed by comparing an older age group with a younger age group recruited from educational classes and student's family members. The items most highly rated by OAs were ranked. This resulted in 25 items measuring a variety of anxiety symptoms. In addition to this, 5 content items were included (not part of total score of GAS) to assess finances, children, health, fear of dying and fear of becoming a burden to family members. This

additional information was included to provide some context to the individual and their anxiety (Segal et al., 2010). Two studies were reviewed in relation to the GAS (Table 3).

Geriatric Worry Scale (GWS; Diefenbach, Tolin, Meunier & Gilliam, 2009). The GWS was constructed using the Geriatric Depression Scale (GDS; Yesavage et al., 1983) as a model. Therefore, the GWS has a yes/no response choice and uses simple concrete language. There are 5 items in total and positive items are scored with 1 point. All items are scored in the same direction apart from the last question which is reverse scored. One study was reviewed in relation to the GWS (Table 3).

Short Anxiety Screening Test (SAST; Sinoff, Ore, Zlotogorsky & Tamir, 1999). The SAST was developed to screen specifically for anxiety in the elderly depressed. The measure includes modified items from other anxiety measures. Sinoff et al (1999) explain that somatic symptom items were deliberately included due to their relevance with OA populations. A cut-off of ≥ 24 was suggested based on pilot research. One study was reviewed in relation to the SAST (Table 3).

Worry Scale (WS; Wisocki & Handen, 1983 cited in Wisocki, Handen & Morse, 1986). The Worry Scale (WS) was devised specifically to consider 'negative cognitive activity' in OAs (Wisocki, Handen & Morse, 1986). The development rationale was (a) due to OAs in previous research finding common anxiety measures difficult to complete/irrelevant, (b) the need for a direct measure of respondents' perception of stress and (c) to review areas that are worrying for this client group. The WS considers finances, health and social conditions and the questions are designed to relate to the experience of OAs. The details of the way in which items were developed are not available, as the reference for the WS is unpublished. The WS has 35 items and respondents are asked to rate on a 5 point scale how relevant statements are. The WS

also provides additional space for respondents to comment on any worries that are not covered in the measure. Four studies were reviewed in relation to the WS (Table 3).

Worry Scale for OAs-Revised (WSOA-R; Wisocki., 1994). The WSOA-R is a revised version of the original WS. Additional items were included and the WSOA-R is comprised of 88 items in 6 domains; finances, health, social conditions, personal concerns, family concerns and world issues. These items were collected by a series of focus groups of OAs, who classified themselves as chronic worriers. Ratings are made on a 5 point scale. The measure also includes a separate 16 item coping inventory which considers coping strategies used to manage worry (e.g. 'I reason with myself' or 'I laugh about it'). One study was reviewed in relation to the WSOA-R (Table 3).

Table 3.

Summary of Older Adult Anxiety Measure Studies

Study Details				Participants			Quality Rating
Measure	Author (year)	Aim	Findings	N (% female)	Mean age (range)	Recruitment (country)	*Downs & Black Checklist (Partial)*
AMAS - E	Lowe & Reynolds (2006)	a) Examine the reliability and validity of the AMAS-E.	Adequate to excellent internal consistency and temporal stability. Support for convergent, and discriminant validity.	226 (51)	76.85 (60 and older)	community (USA)	4
		b) Structure of the AMAS-E was examined across gender.	Structure of the AMAS-E scale and subscales similar across gender.	863 (64)	76.25 (60-100)	community (USA)	

	Study Details			Participants			Quality Rating
Measure	Author (year)	Aim	Findings	N (% female)	Mean age (range)	Recruitment (country)	*Downs & Black Checklist (Partial)*
AMAS-E	Lowe & Reynolds (2000)	Investigate whether the three factor structure of anxiety that they had found to be appropriate with children was appropriate with older adults.	Some similarities of anxiety across the life span. Excellent internal consistency.	458 (80)	78.52 (60-100)	community (USA)	5
GAI	Byrne et al., (2010)	Consider the psychometric properties of the GAI with older Australian women.	High levels of sensitivity and specificity, evidence of convergent validity.	286 (100)	71.7 (60-86)	community (Australia)	4
GAI	Cheung (2007)	Consider the validity of the GAI in late-life depression.	Convergent validity for the GAI with a depressed sample.	32 (62.5)	75.5 (66-85)	clinical community mental health services (New Zealand)	3

	Study Details			Participants			Quality Rating
Measure	Author (year)	Aim	Findings	N (% female)	Mean age (range)	Recruitment (country)	*Downs & Black Checklist (Partial)*
GAI	Cheung et al., (2012)	Consider the sensitivity and specificity of the GAI and HADS in detecting anxiety disorders in older adults with chronic obstructive pulmonary disease.	High levels of sensitivity and specificity for both the GAI and HADS when lower cut off points are applied.	55 (44.4)	72.7 (not stated)	clinical respiratory service (New Zealand)	5
GAI	Matheson et al., (2012)	Consider the validity and reliability of the GAI in Parkinson's Disease.	Excellent internal consistency, high levels of sensitivity and specificity.	58 (43)	66.24 (37-85)	outpatients clinics (Australia)	4

	Study Details			Participants			Quality Rating
Measure	Author (year)	Aim	Findings	N (% female)	Mean age (range)	Recruitment (country)	*Downs & Black Checklist (Partial)*
GAI	Pachana et al., (2007)	a) Development and validation of the GAI in a community sample.	Excellent internal consistency and convergent validity.	313 (66.7) 189 (63.5)	69.5 (42-90) 71.4 (60-88)	community (Australia)	5
		b) Development and validation of the GAI in a clinical sample.	Excellent internal consistency, high levels of sensitivity and specificity.	46 (74)	78.8 (66-94)	clinical geriatric community psychiatric service (Australia)	
GAI - SF	Byrne & Pachana (2011)	Development and validation of a short form of the GAI.	Good internal consistency, high sensitivity and specificity.	284 (100)	72.2 (60-87)	community (Australia)	5

	Study Details			Participants			Quality Rating
Measure	Author (year)	Aim	Findings	N (% female)	Mean age (range)	Recruitment (country)	*Downs & Black Checklist (Partial)*
GAS	Segal et al., (2010)	a) Development and initial validation of the GAS.	Good internal reliability in clinical and community samples. Evidence of convergent validity.	100 younger (83)	24 (17-49)	community (USA)	4
				30 older (70)	67 (60-82)		
		b) Development and initial validation of the GAS with other measures of anxiety and depression.		101 (92)	72 (60-90)	community (USA)	
		c) Development and initial validation of the GAS in a clinical population.		69 (78)	69 (60-87)	clinical outpatients (USA)	

	Study Details			Participants			Quality Rating
Measure	Author (year)	Aim	Findings	N (% female)	Mean age (range)	Recruitment (country)	*Downs & Black Checklist (Partial)*
GAS	Yochim et al., (2011)	Explore the convergent and discriminant validity of the GAS.	Evidence of convergent validity, and discriminant validity with non-mental health problems.	117 (62)	74.75 (60-89)	community (USA)	4
GWS	Diefenbach et al., (2009)	Consider assessment measures for older home care recipients.	Acceptable internal consistency, evidence of convergent validity.	66 (83.3)	76.46 (65-92)	community home care recipients (USA)	5

	Study Details			Participants			Quality Rating
Measure	Author (year)	Aim	Findings	N (% female)	Mean age (range)	Recruitment (country)	*Downs & Black Checklist (Partial)*
SAST	Sinoff et al., (1999)	Investigate the psychometric properties of the SAST, particularly with depressed individuals.	Acceptable internal consistency, high levles of sensitivity and specificity, including in the presence of depression.	150 (63.3)	81.7 (≥ 70)	medical inpatients and outpatients (Israel)	4
WS	Hopko et al., (2000)	Investigate the relationship between clinician severity ratings and patient self report measures.	Evidence of convergent validity.	64 (75)	66.5 (60-80)	community GAD diagnosed (USA)	5

	Study Details			Participants			Quality Rating
Measure	Author (year)	Aim	Findings	N (% female)	Mean age (range)	Recruitment (country)	*Downs & Black Checklist (Partial)*
WS	Stanley et al., (2001)	Consider the psychometric properties of five anxiety measures in older adults.	Excellent internal consistency, evidence of convergent validity, test retest reliability, poor discriminant validity with depression.	57 (77.2)	Not stated (60-80)	community with GAD diagnosis (USA)	4
WS	Stanley, Beck & Zebb (1996)	Consider the psychometric properties of four anxiety measures in older adults	Excellent internal consistency for GAD sample, evidence of convergent validity	50 GAD (72) 94 Control (69.1)	67.92 (55-81) 67.53 (55-82)	community (USA)	5

Study Details				Participants			Quality Rating
Measure	Author (year)	Aim	Findings	N (% female)	Mean age (range)	Recruitment (country)	*Downs & Black Checklist (Partial)*
WS	Wisocki et al., (1986)	Consider the WS in community and homebound samples.	Some evidence of convergent validity for the WS.	a) 54 (76)	70 (not stated)	community (USA)	4
				b) 44 (88)	77 (not stated)	community homebound (elderly)	
WSOA-R	Hunt et al., (2003)	Investigate worry and the use of coping strategies among older and younger adults.	Excellent internal consistency for the WSOA-R. Some evidence of convergent validity.	84 older (65.8)	70.5 (65-86)	community (USA)	4
				110 younger (78.2)	20.7 (18-25)		

Note. AMAS-E=Adult Manifest Anxiety Scale-Elderly, GAD=Generalised Anxiety Disorder, GAI=Geriatric Anxiety Inventory, GAI-SF=Geriatric Anxiety Inventory-Short Form, GAS= Geriatric Anxiety Scale, GWS=Geriatric Worry Scale, HADS=Hospital Anxiety & Depression Scale, SAST=Short Anxiety Screening Test, WS=Worry Scale, WSOA-R=Worry Scale for Older Adults-Revised.

Discussion

Psychometric Foundations and Practical Utility

Practical implications for the 8 measures are summarised in Table 4 and psychometric properties are displayed in Table 5.

AMAS-E. Lowe & Reynolds (2000) investigated if the three factor structure of anxiety found with children (worry/oversensitivity, physiological, and fear/concentration) was appropriate with OAs. Four hundred and fifty eight participants were recruited from the community who did not have a DSM-IV diagnosis of anxiety (prior or current). A three factor structure of anxiety for OAs was found with 'fear of aging' replacing 'fear/concentration'. Internal consistency was found to be excellent for the full scale and in the acceptable-excellent range for all subscales.

The psychometric properties of the AMAS-E were further researched by Lowe and Reynolds (2006). A community volunteer sample completed the 44 item AMAS-E and State Trait Anxiety Inventory (STAI; Spielberger, Gorssuch, Lushene, Vagg, & Jacobs, 1983). Measures were repeated two weeks later. The full AMAS-E demonstrated excellent internal consistency with the three subscales having adequate-good internal consistency. The AMAS-E has a reliable 'lie' scale of seven items, which serves as a validity index. Convergent and discriminant validity was investigated using the STAI scores. Validity coefficients were relatively higher for AMAS-E anxiety scores and STAI-Trait scale scores suggesting some evidence of convergent validity for the AMAS-E as a measure of manifest/trait anxiety. There was also some evidence of discriminant validity as the AMAS-E correlated significantly higher with STAI-Trait than the STAI-State scale score.

These studies highlight some support for the construct validity of the AMAS-E, particularly as it has undergone factor analysis and the subscales and total score significantly correlate with each other. Evidence of test-retest reliability is also high;

however, research has yet to address sensitivity and specificity with this measure. The AMAS-E is only available by purchase which can have practical implications for clinical use.

GAI. Pachana et al., (2007) investigated validation of the GAI initially using two community samples of healthy OAs. Sixty items were condensed to 20 using correlations to consider the most useful items; the internal consistency of the 20 item version with community healthy OAs was excellent. Convergent validity was demonstrated, as several anxiety measures significantly correlated with the GAI (Table 5).

The GAI was then considered with a clinical sample. Convergent validity was measured and demonstrated strong positive correlations. The GAI discriminated between participants with (or without) an anxiety disorder or GAD. For detecting GAD the cut-off was found to be optimal at 10/11, and to identify participants with any anxiety disorder the cut-off was 8/9.

Byrne et al., (2010) specifically considered the psychometric properties of the GAI in community residing women. Two hundred and fifty three of the 286 women in the sample were also interviewed to assess for DSM-IV diagnoses and were administered the mini mental state examination (MMSE; Folstein, Folstein & McHugh, 1975). Results indicated that GAI score was associated with STAI-State scores, but not with age, MMSE score, self-reported life events or perceived social support suggesting that the GAI has discriminant validity with non-mental health problems. The mean total was significantly different for those classified as having current GAD than those who were not. The optimal cut-off for detecting current GAD was 8/9 and the GAI demonstrated high levels of sensitivity and specificity. The research is comparable to that of Pachana et al., (2007) who used a mixed gender sample.

The convergent validity of the GAI was investigated with a clinical population with a history of depression (Cheung, 2007). Participants were from community mental health services. This research highlighted that participants who were depressed also indicated greater anxiety symptoms and vice versa. This supports the notion that anxiety and depressive symptoms are highly interrelated in this population (Lenze., 2001). Overall, the cut-off point of 8/9 identified participants with anxiety symptoms in late-life depression. Convergent validity for the GAI was supported as significant relationships were found with other measures of anxiety, particularly the GAS.

Matheson et al., (2012) considered the psychometric properties of the GAI in patients with Parkinson's disease (PD). Fifty eight Neurology outpatients scoring ≥27 on the MMSE with a diagnosis of idiopathic PD took part. Results indicated no significant differences in relation to gender. GAI scores were significantly higher in PD participants with an anxiety disorder suggesting that the GAI was measuring what it set out to measure. The GAI indicated a satisfactory test-retest reliability and excellent internal consistency. The optimum cut-off for anxiety with this clinical group was 6/7. This research highlights the GAI as a useful tool with PD patients; a population prone to anxiety disorders. Despite the GAI's deliberate exclusion of somatic items, it seems to capture the anxious symptoms of participants within a medically unhealthy sample, suggesting it may be useful in other health settings where samples are predominantly OAs.

Anxiety disorders are highly prevalent in people with chronic obstructive pulmonary disease (COPD), a condition that commonly affects OAs (Cheung et al., 2012). The GAI and Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) have been recently used with this clinical group to consider sensitivity and specificity of detecting anxiety disorders (Cheung et al., 2012). Fifty five volunteer participants completed the study, 14 of whom were identified as having an anxiety

and/or depressive disorder. Participants with an identified anxiety disorder scored significantly higher on the GAI. The optimum cut-off point for the GAI was 2/3. Psychiatric assessments were completed by an independent assessor who was blinded to the respiratory assessment results, suggesting assessment was not influenced by this information. Diefenbach et al., (2009) also indicated some promising results for the GAI as a screening measure for anxiety. This research is further discussed in relation to the Geriatric Worry Scale.

The GAI has demonstrated construct validity based on significant correlations between items, evidence of convergent validity, high test-retest and inter-rater reliability, and consistently excellent internal consistency. Research also highlights the importance of changing cut-off scores to reflect the client group. Although discriminant validity has been demonstrated in relation to non-mental health difficulties, further research is needed to address whether the GAI is able to discriminate between different mental health problems. The significant correlation with the GDS (Diefenbach et al., 2009) suggests poor discriminant validity thus far.

GAI-SF. A recent development has been a short form version of the GAI. Byrne & Pachana (2011) recruited 284 female participants aged $\geq$60. The most commonly endorsed items of the GAI were investigated in different combinations and five items were ultimately chosen to make up the GAI-SF. The GAI-SF demonstrated good internal consistency and was highly correlated with the GAI and somewhat with the STAI-State, demonstrating convergent validity. A strength of the GAI-SF is that it did not correlate with age, educational level or MMSE suggesting discriminant validity with non-mental health problems. Similarly to findings with the GAI, the GAI-SF did correlate with the GDS, again questioning discriminant validity. High test-retest reliability was found. The generalisability of these results is limited due to the

completely female sample. These psychometric properties are particularly promising in the context of the ease of practical administration and interpretability of the measure.

GAS. The psychometric properties of the GAS were considered with a community and a clinical sample (Segal et al., 2010). The total GAS score had excellent internal consistency with good-excellent alphas for the three subscales. The GAS also demonstrated construct validity, with strong positive relationships between GAS subscales and GAS total and each subscale. The total GAS and subscale scores significantly correlated with other anxiety measures suggesting evidence of convergent validity; however, discriminant validity was questionable based on the positive correlations between the GAS and GDS. Within the clinical sample, internal consistency for the GAS was again good-excellent for the three subscales. In terms of convergent validity, strong positive relationships were demonstrated between the GAS total score and each of the 3 subscales. The GAS total score and subscales significantly correlated with the GDS, again questioning discriminant validity. Discriminant validity was further tested by correlating the GAS total and subscales with non-mental health problems e.g. education, with these results not significant.

Yochim, Mueller, June & Segal, (2011) further considered the convergent and discriminant validity of the GAS. Discriminant validity was investigated by comparing GAS scores to reading ability and processing speed (separate constructs from anxiety). OA volunteers from the community completed measures. Results indicated that the GAS had good internal consistency. The GAS correlated more strongly with both the Beck Anxiety Inventory (BAI; Beck, Epstein, Brown & Steer, 1988) and the GAI than the BAI and GAI did with each other. Twenty eight participants scored a BAI score of eight or higher (indicative of clinically significant anxiety), these participants scored significantly higher on the GAS suggesting that the GAS detected clinically significant

anxiety. However, similar to previous findings, discriminant validity is questionable based on the high correlations with two measures of depression.

One of the notable strengths is that the items of the GAS have been directly derived from the DSM-IV. The GAS correlated more strongly with the GDS than the BAI (Yochim et al., 2011); as aforementioned, literature suggests there are strong conceptual overlaps between anxiety and depression in this client group. The GAS did demonstrate discriminant validity in relation to non-mental health variables, as demonstrated by the lack of correlation with reading ability and processing speed. The development of further data considering cut-off scores and interpretation would be clinically useful as well as further exploration of psychometric properties including test-retest reliability.

GWS. The psychometric properties of the GWS and GAI were investigated in home-care recipients (Diefenbach et al., 2009). The term 'home-care' in this setting refers to individuals who need particular services (e.g. meal delivery, nursing care) to support them to continue living in their own homes. Sixty six OAs were recruited. In addition to the GWS and GAI participants completed a range of anxiety, depression and general health questionnaires. Participants with any anxiety disorder were grouped together and compared with individuals without anxiety symptoms who formed the control group. Participants in the anxiety group scored significantly higher on all measures apart from the BAI. All measures (apart for the BAI) also demonstrated a moderate effect size. In terms of convergent validity, the GAI was the strongest and the BAI was the weakest. Discriminant validity was investigated by correlating with the GDS. The GWS significantly correlated with all anxiety measures implying good convergent validity, however also correlated with the GDS (greater than with the BAI) questioning discriminant validity. This research also considered the ease of use of assessments. The GWS was found to take less than two minutes to administer on

average, with 3% of participants reporting moderate confusion and moderate difficulty when completing. Of all the measures, the GWS and GAI were noted as the least frequently reported for problems from clinicians. Inter-rater reliability was measured using audio taped interviews and found to be excellent. The GWS demonstrates promising psychometric properties and is practically useful in terms of administration time, scoring and financial implications.

SAST. Sinoff et al (1999) recruited 150 geriatric medical inpatients and geriatric day-care centre attendees. All participants underwent a psychiatric evaluation and were classified as depressed or non-depressed. Participants classified as suffering from anxiety scored significantly higher on the SAST. The SAST demonstrated acceptable internal consistency, good test-retest reliability, and high levels of sensitivity/specificity. The SAST was specifically investigated among depressed and non-depressed participants. For these groups, the sensitivity and specificity continued to be high, with the exception of sensitivity for the non-depressed participants. This suggests that the SAST was able to detect both anxiety and depression. The high sensitivity and specificity of the SAST even with a depressed population suggests promising results, particularly within OAs where co-morbid anxiety and depression is highly prevalent. The lack of research into the convergent and discriminant validity of the measure limits these findings.

WS. Wisocki, Handen & Morse, (1986) investigated the efficacy of the WS as an anxiety measure in two OA samples. The first were 54 community dwelling OAs and the second were 44 homebound OAs. Participants completed a range of questionnaires in addition to the WS. Results indicated that both samples reported few worries and there were no differences in terms of gender. Worry was greatest in relation to health for both groups and least in relation to social conditions. The WS across both samples correlated with anxiety scores from the Symptom Checklist-90

(SCL-90; Derogatis, Rickles & Rock, 1976) and Multiple Affect Adjective Checklist (MAACL; Zuckerman, 1960). The MAACL correlated with the WS in the homebound group, but not as highly in the community group. Significant positive correlations were found between health measures and the WS for both samples. The health worries subscale of the WS also significantly correlated with other health measures. Findings suggest that the WS has some convergent validity due to the correlations with other anxiety measures, but no information with regards to reliability or discriminant validity was provided from this research. There was no attempt to measure whether any participants in the research had clinical anxiety, and whether WS scores were reflective of this.

The reliability and validity of the WS was further investigated with individuals with GAD (Stanley, Beck & Zebb., 1996). Participants included a sample of 50 OAs with GAD and 94 controls. All participants completed four anxiety measures (WS, STAI, Padua Inventory (PI; Sanavio, 1988) and Fear Questionnaire (FQ; Marks & Matthews, 1979). A subtest of the controls were re-administered the questionnaires after a two to four week period. Within the GAD sample, the WS demonstrated excellent internal consistency, as well as the total WS score and subscales correlating with one another suggesting evidence of construct validity. The weakest correlation was between financial worries and total WS score. The WS significantly correlated with the STAI-Trait and PI, demonstrating adequate convergent validity. The WS also had excellent internal consistency for the control group, and demonstrated strong test-retest reliability (with the exception of the health subscale).

Hopko et al., (2000) investigated the relationship between clinician severity ratings for GAD and patient self-report measures using the WS. Sixty four participants completed measures. All anxiety measures significantly correlated with one another, apart from WS with the clinician rated GAD severity; this suggests convergent validity

amongst self-report anxiety measures. However, the WS did also significantly correlate with a measure of depression, questioning discriminant validity.

Stanley et al., (2001) noted the paucity of test-retest reliability and discriminant validity data for anxiety measures with OAs and thus tested the WS (the only OA specific measure) along with other anxiety measures. Fifty seven OAs participated in the research, all of whom met DSM-IV criteria for GAD. Participants repeated all measures after a 5-20 week period. Results indicated excellent internal consistency for the WS, with subscales within acceptable-excellent ranges. Test-retest reliability indicated adequate stability over time, apart from the social situations subscale. All WS subscales significantly correlated with one another as well as with the total score suggesting some evidence of construct validity. Similar to previous research by Stanley, Beck & Zebb (1996), the correlations were weaker with the finances subscale. The WS significantly correlated with other measures of worry suggesting evidence of convergent validity. In order to investigate discriminant validity, the WS was correlated against two depression measures. The WS correlated with both depression measures, questioning discriminant validity.

The WS demonstrates potential with its existing psychometric properties, particularly in terms of internal consistency and convergent validity. Similar to other anxiety measures considered throughout the review, the WS lacks discriminant validity in relation to depression. Research does not discuss the scoring of the measure; therefore commenting on the practicality for clinicians is limited. Further research should also consider cut-off scores and the sensitivity/specificity of the WS as this limits the potential usefulness within clinical practice.

WSOA-R. Hunt, Wisocki & Yanko (2003) considered the psychometric properties of the WSAO-R. An OA and younger (student) sample was recruited. The WSAO-R demonstrated excellent internal consistency for both samples. Within both

age groups the WSAO-R subscales correlated with one another, as well as with the totals score and another measure of worry, suggesting evidence of construct and convergent validity. Overall, the results of the WSOA-R suggested a trend towards OAs reporting greater worry; however these results were not significant. In terms of coping strategies, younger adults reported a greater number than OAs. The WSOA-R lacks evidence of discriminant validity, test-retest data and sensitivity/specificity. There is also limited practical information for clinicians (e.g. cut-off scores, time taken to complete or complexity of scoring). As this is the longest of the measures reviewed, such information could potentially influence practical use of the measure in clinical settings. Further research should also consider the psychometric properties of the WSOA-R with a clinical sample.

Methodological Critique of the Evidence Base

Research within this review shares methodological limitations such as the common lack of clinical samples (e.g. Lowe & Reynolds, 2006; Lowe & Reynolds, 2000; Yochim et al., 2011). There were also examples of participant selection bias such as using participants who were rewarded financially (Stanley et al., 1996), volunteers (Yochim et al., 2011), or students and family members (Segal et al., 2010). Across research, there is a theme of ethnic homogeneity, with most research predominantly recruiting Caucasian participants (e.g. Pachana et al., 2007 Matheson et al., 2012; Yochim et al., 2011). It should also be considered that all the research was conducted in USA, Australia, New Zealand or Israel, questioning applicability within the UK. There is a recurring theme of somatic items being confused with poor physical health symptoms for OAs. This highlights the need to assess medical problems in OAs, which was not consistently done across studies (e.g. Segal et al., 2010). Another inconsistency across the studies was whether participants were assessed for cognitive impairment or not. Despite these limitations, several strengths should also be noted such as validating

measures with clinical as well as community samples (e.g. Pachana et al., 2007; Segal et al., 2010), diagnosing clinical anxiety by staff with extensive training (e.g. Hopko et al., 2000) and taping diagnosis interviews to assess for inter-rater reliability (e.g. Stanley et al., 1996).

Psychometric Properties

A consistent theme amongst measures was the lack of discriminant validity. Although evidence of discriminant validity was found with non-mental health problems (e.g. Byrne & Pachana, 2011; Segal et al., 2010; Yochim et al., 2011), this was not evident with depression (e.g. Hopko et al., 2000; Stanley et al., 2001, Diefenbach et al., 2009; Segal et al., 2010 & Yochim et al., 2011). Segal et al., (2010) discuss the overlap between the constructs of anxiety and depression within OAs, and suggested positive correlations with depression measures may be representative of co-morbidity. Krasucki, Howard & Mann (1999) argue that distinguishing between anxiety and depression in late-life may not be feasible, as co-occurrence is reflective of the convergence of anxiety and depression for OAs. Another noteworthy issue was the use of non-OA specific anxiety measures to investigate convergent validity. Although the measures used may have been validated with OAs, they were not developed for this age group. More comparable constructs may be other OA specific measures, as investigated with the GAS and AMAS-E (Segal et al., 2010), GAS and GAI (Yochim et al., 2011) and GWS and GAI (Diefenbach et al., 2009).

Practical Implications

All measures apart from the AMAS-E were available without charge. This could be important in terms of practicality for clinicians. Also, all measures were classified as ‘easy’ to score (items summed together) and reported as taking between 2-15 minutes to complete. The WS does not have information about scoring and the WSOA-R does not have information about scoring or administration time. Those

measures with cut-off scores (e.g. GAI, GAI-SF, GWS & SAST) provide context for clinicians when interpreting results.

Conclusions

Overall there is a dearth of anxiety measures designed specifically for use with OAs. From the literature that is available, the GAI had the most evidence for validity, reliability, sensitivity and specificity with community and clinical samples. Cut-off scores and consideration of practical burden as well as being freely available means the GAI has clinical utility. The GAI-SF also showed promising psychometric properties, however further research beyond the initial validation study would be useful. Similarly, the GWS demonstrated positive psychometric foundations and practical implications, however has only been validated within one piece of research. The AMAS-E, GAS and WS all shared some common psychometric properties (e.g. excellent internal consistency). Despite this, they all lacked investigation of sensitivity/specificity and therefore do not have cut-off scores, limiting practical usage. In addition, the GAS also lacked test-retest information and the AMAS-E must be purchased which may limit its usage. The SAST and WSOA-R both lacked validation research to extensively comment on their robustness. The SAST has some positive findings in relation to sensitivity and specificity; however, further research is needed to be able to comment on convergent and discriminant validity. The WSOA-R is the longest measure reviewed, however the lack of information about practical burden means commenting on how this was received by OAs is unknown. There is also further investigation needed of the responsiveness and test-retest reliability of the WSAO-R.

Future Research

There are definite areas for further research highlighted from the review. Firstly, further validation of the existing OA specific measures particularly with regard to

discriminant validity with other mental health problems, validation amongst different clinical groups, and validation with more diverse groups in terms of ethnicity.

Secondly, there is scope to develop other measures of anxiety designed specifically with OAs. More measures in this field would increase the choice for clinicians and service users to find measures that suit the individual. Overall, further validation of OA specific anxiety measures would provide a more robust evidence base and more information about clinical utility with this client group.

Table 4.

Overview of the Practical Implications of Each Measure

Measure	Interpretability					Practical Burden		Financial
	Domains	No. Of Items	No. of Response Options	Range of Scores	Cut off scores	Time taken to complete (mins)	Complexity of scoring[a]	Cost
AMAS - E	fear of aging, physiological anxiety, worry/oversensitivity	44	2 (yes/no)	0 - 44	x	5-10	Easy	$55 plus costs of forms ($39.50 per pack of 20) purchasable from internet

Measure	Interpretability				Practical Burden		Financial
	Domains	No. Of Items	No. of Response Options	Range of Scores	Cut off scores	Time taken to complete (mins)	Complexity of scoring[a]	Cost
GAI	symptoms of anxiety - less focus on somatic items	20	2 (agree/disagree)	0 - 20	**≥11** (GAD) **≥9** (any anxiety disorder or depressed sample) **≥7** (Parkinson's Disease sample)	5-10	Easy	Free from GAI website
GAI - SF	symptoms of anxiety - less focus on somatic items	5	2 (agree/disagree)	0 - 5	≥3	2-5	Easy	Free from author

Measure	Interpretability					Practical Burden		Financial
	Domains	No. Of Items	No. of Response Options	Range of Scores	Cut off scores	Time taken to complete (mins)	Complexity of scoring[a]	Cost
GAS	somatic, cognitive, affective	30	4 point scale (not at all, sometimes, most of the time, all of the time)	0 - 75	x	10	Easy	Free from author
GWS	cognitive and affective symptoms of anxiety	5	2 (yes/no)	0-5	≥ 2 ≥ 4 (GAD)	2	Easy	Free from author
SAST	symptoms of anxiety - including somatic items	10	4 point scale (rarely or never, sometimes, often, always)	0-40	≥ 24	10-15	Easy	Free from internet
WS	worry in relation to finances, health & social conditions	35	5 point scale (never, rarely, sometimes, often, much of the time)	0-140	x	2-5	x	Free from author

Measure	Interpretability					Practical Burden		Financial
	Domains	No. Of Items	No. of Response Options	Range of Scores	Cut off scores	Time taken to complete (mins)	Complexity of scoring[a]	Cost
WSOA-R	finances, health, social conditions, personal concerns, family concerns, and world issues	88	5 point scale (never, rarely, sometimes, often, much of the time)	0-352	x	x	x	Free from author

[a] Based on criteria set by Bot et al., (2003) Easy = summed items, Moderate = simple formula, Difficult = complex formula
x = Information unavailable

Table 5.

Psychometric Properties of Measures

Measure	Reliability			Validity		Responsiveness	
	Internal Consistency *(α)*	Test-retest (*Pearson's r)*	Inter-rater *(Pearson's r)*	Convergent *Significant Intercorrelations (r)*	Discriminant *Correlations (r)*	Sensitivity *%*	Specificity *%*
AMAS-E	Lowe & Reynolds (2006) **.90** Lowe & Reynolds (2003) **.71-.92** Lowe & Reynolds (2000) **.91-.92**	Lowe & Reynolds (2006) **.91** Lowe & Reynolds (2003) **.83**	x	Lowe & Reynolds (2006) **STAI-T .65**	Lowe & Reynolds (2006) **STAI-S .39**	x	x

Measure	Reliability			Validity		Responsiveness	
	Internal Consistency *(α)*	Test-retest (*Pearson's r)*	Inter-rater *(Pearson's r)*	Convergent *Significant Intercorrelations (r)*	Discriminant *Correlations (r)*	Sensitivity *%*	Specificity *%*
GAI	Byrne et al., (2010) **.92** Cheung et al., (2012) **.92** Diefenbach et al., (2009) **.93** Matheson et al., (2012) **.95** Pachana et al., (2007) **.91-.93**	Diefenbach et al., (2009) **.95** Matheson et al., (2012) **Spearman's Rho .99** Pachana et al., (2007) **.91**	Diefenbach et al., (2009) **1.0** Pachana et al., (2007) **.99**	Byrne et al., (2010) **NEO FFI .57** **STAI-S .58** Cheung (2007) **GAS .82** **STAI .69** Diefenbach et al., (2009) **GADQ-IV .65** **PSWQ .79** **PSWQ-A .79** **BAI .61** **BMWS .77** **GADSS .83** **GWS .86** Matheson et al., (2012) **STAI .69** Pachana et al., (2007) **STAI-S .80** **GAS .70**	Diefenbach et al., (2009) **GDS .79**	Cheung et al., (2012) **85.7** Diefenbach et al., (2009) **87.5** Matheson et al., (2012) **87.5** Pachana et al., (2007) **73 - 75**	Cheung et al., (2012) **78** Diefenbach et al., (2009) **95.5** Matheson et al., (2012) **85.7** Pachana et al., (2007) **80 - 84**

Measure	Reliability			Validity		Responsiveness	
	Internal Consistency *(α)*	Test-retest (*Pearson's r)*	Inter-rater *(Pearson's r)*	Convergent *Significant Intercorrelations (r)*	Discriminant *Correlations (r)*	Sensitivity *%*	Specificity *%*
GAI - SF	Byrne & Pachana (2011) **.81**	Byrne & Pachana (2011) **Spearman's Rho .80**	x	Byrne & Pachana (2011) **GAI .88** **STAI-S .48**	Byrne & Pachana (2011) **GDS .37** **MMSE -.04** **Education -.08**	Byrne & Pachana (2011) **75**	Byrne & Pachana (2011) **87**
GAS	Segal et al., (2010) **.93**	x	x	Segal et al., (2010) **STAI-T .79** **STAI-S .74** **BAI .82** **AMAS-E .77**	Segal et al., (2010) **Education -.01** **GDS .78**	x	x
	Yochim et al., (2011) **.90**			Yochim et al., (2011) **GAI .69** **BAI .61**	Yochim et al., (2011) **WAIS-CD -.22** **WTAR -.36** **GDS .74** **BDI-II .73**		

Measure	Reliability			Validity		Responsiveness	
	Internal Consistency *(α)*	Test-retest (*Pearson's r)*	Inter-rater *(Pearson's r)*	Convergent *Significant Intercorrelations (r)*	Discriminant *Correlations (r)*	Sensitivity *%*	Specificity *%*
GWS	Diefenbach et al., (2009) **.78**	Diefenbach et al., (2009) **.85**	Diefenbach et al., (2009) **1.0**	Diefenbach et al., (2009) **GADQ-IV .67** **PSWQ .67** **PSWQ-A .66** **BAI .50** **BMWS .72** **GADSS .70** **GAI .86**	Diefenbach et al., (2009) **GDS .55**	Diefenbach et al., (2009) **.88**	Diefenbach et al., (2009) **74**
SAST	Sinoff et al., (1999) **.70**	Sinoff et al., (1999) **.73**	Sinoff et al., (1999) **Kappa .71**	x	x	Sinoff et al., (1999) **75.4**	Sinoff et al., (1999) **78.7**

Measure	Reliability			Validity		Responsiveness	
	Internal Consistency *(α)*	Test-retest (*Pearson's r)*	Inter-rater *(Pearson's r)*	Convergent *Significant Intercorrelations (r)*	Discriminant *Correlations (r)*	Sensitivity *%*	Specificity *%*
WS	Stanley et al., (2001) **.93**	Stanley et al., (2001) **.70**	x	Hopko et al., (2000) **PSWQ .56** **STAI-T .55**	Hopko et al., (2000) **BDI .52**	x	x
	Stanley, Beck & Zebb (1996) **.94** (NC)	Stanley, Beck & Zebb (1996) **Correlation Coefficient .69**		Stanley et al., (2001) **STAI-S .33** **STAI-T .55** **PSWQ .54**	Stanley et al., (2001) **BDI .54** **GDS .41**		
	Stanley, Beck & Zebb (1996) **.93** (GAD)			Stanley, Beck & Zebb (1996) **(GAD) STAI-T .40** **(GAD) PI .46** (**NC) STAI-S .41** **(NC) STAI-T .57** **(NC) PI .50**			
				Wisocki et al (1986) **(CA) SCL-A .54** **(CA) MAACL-A .24** **(HB) SCL-A .62** **(HB) MAACL-A .71**			

Measure	Reliability			Validity		Responsiveness	
	Internal Consistency (α)	Test-retest (*Pearson's r)*	Inter-rater *(Pearson's r)*	Convergent *Significant Intercorrelations (r)*	Discriminant *Correlations (r)*	Sensitivity *%*	Specificity *%*
WSOA-R	Hunt et al., (2003) **.97**	x	x	Hunt et al., (2003) **PSWQ .45**	x	x	x

Note. AMAS-E=Adult Manifest Anxiety Scale-Elderly, BAI=Beck Anxiety Inventory, BDI=Beck Depression Inventory, BDI-II=Beck Depression Inventory-II, BMWS=Brief Measure of Worry Severity, CA=Community Active, GAD=Generalised Anxiety Disorder, GADSS=Generalised Anxiety Disorder Severity Scale, GBAS=Goldberg Anxiety Scale, GADQ-IV=Generalised Anxiety Disorder Questionnaire for DSM-IV, GAI=Geriatric Anxiety Inventory, GAI-SF=Geriatric Anxiety Inventory-Short Form, GAS= Geriatric Anxiety Scale, GDS=Geriatric Depression Scale, GWS=Geriatric Worry Scale, HADS=Hospital Anxiety & Depression Scale, HB=Homebound, MAACL-A=Multiple Affect Adjective Checklist-Anxiety, MMSE-Mini Mental State Examination, NC=Normal Control, NEO-FFI=NEO Five-Factor Inventory, PI=Padua Inventory, PSWQ=Penn State Worry Questionnaire, PSWQ-A= Penn State Worry Questionnaire-Abbreviated, SAST=Short Anxiety Screening Test, SCL-A=Symptom Checklist-Anxiety, STAI=State Trait Anxiety Inventory, STAI-S=State Trait Anxiety Inventory-State, STAI-T=State Trait Anxiety Inventory Trait, WAIS-CD=Wechsler Adult Intelligence Scale-Coding, WTAR=Wechsler Test of Adult Reading, WS=Worry Scale, WSOA-R=Worry Scale for Older Adults-Revised.

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SECTION TWO: RESEARCH REPORT

The Clinical Effectiveness of Group Psychoeducational Cognitive Behavioural Therapy for Mixed Anxiety and Depression in Older Adults: A Feasibility Study

Abstract

Purpose. There is a dearth of literature in relation to group interventions that address co-morbid anxiety and depression for older adults. This research evaluated the clinical effectiveness of a manualised six session cognitive behavioural psychoeducational group programme for older adults.

Design. A pre-post and short term follow up design was used.

Method. Patients (N=34) meeting specified inclusion criteria attended a group (N=8). A battery of process and outcome measures, Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983), Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM; Barkham et al., 1998) and Health of the Nation Outcome Scale 65+ (Burns et al., 1999) were completed at assessment, termination and six week follow up. Patients rated therapy alliance using the Group Session Rating Scale (Duncan & Miller, 2007) following each session.

Results. All outcome measures demonstrated improvement in assessment to termination and assessment to follow up comparisons. On the CORE-OM, 28% of patients reliably improved and 22% were classified as recovered at termination.

Conclusions. The current research considered the management of mixed anxiety and depression with older adults via a group cognitive behavioural therapy intervention. The intervention shows promising findings with anxiety, depression, psychological well-being and staff observation ratings of patient well-being, all improving following intervention. Methodological limitations and directions for future research are identified and discussed.

Keywords: older adult, CBT, group, anxiety, depression, psychoeducation.

Depression and anxiety co-occur at high rates in older adult populations; Beekman et al., (2000) found that 47.5% of those with major depressive disorder had co-morbid anxiety disorders and 26.1% of people with anxiety disorders had co-morbid major depressive disorders. Katona, Manela and Livingstone (1997) found high rates of co-morbid generalised anxiety disorder (GAD) in older adults diagnosed with depression and Flint (1999) noted that late-life GAD was typically associated with depression. Co-morbidity in older adults is twice more likely in women than men, with more severely depressed individuals more likely to suffer with severe anxiety and vice versa (Schoevers, Beekman, Deeg, Jonker & van Tilburg, 2003).

For the treatment of anxiety and depression in working age adults, the National Institute for Clinical Excellence (NICE) recommends Cognitive Behavioural Therapy (CBT; 2004a & 2004b). Whilst group CBT is also recommended by NICE for working age adults (NICE Guideline 90, 2009) there are no specific guidelines in relation to older adults. Despite the evidenced overlap between anxiety and depression in older adults, there is a dearth of literature investigating the effectiveness of group CBT for the management of such co-morbid difficulties. Payne and Marcus (2008) reviewed the efficacy of group psychotherapy in older adults across 44 studies and concluded CBT was more effective than reminiscence therapy. There are a number of age specific challenges in providing group therapy including sensory deficits, transportation to group and fears of being around other older/disabled persons (Agronin, 2009).

CBT Groups for Depression

A recent systematic review of older adult group CBT for depression concluded that the approach is effective (Krishna et al., 2011), and highlighted six CBT randomised controlled trials (RCTs). All CBT was delivered via weekly group therapy, with treatment duration varying from eight (Kunik, et al., 2008), 10 (Rokke et al. 2000), 11 (Klausner et al., 1998), 12 (Arean et al., 1993, Hautzinger & Welz, 2004), and 24

weeks (Abraham et al., 1992). Although the results indicated CBT based group interventions were effective when compared to waiting list controls, results were not statistically superior to other active interventions e.g. reminiscence, educational, or group visual imagery.

A further four RCTs have considered the efficacy of CBT groups for depression. A trial with nursing home residents found that patients in group CBT (13 sessions, twice weekly) demonstrated statistically significant improvement when compared to treatment as usual (TAU; Konnert, Dobson & Stelmach, 2009). Similarly, a CBT depression management intervention (10 weekly sessions) demonstrated a significant decrease in depressive symptoms when compared to waiting list controls (Haringsma, Engels, Cuijpers & Spinhoven, 2006). Arean et al., (2005) compared group CBT (18 sessions over 6 months), clinical case management and a combination of both. A combination of case management and group CBT resulted in significantly lower depression symptoms and group CBT improved physical functioning more than case management alone or a combination of both. Wilkinson et al's (2009) pilot trial reported mixed findings when patients were randomised to eight group sessions of CBT/antidepressant condition or antidepressant alone. Although depression scores were lower for the group CBT condition, these findings were not significant.

Four pieces of practice-based research (Barkham, Stiles, Lambert & Mellor-Clark, 2010) have considered group CBT with comparative treatments, but did not randomise patients. Beutler et al. (1987) compared the following treatments: (a) medication and support, (b) placebo and support, (c) group CBT (20 weekly sessions), placebo and support or (d) group CBT, medication and support. 'Support' was defined as 20-30 minute weekly sessions to note side effects and adjust medication. Findings indicated that the CBT patients reported improvements in sleep hygiene and patients were less likely to drop out. Steuer et al., (1984) compared group CBT with

psychodynamic group psychotherapy (46 sessions over nine months). Patients in both groups showed clinically significant reductions for depression and anxiety, with treatment comparisons favouring the CBT intervention. Cappeliez (2000) tracked the intensity of depression during weekly group CBT for 12 weeks, finding a gradual decrease in depressive symptoms. Nance (2012) described a nurse led group over 12 weekly sessions, finding that patients' outcome measures indicated mild to moderate improvement for depression and overall improvements in personal growth, changing negative thoughts and relationships with family.

The extant evidence base suggests that group interventions for older adults can be beneficial in managing depression, particularly when compared with control conditions. However, the literature is too sparse to provide conclusive evidence, especially in relation to whether CBT groups are the most beneficial form of therapy in comparison to other active treatments.

CBT Groups for Anxiety Disorders

The most common disorder treated with group CBT for older adults is GAD with the evidence base consisting of three RCTs. Stanley, Beck and DeWitt Glassco (1996) compared CBT (14 weekly group sessions) and non-directive group supportive therapy. Whilst both methods created significant improvements to anxiety, there were no significant differences evident between treatments. Wetherell, Gatz and Craske (2003) found CBT groups (12 weekly sessions) and discussion groups created greater improvement in GAD than waiting list control. Again, there were no significant differences between treatments. Stanley et al., (2003) compared group CBT (15 weekly sessions) with a minimal contact group (phone contact). Findings indicated a significant improvement of anxiety, worry, depression and quality of life following CBT and these improvements were maintained at one year follow-up. Wetherell et al., (2005) pooled data from these three RCTs and found approximately half of patients

achieved a significant pre-post reliable change. Better outcomes were associated with greater adherence to homework and higher baseline anxiety.

In terms of practice-based evidence, Radley, Redston, Bates, Pontefract and Lindesay (1997) conducted a small study (N=6) where patients acted as their own controls prior to attending eight weekly CBT treatment sessions. They found CBT treatment was associated with a significant reduction in anxiety symptoms in two of their three outcome measures. Similarly to the research in this field relating to depression, it does appear that group CBT is beneficial in managing anxiety with this client group.

CBT Groups for Anxiety and Depression

Much less empirical attention has focussed on group CBT treatment of mixed anxiety and depression, as only a single study has been conducted. Schimmel-Spreeuw, Linssen and Heeren (2000) devised a 'coping with depression and anxiety course' (20 weekly sessions) with outpatient elderly depressed women, to increase knowledge by psychoeducation and skills training. Findings indicated that 53.1% of patients who completed the basic module reported that their knowledge of anxiety and depression had improved. A statistically significant decline in depression, anxiety and neuroticism from pre to post treatment and at follow-up was found.

Clearly literature in relation to group interventions that address co-morbid anxiety and depression for older adults is sparse, despite this being a highly prevalent clinical issue with this population (Cairney, Corna, Velhuidzen, Herrmann & Streiner, 2008). Considering such prevalence, evaluations of group interventions is potentially clinically and economically useful. The present research therefore presents a feasibility study considering the effectiveness of a manualised group CBT intervention with older adults in reducing anxiety and depression. The study adopts a pragmatic, naturalistic design. The rationale for this is that naturalistic designs have high external validity (Hotopf,

2002), with patients representative of routine clinical practice, treated in a setting that they would have experienced as part of their care. This is an innovative piece of research as it is one of the only known manualised group CBT interventions addressing both anxiety and depression with older adults. To address the gender bias in the Schimmel-Spreeuw et al., (2000) study, the group was open to both male and female older adult patients. As this is a feasibility study, the practicality of undertaking further research will also be considered.

Aims

1. To investigate whether a manualised CBT psychoeducational group for mixed anxiety and depression is clinically effective.

1.2. To investigate whether improvements are maintained at follow-up.

The two secondary aims as follows:-

2. Whether attendance has any effect on psychological well-being and staff members' observation of a patient's well-being.

3. To examine the perceived group therapy alliance, and self reported anxiety and depression, following each session.

Hypotheses

In relation to the primary aim, hypotheses are as follows:

1. Patients will report reduced anxiety and depression following treatment, in comparison to assessment.

1.2 Reductions to anxiety and depression scores will be maintained at follow-up.

In relation to the secondary aims, hypotheses are as follows:

2. Patients will report improved psychological well-being following treatment and at follow-up in comparison to assessment. Staff will observe an improvement in

patients' well-being following treatment and at follow-up in comparison to assessment.

3. Patients will report increased therapy alliance and reductions in self reported anxiety and depression across weekly therapy sessions.

Method

Sample

A total of 41 patients were recruited, with 34 completing treatment (seven were lost to attrition). Figure 1 details patient flow through the research. Completers were aged between 66 to 95, with a mean age of 74.8 (SD=7.5), 82% were females (N=28) and 97% (N=33) prescribed medication for their anxiety/depression. All patients were white British. Marital status was classified as 50% married (N=17), 15% divorced (N=5), 32% widowed (N=11) and 3% single (N=1). Original reason for referrals were 18% anxiety (N=6), 20% depression (N=7) and 62% mixed anxiety and depression (N=21). Demographic information of patients is reported in Table 1.

Patients were recruited from a secondary mental health service in a large Northern city in the UK. This included community mental health teams (four separate teams that cover across the city), psychiatric outpatients, day hospitals, and inpatient wards (two wards that cover the city). Mental health professionals across older adult services were made aware of the intervention, ensuring referrals to the group were appropriate.

Inclusion criteria for the study were, (1) individuals were over 65 years of age, (2) already have contact with secondary mental health services, (3) been assessed as having anxiety, depression or mixed anxiety/depression as their primary difficulty, (4) potentially able to make use of a psychoeducational approach and (5) be willing to attend a group for six weeks. The exclusion criteria were, (1) if either anxiety or depression was not the individual's primary reason for referral, (2) if the individual had an insufficient understanding of English and (3) presence of significant cognitive impairment.

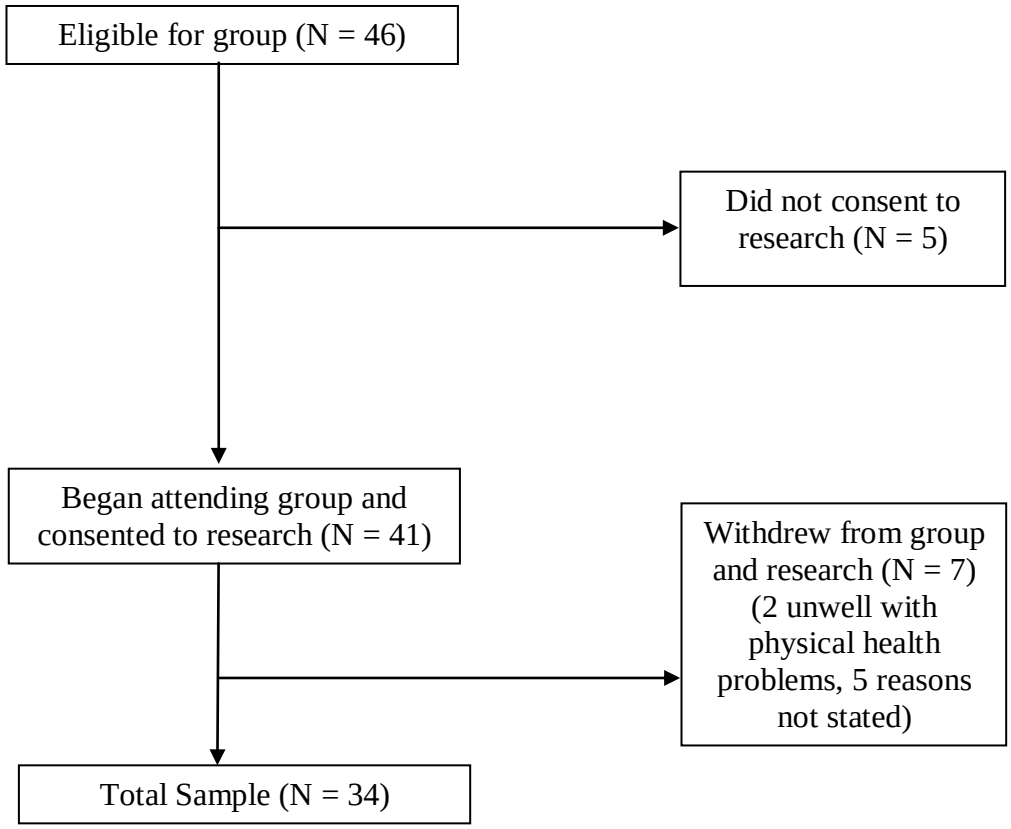

Figure 1. Patient Flow Chart through Research

Measures

Patients completed a battery of psychometric assessments at three time points; assessment (prior to intervention), termination (end of intervention) and follow-up (six weeks following end of intervention). Assessment and termination were administered to patients either within the group or through the patient's usual clinical contact with the service. If this was not possible, patients were either visited by the Chief Investigator at a mutually convenient time or assessments were sent by post with pre paid envelopes for return. This was also the method for follow-up data collection. The following measures were administered.

Primary outcome measure: Hospital Anxiety & Depression Scale (HADS; Zigmond & Snaith, 1983). The HADS (Appendix B1) measures anxiety and

depression over 14 items, over the last week. Anxiety and depression scores range from 0 – 21 and a higher score indicates greater severity. All items are rated on a four point scale. HADS scores of < 8 for either subscale are sub-clinical, scores between 8 – 10 indicate 'mild anxiety and/or depression' and scores >11 indicate anxiety and depression 'caseness'. The HADS has good concurrent validity (Zigmond & Snaith., 1983; Bjelland, Dahl, Haug & Neckelmann, 2002), internal consistency (Bjelland et al., 2002) and test retest reliability (Spinhoven et al., 1997).

Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM; Barkham et al., 1998). The CORE-OM (Appendix B2) is a 34 item measure of global psychological distress, with subscales of subjective well-being, functioning, psychological problems and risk. Items are scored on a five point scale from 0 – 4 and a higher score is indicative of greater distress. The CORE-OM has shown good reliability, validity against longer and less general measures, and has been shown to be sensitive to change (Evans et al., 2000). The CORE-OM has been found to be a reliable and structurally sound measure to use with older adults and a lower clinical cut-off of 0.952 has been suggested for this client group (Barkham, Culverwell, Spindler & Twigg., 2005).

Health of the Nation Outcome Score (HoNOS 65+; Burns et al., 1999). The HoNOS 65+ (Appendix B3) is a clinician rated measure of different health and social domains. Twelve single item scales measure various aspects of mental and social health each on a five item scale from 0 - 4. The HoNOS 65+ has been reported as 'easy' to administer, has moderate concurrent validity and good inter-rater reliability, (Spear, Chawla, O'Reilly, & Rock., 2002). It has also evidenced good criterion validity and content validity, (Shergill, Shankar, Seneviratna, & Orrell., 1999).

Group Session Rating Scale (GSRS; Duncan & Miller, 2007). The GSRS (Appendix B4) is a four item rating scale measuring group therapy alliance. The scale

is based upon the Session Rating Scale which is used within one to one sessions and has demonstrated high levels of reliability (Duncan et al., 2003).Group patients rate the 'relationship' aspect of the group, whether their 'goals and topics' were addressed, the facilitators 'approach and method', and their 'overall' view of the group. The GSRS uses a 0-10 visual analogue scale and responses are summed together out of a possible score of 40 (higher scores indicative of a more positive group therapy alliance). The GSRS has been found to have excellent internal consistency and good concurrent validity, (Miller & Duncan, *in press)*. An additional two questions (0-10 visual analogue scales) were added to the GSRS asking patients to rate current levels of anxiety and depression. This provided data relating to the patient's mood each week (a higher response being indicative of improved mood and decreased anxiety).

Design

Patients were given an information sheet (Appendix C1) about the research, and completed a consent form (Appendix C2) prior to intervention. Outcome measures (HADS, CORE-OM, HoNOS 65+) were collected at three time points, assessment (prior to group intervention), termination (end of group intervention) and follow-up (six weeks following group intervention). Patients attended the six week Anxiety and Depression Management Group as soon as a place was available. As groups were regularly run over the data collection period, wait-time was never longer than four weeks. At the end of each group session, patients completed the GSRS and rated current anxiety and depression. During the group, patients continued to receive treatment as usual from secondary mental health services. Demographic and medication information was recorded at all time points. Service users were able to attend the groups even if they did not wish to take part in the research. Eight nine percent (N=41) of referrals to the group also consented to the research. Eight groups were run over the data collection period (group size range 4 – 7).

Intervention

The group intervention was based on the theoretical model of CBT (Beck, 1976) which focuses on the relationship between an individual's physical symptoms, thoughts, behaviours and mood. CBT has proven to be efficacious with older people (Laidlaw, Thompson, Dick-Siskin & Gallagher-Thompson, 2003, p.16). Zeiss & Steffen (1996) suggest a number of adaptations to CBT when working with an older client group, including slower pacing, multimodal training and memory aids such as written information. The Anxiety and Depression Management Group Manual was written in accordance with such guidance. The intervention is structured to provide psychoeducation about anxiety and depression, use behavioural and cognitive change methods e.g. activity scheduling, relaxation and thought challenging. The intervention uses a multimodal approach (e.g. visual information, role play, between session work). The manual can be seen in Appendix D.

The intervention was facilitated by three clinicians in every group; a facilitator, co-facilitator and observer (roles were rotated as clinicians felt appropriate). All disciplines of staff were invited to facilitate the groups, and training days were offered by the Chief Investigator and NHS Supervisor. Groups were facilitated by clinical psychologists, trainee clinical psychologists, mental health nurses, occupational therapists and student occupational therapists. Two pilot groups had been run using the Anxiety and Depression Management Manual prior to data collection, which highlighted some minor changes to the manual in its current form e.g. order of information and simplification of language.

Intervention Integrity and Risk Management

The Anxiety and Depression Management Group intervention was manualised and therefore facilitators followed the manual. Fidelity was monitored through group supervision from the NHS Supervisor. The observer in each session monitored whether

key themes were covered each week by using checklists (Appendix E1) which detailed the core components of each session. The intervention was delivered by mental health professionals who had access to the mental health records of patients and line management to support them with any issues of risk. Facilitators were also provided with an adverse incident form (Appendix E2) to be completed should any issues arise. Facilitators had access to General Practitioners and Psychiatrists to share any pertinent risk information.

Ethics

The research proposal underwent scientific review at the University of Sheffield and received a favourable ethical opinion from the National Research Ethics Service in June 2011 (Appendix F1), as well as research governance approval from Sheffield Health and Social Care NHS Foundation Trust Research Development Unit (Appendix F2).

Data Analysis Strategy

Statistical analyses were conducted using the SPSS Software (PASW version 18 for Windows). Independent samples t-tests compared HADS, CORE-OM and HoNOS 65+ between completers and non-completers. For the investigation of the primary aim, an uncontrolled effect size (Cohen's *d*) with 95% confidence intervals, was calculated by subtracting the mean termination figure from the assessment figure and dividing this by the assessment standard deviation (Barkham, Gilbert, Connell, Marshall & Twigg, 2005; Westbrook & Kirk, 2005). Cohen (1988) defines three values for *d*: small (0.20), medium (0.50) and large (0.80). The effect sizes of extant research considering anxiety and depression CBT groups with older adults were also calculated using this formula, to provide benchmarking information for the current findings. This was repeated for the assessment to follow-up data. Paired samples t-tests assessed the mean difference from

assessment to termination, termination to follow-up and assessment to follow-up on the HADS, CORE-OM and HoNOS 65+.

Reliable and clinical significant change (RCSC) rates were calculated on the HADS and CORE-OM from assessment to termination and assessment to follow-up. The Reliable Change Index (RCI; Jacobson & Truax, 1991) is used to assess the degree of clinical change beyond what could be deemed as measurement error (Jacobson & Truax, 1991). As there is no published RCI for the HADS, this was calculated using the means and standard deviation from the current study, and the test-retest figures from a published piece of research considering the validation of the HADS (Spinhoven et al., 1997). Calculating significant clinical change entails also using the clinical cut-off between clinical and non-clinical populations; consideration of clinical change alone may inflate recovery rates as a patient may move from being clinical to non-clinical but within the boundaries of measurement error. Therefore the RCSC considers both reliable and clinical change contemporaneously and denotes whether 'recovery' has been achieved.

The rates of 'recovery' are dependent upon the number of patients scoring within the clinical range at assessment, for those not within the clinical range at assessment, it is impossible to achieve clinically significant improvement to a non-clinical population, (Barkham, Stiles, Connell & Mellor-Clark, 2011). Therefore, 'recovery' is calculated using the number of patients demonstrating RCSC as a proportion of those scoring within the clinical range at assessment. In addition to improvement, deterioration was assessed by using the same principles. The rates of 'harm' are dependent upon the number of patients non-clinical at assessment, for those individuals classified as clinical at assessment, it is impossible to achieve clinical deterioration, (Barkham, Stiles, Connell & Mellor-Clark, 2011). Therefore, the rate of 'harm' is calculated as the number of patients demonstrating RCSC as a proportion of

those who were non-clinical at assessment. Patients were classified as the following *'reliably improved'* (positive RCI), *'clinically improved'* (shift from case to non-case), *'recovered'* (positive RCI and case to non-case), *'reliably deteriorated'* (negative RCI), *'clinically deteriorated'* (shift from non-case to case) and *'harmed'* (negative RCI and non-case to case).

To consider the potential incremental increase of group alliance (GSRS scores), repeated Analysis of Variance (ANOVA) compared the means from each weekly session. Repeated ANOVA was also used to analyse the weekly rated anxiety and depression data. In addition, non-parametric tests (Mann-Whitney U) were used to investigate the potential relationship between recovery and reported group alliance.

Finally, potential confounding variables were considered as follows. Non-parametric tests (Mann-Whitney U) were run to consider any differences in gender. Independent samples t-tests were used to investigate any differences based on whether patients completed all six sessions of the group. A one-way ANOVA was used to consider any differences according to referral reason (anxiety, depression or mixed).

Results

Power Analysis

A priori power analysis was carried out using G*Power-3 (Faul, Erdfelder, Lang, & Buchner (2007) to calculate the required sample size; Cohen (1977) suggested that 80% power is required to achieve significant findings when conducting a power analysis. Based on previous research in this field (Haringsma et al., 2006), in order to show a similar effect size with an alpha or significance level of .05, and a power of 0.8 based on linear multiple regression, the required sample size was 41. The power analysis was repeated using paired samples t-test, as was used in analysis, alpha or significance level of .05, effect size of 0.4 and the actual sample size of 34 patients, which suggests the study has a power of 0.62. In order to achieve power of 80% (0.8), a power analysis suggests that 52 patients were actually needed. All statistical results should be considered in the context of this information.

Attrition

Of the 41 patients who consented to the research, 7 (17%) dropped out of the study during group treatment. Reasons were physical illness (N=2), and not stated (N=5). Independent samples t-tests (95% confidence interval) showed no significant differences in assessment scores for HADS anxiety (t (38) = -.360, p = .720), HADS depression (t (38) = .583, p = .563), CORE-OM (t (38) = -.338, p = .737) and HONOS 65+ (t (37) = -1.185, p = .244) between completers and non-completers.

Completer Analyses

Table 1 displays the demographic details and assessment scores for completers and non-completers. The sample was culturally homogenous in both groups (100% white British) and a high percentage (97%) were prescribed medication. Figure 2 shows a box plot of gender and age for completers, highlighting the median age in both genders of patients, and that there was a wider age range of female patients, although this is likely a reflection of the higher number of female patients (82%). Patient ages

ranged from 65 years to 90 years, apart from one patient who was an outlier at 95 years old. Normal distribution was considered using Z scores by dividing skewness from the standard error of skewness, and kurtosis from the standard error of kurtosis (Field, 2009). Using this method, assessment scores were normally distributed based on skewness; HADS anxiety (Z = -1.01), HADS depression (Z = 0.02), CORE-OM (Z = 1.09), HoNOS 65+ (Z = 1.32), and kurtosis; HADS anxiety (Z = -0.77), HADS depression (Z = -0.21), CORE-OM (Z = 1.54) and HoNOS 65+ (Z = 0.03). Normal distribution histograms can be seen in Appendix G.

Table 1

Demographic and Assessment Scores for Completers and Non-Completers

	Completers %, (N = 34)	Non-Completers %, (N = 7)
Mean age in years	74.8 (SD=7.5)	78.3 (SD=8.0)
Gender		
Male	18 (6)	14 (1)
Female	82 (28)	86 (6)
Ethnicity		
White British	100 (34)	100 (7)
Other	0	0
Marital Status		
Married	50 (17)	43 (3)
Divorced	15 (5)	0 (0)
Widowed	32 (11)	57 (4)
Single	3 (1)	0 (0)
Medication for anxiety/depression		
Yes	97 (33)	86 (6)
No	3 (1)	14 (1)
Referral Reason		
Anxiety	18 (6)	14 (1)
Depression	20 (7)	14 (1)
Mixed	62 (21)	72 (5)
Assessment HADS A	10.82 (SD=5.2)	11.67 (SD=5.8)
Assessment HADS D	9.15 (SD=4.5)	8 (SD=4.1)
Assessment CORE-OM	14.40 (SD=6)	15.30 (SD=9)
Assessment HoNOS 65+	9.13 (SD=4.7)	11.43 (SD=4.5)

Note. HADS A=Hospital Anxiety and Depression Scale anxiety subscale, HADS D=Hospital Anxiety and Depression Scale depression subscale, CORE-OM=Clinical Outcomes in Routine Evaluation-Outcome Measure, HoNOS 65+=Health of the Nation Outcome Scale 65+.

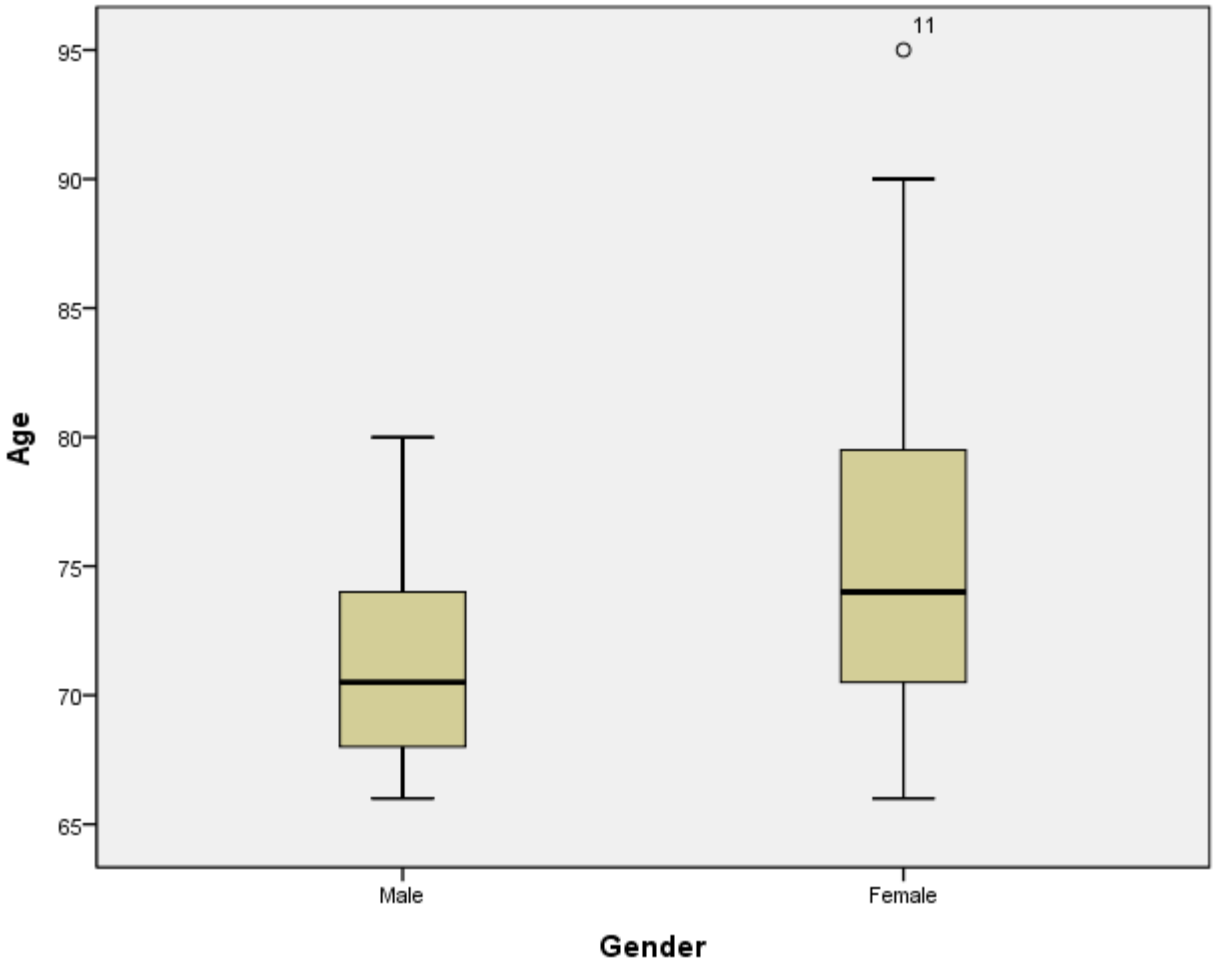

Figure 2. Box Plot to Show Age Distribution and Gender of Patients

Effectiveness; Group Level Analysis

Tables 2, 3 and 4 display the means and standard deviations for measures from assessment to termination, termination to follow-up and assessment to follow-up respectively. Mean scores improved for all measures from assessment to termination. From termination to follow-up differences in scores continued to improve except for the HADS depression subscale which slightly deteriorated (difference indicated as a negative number). Differences in scores between assessment and follow-up indicate continued improvement across all measures, most of which are larger than the differences measured at termination (apart from the HADS depression subscale which has a smaller improvement at follow-up).

Table 2

Assessment versus Termination Data and Comparisons

Measure *Assessment-Termination*	N[a]	*df*	Assessment Mean (SD)	Termination Mean (SD)	Difference	*t*	*p*	*d*
HADS-Anxiety	33	32	10.85 (5.30)	9.35 (4.61)	1.50	2.08	.045*	0.3
HADS-Depression	33	32	9.10 (4.54)	7.24 (3.80)	1.86	2.01	.053	0.4
CORE-OM	32	31	14.30 (6.00)	12.00 (7.10)	2.30	2.73	.01*	0.4
HONOS 65+	30	29	9.23 (4.81)	8.40 (4.60)	0.83	1.4	.171	0.2

Table 3

Termination versus Follow-Up Data and Comparisons

Measure *Termination-Follow Up*	N[a]	*df*	Termination Mean (SD)	Follow Up Mean (SD)	Difference	*t*	*p*	*d*
HADS-Anxiety	33	32	9.35 (4.61)	9.06 (5.40)	0.29	0.37	.714	0.1
HADS-Depression	33	32	7.24 (3.80)	7.26 (4.31)	-0.02	-0.02	.981	-0.01
CORE-OM	33	32	12.0 (7.0)	11.30 (7.67)	0.70	0.54	.592	0.1
HONOS 65+	31	30	8.19 (5.0)	7.74 (4.40)	0.45	0.69	.493	0.1

Table 4

Assessment versus Follow-Up Data and Comparisons

Measure *Assessment-Follow Up*	N[a]	*df*	Assessment Mean (SD)	Follow Up Mean (SD)	Difference	*t*	*p*	*d*
HADS-Anxiety	34	33	10.82 (5.20)	8.94 (5.35)	1.88	2.03	.051	0.4
HADS-Depression	34	33	9.15 (4.50)	7.43 (4.35)	1.72	1.71	.097	0.4
CORE-OM	33	32	14.30 (6.0)	11.40 (7.6)	2.90	3.45	.002**	0.5
HONOS 65+	31	30	9.23 (4.73)	7.65 (4.40)	1.58	2.53	.017*	0.3

[a] N differs dependent on completion of measures at both time points
**p* <.05, two-tailed test
***p* < .01, two-tailed test

Statistically Significant Changes

Table 2 also displays the assessment to termination paired samples t-tests (95% confidence interval) and the uncontrolled effect sizes. Both HADS anxiety subscale (t (32) = 2.086, p = .045) and CORE-OM (t (31) = 2.732, p = .010) significantly reduced over time, with the HADS depression subscale close to significance (t (32) = 2.013, p = .053). There was a 'small' effect size for the HONOS 65+ and 'small to medium' effect size for both HADS subscales and the CORE-OM (Cohen, 1988).

There were no significant differences for HADS anxiety (t (32) = 0.37, p = .714), HADS depression (t (32) = -0.02, p = .981), CORE-OM (t (32) = 0.54, p = .592) or HONOS 65+ (t (30 = 0.69, p = .493) and effect sizes were 'small' for all measures on the termination to follow-up comparisons.

Table 4 displays the assessment to follow-up paired samples t-tests and uncontrolled effect sizes. There were significant differences on the CORE-OM (t (32) = 3.45, p = .002) and HoNOS 65+ (t (30) = 2.53, p = .017). The HADS depression (t (33) = 1.71, p = .97) and HADS anxiety subscale (t (33) = 2.03, p = .051) were non-significant. Effect sizes were 'small to medium' for all measures; all effect sizes were larger assessment to follow-up than assessment to termination.

Effectiveness; Benchmarking Data

Table 5 compares current effect sizes with the extant older adult evidence base for group interventions where it was possible to calculate effect sizes. The current anxiety effect size appears comparable with previous anxiety group research, whilst the current depression effect size is much lower than previous depression group research. Current effect sizes are similar to the one other mixed anxiety and depression intervention research.

Table 5

Comparison of Effect Sizes using Extant Research

		Intervention		
Study	N	Depression	Anxiety	Mixed
		Mean = 1.1	Mean = 0.6	
Arean et al., (1993)[1]	39	1.53		
Arean et al., (2005)[3]	67	0.27		
Beutler et al., (1987)[1]	56	0.74		
Cappeliez (2000)[1]	21	1.8		
Haringsma et al., (2006)[4]	119	0.6		
Hautzinger & Welz (2004)[2]	55	0.9		
Klausner et al., (1998)[1]	24	0.75		
Konnert et al., (2009)[2]	64	1.17		
Kunik et al., (2008)[1]	123	0.74		
Rokke et al., (2000)[1]	34	1.92		
Steur et al., (1984)[1]	20	1.3		
Radley et al., (1997)[5]	6		0.33	
Stanley et al., (1996)[7]	48		0.62	
Stanley et al., (2003)[7]	85		1	
Wetherell et al., (2003)[6]	75		0.35	
Schimmel-Spreeuw et al., (2000)[2] [8]	51			0.5-depression 0.34-anxiety
Current Study[4]	34			0.3-depression 0.4-anxiety

Measures used to calculate effect sizes:
[1] Beck Depression Inventory-II
[2] Geriatric Depression Scale
[3] Hamilton Depression Rating Scale
[4] Hospital Anxiety and Depression Scale
[5] Hospital Anxiety and Depression Scale (Anxiety Subscale)
[6] Beck Anxiety Inventory
[7] State Trait Anxiety Inventory
[8] Symptom Checklist-90

Effectiveness; Individual Level Analysis

Category outcome rates were calculated for assessment to termination and assessment to follow-up. Table 6 displays the rates for positive and negative clinical change, positive and negative reliable change, recovery and harm. When comparing assessment to termination, 15 patients were classified as either reliably improved or recovered on the CORE-OM, 9 patients on the HADS anxiety, and 12 patients on the HADS depression. Using the same comparison, the single patient reliably deteriorated and no patients were harmed on the CORE-OM, five patients reliably deteriorated or were classified as harmed on the HADS anxiety measure and two patients reliably deteriorated with the single patient classified as harmed on the HADS depression measure.

Between assessment and follow-up, rates of reliable improvement and recovery increased on all measures; 20 patients on the CORE-OM, 15 patients on the HADS anxiety measure and 14 patients on the HADS depression measure respectively. Using the same comparison, rates of reliable deterioration and harm were least found on the CORE-OM with the single person reliably deteriorating and no patients classified as harmed. Both the HADS anxiety and depression measures indicated six patients reliably deteriorated or were classified as harmed.

Table 6

Reliably and Clinically Significant Change at Termination and Follow-Up

	N	Clinical at Assessment N (%)	Reliably Improved N (%)	Clinically Improved N (%)	Recovered N (%)	Non Clinical at Assessment N (%)	Reliably Deteriorated N (%)	Clinically Deteriorated N (%)	Harmed N (%)
Termination Anxiety (HADS-A)	33	24 (73)	7 (21)	2 (8)	2 (8)	9 (27)	3 (9)	3 (33)	2 (22)
Termination Depression (HADS-D)	33	18 (55)	7 (21)	6 (33)	5 (28)	15 (45)	2 (6)	3 (20)	1 (7)
Termination Well-Being (CORE-OM)	32	27 (84)	9 (28)	7 (26)	6 (22)	5 (16)	1 (3)	0	0
Follow Up Anxiety (HADS-A)	34	25 (74)	8 (23)	9 (36)	7 (28)	9 (26)	3 (9)	3 (33)	3 (33)
Follow Up Depression (HADS-D)	34	19 (56)	8 (23)	9 (47)	6 (31)	15 (44)	4 (12)	4 (27)	2 (13)
Follow Up Well-Being (CORE-OM)	33	28 (85)	11 (33)	12 (43)	9 (32)	5 (15)	1 (3)	2 (40)	0

Session Analysis; Therapy Alliance, Anxiety and Depression

Table 7 displays the ANOVA results for the total GSRS scores and weekly anxiety and depression. Mean scores for the total GSRS suggest weakest group alliance for sessions 3 and 4 of the intervention, however the larger standard deviations suggest that there may have been more variability in these scores than is reflected in the means. GSRS mean score was highest at week 6 suggesting therapy alliance was at its strongest at the end of the group. Mauchly's Test of Sphericity indicated that the assumption of sphericity had been violated (X^2 (14) = 86.572, p <.001), therefore degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity ($\acute{\varepsilon}$ = 0.462). Results show that there was no significant effect of sessions on therapy alliance as measured by the GSRS (F (2.312, 41.621) = 2.856, p = .062).

Table 7 also displays that anxiety was reported as most improved by session 5 and as worst at session 1. Mauchly's Test of Sphericity indicated that the assumption of sphericity had not been violated (X^2 (14) = 21.793, p =.086). Results show that there was a significant effect of sessions on reported anxiety (F (5, 90) = 2.598, p = .030). Post hoc analyses using the Bonferroni correction revealed that there was no significant effect of anxiety when considering pair-wise comparisons of session 1 with all subsequent sessions (all p's > .05). Depression was rated as most improved in session 6 and worst in week 1. Mauchly's Test of Sphericity indicated that the assumption of sphericity had been violated (X^2 (14) = 24.068, p = .047), therefore degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity ($\acute{\varepsilon}$ = 0.691). Results show that there was no significant effect of sessions on reported depression (F (3.454, 62.166) = 1.841, p = .141).

No significant results were found for between therapy alliance (GSRS scores) and patients who recovered (RCSC) versus those who did not at assessment to termination, HADS anxiety (U = 15.00, z = -1.257, p = .209), HADS depression (U =

65.50, z = -.344, p = .731), CORE-OM (U = 69.00, z = -.685, p = .494) or assessment to follow up, HADS anxiety (U = 73.50, z = -.904, p = .366), HADS depression (U = 71.50, z = -.571, p = .568), CORE-OM (U = 108.00, z = -.178, p = .859).

Table 7

Means, Standard Deviations and ANOVA scores from the Group Session Rating Scale and Additional Anxiety and Depression Scales

N = 19#	Session 1 Mean (SD)	Session 2 Mean (SD)	Session 3 Mean (SD)	Session 4 Mean (SD)	Session 5 Mean (SD)	Session 6 Mean (SD)	F-Value
GSRS Total	36.20 (2.4)	36.32 (3.14)	32.74 (7.50)	34.16 (7.86)	35.84 (3.80)	37.11 (2.50)	2.856 (p=.062)
Anxiety	5.42 (3.90)	6.42 (3.60)	5.89 (3.20)	5.74 (3.60)	7.84 (2.34)	7.32 (3.33)	2.598 (p=.030)
Depression	5.37 (3.63)	5.74 (3.70)	6.32 (3.61)	6.00 (3.40)	7.16 (3.13)	7.47 (3.10)	1.841 (p=.141)

*p<0.05, two tailed test
#N is lower as patients needed to complete all six sessions to be include in analysis

Potential Confounding Variables

No significant differences were found with regards to gender for any of the outcome measures at assessment HADS anxiety (U = 76.00, z = -.362, p = .717), HADS depression (U = 56.00, z = -1.275, p = .202), and CORE-OM (U = 66.00, z = -.700, p = .484), termination HADS anxiety (U = 76.50, z = -.211, p = .833), HADS depression (U = 80.50, z = -.023, p = .981), and CORE-OM (U = 78.50, z = -.117, p = .907) or follow-up HADS anxiety (U = 83.00, z = -.045, p = .964), HADS depression (U = 67.50, z = -.749, p = .454) and CORE-OM (U = 71.50, z = -.565, p = .572).

Any differences between patients who attended all six sessions of the group and patients who had missed any session were investigated. Results showed no significant differences at assessment for HADS anxiety (t (32) = -0.615, p = .543), HADS

depression (t (32) = 0.441, p = .662), or CORE-OM (t (17.71) = -0.096, p = .925). No significant differences were found for termination HADS anxiety (t (31) = -0.316, p = .754), HADS depression (t (31) = -0.238, p = .813), or CORE-OM (t (31) = 0.095, p = .925). No significant differences were found for follow-up HADS anxiety (t (32) = 0.502, p = .619), HADS depression (t (32) = 0.203 p = .840), or CORE-OM (t (20.32) = 0.175, p = .863).

Table 8 contains the one-way ANOVA results for any differences dependent on whether patients were referred for anxiety, depression or mixed anxiety and depression. Results were not significant at assessment for the HADS depression (F (2, 31) = 1.547, p = .229, however, were significant for HADS anxiety (F (2, 31) = 3.499, p = .043) and CORE-OM (F (2, 30) = 4.941, p = .014). There continued to be a significant difference for termination HADS anxiety (F (1, 9) = 17.908, p < .001) and CORE-OM (F (1, 28) = 23.186, p <.001) after controlling for the effect of assessment HADS anxiety and CORE-OM using analysis of co-variance (ANCOVA). Termination HADS depression was also significant (F (2, 30) = 3.508, p = .043) and continued to be significant at follow-up (F (2, 31) = 4.286, p = .023). There also continued to be a significant difference at follow-up for HADS anxiety (F (1, 30) = 6.856, p = .014) and CORE-OM (F (1, 29) = 29.816, p <.001) after controlling for the effect of assessment HADS anxiety and CORE-OM.

Post hoc analyses (Bonferroni) revealed all significant differences were between patients referred with depression and those referred with mixed anxiety and depression. Differences were evident at assessment on HADS anxiety (p = .046), and CORE-OM (p = .011), and also termination HADS depression (p = .039) and follow-up HADS depression (p = .041). All significant results suggested that patients referred with mixed anxiety and depression had greater levels of distress.

Table 8

Comparison of Assessment, Termination and Follow-up Measures Based on Reasons for Referral

	Assessment Means (SD)			Termination Means (SD)			Follow-Up Means (SD)		
	HADS A	HADS D	CORE-OM	HADS A	HADS D	CORE-OM	HADS A	HADS D	CORE-OM
Anxiety	9.67 (4.88)	7.67 (3.32)	14.5 (6.15)	9.83 (4.30)	7.50 (3.10)	9.5 (4.91)	6.83 (5.34)	5.50 (3.02)	9.70 (7.39)
Depression	7.00 (6.90)	7.29 (6.04)	8.90 (4.74)	6.43 (4.35)	4.14 (3.93)	7.5 (6.10)	7.43 (5.88)	4.43 (3.50)	5.90 (5.32)
Mixed	12.43 (4.02)	10.19 (4.06)	16.20 (5.34)	10.23 (4.60)	8.25 (3.52)	14.00 (7.10)	10.05 (5.14)	8.98 (4.31)	13.50 (7.52)
F-Value (p value)	3.499 (p=.043)*	1.547 (p=.229)	4.941 (p=.014)*	17.908 (p<.001)**	3.508 (p=.043)*	23.186 (p<.001**)	6.856 (p=.014)*	4.286 (p=.023)*	29.816 (p<.001)**

*p < 0.05, two tailed test
**p < 0.01, two tailed test

Discussion

This study adds to the sparse evidence considering anxiety and depression group CBT with older adults. The main aim of the research was to investigate whether a manualised CBT group intervention for anxiety and depression was effective with older adults. As this was a feasibility study, the research was also an opportunity to explore the practicalities of conducting such research, and identify avenues for further investigation. Previous practice based evidence considering CBT groups for depression and CBT groups for anxiety with this age group have indicated promising findings (Beutler et al., 1987), Cappeliez, (2000), Nance (2012), Radley et al., (1997), Schimmel-Spreeuw et al., (2000) and Steur et al., (1984). The present study compared anxiety, depression and psychological well-being at assessment, termination, and six week follow-up from a group CBT intervention. Staff observations of patient health were also monitored. In addition, group therapy alliance and weekly rated anxiety and depression was considered across all six sessions of the intervention.

Summary of Findings

The findings suggest that attendance at a group CBT intervention appears to lower anxiety, depression and improve psychological well-being for older adults. All measures demonstrated improvement immediately after the intervention and at six week follow-up, in comparison to initial assessment. Mean scores significantly improved between assessment and termination for anxiety and psychological well-being. Psychological well-being also significantly improved between assessment and follow-up. The termination to follow-up comparisons indicated stasis in patient outcomes suggesting that patients were not losing the gains made in the group, nor making further gains without the support of the group.

Effect sizes were ‘small to medium’ for all outcome measures from assessment to termination and follow-up. The smallest effect sizes were for staff rated patient well-

being and the largest effect sizes were found for the self reported psychological well-being. Benchmarking of effect sizes with the existing CBT group intervention literature indicates depression effects were larger in previous studies. In terms of anxiety, effect sizes were consistent with previous research. The current anxiety and depression effect size is very similar to the Schimmel-Spreeuw et al., (2000) study using a similar method with a similar patient group. The existing evidence base for depression CBT groups is more extensive than anxiety and has a number of RCTs (Abraham et al., 1992; Arean et al., 1993; Arean et al., 2005; Haringsma et al., 2006; Hautzinger & Welz, 2004; Klausner et al., 1998; Konnert et al., 2009; Kunik et al., 2008; Rokke et al., 2000; Wilkinson et al., 2009) which may have yielded higher effect sizes when compared to practice based evidence.

Statistical significance has limited bearing on how clinically meaningful results can be (Jacobson & Truax, 1991). This highlights the importance of an effective clinical intervention needing to produce both clinical and reliable significant change. Recovery rates were evident on all measures at termination and follow-up. Rates of recovery were highest for psychological well-being as measured by the CORE-OM. However, there was evidence that harm did also occur. Evidence suggests that it is imperative to consider rates of harm in psychological therapy (Lilienfeld, 2007) and that a relatively small minority can deteriorate following psychological intervention with estimates ranging from three to 10% (Mohr, 1995; Strupp, Hadley, & Gomez-Schwartz, 1977). Current rates of harm from the group were greater than this, varying from 7% (N=1) to 33% (N=3). It should be noted that these proportions may seem inflated as calculations only included patients who were non-clinical at assessment. Rates of reliable deterioration (including all patients) were lower, varying from 3% (N=1) to 12% (N= 4) which is comparable with suggested estimates (Mohr, 1995; Strupp et al., 1977). Minimal information was collected about other confounding variables that could

have impacted self reported mental health, therefore rates of recovery and harm could be unrelated to the group intervention.

The measure of therapy alliance suggested that the final session of the intervention was rated more positively than the previous sessions, although these results were not significant. The lack of significant results were surprising, particularly as the latter half of the intervention was more focussed on change methods, which could be hypothesised to seem more relevant to the goals and topics of patients. There were no significant differences for individuals who made RCSC and their rating of therapy alliance. Patients reported significant improvements to weekly rated anxiety and improvements to depression, however these were not significant.

Rate of attrition is consistent with other older adult group CBT research (Stanley et al., 1996; Stanley et al., 2003). Attrition rates in studies of older adults have been found to be higher than younger patients (Gould, Otto, Pollack, & Yap, 1997), this could be due to practical difficulties (e.g. physical illness, lack of transport) reported by older adults as reasons for dropping out of therapy (Wetherell, Gatz & Craske, 2003).

Findings suggested that gender or full attendance at all therapy sessions did not have a significant impact on outcome measures. As previous research considering mixed anxiety and depression used a female only sample (Schimmel-Spreeuw et al., 2000), current findings suggest this is a suitable intervention for both genders. Results suggested that patients referred with mixed anxiety and depression were significantly more anxious, depressed and reported greater psychological distress at assessment, termination and follow up. This supports the notion that individuals with mixed anxiety and depression tend to have greater severity of both disorders, (Schoevers et al., 2003). This encourages the targeted use and evaluation of clinical intervention with this patient group, particularly as there are no known group manualised interventions with older adults addressing both anxiety and depression effectively.

The mean age of the current research (74.8 years) was generally higher than that of existing literature for group CBT with older adults. Only two studies report a higher mean age for group depression interventions of 81.10 years (Konnert et al., 2009; Abraham et al., 1992), and one study for group anxiety of 85 years (Stanley et al., 2003). This research is also the first to consider clinical effectiveness of mixed anxiety and depression group CBT with both genders.

Methodological Critique

There are numerous compromises when collecting data in routine clinical practice (Barkham & Margison, 2007) and therefore results from this research should be interpreted within this context. An obvious limitation is the lack of control comparison group (Corney & Simpson, 2005; Lilienfeld, 2007). This limits the certainty with which improvement can be attributed to the group intervention. As all patients were already in receipt of mental health services, varying degrees of ongoing input from the service occurred before and during the group. Patients were asked about any other mood management (e.g. one to one therapy sessions) or any significant life events (e.g. bereavement) at each time point. This data was not consistently collected, and varied dependent on subjective ratings of other ongoing mental health interventions (such as some patients gave information about community psychiatric nurse visits or luncheon clubs), or subjective ratings of significant life events (such as ongoing family or health problems). It was not possible to ascertain duration of other ongoing mental health interventions if the data was not collected by the Chief Investigator; therefore it was omitted from any analysis. Systematic recording of concurrent interventions and duration of anxiety and depression would have helped ascertain the relationship between improvement in anxiety and depression and the intervention more clearly. The length of follow-up (six weeks) was also very short and may not have been an indication of longer term effects of the group.

Due to a service reconfiguration during the data collection period, it was only possible to recruit 34 patients. The first six groups were run from a day hospital, but as a result of service reconfiguration the day hospital was shut. This impacted the number of referrals and practicalities of attending the group, as transport to the group was no longer available. The last two groups were therefore delivered in the community. Unavailable transport can substantially impact how realistic attendance is for older adult patients (Agronin, 2009). Although the sample size was smaller than was anticipated, in comparison to extant evidence the numbers were not dissimilar.

Outcome measures such as the HADS and HoNOS 65+ were chosen based on the practicality of use within the service, rather than whether they were the most psychometrically sound for this client group. The HoNOS 65+ tended to be completed by different members of staff at all time points, which brings into question the reliability of the data and may explain the relatively small effect sizes. Older adult specific measures of anxiety and depression e.g. Geriatric Anxiety Inventory (Pachana, Byrne, Siddle, Koloski, Harley & Arnold, 2007) and Geriatric Depression Scale (Yesavage et al., 1983) may have been better suited to capture the specific needs of this client group.

From the available data, it is not possible to ascertain which aspects of the group created any change, e.g. psychoeducation or 'being understood by, and understanding others' through the group format (van der Ven, 2003). Also, the lack of competency/model fidelity measure limits how much is known about the intervention delivery. Although facilitators received group supervision with the NHS Supervisor of the research, and completed observer checklists in every session, there was natural variability in the delivery of the Anxiety and Depression Management Manual in terms of how rigidly session content was maintained or possible other variables e.g. the clinical experience of facilitators.

All findings must be considered in the context of the sample size being statistically underpowered. This is particularly pertinent for the repeated measures ANOVA results as the sample number was as low as 19 when considering the session analysis of therapy alliance, anxiety and depression.

Clinical Implications

Overall, this study suggests that the Anxiety and Depression Management Group is a promising clinical intervention. This is an innovative piece of research, from which the clinical implications of the intervention demonstrate potential. As mixed anxiety and depression is a core part of standard clinical work with older adults, an effective group manualised intervention is valuable. The increasing demands on the modern NHS mean that effectively engaging service users via a group intervention is potentially both time and cost effective (Simpson, Carlson & Trew, 2001; van der Ven, 2003). This is particularly pertinent when delivering a low-intensity, short psychoeducational intervention to secondary care mental health service users (NICE guideline 113, 2011). The Anxiety and Depression Management Group is the shortest reported intervention from the literature in this field and also addresses both anxiety and depression, heightening its clinical potential.

The manualised intervention offered skill development for staff members and confidence with regard to CBT knowledge, potentially increasing psychological awareness amongst mental health professionals and promoting a client centred approach.

Future Research

Due to the limited literature investigating CBT groups with older adults, this research provides impetus and avenues for future research. The current study has highlighted the feasibility of conducting further research to develop these preliminary findings. The practicality of delivering group CBT with OAs has raised issues about the

importance of transport and venue to support patient attendance and ultimately obtain a larger sample size. It is important to evaluate the Anxiety and Depression Management Manual using both passive (i.e. TAU) and active (i.e. other psychotherapies) control comparisons. Extant research suggests that the effectiveness of group CBT is less clear when compared to other active conditions (Stanley et al., 1996; Steur et al., 1984; Wetherell et al., 2003; Wilkinson et al., 2009).

Investigations of how group psychological intervention creates both recovery and harm are indicated. Also, longer term follow-up of the group would access durability of clinical change far more effectively.

The Anxiety and Depression Management Manual encourages between session work. Previous research has suggested that better outcomes are associated with greater adherence to homework (Wetherell et al., 2005). Adherence to homework was not formally recorded; however this could be considered in future research. Other information that was not recorded but could be further explored was the onset and duration of mixed anxiety and depression, and systematic consideration of model fidelity/competency to check that the intervention is consistently being delivered.

Clearly, there is a need for more research considering concurrent depression and anxiety management for older adults. Potentially valuable information was missed through using solely quantitative methods. As data was collected (particularly at the follow-up stage), patients gave examples of what they found helpful about the group, and which strategies they were continuing to implement. This may have also provided further insight into those patients classified as recovered or harmed. Therefore, further research could incorporate a qualitative element to data collection.

Finally, the manualised intervention has received positive feedback from different clinical disciplines that have facilitated the groups. There is potential for research to consider how manualised psychological interventions, such as this one,

influence the clinical practice and confidence of using a psychological model (in this case CBT for anxiety and depression) for non psychological professionals.

Conclusions

The current research considered the clinical effectiveness of a six week group CBT intervention with older adults with mixed anxiety/depression. The intervention indicates promising findings with anxiety, depression, psychological well-being and staff observation ratings of patient well-being, all improving following the group intervention. The research highlights the potential clinical advantages of manualised group CBT with older adults. Future more controlled evaluations are indicated to meet the evident needs of this patient group and provide a more credible evaluation of change.

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APPENDIX A

Author, year	Outcome Measure	Is the hypothesis/aim/objective of the study clearly described?	Are the characteristics of the patients included in the study clearly described?	Are the main findings of the study clearly described?	Have actual probability values been reported(e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	Were the statistical tests used to assess the main outcomes appropriate?
Lowe & Reynolds (2006)	AMAS - E	1	1	1	0	0	0	1
Segal et al (2010)	GAS	1	1	1	0	0	0	1
Yochim et al (2011)	GAS	1	1	1	0	0	0	1
Pachana et al (2006)	GAI	1	1	1	1	0	0	1
Byrne et al (2010)	GAI	1	1	1	0	0	0	1
Cheung (2007)	GAI	1	1	0	0	0	0	1
Matheson et al (2012)	GAI	1	1	1	0	0	0	1
Cheung et al (2012)	GAI	1	1	1	1	0	0	1
Byrne & Pachana (2011)	GAI - SF	1	1	1	1	0	0	1
Diefenbach et al (2009)	GWS	1	1	1	1	0	0	1
Hopko et al (2000)	WS	1	1	1	1	0	0	1
Wisocki et al (1986)	WS	1	1	0	1	0	0	1
Hunt et al (2003)	WSOA-R	0	1	1	1	0	0	1
Stanley, Beck & Zebb (1996)	WS	1	1	1	1	0	0	1
Stanley et al (2001)	WS	1	0	1	1	0	0	1
Lowe & Reynolds (2000)	AMAS - E	1	1	1	1	0	0	1
Sinoff et al (1999)	SAST	1	1	1	0	0	0	1

APPENDIX A

Measure		**Reliability**			**Validity**		**Responsiveness**		**Interpretability**					**Practical Burden**	
		Internal Consistency (α)	Test-retest (*Pearson's r)*	Inter-rater *(Pearson's r)*	Convergent *Significant Intercorrelations (r)*	Discriminant *Correlations (r)*	Sensitivity *%*	Specificity *%*	Domains	No. Of Items	No. of Response Options	Range of Scores	Cut off scores	Time taken to complete (mins)	Complexity of scoring

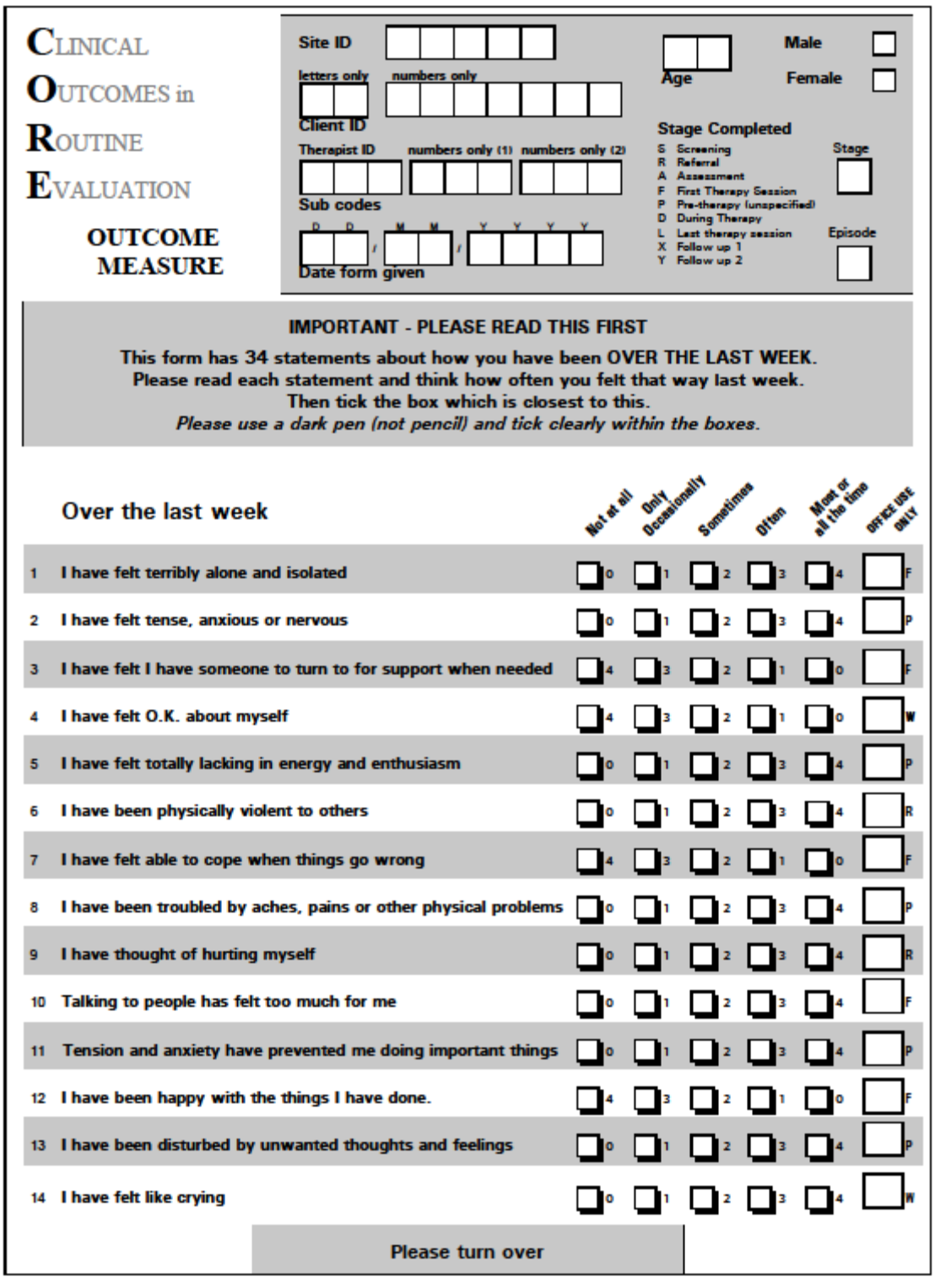
APPENDIX B

Appendix B1

Hospital Anxiety and Depression Scale removed to ensure conformance with copyright legislation.

APPENDIX B

Appendix B2



CLINICAL OUTCOMES in ROUTINE EVALUATION

OUTCOME MEASURE

Site ID

letters only

numbers only

Client ID

Therapist ID

numbers only (1)

numbers only (2)

Sub codes

D D / M M / Y Y Y Y

Date form given

Age

Male

Female

Stage Completed

S Screening
R Referral
A Assessment
F First Therapy Session
P Pre-therapy (unspecified)
D During Therapy
L Last therapy session
X Follow up 1
Y Follow up 2

Stage

Episode

IMPORTANT - PLEASE READ THIS FIRST

This form has 34 statements about how you have been OVER THE LAST WEEK.
Please read each statement and think how often you felt that way last week.
Then tick the box which is closest to this.
Please use a dark pen (not pencil) and tick clearly within the boxes.

	Over the last week	Not at all	Only Occasionally	Sometimes	Often	Most or all the time	OFFICE USE ONLY
1	I have felt terribly alone and isolated	0	1	2	3	4	F
2	I have felt tense, anxious or nervous	0	1	2	3	4	P
3	I have felt I have someone to turn to for support when needed	4	3	2	1	0	F
4	I have felt O.K. about myself	4	3	2	1	0	W
5	I have felt totally lacking in energy and enthusiasm	0	1	2	3	4	P
6	I have been physically violent to others	0	1	2	3	4	R
7	I have felt able to cope when things go wrong	4	3	2	1	0	F
8	I have been troubled by aches, pains or other physical problems	0	1	2	3	4	P
9	I have thought of hurting myself	0	1	2	3	4	R
10	Talking to people has felt too much for me	0	1	2	3	4	F
11	Tension and anxiety have prevented me doing important things	0	1	2	3	4	P
12	I have been happy with the things I have done.	4	3	2	1	0	F
13	I have been disturbed by unwanted thoughts and feelings	0	1	2	3	4	P
14	I have felt like crying	0	1	2	3	4	W

Please turn over

Survey : 151

APPENDIX B

Appendix B2

Over the last week	Not at all	Only Occasionally	Sometimes	Often	Most or all the time	OFFICE USE ONLY
15 I have felt panic or terror	0	1	2	3	4	P
16 I made plans to end my life	0	1	2	3	4	R
17 I have felt overwhelmed by my problems	0	1	2	3	4	W
18 I have had difficulty getting to sleep or staying asleep	0	1	2	3	4	P
19 I have felt warmth or affection for someone	4	3	2	1	0	F
20 My problems have been impossible to put to one side	0	1	2	3	4	P
21 I have been able to do most things I needed to	4	3	2	1	0	F
22 I have threatened or intimidated another person	0	1	2	3	4	R
23 I have felt despairing or hopeless	0	1	2	3	4	P
24 I have thought it would be better if I were dead	0	1	2	3	4	R
25 I have felt criticised by other people	0	1	2	3	4	F
26 I have thought I have no friends	0	1	2	3	4	F
27 I have felt unhappy	0	1	2	3	4	P
28 Unwanted images or memories have been distressing me	0	1	2	3	4	P
29 I have been irritable when with other people	0	1	2	3	4	F
30 I have thought I am to blame for my problems and difficulties	0	1	2	3	4	P
31 I have felt optimistic about my future	4	3	2	1	0	W
32 I have achieved the things I wanted to	4	3	2	1	0	F
33 I have felt humiliated or shamed by other people	0	1	2	3	4	F
34 I have hurt myself physically or taken dangerous risks with my health	0	1	2	3	4	R

THANK YOU FOR YOUR TIME IN COMPLETING THIS QUESTIONNAIRE

Total Scores

Mean Scores
(Total score for each dimension divided by number of items completed in that dimension)

(W) (P) (F) (R) All items All minus R

Survey : 151 Page : 2

APPENDIX B

Appendix B3

Health of the Nation Outcome Score 65+ score sheet removed to ensure conformance with copyright legislation.

APPENDIX B

Appendix B4

Group Session Rating Scale removed to ensure conformance with copyright legislation.

Sheffield Health and Social Care NHS
NHS Foundation Trust

The effectiveness of group psychoeducational CBT for mixed anxiety and depression in older adults: A feasibility study

Information Sheet

Anxiety and depression are common mental health difficulties. It would be very useful to understand what helps with managing these difficulties. We would like to know whether the anxiety and depression management group we run is helpful. This will mean services can adapt in the future and improve what is offered to be what is needed. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

"Why do this study?"
The study aims to find out what type of help is useful for people over the age of 65 to manage their anxiety and depression. This will help us ensure the service we provide is appropriate for you and others. This is a 'feasibility study' which means it is an initial study to look at what is helpful before any future research in this area is planned.

"Why have I been chosen?"
You have been identified as someone who may benefit from attending the anxiety and depression management group. The study aims to have 41 participants in total in order to get enough information about the group.

"What is the anxiety and depression management group?"
The group is for two hours per week for six weeks and is an opportunity to meet other people who may be dealing with similar difficulties. The group is led by members of staff who work in the NHS Trust, and is a way of looking at ways to manage depression and anxiety.

"Does this affect my other care, for example my medication or other appointments?"
No. Everything continues as usual.

"Do I have to take part?"
Taking part is completely voluntary. Your healthcare will not be affected in any way if you decide to not take part.
If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form).

"What if I change my mind?"

You can withdraw at any time from the research without it affecting any of your care. You do not have to give a reason. If you decide to stop attending the group sessions, this would also be your choice and would not affect the rest of your healthcare in any way.

"What does taking part in the study involve?"

Completing some questionnaires about your mental health difficulties. These should take about half an hour, and you will be asked to complete these three times (once before attending the group, once immediately after and a final time six weeks after the group has ended). The anxiety and depression management group runs for six weeks and you will be given details of the dates of which group you can attend.

"What are the benefits of taking part?"

You can attend the anxiety and depression management group regardless of whether you decide to take part in this research. If you do take part, it will help give us information about how our services can be improved.

"What are the possible risks of taking part?"

The anxiety and depression management group asks you to think about the different ways anxiety and depression affects your life, this may sometimes be upsetting. You will not be asked to do anything that you do not consent to and the members of staff that facilitate the group will be there to support you. It will take about half an hour per time to fill out the questionnaires. This can be arranged for a time that is suitable for you and if at any time you feel you do not wish to continue taking part in the research you can withdraw without giving a reason.

"Will the information collected in the study be confidential?"

Yes, all information will be kept confidential. Your name or personal information will not be mentioned in any reports of the study. If you would like to be informed of the results of the study please mention this to your clinician. One of the researchers may contact you to arrange to help you fill in the questionnaires if this is needed, however all information will be confidential.

"What if I have further questions?"

Please call 0114 2226650 and leave a message for Manreesh Bains (Trainee Clinical Psychologist) who will call you back as soon as possible.

"What if something goes wrong?"

Please contact the chief investigator, Manreesh Bains on 0114 2226650 and leave a message to be contacted back. This study is being sponsored and indemnified by the University of Sheffield. If you feel your concerns are not being dealt with, you can contact the University Secretary on 0114 2226649.

Thank you for taking the time to read this information.

APPENDIX C

Appendix C2

Sheffield Health and Social Care NHS
NHS Foundation Trust

The effectiveness of group psychoeducational CBT for mixed anxiety and depression in older adults: A feasibility study

Name of Researcher: Manreesh Bains

Participant Identification Number for this project:

Please tick box

1. I confirm that I have read and understand the information sheet dated 27th May 2011 explaining the above research project and I have had the opportunity to ask questions about the project. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline. ☐

3. I understand that my responses will be kept strictly confidential. I give permission for members of the research team to have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research. ☐

4. I agree for the data collected from me to be used in future research ☐

5. I agree to take part in the above research project. ☐

_____	_____	_____
Name of Participant	Date	Signature

_____	_____	_____
Name of person taking consent	Date	Signature

To be signed and dated in presence of the participant

Manreesh Bains _____	_____	_____
Lead Researcher	Date	Signature

APPENDIX D

The Anxiety and Depression Management Manual removed to ensure conformance with copyright legislation.

APPENDIX E

Appendix E1

Observation checklists removed to ensure conformance with copyright legislation.

APPENDIX E

Appendix E2

Adverse Incident/Complaint Form (Psychology Version)

for health care research projects that the University of Sheffield is the research governance sponsor of

This report form is for use if and when an adverse event incident occurs or a complaint is made relating to a health care research project where the University is the research governance sponsor. It should be completed by the Principal (or Chief) Investigator of the project and agreed with the Chair of the Ethics Committee or if a Clinical Unit project with the Director of Research Training. It will then be discussed with the Head of Department.
Guidance notes are included at the end of the report form (boxes on the form can be expanded).

1. Research Project Title:	The effectiveness of group psychoeducational CBT for mixed anxiety and depression in older adults: A feasibility study
2. 6 digit URMS number (if applicable):	131005
3. Principal/Chief Investigator:	Manreesh Bains
4. Supervisor/s:	Stephen Kellett & Shonagh Scott
5. Who initially discovered the adverse event/Complaint?	
6. When was the adverse event/complaint reported to the Principal/Chief Investigator?	
7. When was the adverse event/complaint reported to the Head of Department/School?	
8. When did the adverse event/complaint actually occur?	
9. Where did it happen?	

10. What actually happened and what was the impact of the adverse event/complaint?
11. Why did the adverse event/complaint occur?
12. Describe what action(s) have been taken to address the impact of this specific adverse event/complaint:

13. Describe what action(s) have been taken or are planned to limit the risk of a similar event/complaint re-occurring (add any general notes here to qualify the information given elsewhere in the report):	
Agreed and authorised by:	
Name of Principal/Chief Investigator: *Manreesh Bains* Signature:	Date: *insert date here*
Name of Head of Chair of Ethics Committee/Director of Research Training: *Insert name here* Signature:	Date: *insert date here*

Guidance Notes:

1.
Adverse events/complaints should be reported to the Head of Department/School as soon as possible and normally within 5 working days. If the time exceeds this, this should be a consideration in 13.

2.
Once complete, this report should be kept in the project's site file for reference and a copy sent to Research and Innovation Services, New Spring House, 231 Glossop Road marked for the attention of the Head of the Planning and Business Support Section (Mrs Deborah McClean).

3.

Advice and guidance on completion of the report, analysis of the event and potential actions can be obtained from Research and Innovation Services (Lauren Smaller: ext. 21400).

4.
An 'adverse event' is an unexpected event that includes, but is broader than, unintended errors and mistakes which arise as a result of research activity and result in one or more research participants having symptoms or being caused physical or psychological harm or serious distress.

Examples of this include:

- A human participant has an adverse reaction to a drug treatment, the use of which had been approved by a Research Ethics Committee.
-
- An invasive instrument is used incorrectly, the use of which had been approved by a Research Ethics Committee, and the human participant suffers harm or has an extended stay in hospital.
- A human participant is asked a series of questions regarding his/her sex life, a line of questioning that a Research Ethics Committee approved. However, for the interviewee, the questions revive

painful memories of being abused as a child and the interviewee suffers serious distress such as to warrant therapy.

5.

A ‘complaint’ is any approach made by a research participant to the researcher, their supervisor or collaborator with respect to the conduct of the study

APPENDIX F

Appendix F1

NRES Committee North East - Northern & Yorkshire
Room 002
TEDCO Business Centre
Viking Business Park
Rolling Mill Road
Jarrow, Tyne & Wear
NE32 3DT

Telephone: 0113 4283545
Facsimile: 0191 4283432

21 June 2011

Miss Manreesh Bains
Trainee Clinical Psychologist
Sheffield Health & Social Care NHS Trust
Clinical Psychology
University of Sheffield
Western Bank
S10 2TN

Dear Miss Bains

Study title:	**The efficacy of group psychoeducational CBT for mixed anxiety and depression in older adults: A feasibility study**
REC reference:	**11/NE/0135**
Protocol number:	**131005**

Thank you for your letter of 27 May 2011, responding to the Committee's request for further information on the above research.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

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

Ethical review of research sites

NHS sites

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

Non-NHS sites

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

Conditions of the favourable opinion

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

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

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

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

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

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

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

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).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter		11 April 2011
Covering Letter		27 May 2011
Evidence of insurance or indemnity		16 March 2011
Evidence of insurance or indemnity		02 June 2011
Investigator CV		
Letter from Sponsor		16 March 2011
Other: CV - S Kellett (supervisor)		
Other: CV - S Scott (supervisor)		
Other: The Anxiety & Depression Management Group Leaflet	1	21 February 2011
Other: Demographic collection sheet	Version 2	27 May 2011
Other: Adverse incident form		
Participant Consent Form	Version 3	27 May 2011
Participant Information Sheet	2	21 February 2011
Participant Information Sheet	Version 3	27 May 2011
Protocol	Version 3	27 May 2011
Questionnaire: HADS, CORE-OM, HONOS 65+, GSRS (Validated)		
REC application	1	05 April 2011
Referees or other scientific critique report		16 April 2011
Response to Request for Further Information		

APPENDIX F

Appendix F1

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

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

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
Progress and safety reports
Notifying the end of the study

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

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

11/NE/0135	**Please quote this number on all correspondence**

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

Yours sincerely

pp

Professor Peter Heasman
Chair

Email: kerri.jude@sotw.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Mr. Richard Hudson, The University of Sheffield, Research and Innovation Services, Academic Services, Sheffield, S10 2GW*

Ms Yiwei Harland, Research Development Unit, Fulwood House, Old Fulwood Road., Sheffield, S10 3TH

APPENDIX F

Appendix F2

Sheffield City Council

Sheffield Health and Social Care

NHS Foundation Trust

NHS

Medical Directorate

Research Development Unit
Fulwood House
Old Fulwood Road
Sheffield
S10 3TH

Tel: 0114 2718804
Fax: 0114 2716736
E-mail: shsrc@shsc.nhs.uk
www.shsc.nhs.uk

20 April 2011

Miss Manreesh Bains
Trainee Clinical Psychologist
Clinical Psychology
University of Sheffield
Western Bank
Sheffield S10 2TN

Dear Miss Bains

Project Reference: ZM73

Full Project Title: The efficacy of group psychoeducational CBT for mixed anxiety and depression in older adults: A feasibility study

I can confirm on behalf of Sheffield Health and Social Care NHS Foundation Trust that you now have NHS Permission to start research as described in documentation you have supplied to us, **subject to a favourable opinion from an NHS REC. Copies of favourable opinion should be forwarded to this office. Should an unfavourable opinion be received from the REC, then we should wish to receive the relevant correspondence including any reply you make.**

We also advise you of the following conditions which apply to all given NHS Permission to start research through this office:

1. **Please inform us of the actual project start date immediately you do start and at that time inform us also of the expected end date.**
2. In order to comply with the NHS Research Governance Framework, please copy this office into all future project monitoring forms that you send to the relevant Research Ethics Committee, including the "Declaration of End of Study".
3. We recommend the attached format for maintenance of your project site file to ensure all documentation is readily accessible.
4. You will also need to seek approval for every future change to protocol or project title and I suggest you do this by sending us a draft of the submission you will also have to make to the NHS REC and that you do so at the same time as that submission to the REC. See the following web reference for details: http://www.nres.npsa.nhs.uk/applications/after-ethical-review/notification-of-amendments/
5. We recommend the attached amendment log in order to track amendment submissions to, and approvals from, the relevant REC and R&D office(s)
6. As Chief Investigator, you have an obligation to report all research-related Serious Adverse Events (SAEs) directly to this office.

APPENDIX F

Appendix F2

7. As Chief Investigator, you are reminded of your obligations in relation to the Mental Capacity Act 2005. See the following web reference for details: www.rdforum.nhs.uk/docs/mca_guidance.doc

8. You are reminded to familiarise yourself with our partner organisation(s) Information Governance policies and procedures regarding the storage of patient-identifiable data

9. You need to seek approval from this office for any additions to your research team not already included in documentation sent to us. For this purpose, please send a short CV, preferably in the format required by the NHS REC.

10. This Research Governance approval is given on the understanding that the findings of the research will be appropriately disseminated in peer-reviewed journal(s) and to research participants and any organisations representing their interests.

We wish you every success with the project and please feel free to contact us if you need further assistance from this office.

Yours sincerely

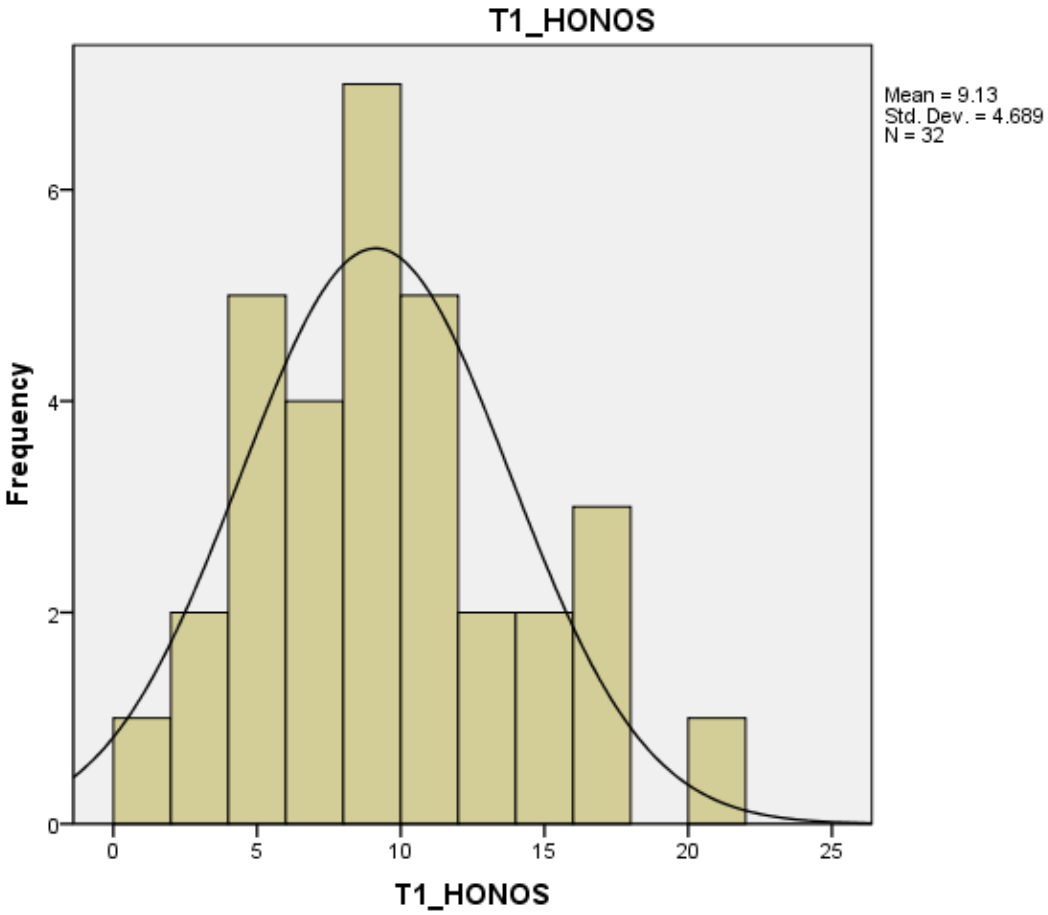
Nick Bell
Acting Director

Enc Site File Guidance
Amendment Log

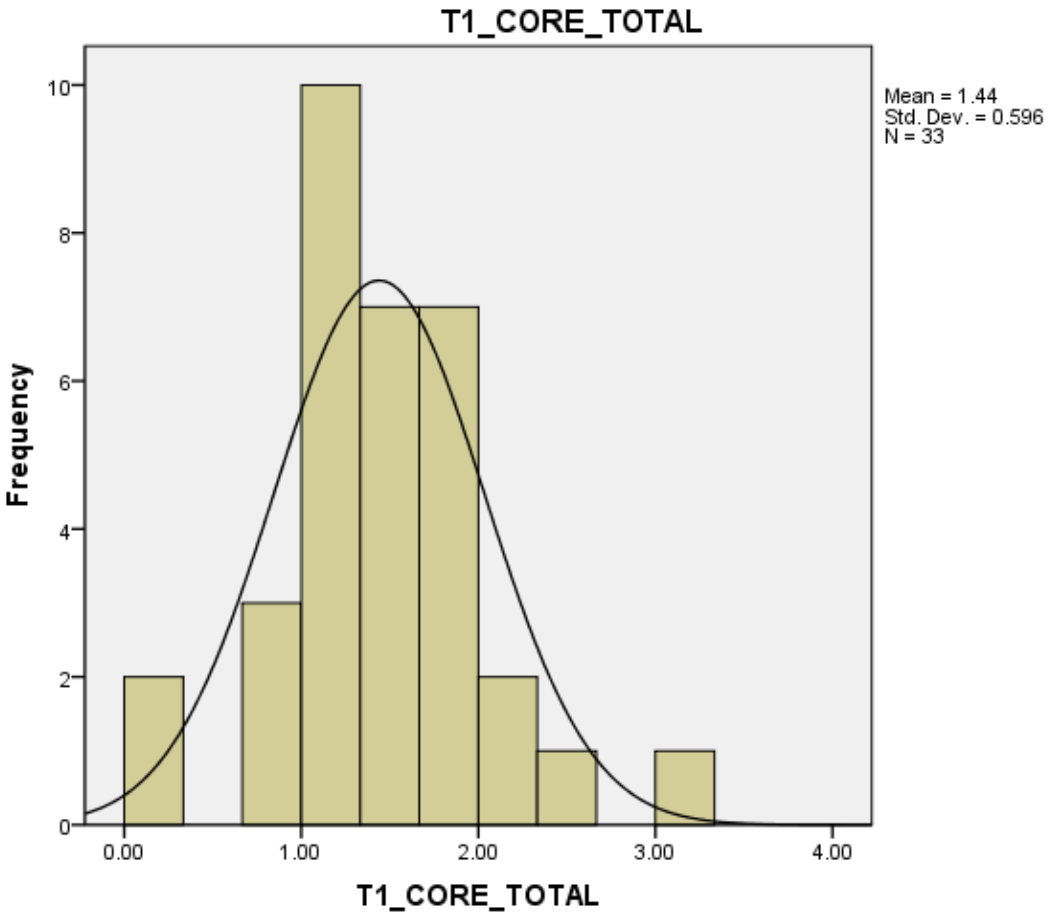
Cc Project File

Statistics

		T1_HONOS	T1_CORE_TOTAL	T1_HADS_A	T1_HADS_D
N	Valid	32	33	34	34
	Missing	2	1	0	0
Mean		9.13	1.4394	10.82	9.15
Median		9.00	1.3800	12.00	8.50
Std. Deviation		4.689	.59636	5.202	4.487
Variance		21.984	.356	27.059	20.129
Skewness		.547	.446	-.411	.011
Std. Error of Skewness		.414	.409	.403	.403
Kurtosis		.029	1.232	-.604	-.165
Std. Error of Kurtosis		.809	.798	.788	.788



APPENDIX G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Std. Dev. = 0.596
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Frequency
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4
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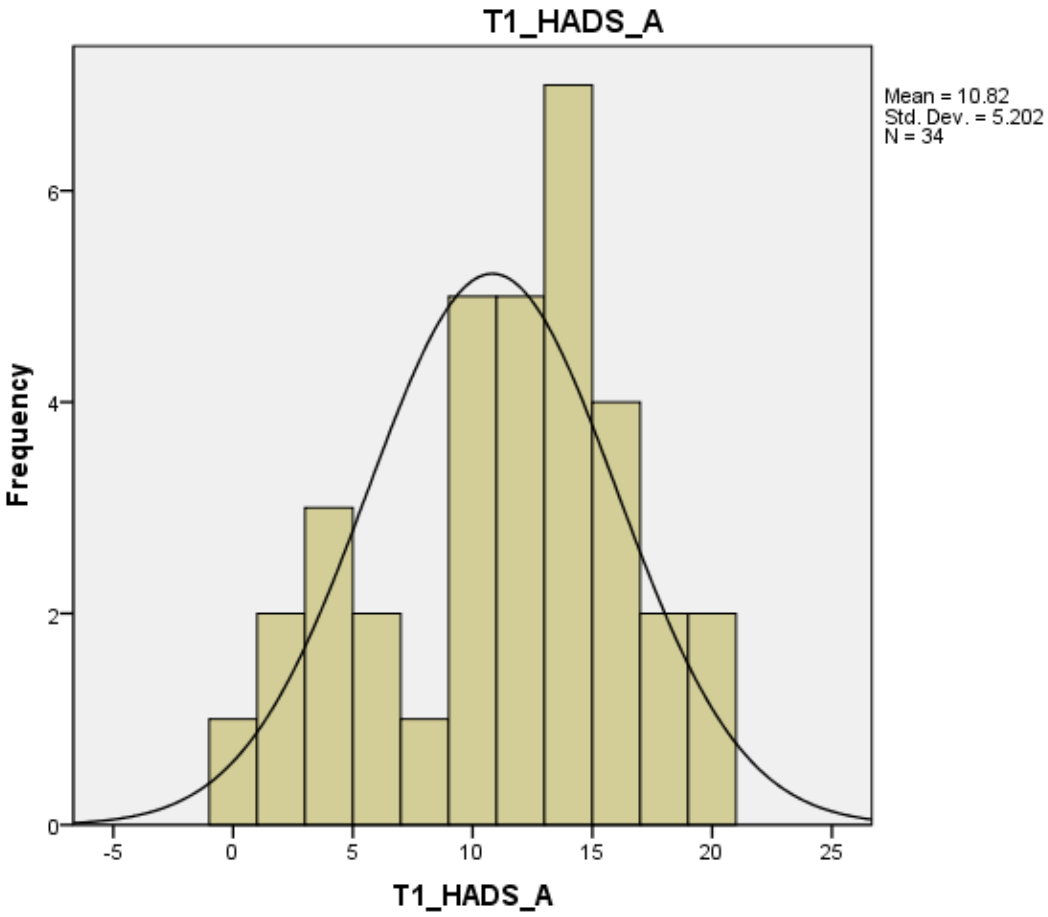
2.00
3.00
4.00
T1_CORE_TOTAL

APPENDIX G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4
6
-5
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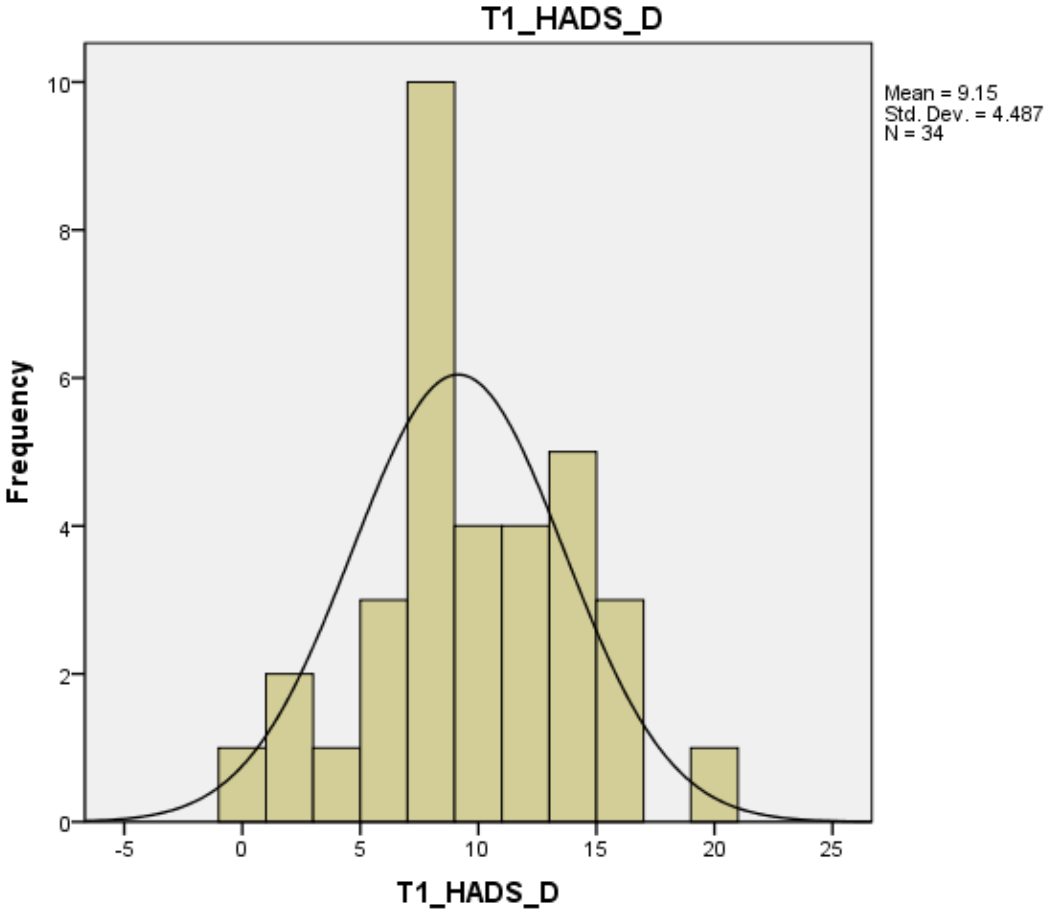
5
10
15
20
25
T1_HADS_A

APPENDIX G


T1_HADS_D
Mean = 9.15
Std. Dev. = 4.487
N = 34
Frequency
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2
4
6
8
10
-5
0
5
10
15
20
25
T1_HADS_D