

Exploring
Stepping-up in a Stepped Care Model
of Service Delivery

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Doctorate in Clinical Psychology

Declaration

**I declare that this work has not been submitted for any other degree or to
any other institution.**

Structure and Word Counts.

Literature Review: Do Individual Characteristics Predict Outcome in Low Intensity Psychological Interventions for Adults with Anxiety and/or Depression?

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Abstract

This thesis adds to the literature on stepping-up which is a defining feature of the proposed stepped care model for delivering psychological therapies in primary care. A literature review synthesises primary studies which investigate potential predictors of outcome following Low Intensity Psychological Interventions (LIPI) for people with anxiety and/or depression. It is concluded that the limited literature is methodologically weak and that data collected in routine clinical practice is required to investigate this area further.

The research report explores stepping-up from LIPI to CBT within the UK pilot site for the stepped care model. Using routinely collected data from this site, Study 1 found that people who were stepped-up did not differ significantly in assessment characteristics or their outcomes compared to those who received only LIPI or CBT. Also, stepping-up cannot be predicted from the assessment variables currently collected by this service. In Study 2 eleven people who had been stepped-up were interviewed about their service experience. Using Interpretative Phenomenological Analysis five super-ordinate themes emerged along with a common process of making sense of the experience of stepping-up. Together these studies suggest that stepping-up can produce acceptable outcomes and the experience of stepping-up is affected by other aspects of the service. Further research is required to explore the outcomes and experiences of service users in relation to the different reasons for stepping-up which emerged in these studies. It is also suggested that the therapeutic alliance may be an important factor to investigate in relation to LIPI and their outcomes.

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Section 1: Literature Review

Do Individual Characteristics Predict Outcome in Low Intensity Psychological Interventions for Adults with Anxiety and/or Depression?

Abstract

This literature review locates, appraises and synthesises primary studies which examine individual characteristics that predict outcome following a range of Low Intensity Psychological Interventions. This is pertinent to the current development of stepped care models of service delivery in primary care and to the development of Low Intensity Psychological Interventions. Twelve studies were included in the review. Overall, their quality meant that firm conclusions about common predictor variables could not be made. These methodological limitations are discussed along with synthesising the findings of the studies in relation to different categories of predictors. It is suggested that utilising data collected in routine clinical practice may yield more useful information about outcome predictors in the future.

1. Introduction

1.1 Improving Access to Psychological Therapies and Stepped Care

Since the publication of the National Service Framework (NSF) for Mental Health (Department of Health, 1999), Improving Access to Psychological Therapies (IAPT) for those with mild to moderate common mental health problems, such as anxiety and depression, has been a theme in research, policy and service development. It is acknowledged that increasing access to therapy requires more than simply increasing the number of trained therapists (Lovell & Richards, 2000). The focus since the NSF has been on developing psychological interventions that range in intensity in terms of therapist time and level of training. Examples of Low Intensity Psychological Interventions (LIPI) include; guided self-help, bibliotherapy, case management and computerised self-help. The commitment to IAPT was confirmed in national guidance for anxiety and depression which recommended Cognitive Behavioural Therapy (CBT) administered through guided self-help, computerised CBT (CCBT) and standard one-to-one CBT (NICE, 2004a, 2004b). This guidance suggested a graduated approach to service delivery known now as “stepped care” (NICE, 2004a; 2004b).

The principle of stepped care is that the least restrictive/lowest intensity treatment likely to result in a significant improvement is provided initially, with people being “stepped-up” to a more intensive treatment via a self correcting mechanism (Bower & Gilbody, 2005, p. 11). In theory, such systems provide low intensity treatments to the majority of people with the more intensive specialist treatments reserved for those who do not benefit (Bower & Gilbody, 2005).

1.2 Aim and Rationale

The aim of this literature review is to locate, synthesise and appraise the research evidence on individual characteristics that may predict the outcome of LIPI for anxiety and depression in adults. This is pertinent for a number of reasons. Firstly, this has been highlighted as a gap in the literature by a number of authors who feel it is important to be able to select people for LIPI on the basis of suitability (e.g. Papworth, 2006; Williams & Martinez, 2008). Secondly, in the proposed stepped care models of service delivery, the decision to step-up is based on a lack of symptom improvement with access to a LIPI (Bower & Gilbody, 2005). It is potentially economically and clinically valuable to identify those who are unlikely to benefit from lower steps so they can be offered quicker access to a higher step.

Finally, identifying characteristics of those who do not improve significantly with LIPI could inform the development of these treatments to increase both their accessibility and effectiveness. Gulliford et al. (2002) argue that *access* to interventions goes far beyond availability and waiting times which are clearly driving forces in the development of LIPI. Access includes concepts such as patients' ability to *utilise* available services when they need them and these services being *appropriate* to their needs. LIPI have reported pooled effect sizes of 0.80 for guided self-help, 0.43 when studies of guided and non-guided self-help are combined (Gellatly, et al., 2007), and 0.65 for CCBT (NICE, 2006). This indicates that LIPI are effective for some but there are a significant proportion of people who do not benefit. It is unclear who these people are and why these interventions do not bring about change for them. It may be that, in Gulliford et al.'s (2002) terms, they are unable to fully

access the intervention in some way if this is the case then understanding who this group is may develop these interventions further.

1.3 Predictors of Outcome in Traditional Therapy

There is existing literature regarding predictors of outcome following traditional psychological therapies which is useful to consider in relation to this review. The most robust finding is that irrespective of therapeutic approach “common factors”, such as the therapeutic alliance, extensively mediate treatment outcomes (Lambert & Ogles, 2004; Martin, Garske, & Davies, 2000; Wampold, 2001). In terms of client specific predictors of outcome, Asay and Lambert’s review (2006) acknowledges methodological flaws in this area but suggests that consistent client predictors of therapy outcome are; baseline symptom severity, motivation, accepting personal responsibility, and coping styles (p. 43). Given that the majority of LIPI are based on CBT, specific predictors of outcome in traditional CBT are of interest. Hamilton and Dobson (2002) reviewed this literature and found that pre-treatment severity of depression was associated with outcome, those with chronic depression benefit from more intense therapy and being in a relationship predicted positive outcome. These authors suggest that the prediction literature is of poor quality and it is difficult to draw conclusions (Hamilton & Dobson, 2002). A similar review relating to anxiety disorders was not found.

Other types of study have linked symptom severity and outcome. A meta-regression that examined CBT for depression, panic disorder and generalised anxiety disorder found that the heterogeneity in outcomes was accounted for by the severity of symptoms (Haby,

Donnelly, Corry, & Vos, 2006). Lambert et al. (2003) found pre-treatment symptom severity and early response to treatment to be the most effective predictors of outcome.

2. Search Strategy

2.1 Scoping Search

Given the increased interest in stepped care over the last 10 years, it was hypothesized that systematic reviews, meta-regression and meta-analyses regarding LIPI for anxiety and depression may include information regarding individual predictors of outcome. A scoping search of the Cochrane Database of Systematic Reviews and the NHS Centre for Reviews and Disseminations was conducted in March 2009. None of the 47 reviews and meta-analyses contained information pertinent to the current question despite the good methodological quality. They focused on explaining the heterogeneity in the effect sizes through study variables such as the amount of therapist contact and number of sessions. Although meta-analyses are useful in determining the effectiveness of interventions, they say little about how individual variables might influence outcome. Therefore, this review located primary studies concerning predictors of outcome in LIPI for anxiety and depression.

For the purpose of this review, LIPI are defined as any psychological intervention where the onus is on the patient to read/do the majority of the intervention work. Sessions with professionals should be less than 50 minutes in duration and not exceed a total of 4 hours support. Given the paucity of research into outcome predictors in traditional psychological interventions it was predicted that few studies would be located. Therefore studies predicting the outcome of psychoeducational group interventions were also included.

2.2 Databases and Search Terms

The following databases were searched in April 2009;

- Cochrane Library
- NHS Centre for Reviews and Dissemination
- OVID (to search AMED (1985-), Ovid MEDLINER(R) In Progress & Other non-indexed Citations and Ovid MEDLINE(R) (1950-), PsychINFO (1967-))
- Web of Knowledge (WOS with conference proceedings (1900-), MEDLINE (1950-), BIOSIS review (1985-), Journal citation reports (2004-2007))

The following terms were used in a search of the title, keywords and abstract fields;

1. Predict*
2. Prognosis
3. Factor
4. Associat*
5. #1 OR #2 OR #3 OR #4
6. Outcome
7. "drop out"
8. Attrition
9. Improve*
10. Effective*
11. Benefit
12. Success
13. Fail*
14. #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13
15. Depress*
16. Dysthymi*
17. Mood

18. Anxi*
19. Panic
20. Phobi*
21. GAD
22. Agoraphobi*
23. #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22
24. "Self help"
25. Bibliotherapy
26. Psychoeducation
27. CCBT
28. (Computer* OR Internet OR web) AND (psycholog* OR psychotherap* OR therapy OR CBT)
29. "Case management"
30. "Condition management"
31. "Care management"
32. (brief OR "low intensity" OR "short term" OR "minimal") AND (psycholog* OR psychotherap* OR therap*)
33. #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32
34. #5 AND #14 AND #23 AND #33
35. "Stepped Care" AND #23.

2.3 Study Selection

Studies were selected based on the inclusion and exclusion criteria below. Where there was a query regarding the title, the abstract and then the full text of an article was retrieved in

order to assess whether studies met these criteria. The reference lists of included studies were searched to identify further studies of interest. The search was not limited by language. Authors of non-English articles were contacted and an English version was retrieved where possible.

2.3.1 Inclusion Criteria

The studies were included if they contained the following characteristics;

- Adults (age 18-65),
- Depression and/or anxiety disorders,
- Primary care population,
- LIPI
 - Psychological component to intervention e.g. self-help manual, self-exposure.
 - Sessions that last less than 50 minutes
 - Total therapeutic input less than or equal to 4 hours
 - Group treatment where the input is less than 4 hours per person and the focus is on psychoeducation.

2.3.2 Exclusion Criteria

Studies were excluded if they contained the following characteristics;

- Children and adolescents (<18), older people (>65),
- Inpatient populations,
- Studies where the main intervention is medication,
- Interventions that target co-morbid mental health problems with people who have health conditions (e.g. depression in cancer patients),
- High intensity interventions,

- 5 or more 50-60 minute sessions
- total therapeutic input greater than 5 hours
- group psychotherapy.

2.4 Search Results

Figure 1 illustrates the exclusion of studies from those retrieved. The search identified 12 studies which are summarised in Table 1. Some of these studies involved high intensity interventions but are included as they also examine a LIPI condition. Four focused on people with depression, six on anxiety disorders and two on mixed anxiety and depression. All but one study used CBT based interventions with Hegal, Barrett, Cornell and Oxman (2002) investigating a problem solving treatment. Five studies investigated outcomes following a computerised intervention, four investigated a guided self-help manual, four investigated a non-guided self-help manual and four investigated a group treatment.

Figure 1: Flow Diagram of Study Inclusion and Exclusion

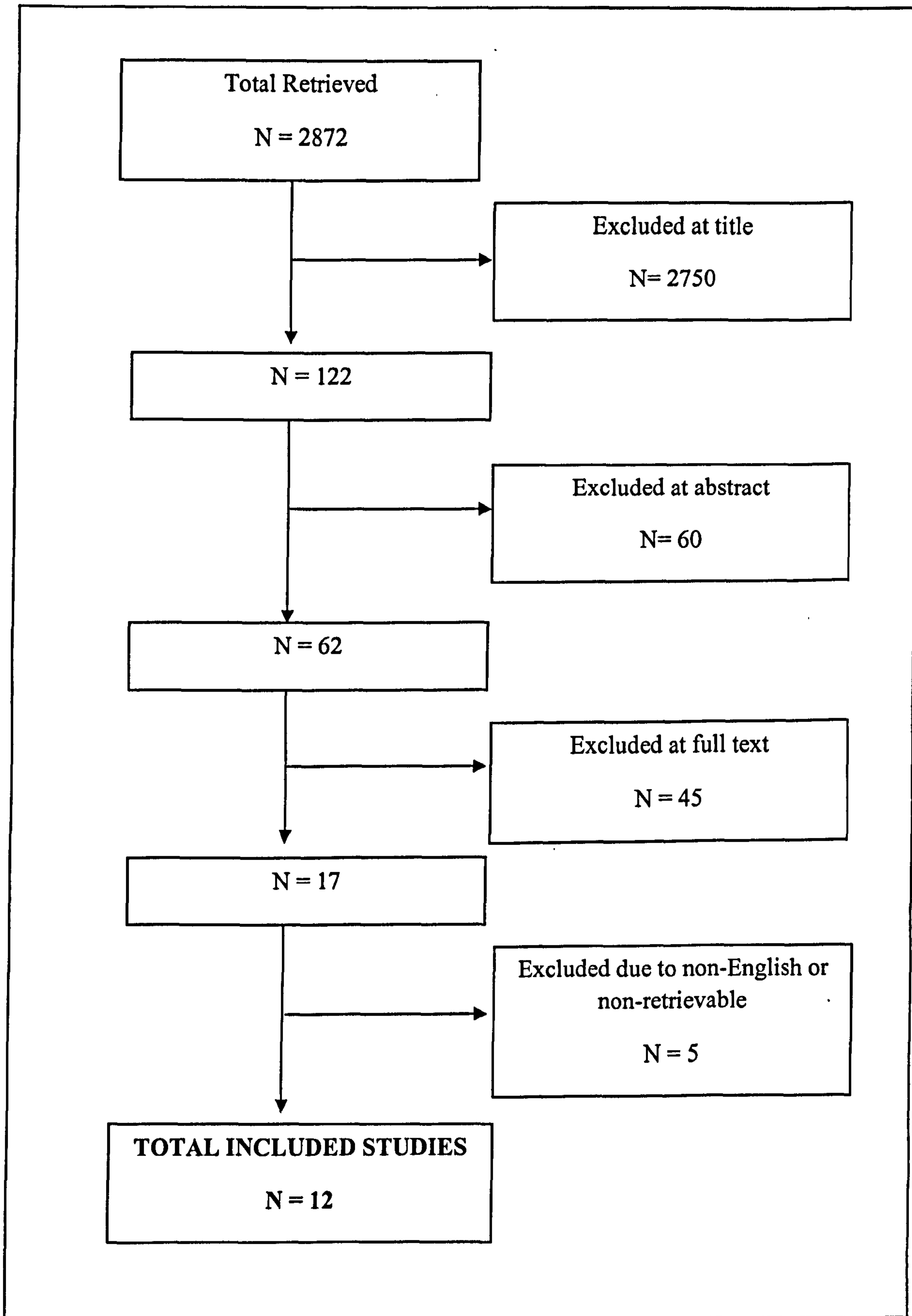


Table 1: Summary Table of Studies Included In Literature Review

Authors	Population	Treatment	Dependent variables	Predictors/Independent variables	Analyses	Results
Andersson, Bergström, Holländare, & Ekselius, & Carlbring (2004)	N = 71 Mild to moderate depression (15-30 on MADRS)	Web-based CBT self-help manual + access to internet discussion forums [Therapist Contact via email = ? time] (N=71)	1. Change index on BDI and MADRS (Assessment and Post-treatment) 2. BDI and MADRS at 6-month follow-up	1. Pre-treatment age, gender, education, episodes of depression, anxiety (BAI), quality of life (QOLI), depression (BDI) 2. Pre-treatment depression (BDI, MADRS) anxiety (BAI), quality of life (QOLI)	Standard Multiple Regression	1. No. previous episodes of depression predict poorer outcome on BDI (t = -2.1, p = 0.05, beta = -0.25). 2. BDI model significant (p = 0.008) Significant predictors alone were QOLI (-ve predictor; t = -2.1, p = 0.05, beta = -0.29) and BAI (+ve predictor; t = 2.4, p = 0.05, beta = 0.29)

Table 1 Continued Over

Authors	Population	Treatment	Dependent variables	Predictors/Independent variables	Analyses	Results
Andersson, Carlbring, & Grimlund (2008).	N = 49 Panic disorder	-CBT [Therapist time = upto 10 hours] (N = 24) -Internet CBT Guided self help manual [Therapist contact via email = ? time] (N = 25)	Residual gain scores ACQ & BSQ at post-treatment & 1 year follow-up	Agoraphobic avoidance (MI-A), verbal fluency (COWAT), perceived treatment credibility, personality disorder (SCID-C)	Standard Multiple Regression	All regression models statistically significant in face-to-face condition (p<0.05). Internet group no model statistically significant. Higher rating for personality disorder statistically sig. and negatively associated with outcome on the ACQ.

Table 1 Continued Over

Authors	Population	Treatment	Dependent variables	Predictors/Independent variables	Analyses	Results
Baillie & Rapee (2004)	N = 117 Panic attacks	Stepped-care model (Stepped up if not achieved CSC) (N=117) 1. Psychoeducational book [Therapist input = 0] 2. Stepped up to self-help workbook [Therapist input = 0] 3. 2 hour group sessions CBT [Therapist input = upto 10 hrs]	General Mental Health (SF12MCS); Composite score of PDA severity and rate of change; made up of panic symptoms on CIDI, Anxiety scale from DASS21, MIA-A, Agoraphobia and Interceptive fear Scales on APPQ Measured at assessment, 6 weeks, 4.5 months, 9 months	Gender, formal education, propensity to read, age at onset, duration, depression, social phobia, anxiety, neuroticism, alcohol use, motivation, PDA composite and general mental health at baseline.	Random Regression Models	Severity PDA -vely predicted by social phobia (p=0.0013) and general mental health (p=0.0001) Age of onset (p=0.001), neuroticism (p<0.0001), PDA symptoms (p<0.0001) and alcohol use (0.0002) -vely predict general mental health

Table 1 Continued Over

Authors	Population	Treatment	Dependent variables	Predictors/Independent variables	Analyses	Results
Buwalda & Bouman (2008)	N = 123 Hypochondria sis	CBT group [Therapist input = 12 hours over 6 weeks. N=5-8 per group: max=2.5 hrs per person]	Residual gain score Severity of hypochondriasis (GIAS) Pre-post Pre-6month follow up Post- 6months follow-up	Depression (BDI), trait Anxiety (STAI), age, education, gender, duration of illness, treatment expectancy.	Correlation Regression analysis	Severity of hypochondriacal complaints +vely correlated with treatment effect at all time points ($p<0.05$) Pre-Post treatment, age and trait anxiety predicted 9% of the variance in residual gain.
Harcourt, Kirkby, Daniels, & Montgomery (1998)	N=18 Adults with agoraphobia	3 x 45mins computerised exposure [Therapist contact = 0]	Change on FQ, ACQ, BSQ Measured at - Assessment - Session 3	Personality factors (NEO- PI-R) -Neuroticism -Extroversion -Openness -Agreeableness -Conscientiousness	Two-tailed independen t samples t- test	Ss with low agreeableness improved on FQ and ACQ compared to high agreeableness ($p<0.05$)

Table 1 Continued Over

Authors	Population	Treatment	Dependent variables	Predictors/Independent variables	Analyses	Results
Hegal, Barrett, & Cornell, & Oxman (2002)	N= 179 Adults with minor depression or dysthymia	Self-help problem solving treatment [Therapist contact = max 4 hours contact over 11 weeks]	Remission at 11 weeks on HSCL-D-20 (score <6)	Therapist rated homework compliance & understanding of PST, CBT vs. non-CBT therapist, age, diagnosis severity of depression, beliefs about depression (PAB), gender, education	Logistic regression Chi Squared (depression severity)	3 variables significantly predicted remission understanding the rationale of PST (OR=0.274; p<0.05) Professional being a CBT therapist (OR=3.936; p,0.01) Lower depression severity score at baseline (χ^2 (2,=78) =0.1806, p=0.9136).

Table 1 Continued Over

Authors	Population	Treatment	Dependent variables	Predictors/Independent variables	Analyses	Results
Hellström & Öst (1996)	N = 138 Adults with specific phobia	Exposure treatment -self directed manual (N=50) [Therapist contact = 0] -1-2 sessions (N = 60) [Therapist contact = max. 3hrs] -5 sessions (N=29) [Therapist contact = max 5 hours]	CSC on -avoidance behaviour -self-rated anxiety -assessor rated phobic severity Measured at -assessment -1 week post treatment -1 year post treatment	Age, age of onset, duration, acquisition, family prevalence, anxiety (BAI), depression (BDI), specific phobia (FSS-III), severity of phobia (SPQ, MQ, IPS), treatment expectation and credibility, heart rate, systolic and diastolic blood pressure (SBP & DBP)	Stepwise forward multiple regression	DBP accounted for 15% variance in self directed treatment at 1 year follow up (F=4.45, p=0.05, Adjusted R ² =0.838).

Table 1 Continued Over

Authors	Population	Treatment	Dependent variables	Predictors/Independent variables	Analyses	Results
Mahalik & Kivlighan (1988)	N= 52 with 35 completing Depression	7 weeks CBT based self help manual [Therapist Contact = approx 2 hours]	Change on BDI, ATQ Pre-treatment and Post-treatment	Assessment depression, (BDI), personality type (SDS and SES), Self Efficacy (GSE), locus of control (Nowicki Strickland Internal-External Control Scale), satisfaction	Correlation	Participants high on realistic scale of the SDS had largest decrease in depression ($r=-0.37$) Participants high on Self Efficacy had a large decrease in depression ($r=-0.40$)
Matix-Cols, Cameron, Gega, Kenwright, & Marks (2006)	N= 335 depression and/or anxiety	CCBT [therapist contact = minimal]	WSAS, Motivation to do self-help Syndrome specific measures; depression (BDI, HDS), GAD (BAI, FQ), OCD (YBOCS)	Referral source (Self-referral, GP referral, Mental Health Professional Referral)	Chi squared on source vs. Pre-treatment variables MANOVA source vs. change	Self referrals and GP referrals had significantly better outcomes compared to those referred from a mental health professional.

Table 1 Continued Over

Authors	Population	Treatment	Dependent variables	Predictors/Independent variables	Analyses	Results
Öst, Stridh, & Wolf (1998)	N = 103 women Spider phobia	Stepped care model 1. CBT self-help manual [therapist input=0], 2. video observation of exposure [therapist input=0] 3. therapist directed group [=3hrs] 4. individual therapy [Therapist contact max =1hr].	CSC on -behavioural approach test, -assessor rating of phobic severity, -self rating of anxiety.	Age of onset, duration, family prevalence, fear, avoidance, handicap, treatment credibility and expectation, motivation, depression (BDI), anxiety (BAI, STAI, FSS)	1. Standard multiple regression to predict outcome 2. Logistic regression to predict attrition 3. Discriminant function analysis to predict level of treatment required	1. Treatment credibility had the highest predictive value for outcome on self-help manual ($F(7,57)=3.01$, $p,0.01$, $R^2=0.27$) 2. Model non-significant. 3. Canonical R (0.59) statistically significant ($\chi^2(7)=22.48$, $p<0.005$). Credibility and motivation were strongest predictors of treatment intensity. 71% patients correctly classified

Table 1 Continued Over

Authors	Population	Treatment	Dependent variables	Predictors/Independent variables	Analyses	Results
Spek, Nyklíček, & Cuijpers, & Pop (2008).	N = 201 Subthreshold depressed people	Randomised to -Group CBT [Therapist Contact = 10 sessions, N=10 per group:2hrs per person] (N=99) -CCBT same as the group [Therapist Contact=0] (N=102)	Change on the BDI	Previous episodes, gender, education, marital status, pre-treatment BDI, NEO-FFI	1.ANCOV A. MANOVA, Chi Squared -differences between drop outs and those who enrolled, and completers, 2.ANCOV A with all predictors except NEO-FFI 3.ACOVA with significant covariates and NEO- FFI	1.Lower educational level amongst drop outs ($\chi^2(2)=7.62, p=0.02$) 2. Higher pre-test BDI (F(1, 116)=48.86, p<0.01), females(F(1, 116)=4.74, p=0.03), higher education ((F(1, 116)=5.14, p=0.03) improved more after treatment. 3.High neuroticism associated with poor outcome (F(1,111)=7.24, p=0.01) High altruism associated with better outcome in the group treatment compared to CCBT (F=(1,111)=3.94, p=0.05).

Table 1 Continued Over

Authors	Population	Treatment	Dependent variables	Predictors/Independent variables	Analyses	Results
Tyrer, Seivewright, Ferguson, & Murphy, & Johnson (1993)	N = 181 Adults with anxiety and/or depression	Randomised to - drug (N=74), -CBT [Therapist Contact=6hrs max] (N= 71), -CBT based self- help [Therapist Contact =0] (N=36)	CPRS (Comprehensive Psychopathologic al Rating Scale)	Depression, anxiety (CPRS, MADRS, BAS, HADS, PAS)	Repeated measures ANOVA	Personality Disorder did less well with self-help. Self-help was effective in severe depression group

FQ = Fear Questionnaire; ACQ = Agoraphobic Cognitions Questionnaire; BS = Body Sensations Questionnaire; CSC = Clinically Significant Change; BDI = Beck Depression Inventory; BAI = Beck Anxiety Inventory; ATQ = Automatic Thoughts Questionnaire; NEO PI-R = NEO Personality Inventory; FSS-III = Fear Survey Schedule-III; SPQ=Spider Phobia Questionnaire; MQ=Mutilation Questionnaire; IPS=Injection Phobia Scale; HSCL-D-20=Hopkins Symptom Checklist Depression Scale; PAB=Patient Attitudes and Beliefs; MADRAS = Montgomery Åsberg Depression Rating Scale; QOLI=Quality of Life Index; PDA=Panic Disorder and Agoraphobia; SF12MCS=Short form from Medical Outcomes Study; CIDI=WHO Composite International Diagnostic Interview; MIA-A= Mobility Inventory for Agoraphobia-Alone Scale; APPQ=Albany Panic and Phobias Questionnaire; DASS-21=Depression Anxiety and Stress Scales; GIAS=Groningen Illness Attitude Scales; SDS=Self Directed Search; SEI=Self-Expression Inventory; GSE=Generalized Self-Efficacy Scale; WSAS=Work and Social Adjustment Scale; HDS=Hamilton Depression Scale; YBOCS=Yule-Brown Obsessions and Compulsion Scale; STAI = State-Trait Anxiety Inventory; BAS=Brief Anxiety Scale; NART = The National Adult Reading Test

3. Methodological Issues

Steketee and Chambless (1992) highlight the common methodological weaknesses in the outcome prediction research for traditional therapy. The studies located for this review also demonstrate these flaws which will be highlighted prior to synthesising their findings.

3.1 Study Design

Many studies of outcome prediction utilise data collected as part of other studies. These are often efficacy trials of different treatments. Although maximising the utility of research data is admirable, this approach only allows the investigation of variables that were of interest to the outcome study and has implications for sample variation (see Section 3.2). It is therefore considered preferable that prediction studies are hypothesis driven (Clarkin & Levy, 2004; Steketee & Chambless, 1992). Of the twelve studies in Table 1, six appear to have been hypothesis led (Harcourt, Kirkby, Daniels, & Montgomery, 1998; Mahalik & Kivlighan, 1988; Mataix-Cols, Cameron, Gega, Kenwright, & Marks, 2006; Öst, Stridh, & Wolf, 1998; Spek, Nyklíček, Cuijpers, & Pop, 2008; Tyrer, Seivewright, Fergusin, Murphy, & Johnson, 1993) and five use data collected as part of outcome studies (Andersson Bergström, Holländare, Ekselius, & Carlbring, 2004; Baillie & Rapee, 2004; Buwalda & Bouman, 2008; Hegal et al., 2002; Helleström & Öst, 1996). Andersson, Carlbring, and Grimlund (2008) perhaps reach a compromise stating that their data was from a Randomised Control Trial (RCT) but the prediction study was planned from the outset so that variables of interest could be collected. To improve statistical power two studies combined data from several RCTs of the same interventions which is acceptable (Buwalda & Bouman, 2008; Hegal et al., 2002). Helleström and Öst (1996) combined four studies of slightly different exposure treatments for specific phobias, which was more problematic and interpreted with caution.

3.2 Sample and Outcome Variance

Reliably predicting outcome from one or more variables requires variation in both the population and in their outcomes. To be confident that any predictors of outcome are not caused by Type 1 or 2 errors the sample used must be representative of the population and their outcomes. Surprisingly, the major limitation in predicting outcomes of both traditional psychological interventions and LIPI seems to be low sample variation (Steketee & Chambless, 1992). Most studies employ strict inclusion and exclusion criteria, immediately limiting the variance in the sample. In addition, the individuals who volunteer to participate in research are inherently different to the population seen in routine clinical practice both through being research volunteers and often being recruited in non-health care settings. Similarly, outcome prediction research is made more difficult when interventions are successful for the majority of people. In this case a larger sample size is required to find any predictors of outcome. A number of studies in this review used treatments which achieved moderate to large effect sizes (e.g. Andersson et al., 2004; Andersson et al., 2008; Buwalda & Bouman, 2008) therefore the variation in outcome is very low, making these studies vulnerable to Type 2 errors.

3.3 Measures

Measurement of predictors and outcomes should employ reliable and valid measures which can be used in clinical practice. Steketee and Chambless (1992) state that, unlike outcome research, measures in prediction research are often chosen haphazardly and are “casually constructed” (p. 390). This increases the likelihood that scales do not measure what they claim to and that statistically significant findings are more likely to be by chance. In the studies located for this review this flaw is particularly common in measures of motivation,

treatment credibility and expectation (see Section 4.5). Another example is Andersson et al. (2008) who measured verbal fluency with the COWAT and assumed that this might indicate reading level when in fact, it is a measure of executive functioning.

With regard to outcome measures, Steketee and Chambless (1992) suggest that combining a number of outcomes into a composite score increases the reliability of any findings. As Table 1 illustrates, a number of studies have used this method. Others dichotomise outcome into those who have achieved a clinically significant change and those who have not. Although a valid and useful measure, it does involve reducing continuous data to data that is dichotomous. These authors suggest that the most suitable outcome measure in prediction research is the residual gain score as this allows data to remain continuous and takes account of pre-treatment scores on outcome measures.

If the goal of this area of research is to find predictors that are clinically useful then measures must be applicable to practice. Measures such as heart rate and blood pressure (see Helleström & Öst, 1996; Öst et al., 1998) are unlikely to be routinely used. Other measures are extremely long or involve completion of a number of measures or interviews (e.g. Spek et al. (2008) who included a 60 and 21 item measure and a diagnostic interview). The new IAPT services are being encouraged to use brief outcome measures, the PHQ-9 (Kroenke, Spitzer, & Williams, 2001) and GAD-7 (Spitzer, Kroenke, Williams, & Löwe, 2006). Unfortunately none of the studies located used these measures decreasing the applicability of any results to current UK services.

3.4 Statistical Analysis

Given the complexity of individuals it is unlikely that one factor will be identified that consistently predicts treatment outcome but that a combination of variables will have predictive power (Clarkin & Levy, 2004). Locating a combination of variables requires the use of regression or other multivariate analyses. Not all of the studies located utilise these methods. Those that do, have not necessarily attempted to look at combinations of predictors and/or have not provided enough details to evaluate their statistical models.

The studies which use regression analysis vary in their statistical power due to the ratio of predictors to sample size. There are various recommendations regarding this ratio, Field (2005) suggests 15 cases per predictor, Miles and Shevlin (2001) suggest over 100 participants and at least 20 cases per predictor, Tabachnick and Fidell (1996) suggest 10 cases per predictor which seems to be the criteria that most studies use. Efforts have been made across studies to meet this criterion by combining studies to increase sample size. Some compute composite scores to reduce the number of predictors and outcomes or include only predictors that correlate with the outcome variable (e.g. Buwalda & Bouman, 2008; Hegal et al., 2002). Many studies use far more predictors than the guidance recommends in their regression analysis (e.g. Andersson et al., 2004). Also, some studies claim to meet the 10:1 ratio on their overall sample, then conduct regression analyses on one sub-group of cases and the conclusions from these analyses are subsequently underpowered (e.g. Helleström & Öst, 1996).

To overcome issues of power some studies used correlations to look at the relationship between two variables. However, correlation does not allow a causal relationship to be concluded. Alternative statistics are also used such as ANOVA, ANCOVA and t-tests.

Although results from such analyses are useful, the data has to be dichotomised which reduces the power of results and does not allow for combinations of variables to be investigated.

4. Predictors

Many different predictors of outcome have been investigated in relation to LIPI. Firstly studies which combine variables are examined then evidence in relation to different individual predictors is considered.

4.1 Models of Outcome Prediction

Seven of the twelve studies used regression analysis but few provide adequate details of the models that were developed. Instead they focused on the predictive values of individual variables (Andersson et al., 2004; Hegal et al., 2002; Helleström & Öst, 1996). Hegal et al. (2002) state that when they included all nine predictors “a goodness of fit test showed that the model adequately fit the data” (p. 520) but do not provide any figures to substantiate this and Helleström and Öst (1996) give no details of the overall model. Andersson et al. (2004) reported limited details of their models. They found that higher pre-treatment depression and anxiety and lower quality of life together predicted higher depression scores at 6-months post treatment following CCBT. They did not report models for the other time points or outcome measures. In their later study of a similar intervention for panic disorder, these authors did display more information about their regression model (Andersson et al., 2008). High treatment credibility ratings, high scores on the cluster C personality disorder scale and agoraphobic avoidance scale, and low executive functioning predicted poorer outcome in the CCBT and traditional face-to-face CBT conditions. This combination of variables was only statistically significant in the CBT condition. This may indicate that the client variables that predict outcome in LIPI are very different to those that predict outcome in high intensity treatment. However, this is likely to have been a result of the small, low variation sample size and failure to achieve the appropriate ratio of predictors to cases and therefore not reliable.

The remaining studies report their analyses more clearly. Buwalda and Bouman (2008) used multiple regression where they included the two variables that had correlated with residual gain from pre to post test i.e. trait anxiety and age. Together they accounted for only 9% of the variance in outcome from the coping with hypochondriasis group. Baillie and Rapee (2004) found that a model including younger age of first panic attack, higher neuroticism and panic symptoms, and using alcohol predicted poorer outcome on a general mental health scale following their stepped care intervention of various LIPI. Öst et al. (1998) found that longer duration of phobia, higher avoidance, depression and state anxiety at baseline and higher treatment credibility, expectancy and motivation together predicted only 27% of the outcome variance. Significant predictors therefore include symptom severity at baseline and duration of symptoms (Baillie & Rapee, 2004; Öst et al., 1998).

That there are so few predictors either reflects the reality of this field of work or may be a product of the methodological issues described above. Larger, more varied samples are required for further research. Examples of research that have overcome some of the methodological limitations include the study by Walker et al. (2000). They focussed on adherence to medication using a case management intervention for depression and present an excellent logistic regression where the following variables combined to predict adherence; depression severity, presence/absence of panic, loneliness and childhood sexual abuse. Another excellent example is the study by Dow et al. (2007) who found pre-treatment panic and number of sessions predicted outcome in CBT.

4.2 Demographics

Interestingly very few studies investigated demographic variables as predictors of treatment outcome. This is despite the likelihood that basic demographic information is routinely

collected in studies and reported when describing the samples. Five studies looked at gender as a predictor (Andersson et al., 2004; Baillie & Rapee, 2004; Buwalda & Bouman, 2008; Hegal et al., 2002; Spek et al., 2008). Only Spek et al. (2008) found it to be a statistically significant predictor with women improving more than men. Four studies looked at age as a predictor of outcome (Andersson et al., 2004; Buwalda and Bouman, 2008; Hegal et al., 2002; Helleström & Öst, 1996) with Buwalda and Bouman (2008) the only authors to find a significant link between age and outcome. Using correlation they found that as age increased, residual gain scores increased indicating that older people improved more than younger people. In their multiple regression analysis, age was also a significant predictor of outcome in a model with state anxiety. Spek et al. (2008) also investigated the predictive power of marital status but there was no significant difference between groups on depression change scores following the intervention.

Table 2: Variation in Age and Gender in the Included Studies

Authors	Percentage of Women in Sample	Mean (Std. Deviation) Age
Andersson et al. (2004)	79	37(11)
Baillie & Rapee (2004)	76	(38(12))*
Buwalda & Bouman (2008)	71	40(11)
Hegal et al. (2002)	50	≥60 years N = 89 <60 years N = 90
Helleström & Öst (1996)	(88)*	28(8)
Spek et al. (2008)	68	(55(5))*

*study reported but did not investigate as a predictor

Given the mixed results it is difficult to draw conclusions about gender and age as predictors of outcome. It may be the case that neither variable alone have predictive power. However, Table 2 illustrates the low variation in age in the individual studies and that in general there was a low proportion of males included in each study. Although there is a good spread of age across the studies, within each study there is only moderate variation which is not representative of the diversity seen in clinical practice. It is likely that the results are at risk of being a result of Type 1 and 2 errors due to limited non-representative sample sizes. It is surprising that so few demographic variables were investigated with the absence of any studies looking at ethnicity, socioeconomic or employment status at assessment. It is suggested that these issues should be addressed in future research.

4.3 Educational Level

Many LIPI involve little or no input from a professional and require the service user to read and utilise information in text either in booklets or on computers (Martinez, Whitfield, Dafters, & Williams, 2008). Some of this information may be lengthy and complicated to understand. For example, in their study of internet based self-help for depression, Andersson et al.'s (2004) intervention was 89 pages of text in total. Similarly in their study on internet based self-help for panic attacks they estimated that 250 pages of text would be read over 10 weeks. It is therefore important to ask whether people with the range of ability seen in primary care settings in the UK can use the LIPI on offer. It seems very likely that a proportion of people will struggle to do this because of their cognitive ability and/or their mental health problems. This hypothesis is supported by Martinez et al. (2008) who found that around 16% of the UK's population would struggle to read many self-help materials commonly used in the UK.

A number of studies have investigated education level but none of them found this variable to be a statistically significant predictor of outcome (Andersson et al., 2004; Baillie & Rapee, 2004; Buwalda & Bouman, 2008; Hegal et al., 2002; Spek et al., 2008). It is unlikely that these studies included those who are most likely to struggle with self-help due to the bias incurred through sampling and recruitment methods. For example, Baillie and Rapee (2004) actually excluded people who could not read. Another consideration is whether the correct construct is being measured. Education has been measured by years in education which does not necessarily reflect the ability to understand the self-help materials. An interesting finding from Spek and colleagues (2008) was that those who dropped-out of treatment with CCBT were more likely to have been classified in the “low education” group possibly indicating that they could not access the information.

Further research is clearly needed concerning the ability level required to be able to access LIPI. It may continue to be difficult to investigate this factor as potentially routine outcome measurement might not capture those people who cannot read the letter sent out by many services asking them to attend an appointment.

4.3 Severity of Symptoms, Historical Factors, Co-morbidity and Functioning

4.3.1 Symptom severity

Eleven out of the twelve studies investigated severity of symptoms as a predictor of treatment outcome. Andersson et al. (2004) found that although pre-treatment depression severity did not predict symptom change at follow-up, it did predict outcome 6-months post-treatment on both depression measures. Depression severity was also one of three variables that predicted change at 6-months as part of their regression model (Andersson et al., 2004). Spek et al. (2008) found that severity of depression at baseline predicted change

on depression scores. Higher depression at baseline was associated with more change on the depression scale. In Hegal et al.'s (2002) study, baseline severity of depression was found to be a significant predictor of remission at the end of treatment along with an interaction between diagnosis and severity. To investigate this further these authors split the sample by diagnosis (dysthymia and minor depression) and severity of symptoms. They found that those diagnosed with minor depression and who had moderate or severe symptoms were less likely to enter remission than those with a diagnosis of dysthymia. Tyrer et al. (1993) report that self-help for different anxiety and depressive disorders was effective even in cases where individuals had severe depression and/or anxiety, although the number of cases on which this is based is extremely small.

The conclusions from studies of anxiety are more varied. None of the following, Andersson et al. (2008), Baillie and Rapee (2004), Helleström and Öst (1996), Öst et al. (1998), found anxiety severity to be a significant predictor of treatment outcome. Buwalda and Bouman (2008) found that severity of hypochondriasis symptoms correlated positively and significantly with outcomes from their group treatment at follow-up. In addition they found that higher trait anxiety predicted less treatment gain. This may be because a number of these studies focussed on specific phobias which may not have the same impact on an individual's functioning compared to depression or anxiety disorders. It is hypothesised that severity of symptoms combined with severity of impact on a person's general functioning, may together predict outcome (although this was not examined in any of these studies). In general it seems that severity of symptoms has a negative association with treatment outcome in interventions for depression with inconclusive results for anxiety disorders.

4.3.2 Historical Factors

Andersson et al. (2004) found that the more episodes of depression people had experienced the less change they demonstrated following treatment with computerised self-help. This was a weak but significant correlation. Other studies that investigated this variable did not find it predicted outcome (Buwalda & Bouman, 2008; Helleström & Öst, 1996; Öst et al., 1998; Spek et al., 2008) therefore a firm conclusion about historical factors cannot be drawn.

4.3.3 Co-morbidity

Many efficacy studies choose to exclude participants with co-morbid difficulties, perhaps reflecting a hypothesis that co-morbidity equals complexity and poorer outcomes which has been found in studies of CBT (e.g. Durham, Allan, & Hackett, 1997). Six studies measured the severity of co-morbid depression/anxiety. In the studies on depression, Andersson et al. (2004) measured pre-treatment anxiety levels and found that higher pre-treatment anxiety predicted less change at 6-months following a treatment for depression. With interventions for anxiety, Baillie and Rapee (2004) found that higher co-morbid baseline social anxiety predicted poorer outcome following psychoeducation or self-help for panic attacks but co-morbid depression did not. However, neither Buwalda and Bouman (2008) nor Öst et al. (1998) found any link between pre-treatment depression with anxiety outcomes in their studies.

Andersson et al. (2008) used the SCID II (C), which is the scale for cluster C personality disorders. In their internet-based self-help manual for people with panic disorder, this was the only variable that had a statistically significant relationship with any outcome. People with a Personality Disorder showed worse outcomes. Tyrer et al. (1993) also found this pattern in their study although the number of patients treated is extremely small. Again,

these mixed results allow few conclusions to be drawn. It is likely that if co-morbidity is a predictor of outcome in LIPI, the limited sample variation due to inclusion/exclusion criteria may have resulted in Type 1 or 2 errors.

4.3.4 General Functioning

A number of studies used measures of general functioning or impact in addition to symptom specific measures. Whilst Öst et al. (1998) did not find “handicap” to be a significant predictor of outcome, other studies did. Andersson et al. (2004) found that poor quality of life at assessment was associated with less change in depression 6-months post treatment. Baillie and Rapee (2004) found that poorer general functioning at pre-treatment predicted poorer outcome following a LIPI for panic attacks. Matix-Cols and colleagues (2006) explained their results of GP referrals having the better outcome following CCBT compared to mental health worker and self referrals due to their higher general functioning.

4.4 Personality

Harcourt et al. (1998), Mahalik and Kivlighan (1988) and Spek et al. (2008) investigated whether different personality types improved more with LIPI compared to others. Mahalik and Kivlighan (1988) found that people who scored highly on the Realistic sub-scale of Hollond’s Self-Directed Search (Hollond, 1985) made greater improvements than those who had a low score on this scale. The authors explain this as being because this group of people “have a preference for interaction with objects not people” (p. 241). In addition those participants with high pre-treatment self-efficacy had a larger decrease in depression than those with a low score.

Harcourt et al. (1998) use the NEO-PI-R (Costa & McCrae, 1992) to examine personality factors that might predict outcome to a brief computerised exposure task. They used inferential statistics rather than regression and had a very small sample of 18 people which they split at an arbitrary level into high and low scorers on the subscales. The lack of statistically significant findings was unsurprising given the poor methodology. More recently Spek et al. (2008) investigated personality using the NEO-FFI (Costa & McCrae, 1992). People with high altruism improved more in group treatment compared to internet treatment. Higher scores on neuroticism were associated with poorer outcome across both treatments.

Both Mahalik and Kivighan (1988) and Harcourt et al. (1998) lack statistical power which means that neither result should be treated as valid or reliable. Spek et al. (2008) had a far more respectable sample size but it is likely that the predictor, high neuroticism, is likely to indicate that co-morbid anxiety and depression predict a poorer outcome. Altruism as a predictor of outcome in group treatment is a useful finding suggesting that asking about how sociable a person is may help determine whether they will do well in a group rather than a one-to-one intervention.

4.5 Motivation, Expectation, Treatment Credibility

The final group of variables relates to constructs which clinicians have rated as very important predictors in outcomes of LIPI (MacLeoad, Martinez, & Williams, 2009) and have been found to predict outcome in traditional therapies (Asay & Lambert, 2004). The suggestion is that people who are motivated and expect a treatment to work and/or feel it is credible are more likely to improve than those who do not.

Andersson et al. (2008), Helleström and Öst (1996) and Öst et al. (1998) investigated perceived treatment credibility as a predictor of outcome. Only Öst et al. (1998) found this factor to predict outcome following self-exposure for specific phobias. They found that although their regression model predicted 27% of the variance in the outcome, treatment credibility rating was the only individual variable which significantly contributed to this model. When a discriminant analysis was conducted in this study, motivation and treatment credibility were the strongest predictors of intensity of treatment required to achieve clinically significant change. Buwulda and Bouman (2008), Helleström and Öst (1996), and Öst et al. (1998) did not find expectancy to significantly predict treatment outcome. Matix-Cols et al. (2006) found that people who were referred from a mental health professional to a CCBT clinic did not expect this treatment to help them and had poorer outcomes than those referred from a GP who did expect it might help them. This result could however be accounted for by other variables such as severity.

Motivation was investigated as a predictor by Baillie and Rapee (2004) and Öst et al. (1998). Öst et al. (1998) used a validated scale of treatment motivation (Nijmegen Motivation List; Keijsers, 1994) whilst Baillie and Rapee (2004) used a “motivation ladder” (Biener & Adams, 1991). Öst and colleagues (1998) found motivation to be a statistically significant predictor of outcome of their self-help for spider phobia but Baillie and Rapee (2004) did not.

The main problem in these studies is the use of non-validated scales, usually only using one question e.g. on a scale of 0 to 10 how effective do you expect this treatment to be? (e.g. Öst et al., 1998, p. 21). The other issue is the likely bias in the research samples toward people who are motivated to improve their condition and may have some understanding of

what the treatments will involve through the consent process. Whilst clearly this is an important set of variables, future research with valid and reliable measures is essential.

5. Other Studies

A number of other studies were located which approach the subject of predicting outcome following LIPI in a different way to the studies previously described. MacLeod et al. (2008) surveyed practitioners about their views about who benefits from self-help. Clearly this is not the most robust study design however it offers some interesting insights into this topic. From 14 client factors, the top five indicated by practitioners as believed to predict outcome of self-help were; patient motivation, expectancy and credibility that self-help will work, likely adherence, self-efficacy and degree of hopelessness (MacLeod et al., 2008, p. 64). It is interesting that symptom severity was not a factor chosen by practitioners considering this is the variable most commonly investigated in these studies. In an open-ended question, the majority of people reported that they thought literacy would predict outcome which fits with the arguments in this review (MacLeod et al., 2008).

Other studies have tried to develop screening tools for suitability for LIPI (Durham et al., 2004; Gega, Kenwright, Matix-Cols, Cameron, & Marks, 2005). Interestingly these studies do not use the outcome predictor literature to construct the scales. Whilst these variables have face validity in their inclusion in such a scale, it is potentially premature to construct a scale before consistent predictors are found.

6. Discussion and Conclusion

From the studies located it seems that neither age, gender, educational level nor duration of illness are variables which predict the outcome of LIPI. The studies located suggest that symptom severity at assessment, co-morbid mental health problems, general mental health/impact of difficulties, motivation, treatment credibility and expectation might predict treatment outcome. These findings seem to be consistent with the research into prediction of outcome following traditional therapy. However, conclusions can only be very tentative due to the methodological limitations.

In particular samples used have limited variation in the client characteristics. In addition samples are inherently different from those in routine clinical practice. Too few of the studies report appropriate statistical analyses and those that do have found combinations of variables predicting only a small proportion of the outcome variance. The majority of studies focus on identifying individual variables that account for a unique proportion of outcome variance. The likelihood of one variable reliably predicting outcome is however very small (Clarkin & Levy, 2004). In addition a limitation of this review is that there are so few studies to synthesise. Therefore comparisons were made across primary problems (i.e. depression or anxiety) and interventions rather than within the different subgroups. There may be client characteristics that have more predictive power within these groups and this should be investigated further.

In order to improve the information on outcome predictors following LIPI the methodological weaknesses detailed above must be avoided. One option is to use “Individual Patient Data (IPD) Analysis” (Lambert, Sutton, Abrams, & Jones, 2002). This method obtains and synthesises the individual patient data from different RCTs. It is

reported to be superior to meta-regression because it can investigate the relationship between client characteristics and outcome on a larger scale than has been achieved in the studies located in this review (Lambert et al., 2002). Another avenue to explore is “treatment failures”. As in traditional therapies, very little is known about this group. More research is needed to understand the variance in outcome in order that more specific recommendations as to who may not benefit from interventions can be developed.

Finally the methodological limitations described in this review provide evidence supporting the use of routinely collected outcome measures i.e. collecting practice based evidence (See Barkham & Mellor-Clark, 2003). This will generate data with higher variance in both outcome and predictor variables and will have high external validity (Steketee & Chambless, 1992). Future research into predicting outcomes of LIPI should also use the measures that are being recommended to services, in order that the results generalise to practice. Variables of interest must also be easily but reliably measured by the workers that will be doing the assessment. The development of new services delivering LIPI gives the potential for improving what is known about predictors of outcome if routine outcome measurement is rigorously implemented.

7, References

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Section 2: Research Report

Exploring Stepping-up in a Stepped Care Service

Delivery Model

Abstract

Objectives. To explore the process of stepping-up in a stepped care service for delivering psychological interventions.

Design. A mixed methods design was used and two studies are reported. Study 1 used practice based evidence to compare people who were stepped-up with those who received only Low Intensity Psychological Interventions (LIPI), and only CBT. Study 2 explored service users' experience of stepping-up in a qualitative design.

Methods. Study 1 used inferential statistics to compare the groups on assessment characteristics and outcomes. Logistic regression explored whether stepping-up could be predicted from assessment characteristics. In Study 2 eleven individuals were interviewed about their experience of stepping-up and transcripts were analysed using Interpretative Phenomenological Analysis.

Results. Study 1: Those who were stepped-up did not differ substantially from other groups on assessment characteristics or their outcomes. Stepping-up could not be predicted from assessment variables. Study 2: Five super-ordinate themes emerged; Emotional Experience of Stepping-up, The "Fit" of the Intervention, Relationships with Workers, Power and Experience of Change. The sense-making of stepping-up appeared to occur through a process of comparing the interventions experienced at each step.

Conclusions. Stepping-up can produce acceptable outcomes and is experienced in diverse ways. There were a number of possible reasons for stepping-up other than a lack of progress at a lower step. These different reasons may account for the absence of predictors of stepping-up and similarities between the three groups. The therapeutic alliance may be an important factor to investigate in relation to LIPI and their outcomes.

1. Introduction

The NHS recently funded two pilot sites using alternative service models for delivering psychological interventions in primary care recommended for treating anxiety and depression (NICE, 2004a, 2004b). These include Cognitive Behavioural Therapy (CBT) delivered through guided self-help, computerised CBT (CCBT) and traditional one-to-one therapy. The funding of these sites represented an acceleration in the Improving Access to Psychological Therapies (IAPT) agenda. This was largely the result of an economic argument that payments of incapacity benefit would be significantly reduced if The Exchequer supported the development of psychological treatment centres providing the recommended interventions (Layard, 2006, p. 332). The two pilot sites were evaluated by an independent research group for the NHS National Collaborating Centre for Service Delivery and Organisation (NCCSDO). The studies reported here form part of the evaluation of the IAPT site that is piloting a stepped care model of service delivery. They explore a specific aspect of this model called “stepping-up”.

1.1 Stepped Care

The principle of stepped care is that the least restrictive/lowest intensity treatment likely to result in a significant health gain is provided initially, with people being stepped-up to a more intensive treatment if necessary through a self-correcting mechanism (Bower & Gilbody, 2005, p.11). Bower and Gilbody (2005) state that self-correcting refers to the systematic monitoring of an individual’s progress which is then used to make treatment decisions e.g. stepping-up, discharge etc. (p.11). The majority of people receive low intensity treatments with more intensive specialist treatments reserved for those who do not benefit from the lower steps (Bower & Gilbody, 2005). In the case of anxiety and depression, Low Intensity Psychological Interventions (LIPi) such as guided self-help and

CCBT are delivered at the first step with people stepping-up to one-to-one CBT if they do not improve significantly (See Appendix 8 for example).

Stepped care models have been described for a number of mental health problems e.g. eating disorders (Wilson, Vitousek, & Loeb, 2000), panic (Otto, Pollack, & Maki, 2000), anxiety (NICE, 2004a) and depression (NICE, 2004b). However, whilst the individual treatments often have evidence of effectiveness, a literature review found that the service model itself has very little supporting evidence (Bower & Gilbody, 2005). There are some exceptions to this. Treasure et al. (1996) found no difference in outcomes for people with bulimia nervosa randomised to either stepped care (guided self-help followed by CBT) or CBT only. A study in the Netherlands found no difference in outcome for people with depression and anxiety treated within a stepped care model compared to usual treatment (van Straten, Tiemens, Hakkaart, Nolen, & Donker, 2006). These studies indicate that potentially stepped care may be as effective as usual care and higher intensity treatments. With relatively small samples these studies cannot answer some of the important questions about this model of service delivery.

1.2 Stepping-up

Despite being a defining feature of stepped care the process of stepping-up is yet to be the focus of research. The two studies reported here broadly aim to explore the group of people who are stepped-up from LIPI to CBT at an IAPT pilot site. Those who are stepped-up are likely to be the minority of service users and may well be “lost” in the overall evaluation of service effectiveness highlighting the importance of focusing specifically on this group.

It is clear from the descriptions of stepped care that the criterion for stepping-up is non-response to a LIPI (Davinson, 2000; Otto et al., 2000; Wilson et al., 2000). Therefore it would be expected that people who step-up have poorer outcomes with LIPI. It is repeatedly suggested that examining the predictors of success with LIPI is important but little research exists (Bower & Gilbody, 2005; Papworth, 2006; Williams & Martinez, 2008). A minority of studies that do address this issue fail to draw firm conclusions due to methodological limitations (e.g. Andersson, Bergström, Holländare, Ekselius, & Carlbring, 2004; Buwalda & Bouman, 2008; Helleström & Öst, 1996). In particular they use data from Randomised Control Trials (RCTs) where samples have limited variation in many characteristics of interest due to the strict inclusion/exclusion criteria. Steketee and Chambless (1992) argue that the outcome prediction research should utilise routinely collected clinical data to rectify these limitations.

In line with this recommendation, this study uses practice based evidence to compare the characteristics at assessment and the outcomes of people who are stepped-up to those who receive only a LIPI or CBT in a pilot stepped care service. A second aim is to investigate whether stepping-up can be predicted at assessment. This could inform the development of LIPI to increase both their accessibility and effectiveness if, for example, it is found that specific groups of people are stepped-up. It may be economically and clinically useful to identify potential non-responders to LIPI at assessment so they can be offered quicker access to a higher step. Finally, it is important to clarify the outcomes of people who are stepped-up.

1.3 The Experience of Stepping-up

The stepped care model of service delivery is a logical solution to capacity issues in mental health services. However, Bower and Gilbody (2005) suggest a particular concern with the model is the “possible negative effects of treatment failure at lower steps and loss of continuity of provider” (p. 15). Parry, Roth and Fonagy (2005) also wonder what the effects might be of delaying access to a potentially helpful treatment. Conversely, nothing is known about the possible positive impacts of having a LIPI before CBT. Understanding how people experience and make sense of stepping-up is essential to fully evaluate this service model. Qualitative methods are the most appropriate way of researching a person's experience, especially when the topic is relatively unexplored (Elliott, Fischer, & Rennie 1999; Willig, 2001). Therefore service users who have been stepped-up will be interviewed as part of this study.

1.4 Summary of Aims

This is an exploratory study of stepping-up in the proposed stepped care model for delivering psychological therapies. Study 1 will use practice based evidence from an IAPT pilot site to describe the people who have been stepped-up and compare them at assessment and outcome to those who are not stepped-up from a LIPI and those who are stepped directly to CBT. The data will also be used to examine whether stepping-up can be predicted from information collected at assessment. Study 2 will explore how service users make sense of stepping-up through qualitative analysis of interviews. Using this mixed method approach a fuller understanding of this unknown aspect of this service model will be presented.

1.5 Ethical Approval

NHS Ethics and Governance approval has been granted for the NCCSDO evaluation team to access the IAPT pilot site data and interview service users. This application included approval for a DClinPsy trainee to access the data as a member of the research team. A unique research ethics and governance application was not required for this project (see Appendix 4 and 5 for Ethical Approval).

Study 1:

Using Practice Based Evidence to Explore Stepping-up

2. Study 1 Method

2.1 Stepped Care Pilot Site¹

This service takes referrals for people over 16 with common mental health problems from a number of sources (e.g. Primary Care, self-referrals, Pathways to Work). At a telephone screening people are assigned either to a Low Intensity Worker (LIW), a CBT therapist, a counsellor or to the Community Mental Health Team depending on their level of need. The majority of referrals pass to a LIW who conducts an initial face-to-face assessment and introduces a range of possible LIPI e.g. guided self-help, CCBT etc. The LIW then supports the use of these interventions in brief contacts (20-30 minutes) many of which are conducted via the telephone. Where people are not demonstrating progress with the LIPI, they are stepped-up to access CBT.

2.2 Variables

Integral to this pilot site is the compulsory recording of an individual's score on a depression and anxiety scale and attendance at every session along with age, gender at assessment. Other variables are not collected with the same degree of accuracy. The following variables were of interest in this study;

- Age (in years),
- Gender,
- Ethnicity (White or non white),
- Employment status (full/part-time paid work, homemaker, retired, student, unemployed),
- Duration of illness (in months),

¹ Reference not included to maintain service anonymity

- Primary problem definition by referrer (anxiety², depression, other³),
- Depression severity at assessment measured by the PHQ-9 (Kroenke, Spitzer, & Williams, 2001; see Appendix 6). The PHQ-9 is a 9 item self-report questionnaire. It is used both for diagnosing depression, as a measure of severity and outcome (Kroenke et al., 2001; Löwe, Kroenke, Herzog, & Gräfe, 2004). It has a maximum score of 27 with the score indicating the severity of depression; 0-4 not depressed, 5-9 mild depression 10-14, moderately depressed, 15-19 moderate-severe depression, 20-27 severely depressed. This measure has good internal consistency (0.89) and test-retest reliability (0.84; Kroenke, et al., 2001). It has been validated for use in the UK (Gilbody, Richards, & Barkham, 2007). It is completed by all service users at assessment and at each contact,
- Anxiety severity at assessment measured by GAD-7 (Spitzer, Kroenke, Williams, & Löwe, 2006; see Appendix 7). GAD-7 is a measure of generalised anxiety severity but has also shown utility in other anxiety disorders (Kroenke, Spitzer, Williams, Monahan, & Löwe, 2007). It is a 7 item self report questionnaire with a maximum score of 21. Scores indicate the severity of anxiety; 0-4 no anxiety, 5-9 mild anxiety, 10-14 moderate anxiety, 15-21 severe anxiety. The internal consistency has been found to be 0.92 and the test-re-test reliability 0.83 (Spitzer et al., 2006). It is completed by all service users at assessment and at each contact.

² Including agoraphobia with panic disorder, agoraphobia without panic disorder, generalised anxiety, social anxiety, specific phobia

³ "Other" included mixed PTSD, OCD, somatisation, bipolar, psychosis, bereavement, drug/alcohol, eating disorder

2.3 Outcomes

Outcomes were calculated based on the first and last completed score on the PHQ-9 and GAD-7 by three alternative methods.

1. The mean change in each group between first and last score was calculated.
2. Next, Reliable and Clinically Significant Improvement (RCSI; Jacobson & Traux, 1991) was calculated using the least desirable of three potential methods i.e. calculating whether pre-post change was more than 2 standard deviations from the original mean (Evans, Margison, & Barkham, 1998). This was due to the unavailability of any UK norms for these measures which would allow more rigorous RCSI to be calculated.
3. In line with recently published research from this pilot site (Richards & Suckling, 2009), the proportions of people who, at their last contact show improvement, recovery and remission on these measures was also calculated. Appendix 9 provides more in depth information about these different methods of outcome description.

2.4 Procedure

Data from all cases referred to the service was downloaded for the period August 2006 (pilot start data) to August 2008. This included 8054 cases. Procedures were developed to locate the following groups of interest;

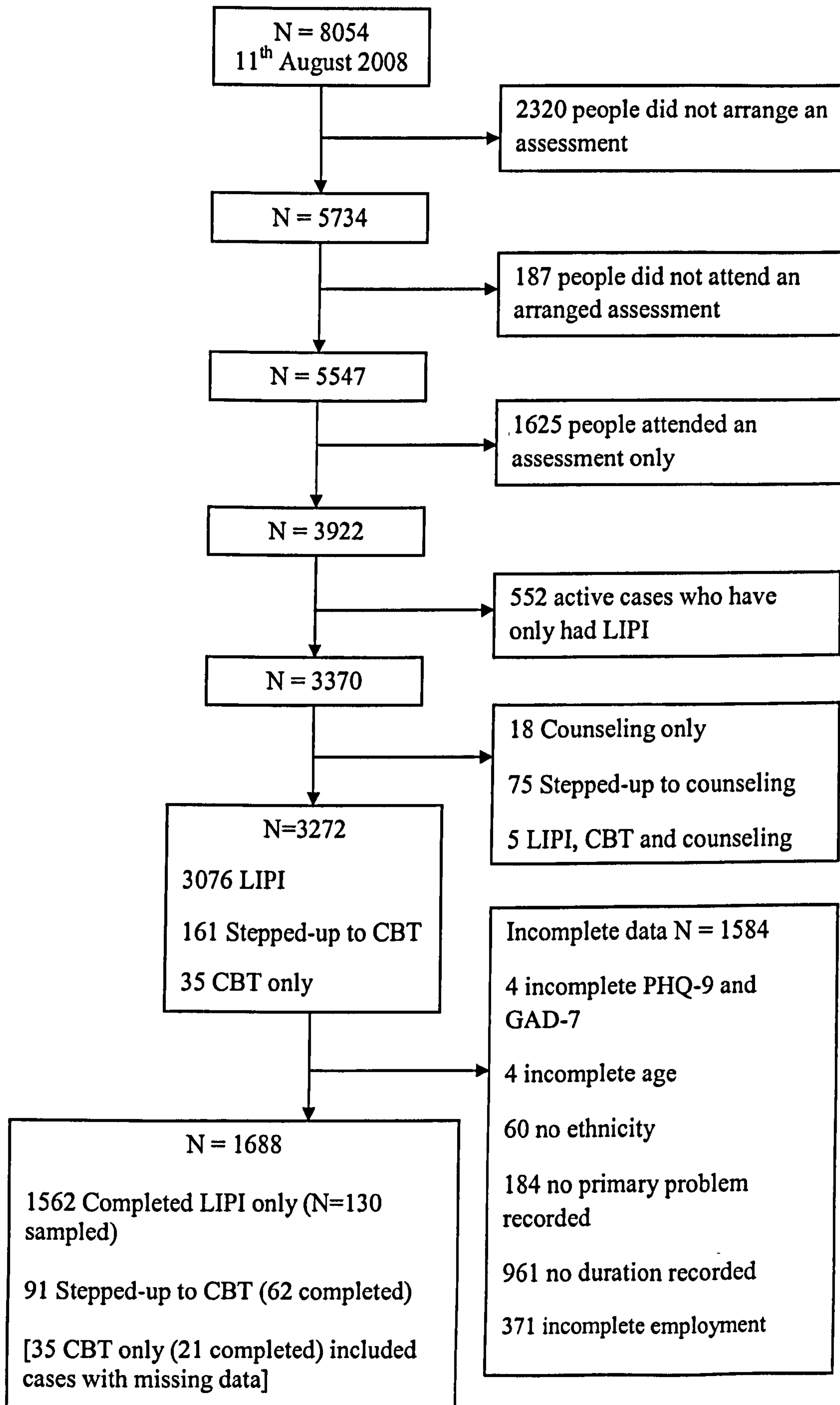
- LIPI only – individuals receiving an assessment plus one or more contacts of a LIPI with no counselling or CBT contacts,
- Stepped-up – individuals who received an assessment plus one or more LIPI contacts and one or more sessions of CBT,
- CBT only – individuals receiving an assessment plus one or more sessions of CBT but no LIPI.

- Cases were excluded if people had;
- been referred but never arranged an assessment,
- arranged assessment but never attended,
- received an assessment only.

To maximise the power of the analysis all active cases who had only received LIPI were excluded as they may be stepped-up in the future. All other active cases were included. As the dependent variables were investigated in combination, only cases with complete data for all variables were included. When examining the outcomes of the three groups the active cases were excluded from the analysis. Figure 2 illustrates the exclusion of cases from the original dataset.

Given the large difference in sample size between the LIPI only and the other groups, a random sample of cases who received LIPI only was taken. This protected against finding trivial results due to the power of the LIPI only group and to ensure that any comparison between groups was made on similarly reliable means/frequencies. The sample size of 130 for the LIPI only group was chosen to satisfy the recommendation that groups should not differ by more than a 3:2 ratio if certain assumptions of statistical analyses need to be rejected and provides adequate statistical power for the analysis (Field, 2005). Analyses in Appendix 10 shows that the sample of LIPI only cases (N=130) does not differ from the population from it was sampled (N=1562) on any variables of interest.

Figure 2: Flow Diagram of Case Exclusion from Original Data Download



2.5 Analysis

To explore the characteristics of people who were stepped-up in comparison with the other groups (LIPI only and CBT only), descriptive statistics were computed and the difference between the groups was assessed using the Chi Squared analysis for categorical variables. The difference between the three groups on age, depression and anxiety severity at assessment was assessed using One-Way Analyses of Variance (ANOVA). Other continuous variables were compared between the stepped-up and LIPI only group using an independent t-test.

To examine whether stepping-up could be predicted, a Standard Logistic Regression was conducted to analyse the predictive power of the assessment variables both in combination and their individual predictive power in relation to the outcome (stepping-up vs. not stepping-up) using the data from the LIPI only and stepped-up groups.

A power analysis was conducted to estimate the sample size required where there are three groups entering an ANOVA using $\alpha = 0.05$, $\beta = 0.80$ and $F = 0.25$. A medium effect size ($F = 0.25$) was chosen as a between groups effect that would be clinically interesting. The power analysis indicated that a total sample size of 159 people would be required to find a medium effect, i.e. $N = 53$ per group. The LIPI only and stepped-up groups satisfy this power analysis but the CBT group does not. Therefore the main focus of the analysis was on LIPI only and stepped-up groups. With regard to regression analysis, Miles and Shevlin (2001) suggest that the sample should be greater than 100 with at least 20 cases per predictor. In this analysis the sample size exceeds this requirement with a maximum of 9 predictors and a total sample of 221.

3. Study 1 Results

3.1 Description of Groups

Table 3 describes the characteristics of the three groups (LIPI only, CBT only and stepped-up). Analyses indicated that the three groups do not differ in the proportions of males and females, $\chi^2(2) = 0.33$, $p = 0.84$, the age of the individuals, $F(2, 253) = 0.697$, $p = 0.499$, or the mean depression severity at assessment $F(2, 253) = 1.245$, $p = 0.29$. They did differ significantly in mean anxiety severity at assessment, $F(2, 253) = 4.808$, $p = 0.009$, with the LIPI group having a lower mean anxiety score compared to the other two groups whose mean was the same.

When individuals were classified according to GAD-7 severity classifications (Table 4) the three groups did not differ significantly on the number of people classified as not anxious, mildly, moderately or severely anxious, $\chi^2(6) = 12.339$, $p = 0.055$. Due to low expected counts the non-depressed and mildly depressed categories were combined when comparing depression severity groups using the PHQ-9. Analysing the data in this way indicated that there were no significant differences between the groups on depression severity, $\chi^2(6) = 3.651$, $p = 0.724$ (Table 4).

Table 3: Comparing Characteristics of the Groups at Assessment

	LIPI only (N=130)	Stepped-up (N=91)	CBT only (N=35)
Mean PHQ-9 at assessment (SD)	16.7 (6.0)	17.4 (5.6)	18.5 (6.9)
Mean GAD-7 at assessment (SD)	13.5 (5.0)	15.5 (4.9)	15.5 (5.7)
Mean Age in years (SD)	38.9 (13.0)	38.3 (11.7)	36.1 (12.4)
Duration of illness months			Not displayed due to missing data
Mean (SD)	31.8 (55.4)	31.5 (43.2)	
Mean Log (Duration +1) (SD)	1.08 (0.63)	1.11 (0.64)	
Median	10.3	25.0	
Gender N (%)			
Male	40 (30.8%)	31 (34.1%)	12 (34%)
Female	90 (69.2%)	60 (65.9%)	23 (66%)
Primary problem N (%)			Not displayed due to missing data
Depression	120 (92%)	77 (85%)	
Anxiety	9 (7%)	11 (12%)	
Other	1 (1%)	3 (3%)	
Ethnicity			Not displayed due to missing data
White	130 (100%)	91 (100%)	
Non-white	0	0	
Employment			Not displayed due to missing data
Paid Work	68 (52%)	43 (47%)	
Student	4 (3%)	5 (6%)	
Retired	7 (5%)	2 (2%)	
Homemaker	17 (13%)	10 (11%)	
Unemployed	34 (26%)	31 (34%)	

On all other variables the LIPI only group was compared with the stepped-up group as there was insufficient data recorded in the CBT only group i.e. too much missing data for some variables. All of the cases indicated their ethnicity was white. The two groups did not differ on employment status, $\chi^2(4) = 3.706$, $p = 0.447$ or primary problem, $\chi^2(1) = 1.907$, $p = 0.167$. In order to satisfy the assumptions of the Chi Squared test, four cases were excluded from the analysis of primary problem. These were the four cases which were “other primary problem”. Finally, there was no difference between these two groups on the transformed duration of illness, $t(219) = -0.334$, $p = 0.739$.

Table 4: Severity of Depression and Anxiety of the Groups at Assessment as Defined by PHQ-9 and GAD-7

	LIPI only (N=130)	Stepped-up (N=91)	CBT only (N=35)
Anxiety			
Not anxious (0-4)	9 (7%)	4 (4%)	3 (9%)
Mild (5-9)	19 (15%)	7 (8%)	2 (6%)
Moderate (10-14)	40 (31%)	20 (22%)	5 (14%)
Severe (15-21)	62 (48%)	60 (66%)	25 (71%)
Depression			
Not depressed (0-4)	5 (4%)	3 (3%)	1 (3%)
Mild (5-9)	13 (10%)	6 (7%)	4 (11%)
Moderate (10-14)	24 (19%)	14 (15%)	5 (14%)
Moderate-Severe (15-19)	38 (29%)	25 (28%)	7 (20%)
Severe (20-27)	50 (39%)	43(47%)	18 (51%)

3.2 Outcomes

Tables 5 and 6 illustrate the mean change from first (assessment) to last score for each group on the PHQ-9 and GAD-7. The PHQ-9 change scores violated the homogeneity of variance assumption and were positively skewed. It was found that a square root transformation solved this difficulty. An ANOVA subsequently demonstrated that the groups did not differ significantly on the amount of change from first to last session, $F(2, 210) = 1.598, p = 0.205$. The GAD-7 data was not transformed and an ANOVA showed that the change between the groups did not differ significantly, $F(2,210) = 0.387, p = 0.680$.

Table 5: Change on the PHQ-9 from First to Last Score

Group	Mean First Score (SD)	Mean Last Score (SD)	Mean Change (SD)
LIPI only (N=130)	16.7 (6.0)	8.13 (6.98)	8.80 (6.43)
Stepped-up (N=62)	17.4 (5.6)	10.23 (6.80)	7.08 (5.44)
CBT only (N=21)	18.49 (6.93)	11.52 (7.63)	9.48 (8.13)

Table 6: Change on the GAD-7 from First to Last Score

Group	Mean First Score (SD)	Mean Last Score (SD)	Mean Change (SD)
LIPI only (N=130)	13.5 (5.0)	7.0 (6.41)	6.99 (5.73)
Stepped-up (N=62)	15.5 (5.6)	9.56 (6.20)	6.26 (4.83)
CBT only (N=21)	15.5 (5.72)	11.0 (6.66)	6.57 (5.72)

Outcomes were analysed using the number of people achieving RCSI on the PHQ-9 and GAD-9 (Tables 7 and 8). The groups do not differ at a statistically significant level on the proportion of people achieving RCSI; PHQ-9 $\chi^2(2) = 1.079$, $p = 0.583$; GAD-7 $\chi^2(2) = 1.208$, $p = 0.547$. It is important to note that those who made a Reliable and Clinically Significant Deterioration (RCSD) were excluded from this analysis in order that the assumptions of this statistical test were not violated.

Table 7: Number (%) of People Achieving Reliable and Clinically Significant Improvement on the PHQ-9

Group	No RCSI	RCSI	RCSD
LIPI only (N=130)	52 (40%)	78 (60%)	0
Stepped-up (N= 62)	28 (45%)	33 (53%)	1 (2%)
CBT only (N=21)	10 (48%)	10 (48%)	1 (5%)

Table 8: Number (%) of People Achieving Reliable and Clinically Significant Improvement on the GAD-7

Group	No RCSI	RCSI	RCSD
LIPI only (N=130)	57 (44%)	70 (54%)	3 (2%)
Stepped-up (N=62)	32 (52%)	28 (45%)	2 (3%)
CBT only (N=21)	10 (48%)	10 (48%)	1 (5%)

Improvement, recovery and remission were computed (Tables 9 and 10). The only statistically significant difference was between the number of people that were classed as in remission (i.e. non-clinical) at their last GAD-7 score, $\chi^2(2) = 8.234$, $p = 0.016$. Running the Chi Squared analysis for the individual comparisons indicated that the number of people classified as in remission at their last appointment was significantly higher in the LIPI only group compared to the CBT only group, $\chi^2(1) = 4.089$, $p = 0.043$ and the stepped-up group, $\chi^2(1) = 6.165$, $p = 0.013$.

Table 9: Number (%) of People Achieving Improvement, Recovery, Remission on the PHQ-9 at Last Session

Group	Improved	Recovered	Remission
LIPI only (N=130)	78 (60%)	73 (56%)	82 (63%)
Stepped-up (N=62)	33 (53%)	26 (42%)	30 (48%)
CBT only (N=21)	10 (48%)	10 (48%)	10 (48%)

Table 10: Number (%) of People Achieving Improvement, Recovery, Remission on the GAD-7 at Last Session

Group	Improved	Recovered	Remission
LIPI only (N=130)	62 (48%)	69 (53%)	91 (70%)
Stepped-up (N=62)	26 (42%)	26 (42%)	32 (52%)
CBT only (N=21)	9 (43%)	9 (43%)	10 (48%)

Table 11 illustrates the total number of sessions people received at outcome for the three groups. This data was positively skewed (i.e. most people had a low number of sessions) and it was found that a log transformation solved this problem and the samples were compared. A one-way ANOVA indicated that the three groups differed significantly in the number of sessions individuals had received at their outcome, $F(2, 210) = 54.645, p < 0.001$. A Tukey HSD post hoc analysis indicated that all three groups differ significantly from each other at or less than $p = 0.0001$.

Table 11: Total Number of Sessions at Outcome

Group	LIPI only (N=130)	CBT only (N= 21)	Stepped-up (N=62)
Mean (SD) No. Sessions	3.79 (3.08)	7.10(5.00)	11.50 (6.18)
Log Mean (SD) No. Sessions	0.45 (0.33)	0.74 (0.34)	0.97 (0.31)
Median No. Sessions	3	6	11.5

3.3 Predicting Stepping-Up

When all predictor variables (at assessment: gender, age, duration of illness, PHQ-9, GAD-7, employment status, primary problem) were entered into a Standard Logistic Regression it

was found that together they predicted only 9.8% of the variance in the outcome (stepping-up or not stepping-up). This model was not statistically significant, $\chi^2(11) = 16.69$, $p = 0.117$, and only predicted stepping-up with 62% accuracy (82% not stepped-up; 33% stepped-up). Only anxiety at assessment was a significant unique predictor, $W^2(1) = 7.45$, $p = 0.006$.

A second Standard Logistic Regression was conducted including the change on the PHQ-9 and GAD-7 between assessment and the next contact as well as the previously included variables. When all predictors were entered into the model it predicted 17.4% of the variance and was a statistically significant model, $\chi^2(13) = 30.61$, $p = 0.004$. Anxiety at assessment was a unique predictor, $W^2(1) = 7.33$, $p = 0.07$, along with change from assessment to first session on the PHQ-9, $W^2(1) = 3.78$, $p = 0.05$. A t-test reveals that people who are stepped-up have less change compared to those who are not stepped-up between assessment and first contact, $t(219) = -3.616$, $p < 0.0001$. Both sets of variables were entered into a Backwards Stepwise Logistic Regression which produced the same results.

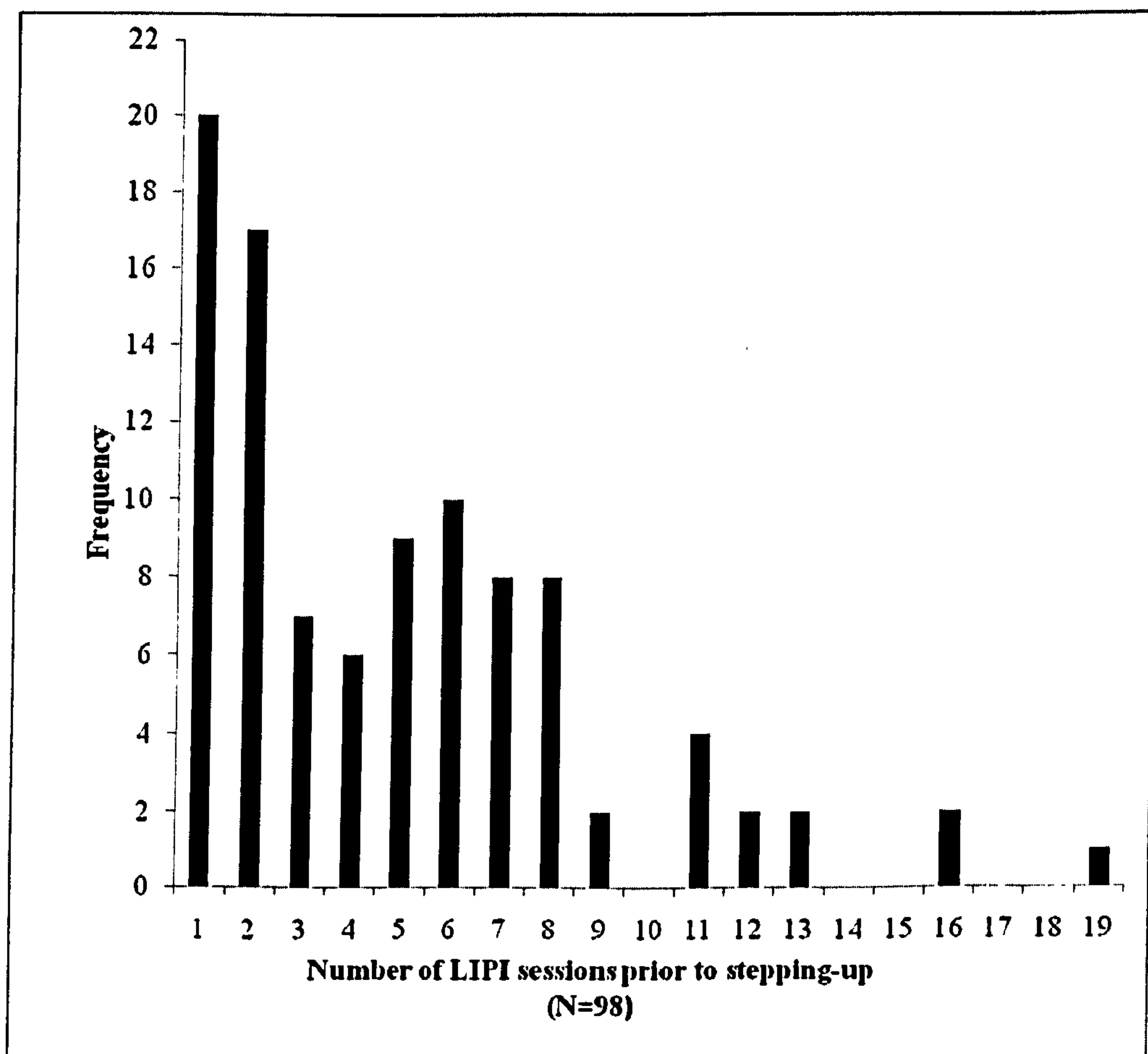
3.4 Stepping-up

To explore in detail the process of stepping-up, the 98 people who were stepped-up, had been discharged and had full PHQ-9 and GAD-7 data for attended sessions were used in the next part of the analysis. Using this group of people increased the power of this part of the investigation.

3.4.1 Number of Sessions

The mean number of LIPI sessions for this group was 4.97(SD=3.88) and the mean number of CBT sessions was 5.93(SD=5.00). Figure 3 illustrates the spread in the number of sessions people had prior to being stepped-up. Given the positive skew the median is the most useful measure of central tendency. The median number of sessions was 4.

Figure 3: Frequency Graph for Number of Low Intensity Sessions Prior to Stepping-up (N=98)



3.4.2 Outcomes at Different Time Points

The mean scores on the PHQ-9 and GAD-7 were computed for this group (N=98) at assessment, last session and the last session of LIPI prior to stepping-up (stepping-up score;

Table 12). A One-Way Within Subjects ANOVA indicated that the participants differed significantly in their mean scores on the PHQ-9 at these different time points, $F(2) = 56.759$, $p < 0.0001$. Post hoc analysis using the Bonferroni correction indicated that the difference between the means was statistically significant between the first and stepping-up score, $t(194) = 4.761$, $p = 0.001$, but not the first and last score, $t(194) = 7.053$, $p = 0.057$, or between the stepping-up and last score, $t(194) = 1.875$, $p = 0.190$.

Maulchly's test indicated that on the GAD-7 comparison, the assumption of sphericity had been violated, $\chi^2(2) = 8.052$, $p = 0.018$. Therefore degrees of freedom were corrected with Huynh-Feldt's estimate of sphericity. The ANOVA indicated that the mean GAD-7 score differed at the three time points, $F(1.886) = 41.468$, $p < 0.0001$, and post hoc analyses indicated that there was a significant difference between the first score and the stepping-up score, $t(194) = 4.069$, $p = 0.001$ and the first and last scores, $t(194) = 5.991$, $p = 0.01$. However, the difference between the stepping-up and the last score was not statistically significant, $t(194) = 1.655$, $p = 0.529$.

Table 12: Mean (standard deviation) Scores on PHQ-9 and GAD-7 at Different Time Points for the Stepped-up Group (N=98)

	PHQ-9	GAD-7
Mean First Score (SD)	17.17 (5.94)	15.09 (5.61)
Mean Step-up Score[*] (SD)	12.59 (7.45)	11.71 (6.51)
Mean Last Score (SD)	10.66 (6.95)	10.19 (6.35)

* at last LIPI session

When change was explored using the RCSI index (Appendix 11 shows calculations) this pattern is repeated with more people achieving a RCSI between the assessment and stepping-up session compared to the stepping-up and the last sessions (Tables 13 and 14).

Table 13: Number of People Achieving Reliable and Clinically Significant Improvement on PHQ-9 for Stepped-up Group at Significant Time Points (N=98).

Time Points	No RCSI	RCSI	RCSD
First to Step-up (N)	59	36	3
Step-up to last (N)	72	22	4
First to Last (N)	44	51	3

Table 14: Number of People Achieving Reliable and Clinically Significant Improvement on GAD-7 for Stepped-up Group at Significant Time Points (N=98).

Time Points	No RCSI	RCSI	RCSD
First to Step-up (N)	66	26	6
Step-up to last (N)	79	14	5
First to Last (N)	39	56	3

4. Study 1 Discussion

The results of this study indicate that people who are stepped-up do not differ significantly from those who received only LIPI or CBT on a range of assessment characteristics or their outcomes. In addition, stepping-up could not be predicted from the assessment characteristics investigated. The GAD-7 score at assessment did have some predictive value along with the progress on the PHQ-9 between assessment and the first contact but far too little to be transferred into clinical practice. These are cautious conclusions in relation to the CBT group where the number of cases did not meet the requirements of the power calculation.

The only statistically significant difference between the groups at assessment was the mean anxiety score which was lower in the LIPI only group compared to the stepped-up and CBT groups. This indicates that those with higher anxiety are potentially more likely to be stepped-up. For this finding to be useful in clinical practice would require a value, above which stepping-up could reliably be predicted. The numbers of people in each of the GAD-7 severity categories (Spitzer et al., 2006) were therefore compared between groups. There was no difference when the three groups were compared on the number of people in the GAD-7 severity categories. This may be because the numbers, particularly in the CBT group, rendered the analysis under-powered or may reflect the reality which is that the groups are generally too similar to see any such difference in anxiety severity.

These results do not provide any evidence to suggest that a particular group of individuals would not benefit from LIPI. All three groups are similar in their assessment characteristics and these do not predict stepping-up even in combination. The range of variables

investigated was limited to those collected by the service and clearly further research is required to understand what characterises people who are stepped-up. This remains an important question because essentially these people are unlikely to have a good outcome with LIPI. Understanding the reasons for this will help to develop these interventions and a more sophisticated stepped care model. Although this study investigated predictors of stepping-up, it does offer some support to the limited literature regarding outcome prediction following LIPI. By using practice based evidence, it remedies some of methodological issues potentially responsible for statistically non-significant findings in relation to outcome prediction. It therefore supports other studies that have failed to find any strong predictors of outcome (e.g. Andersson et al., 2004; Buwalda & Bouman, 2008; Helleström & Öst, 1996).

From the service model⁴ it was expected that a higher proportion of people classified as moderately to severely depressed/anxious and a higher proportion of specific diagnoses such as OCD, PTSD would be found in the CBT only group. This difference was not found perhaps because “primary problem” is defined by the referrer rather than the person who conducts the assessment or potentially due to the low sample size of the CBT only group. The measures of severity are symptom specific and do not capture the impact on general functioning that may be a factor in how clinicians define severity. Finally, the descriptions of stepped care models suggest that people are stepped-up if they do not make sufficient progress with the lower steps (Bower & Gilbody, 2005; Davinson, 2000; Treasure et al., 1996). Conversely this study found that people who were stepped-up changed significantly

⁴ Specific reference not included to maintain anonymity of service

more on the outcome measures between assessment and their last LIPI session compared to the last LIPI session and their outcome.

These are puzzling results which may be explained by a variety of methodological and service factors. It is firstly important to note that the stepped-up session was defined by the researcher rather than the service as the last session of LIPI before CBT commenced. In addition the number of sessions of LIPI varied considerably between individuals which may have cofounded the results. It is possible that the decision to step-up was made early in treatment but the LIPI was continued until a CBT therapist was available and some benefit may have been gained. The outcomes on the PHQ-9 and GAD-7 were considered separately so this analysis will not have captured those people who changed on one measure but not the other. In relation to the research literature, this finding may represent the dose-response curve that has been found in traditional therapies where the majority of change occurs in the first few sessions (Lambert & Ogles, 2004). There is evidence that this occurs even in interventions of just three sessions (Barkham, Shapiro, Hardy & Rees, 1999).

Those who were stepped-up did not differ significantly in their outcomes compared either to those who received only LIPI or those who received CBT only. More people achieved RCSI with a LIPI although this difference was not statistically significant. This pattern was also found when outcomes were computed using the criteria used by Richards and Suckling (2009). Again, more people were improved, recovered and in remission in the LIPI group compared to the other two groups on both measures. The mean change from first to last session does not significantly differ between the groups.

Whichever method of outcome evaluation is used, around 50% of people achieved a clinical change by their last session indicating that the intervention matched their needs. This percentage is not dissimilar to the effectiveness found for all psychological therapies (Wampold, 2001). It is useful to note that people who are stepped-up do not achieve drastically better or worse outcomes than those who have just a LIPI or CBT. Given the difference in the mean number of contacts per group it could be argued that clinical change is achieved more quickly with a LIPI compared to CBT and those who are stepped-up. It may be that the symptom specific measures do not capture the change that was important to service users who potentially received a useful service. Likewise a limitation of the study is that the case status at the last session was not included in the analysis i.e. was the ending planned, unplanned etc. The people who remained at a clinical level or achieved a non-RCSI may have dropped-out and it is important that future research addresses this.

4.1 Strengths and Limitations

This study has good external validity due to the use of practice based evidence. Given that such a small proportion of people were stepped-up, it is argued that it would be difficult to investigate this area in any other way (See Barkham & Mellor-Clark, 2003 for discussion).

One limitation is that data is collected by clinicians on an evolving database. There was far more missing data than was anticipated and in order to compare the groups and combine variables in a regression analysis only cases with complete data were used which significantly reduced the sample sizes. In addition, it is possible that some data was entered

inaccurately and there may be variation in how clinicians record certain data. The study was limited to investigating variables that were collected by the service and it is suggested that other variables may be useful to consider when furthering this work in the future.

Study 2:

Understanding the Experience of Stepping-up

5. Study 2 Method

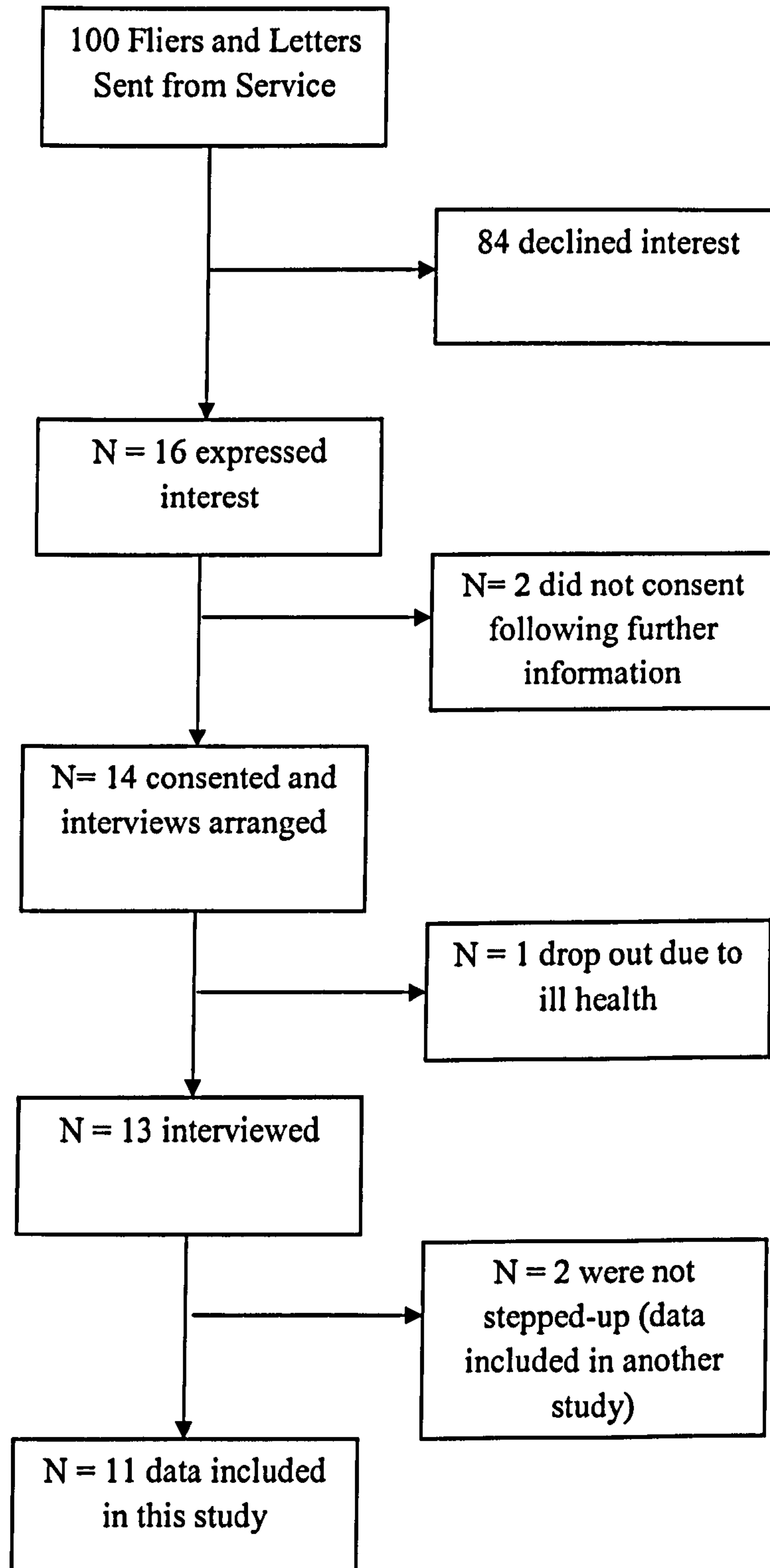
5.1 Rationale for Methodology.

This study used Interpretative Phenomenological Analysis (IPA) a qualitative methodology suited to investigating novel, complex or process issues where the focus is on understanding how people make sense of their experiences (Brocki & Wearden, 2006; Smith, Jarman, & Osborn, 1999; Smith, Flowers, & Larkin, 2009). IPA makes an assumption that it is impossible to fully access the lived experience of the individual (Smith et al., 1999, Smith et al., 2009; Willig, 2001). In light of this, IPA explicitly acknowledges the dynamic process that occurs between the researcher and the interviewees (Smith et al., 1999).

5.2 Recruitment

A sample was recruited from the IAPT pilot site of people who had been stepped-up from LIPI to CBT (as defined in Study 1). IPA suggests purposive sampling of a homogeneous group in order to explore a subject area in depth rather than breadth (Smith et al., 1999; Smith & Osborn, 2003; Willig, 2001). Therefore, people who had been discharged following CBT and those who were nearing the end of treatment were targeted first in the recruitment. Figure 4 illustrates the recruitment process and Appendices 12-14 contain the information given to participants.

Figure 4: Recruitment Flow in Study 2.



5.3 Participants

Eleven participants were included in the analysis. 10 were female and 1 male, aged between 36 and 57 and all were White British. Two reported still to be having CBT sessions and nine reported having completed their treatment. Although data on which workers they saw was not collected, it is noteworthy that nine of the participants named the same person as their CBT therapist.

5.4 Data Collection

Semi-structured interviews were undertaken at local health centres or participants' homes lasting between 45 and 90 minutes. Interviews were recorded and transcribed verbatim. Participants received a £10 retail voucher following their participation in the study.

The interview template (Appendix 15) was constructed in line with recommendations that open questions which avoid making assumptions should be used (Smith, 1999; 2009; Willig, 2001). Drafts were modified based on discussion with a supervisor and a User Researcher. The aim of the interview was to understand the experience of the whole service for people who were identified as having the particular experience of stepping-up in order to broaden the analysis.

5.5 Analysis

The analysis was conducted following recent guidance by Smith et al. (2009). Each transcript was analysed separately prior to looking across cases. Initially a transcript was read and re-read noting initial responses to the data in the left hand margin. These annotations included descriptive statements, questions, comments on language use,

omissions, etc. As a transcript was re-read multiple times emerging themes were labelled and noted in the right hand margin. The emergent themes aimed to be more conceptual incorporating psychological terminology where appropriate with the aim of “capturing something about the essential quality of what is represented by the text” (Willig, 2001, p. 55). A master table of the clustered themes was constructed along with relevant quotes and line numbers from the transcripts. The raw data was referred to throughout this process to ensure that the interpretation fitted with the context of the raw data. This process was repeated with each of the transcripts. Appendix 16 illustrates a worked example of these stages.

Finally, patterns of emergent themes were developed across the cases using the summary tables, moving back and forth between these and the transcripts. Looking across the cases allowed the super-ordinate themes to emerge with the focus firmly on trying to understand how people made sense of stepping-up.

5.6 Validity and User Involvement

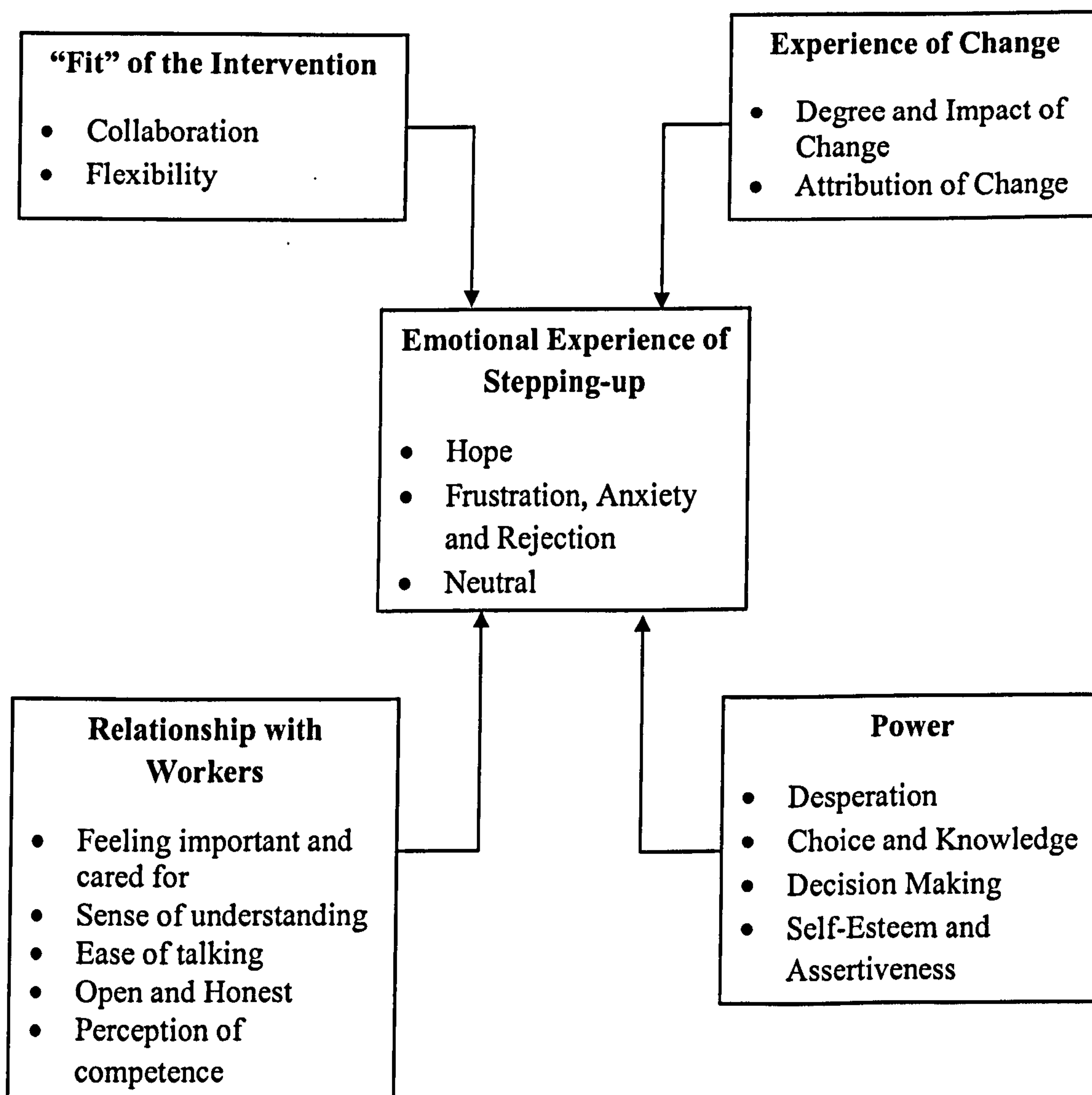
The researcher is a White British female Trainee Clinical Psychologist in her mid twenties who has also worked as a LIW but not in the service in question. She has a strong interest in IAPT and is passionate about the principle of this program. Having delivered both low and high intensity interventions to adults with common mental health problems, she holds some beliefs about the strengths and limitations of the LIPI and had some ideas about how people may make sense of stepping-up although was keen to remain open-minded. To aid reflexivity the researcher kept a reflective log, engaged in supervision and regular meetings with the User Researcher which maintained a transparent audit trail.

In addition to the main analysis, three transcripts were analysed by a User Researcher who carried out the initial noting and developed emergent themes. The User Researcher is experienced in qualitative methods including IPA. She has accessed psychological therapy within the NHS but not in the service in question. She is active in the Service User Involvement movement and is interested in improving the service user experience. Although both individuals felt that they shared a similar perspective regarding the service user experience, it was decided to embrace and explore any differences in the emerging themes from the transcripts read by both people rather than try and force the two together.

6. Study 2 Results

Five super-ordinate themes were found in all eleven transcripts. Figure 5 illustrates the suggestion of how these themes fit together to understand the experience of stepping-up. Each theme is discussed in turn with reference to the *sub-ordinate themes* (in italics) with illustrative verbatim quotes. Names of participants are changed and the acronyms LIW and CBT are inserted in place of worker names or identifying pronouns, [...] indicates a gap in the verbatim quote inserted for readability.

Figure 5: Making Sense of Stepping-up: Diagram Illustrating Themes and the Suggested Link between Them



6.1 The “Fit” of the Intervention

For all participants the degree of “fit” between the interventions and their needs was a key aspect of their experience of the stepped care service and something to which they attributed change/lack of change. Some stated the intervention “suited me very well” (Gina) while others held different views:

Ellie: *“I felt like I was drowning and someone was throwing a ring to me that landed about ten miles away.”*

The first sub-ordinate theme was *Collaboration*. It seemed important that the worker went at the individuals’ pace and had a shared understanding of their goals and circumstances. Several respondents experienced the worker taking the lead rather than collaborating and “telling” them what to do or “pushing” them to do particular tasks.

Fiona: *“I kept thinking this is not for me and s/he was following what s/he thought was his/her thing of treatment but s/he was forcing me to do these things that I wasn’t ready to do.”*

Some participants, however, felt that the workers were collaborative and moved at their pace. This was evidenced with the use of the pronoun “we” as opposed to “she/he”.

Gina: *“When someone empathises and sympathises with that and then goes into a more persuasive ‘well shall we try a little step’ kind of thing...to me that is a much better approach ...anyway s/he probably picked up that it was going to work better.”*

The theme of “Fit” was also captured by the sub-ordinate theme *Flexibility*. Some participants described the intervention being delivered flexibly, whereas others described

both the intervention and their worker as “structured” (Irene), “clerical” (Duncan), “business like” (Kerry), “rigid” (Ellie).

Ellie: *“It was just like these pre-programmed responses, everything was pre-programmed off a sheet you could have got a robot to do them all.”*

There was diversity in how people felt the service/treatment was tailored to their needs.

Heidi: *“S/he adapted it to the needs of the person s/he was dealing with...it felt personal...there would be a standard format won't there because I'm certain on that it's always done on a format....but you wouldn't have known it, it was meant for me...”*

Jackie: *“I feel like I have had an individual service.”*

Gina: *“It was done over the telephone which is brilliant because you don't have to get changed and you don't have to get washed and I know that sounds awful but when you are in a depressed state it is a mountain to climb just to get yourself washed and changed to leave the house.”*

6.2 Relationships with Workers

All participants described their relationship with the workers as being paramount to their experiences. Again, they attributed change/lack of change to various aspects of these relationships. There was considerable diversity in what was found to enable and hinder the formation and maintenance of relationships.

Several participants described their experience of *Feeling Important and Cared For*. Some shared that their worker had put time and effort into planning their sessions or remembered what they had said previously. Most had been told explicitly that they could always call between appointments and had a sense that the service was “always there”.

Heidi: *“I was important to [LIW] and to [CBT] no matter what else were going off and what other schedules they had, and where they had to be next I was important at that minute in time and that’s huge as well.”*

Conversely, a proportion of participants felt that their worker was busy and this was the reason they had telephone rather than face-to-face contact at the first step of the service.

Claire: *“I saw him/her once and then we kept in touch over the phone. I talked to him/her that way because I understood s/he was very busy and I appreciate that because I am not the only one.”*

Another sub-ordinate theme was the *Sense of Understanding* participants felt their worker had of their situation and in turn how the worker helped the individual understand their difficulties, translating what they were experiencing into something manageable.

Irene: *“[CBT]’s got an empathy of what I’m experiencing and is able to translate that...s/he knows I’m trying to do my best.”*

There were a number of participants who felt that the telephone had been a barrier to the worker understanding them and emphasised the importance of visual contact in feeling understood.

Fiona: *"...and it was talking to a faceless voice and because of where I was at that particular time all I saw was on the other end of the phone somebody sniggering, laughing and rolling their eyes as if to say 'oh god hurry up'.."*

Duncan: *"How could my caseworker know if I'm sitting shaking like a leaf and sweat pouring off me and gripping hold of the chair for dear life, s/he'd no idea. Not got a clue..."*

Within the relationships with workers some respondents spoke about the importance of the *Ease of Talking* with the person.

Claire: *"[CBT] makes you feel at ease when you talk to her/him."*

Others felt strongly that the mode of delivery (telephone or face-to-face) had a negative impact on how comfortable they felt talking to their worker. Again, there were diverse experiences of this.

Alice: *"I did feel a bit...perhaps because it was over the phone ...but I didn't feel that I could talk to him/her."*

Jackie: *"I felt more relaxed over the telephone... for somebody that is depressed that lack of pressure is a big help...it means the talking part of therapy is easier because that is all you are concentrating on."*

Some people also spoke how easy it was to be *Open and Honest* with their worker. This was mainly mentioned with regard to the telephone being perceived as hindering the development of a relationship compared to face-to-face contact.

Kerry: *"I think the telephone interviews, anyone can get round them where as when someone is face-to-face not that you would lie for any reason but just sometimes you don't lie but you don't tell the complete truth, you just want to keep things to yourself...whereas when I saw [CBT] face-to-face it was a lot easier to talk to him/her whereas over the phone I just said 'yes, yes'."*

The final sub-ordinate theme was the *Perception of Competence* which several people highlighted as important to how confident they felt in the worker.

Ellie: *"I felt like maybe the staff, I don't know if they had had some sort of quick training....and I felt that s/he was a little bit out of his/her depth with some of the experiences that people had."*

Duncan: *"I do believe [CBT] more trained because [LIW] is only trained to deal, to give you treatment, tell you what to do..."*

6.2 Experience of Change

This super-ordinate theme is woven through people's accounts of the service. The variation within this appears to have an important influence on how people then made sense of stepping-up. The *Degree and Impact of Change* were frequently mentioned. A number of people described all or part of their service experience as resulting a large amount of change and having a hugely positive impact on their lives, some even felt it was "life saving" (Heidi).

Kerry: *"massive response...felt the best I have in probably 6 years."*

Claire: *“You know when I first started with [LIW] and [CBT] there was one black tunnel and there was no light at the end of it but when I finished with [LIW] there was a little bit of light at the end but a long way off but now the light seems to be becoming brighter and brighter.”*

Linked with this is the *Attribution of Change*. This encompasses which aspect of their experience people held responsible for change/lack of change. Some people feel strongly about the mode of delivery of the interventions, others were very animated about the techniques they had integrated into their lives.

Kerry: *“I didn’t really feel the benefit or value because it wasn’t face-to-face”*

Jackie: *“...you are self-helping and it gave you the power to get yourself better, it gave you the tools and the techniques but it was the power to use them.”*

Brenda: *“I get up in a morning and I know I have got to wash so the night before I set my diary exactly how they did...”*

6.3 Power

This theme was present in all transcripts, often related to the workers’ power, and had an impact on many aspects of the respondents’ experiences of the service. Participants’ sense of powerlessness came from their *Desperation* for help.

Heidi: *“All I knew were someone finally were gonna help me and it didn’t matter what it involved, it didn’t matter what they wanted me to do...”*

In all of the transcripts it was clear that participants experienced a lack of *Choice and Knowledge*.

Alice: *"S/he told me when I went to see her at the Doctors Surgery you know 'I will phone you up and you will have a phone call appointment'."*

Even Gina, who was very positive about the use of telephone and her overall service experience, still indicated that she was given little choice.

[Interviewer: "was there a choice offered to you over the telephone or face to face?"]

Gina: *"I don't think there was no. It was a case of 'we do this over the phone'."*

Few people were aware at the outset that there was anything other than the LIPI or telephone contact on offer.

Kerry: *"I wasn't aware...that there was an opportunity to have face-to-face contact. If had known I would have asked for that in the first few weeks."*

Irene: *"I don't know what treatments I should've had."*

Ellie, who had experience of accessing a number of different therapies, stated that she had never been given information about the available therapies or which ones may suit her. Duncan described his sense of this service in relation to choice.

Duncan *"..but you're not given the choice because it's like a conveyor belt. You've got all these people on the conveyor belt, and they've got to push so many people off to get more people on. So that's the way it is it's a conveyor belt. If they can push you off back into work then they push you off back into work, if they can't they'll*

push you off onto somebody else. So it's just a case of pushing somebody off so they can put somebody else back on."

The final aspect of this theme relates specifically to stepping-up and is the experience of *Decision Making*. The interviewees had different understandings of why they were being stepped-up. Interestingly no-one described it using this term, rather they were "passed on" or "referred on". Some had the idea that this was because of a lack of progress with the LIPI, others thought it was because they could only have so many LIPI sessions. The respondents described knowing that they were not progressing but not voicing this and not being asked. Although speaking passionately in the interview, Irene did not voice her concerns that she was not making any progress with her LIW during treatment.

Irene: "I'm trying to make this work so am I allowed to say 'no I'm sorry this isn't working for me I don't want it anymore?' Or have I got to wait for him/her to say 'I don't think this is right for you I'd like to pass you onto somebody else'."

Stepping-up was often experienced as a decision made on the basis of the outcome measures or opinion of the LIW, not a collaborative decision including the individual. Some also understood that the decision was made by the worker and a manager.

Brenda "[LIW] said 'this lady needs more time' and s/he [manager] said 'yes she can have more time'."

Duncan: "...by a certain amount of time your anxiety and depression scores should have come down significantly, whereas my depression came down, my anxiety score was staying the same, which is why I got referred on at the end because we weren't getting anywhere in that respect."

Two participants described a different experience where their worker collaborated with them. Even here there is a sense that they had to be stepped-up, they could not continue with LIPI even if they were finding this helpful.

Jackie: *“[LIW] didn’t force me it was my decision in the end. I had to say yes or else I don’t know what would have happened. [LIW] recommended it quite strongly and explained it quite clearly what it was...”*

The final sub-ordinate theme *Self-Esteem and Assertiveness* emerged in how respondents described their experience of their mental health problem and the impact this had on their sense of power in relation to the service.

Kerry: *“I’d gone from a really good career to having no confidence and fairly low self-esteem, suicidal thoughts...I couldn’t read a paper, I couldn’t turn the news on...I just closed the outside world off...”*

6.5 Emotional Experience of Stepping-up

The process of stepping-up for those who had been unaware of anything other than LIPI seemed to bring them *Hope* that something might help them.

Ellie: *“At least there is some kind of progression to it and the biggest thing for me is if something hasn’t worked or not fully worked, they have referred me onto something different straight away and that has made a huge difference, that focus to just recovering.”*

This also included individuals experiencing validation of their own sense of lack of progress.

Fiona: *“Well I thought at last you are listening because I couldn’t do the things s/he was telling me to do!”*

Participants also experienced what has been termed *Frustration, Anxiety and Rejection*. A minority described anxiety about moving on from the LIPI and LIW that they were finding helpful.

Claire: *“the first couple of times I was a bit wary...I thought if ‘I can’t talk to him/her like I talked to [LIW]’ then I thought ‘I am going to end up back at square one again’, that was the scary part.”*

Despite a number of individuals feeling hope at stepping-up there was a sense of frustration that they had not been aware of further interventions and had to endure the lack of change and the distress before stepping-up. Many described that they had “wasted time” or were “jumping through hoops” with the LIPI.

Fiona: *“I was in a real dark place you know and yet they were content just to let me carry on and battle through every day while all this red tapes going on, letters had been sent and telephone calls are made, you’re sat there screaming for someone to help you, you know?”*

A smaller number of individuals recalled that at the time of stepping-up they felt rejected and let down by the LIW and a sense of failure having not been able to gain more from the LIPI.

Ellie: *"...I felt like s/he didn't want to see me and couldn't cope. Maybe that was my illness and me taking that the wrong way but for me, I took that ending as sort of a failure on myself."*

Irene *"I felt really let down because I thought I'd wasted my time. I felt as if I was trying my best, I can't do this alone but have I just wasted the last 4 months because I've got nothing from this?"*

Gina and Heidi had more *Neutral* emotional reaction to stepping-up. This was linked with their pathway from LIPI to CBT being decided from the beginning to deal with different aspects of their problems.

Gina: *"It was fine for me because it was a different issue....In this particular instance I was starting again because it was a different therapist for a different illness for want of a better word so it wasn't actually a problem. Having a different therapist was almost better I think."*

6.6 Understanding Stepping-up

The importance of stepping-up in relation to these peoples' overall service experience was due to their experience of the other aspects of the service. In analysing the transcripts a common understanding of how these people made sense of stepping-up emerged which applied to all of the individuals and is illustrated in Figure 5. The sense-making of stepping-up and the Emotional Experience of this process was influenced by the comparisons people made between their experience of LIPI and CBT interventions and workers. These comparisons drew on the Experience of Change; the degree and impact of change and where in their journey people attributed this change. The key themes were those

described above, that of The “Fit” of the Intervention to their needs and the Relationship with Workers. Also impacting on this sense-making is their sense of Power in terms of their desperation, choice and knowledge and input on the decision to step-up.

7. Study 2 Discussion

Despite having diverse experiences of this service and stepping-up, the main themes in these participants' experience were similar. The five super-ordinate themes and a common process by which people made sense of stepping-up by comparing their experiences of LIPI and CBT were found in all eleven transcripts.

A strength and limitation of this study was the decision to interview people about their experience of the whole service rather than specifically focus on stepping-up. This permitted the analysis of this process in relation to experiences before and after stepping-up and the impact of these stages on one another. This retrospective perspective undoubtedly impacted on interviewees' sense-making. Interviewing people at the time of stepping-up may offer a very different perspective. What was clear, yet surprising, was the complexity of the experience of this service and stepping-up. This seems to be due to the impact of the therapeutic process on the individual and the impact of the organisation/system on the individual.

7.1 Therapeutic Process

It is suggested that the two themes, Relationships with Workers and Experience of Change, related to individuals' experience of the therapeutic process in the LIPI and CBT. Within the theme Experience of Change interviewees in varying degrees, attributed change to specific techniques from the LIPI and CBT interventions (e.g. thought challenging, activity planning). What was striking was the richness of information regarding the relationship with their LIW and CBT therapist, and how much change/lack of change they attributed to this relationship. There was diversity in the aspects of the relationship which were

important (e.g. therapist competence, ease of talking) but it was clearly central to the service experience. Where interviewees felt there were barriers to forming and maintaining a relationship, they spoke passionately about how much this had influenced their experience of a particular step and consequently this impacted on their experience of stepping-up. Where the relationship with the LIW was perceived to be poor and then more positive with the CBT therapist, the emotional experience was often relief. Others who had more positive relationships with the LIW recalled being more apprehensive about stepping-up.

The finding that specific techniques and the therapeutic relationship were important in people's experience of change reflects what is commonly found in the literature regarding traditional, one-to-one therapies. Lambert (1992) estimates that 15% of therapeutic change can be accounted for by specific factors, 15% by expectancy, 30% by therapeutic alliance and 40% by extra therapeutic factors. Wampold (2001) has argued that far less change can be attributed to specific techniques, in the region of 8%, and over 70% is likely to be attributable to "common factors" which includes the therapeutic alliance. It is accepted that, dependent on therapeutic orientation, the therapeutic relationship is considered necessary if not sufficient for successful outcome of therapy (Hardy, Cahill, & Barkham, 2007).

The finding that these factors were important to the experience of CBT is unsurprising and supports the existing literature (Hardy et al., 2007). What is fascinating is that even in LIPI the relationship holds such importance where, by definition, there is considerably less contact with a worker than in traditional therapy. Other qualitative guided self-help studies have similarly found the importance of speaking with a worker in service users' perceptions

of change (MacDonald, Mead, Bowers, Richards, & Lovell, 2007; Rogers, Oliver, Bower, Lovell, & Richards, 2004). However, neither the role of specific techniques nor the therapeutic alliance has been examined in relation to the process of change with LIPI. Richardson and Richards (2006) highlight that the premise of pure self-help is that the specific factors in CBT are distilled and the relationship with a worker is dispensed of. They hypothesise that the exclusion/minimisation of the relationship in pure self-help may account for its more recent mediocre performance in the effectiveness literature. They propose that the development of self-help should attempt to facilitate a therapeutic alliance with the materials themselves (Richardson & Richards, 2006). The findings of the current study suggest that where a worker facilitates LIPI, the relationship with them is potentially very important to the change process.

7.2 Organisational Influences

It is suggested that the themes Power and the “Fit” of the Intervention are related to the influence of the organisation/system on the individuals’ service experience and hence their experience of stepping-up. Within the “Fit” of the Intervention the interviewees spoke about the importance of collaboration and flexibility. Broadly, flexible collaborative interventions and experiences were perceived as positive (e.g. having LIPI and CBT for different aspects of mental health problems). People described negative experiences where interventions and workers were perceived as being structured and prescriptive. Power is interpreted as having a key role in mediating the emotional experience of stepping-up. Participants who felt frustrated at stepping-up tended to be those who had not been given information that anything other than LIPI was available and were not consulted over their treatment options. A number of interviewees had a sense that if they had been given the

choice about, for example, face-to-face or telephone sessions, they would have opted for the one which matched their needs and saved a lot of “wasted time”.

The influence of these themes on the experiences of the interviewees is in line with a wide qualitative mental health literature on empowerment and choice. Fitzsimons and Fuller (2002) review this literature and suggest that building empowerment with service users should be central to all mental health services and requires; collaboration, a flexible, individualized, strengths focussed approach and the facilitation of social support (p. 490). Nelson, Lord and Ochocka (2001) found a number of empowering processes that facilitated recovery in mental health. These included; access to resources, the ability to make choices about treatment plans and services and meaningful participation in services. With regard to choice and information Lanugharne and Priebe (2006) suggest that choice may improve outcomes “by improving patient attitudes to the treatment they have actively chosen, by increasing the patients’ sense of control, or by the patients successfully matching their needs to the appropriate treatment” (p. 846). This study found similar themes in relation to this pilot stepped care service and therefore supports this literature. The existing literature mainly reports findings from studies with the users of secondary and tertiary mental health services (Fitzsimons & Fuller, 2002; Lanugharne & Priebe, 2006; Nelson et al., 2001). Demonstrating the potential impact of the organisation on an individuals’ service experience in this stepped care service indicates that similar issues may be present for mental health service users across the spectrum.

7.3 Strengths and Limitations

These findings are considered to be valid and reliable in the context of criteria for conducting and reporting qualitative research (Elliott et al., 1999; Smith, 2003; Smith et al., 2009). The researcher acknowledged pre-conceived ideas about the topic from her experience essentially as both a low and high intensity worker, however, regular peer supervision, maintaining a clear audit trail and keeping a reflective log illustrates how reflexivity was incorporated into the analysis. A further strength of the study was the analysis of three transcripts by a User Researcher. Although an *a priori* decision was made to highlight any differences in interpretation, one sub-ordinate theme *self-esteem and assertiveness* became integral to the researchers' analysis following discussions with the User Researcher and was therefore incorporated into the final list of themes. This is considered appropriate in the context of IPA as an iterative process. The validity of the findings could have been strengthened had they been sent and verified by the participants themselves.

Caution must be taken when generalising these results as they are based on only eleven individuals' experiences all of whom were self-selecting and found their CBT helpful. The homogeneity of the sample meant that all interviewees spoke about their experience of stepping-up retrospectively. This perspective is integral to their sense making of stepping-up via the comparative process described. It is acknowledged that interviewing people at the time of stepping-up may offer a very different perspective along with interviewing those who had less favourable experiences of CBT. In addition all participants were recruited from one service which is still under development. It is likely, given the number of factors that were found to influence the experience of stepping-up, that this experience in

another service may well be very different. A larger research team would have enabled more participants to be interviewed and improved the convergent validity of the findings.

8. General Discussion

These studies are the first to have investigated stepping-up within a stepped care service model. The utility of exploring stepping-up using both qualitative and quantitative methods is in the conclusions that can be drawn by bringing both studies together.

The published descriptions of stepped care models suggest that stepping-up should occur when an individual does not make clinically significant progress with a LIPI (e.g. Davinson, 2000). A number of authors highlight that neither clinical change nor the number of sessions of LIPI have been quantified (Bower & Gilbody, 2005; Parry et al., 2005). The findings in this study reflect this ambiguity and suggest that in practice people may be stepped-up for a variety of reasons. The evidence for this suggestion is in the range of LIPI sessions attended prior to stepping-up (1-19, Figure 3) with around 40% of people who were stepped-up having just 1 or 2 sessions of LIPI. It is argued that “lack of progress” may not have been the reason for stepping-up in these cases. In addition, although the majority of interviewees felt that they had been stepped-up due to lack of progress, a number of them said that they had received a LIPI for depression and were stepped-up to CBT to deal with specific anxiety problems.

The diversity in potential reasons for stepping-up may account for finding more change between assessment and the last LIPI session compared to the last LIPI and last CBT sessions in this group. It is also not surprising that no predictors of stepping-up were found, nor were there differences between the three groups (LIPI only, CBT only and Stepped-up) at assessment. Essentially the variation in the reason for stepping-up is a confounding factor in these analyses. Undoubtedly within this group there will be individuals who were not

making progress with LIPI. It is suggested that common variables that characterise this group may be evident in future analysis accounting for this confounding factor.

It is unlikely that the absence variables of that predict stepping-up is entirely due to the diverse group included in this analysis. It seems likely that as in traditional therapies, change as a result of a LIPI involves a complex interplay of factors (Parry et al., 2005). In particular, Study 2 highlights the potential role of the therapeutic alliance in LIPI. In traditional therapy estimates are that at least 30% of change may be attributed to the alliance (Lambert, 1992; Wampold, 2001). If the same is found in LIPI then specific variables relating to the service user are unlikely to account for a large proportion of the variance of stepping-up.

Some authors have hypothesised potential negative effects of delaying access to treatments and treatment failure at lower levels in the stepped care models (Bower & Gilbody, 2005; Parry et al., 2005). The data from Study 1 indicates that on average the outcomes of people who are stepped-up are comparable with those who receive only LIPI or CBT. In addition, none of the interviewees reported any lasting negative effects of stepping-up. This is encouraging evidence in support of the stepped care model. There are, however, some important caveats. Firstly, this study did not investigate individuals who made poor progress with LIPI and dropped-out prior to being stepped-up or those who were stepped-up but did not attend CBT. To gain a full understanding of the impact of this model, the outcomes and experiences of these people must be clarified.

8.1 Further Work

As an initial exploratory study into stepping-up many areas for future work have arisen. Following the suggestion that there may be reasons other than lack of progress for stepping-up, a greater understanding of how this service model is implemented in practice is required. Interviewing LIWs and/or supervisors may illuminate this issue further. With this knowledge, and an ever increasing database, it will be possible to divide those who have been stepped-up into more meaningful groups based on the reasons for this decision. Examining the outcomes of these different groups and interviewing individuals about their experiences will then allow more specific conclusions to be drawn. In addition, both qualitative and quantitative data regarding those who drop-out of the service following lack of progress with a LIPI or prior to stepping-up is required to evaluate the impact of this model on service users.

This study suggests that examining the role of the therapeutic alliance in LIPI may be a useful avenue to explore in the development of these treatments. It is also suggested that the preference for telephone, face-to-face or computer delivery of LIPI is explored in relation to outcomes.

8.2 Clinical and Service Implications

Study 1 was possible only with access to routinely collected practice based evidence and highlights the extent of the research that can be achieved by integrating such systems into practice. Compulsory recording of the PHQ-9 and GAD-7 data made this a particularly useful database. However, large numbers of individuals were excluded from the analysis because of missing data. The importance of accurate, complete recording for all cases must

be emphasised to clinicians in order that important questions can be asked of the data that is recorded.

Although there are challenges in delivering LIPI flexibility, a number of interviewees spoke very highly of their LIW describing how they felt the intervention had been tailored to their needs. Clearly the techniques of those LIW who are successfully implementing LIPI should be closely examined as Wampold (2001) suggests in relation to traditional therapies. The role of the relationship with all workers was striking. All practitioners should be made aware of how central relationships can be to a service users' experience. It is suggested that where individuals are not progressing with LIPI, the alliance may be a useful focus in supervision as in traditional therapies. This is an approach used by Lambert et al. (2003) where patients' predicted trajectories are compared with their actual trajectories and where the two differ, supervision on the case and often the therapeutic relationship (Lambert et al., 2003). Highlighting the choices that people have with regard to treatment may influence their service experience. In particular users should be given information and choice regarding the service and their options. Whilst practitioners may feel that they do this routinely, qualitative research indicates that it is necessary to regularly reiterate information (Martindale, Chambers, & Thompson, 2009).

9. Conclusions

It can be concluded that in the current pilot of a stepped care model of service delivery, people who are stepped-up do not appear to be different to those who receive only a LIPI or CBT on a range of assessment variables. Stepping-up cannot be predicted from these variables. The outcomes for people who were stepped-up were comparable to the other groups investigated indicating that this pathway matches their needs.

The interviews with people who were stepped-up from a LIPI to CBT suggest a common process of making sense of the experience of stepping-up and the emotional experience of this. Retrospectively, people seemed to be comparing their experience of LIPI and CBT with regard to the degree of “Fit” between the intervention and their needs, the Relationship with the Workers and the Experience of Change at these steps. The experience of Power also impacted on the sense making of this process.

Together these findings suggest that, unlike the published descriptions of stepped care models, people may be stepped-up for a variety of reasons. This may account for the absence of predictors of stepping-up and disparities between the expected and actual change at different time points in this study. It is also suggested that as in traditional therapies, the relationship with the LIW may be an important factor in the process of change with an LIPI.

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Section 3: Appendices

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18 March 2009

Rachel Horn
Third year trainee
Clinical Psychology Unit
University of Sheffield

Dear Rachel

I am writing to indicate our approval of the journal(s) you have nominated for publishing work contained in your research thesis.

Literature Review: Journal of Counseling Psychology

Research Report: British Journal of Clinical Psychology

Please ensure that you bind this letter and copies of the relevant instructions to Authors into an appendix in your thesis.

Yours sincerely



Dr Andrew Thompson
Director of Research Training

Appendix 2: Journal of Counseling Psychology Notes to Contributors

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British Journal of Clinical Psychology (BJCP)

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For guidelines on editorial style, please consult the APA Publication Manual published by the American Psychological Association.

5. Brief reports and comments

These allow publication of research studies and theoretical, critical or review comments with an essential contribution to make. They should be limited to 2000 words, including references. The abstract should not exceed 120 words and should be structured under these headings: Objective, Method, Results, Conclusions. There should be no more than one table or figure, which should only be included if it conveys information more efficiently than the text. Title, author name and address are not included in the word limit.

6. Publication ethics

All submissions should follow the ethical submission guidelines outlined in the documents below:

 Ethical Publishing Principles – A Guideline for Authors

 Code of Ethics and Conduct (2006)

7. Supplementary data

Supplementary data too extensive for publication may be deposited with the British Library Document Supply Centre. Such material includes numerical data, computer programs, fuller details of case studies and experimental techniques. The material should be submitted to the Editor together with the article, for simultaneous refereeing.

8. Copyright

On acceptance of a paper submitted to a journal, authors will be requested to sign an appropriate assignment of copyright form. To find out more, please see our Copyright Information for Authors.

Appendix 4: Initial Ethical Approval



National Research Ethics Service

Leeds (West) Research Ethics Committee

A/B Floor, Old Site
Leeds General Infirmary
Great George Street
Leeds
LS1 3EX

Telephone: 0113 392 6788
Facsimile: 0113 392 2963

03 July 2007

Professor Glenys Parry
Professor of Applied Psychological Therapies
University of Sheffield
School of Health & Related Research
Regent Court
30 Regent Street
Sheffield
S1 4DA

Dear Professor Parry

Full title of study: Evaluation of new models improving access to psychological therapies
REC reference number: 07/Q1205/54

Thank you for your letter of 13 June 2007, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Sub-Committee of the REC held on 02 July 2007. A list of the members who were present at the meeting is attached.

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.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

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

Document	Version	Date
Application		01 March 2007

The Research Ethics Committee is an advisory committee to Yorkshire and The Humber Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England

Investigator CV	Glenys Parry	03 March 2007
Protocol	V1.1	28 February 2007
Covering Letter		03 March 2007
Letter from Sponsor		17 January 2007
Peer Review		
Statistician Comments		28 February 2007
Interview Schedules/Topic Guides	Strand 3, Patient / Carer Experience (V1.0)	22 February 2007
Interview Schedules/Topic Guides	V1.0 Strand 2 Topic Guide	22 February 2007
Questionnaire: Patient Health Questionnaire	PHQ-9	
Questionnaire: GAD-7		
Questionnaire: Outcome Measure		
Questionnaire: Disability Assessment Schedule II		
Questionnaire: Client Satisfaction	CSQ-8	
Questionnaire: Health and Employment Questionnaire	Final Version	
Letter of invitation to participant	Letter to Patient from GP V1.1	06 June 2007
Participant Information Sheet: Strand 3 For Patient	V3.1	16 May 2007
Participant Information Sheet: Strand 2 For Employees	V2.1	16 May 2007
Participant Information Sheet: Strand 1 For Patients	V1.1	16 May 2007
Participant Consent Form: Strand 3 For Patient	V3.1	16 May 2007
Participant Consent Form: Strand 2 For Employees	V2.1	16 May 2007
Participant Consent Form: Strand 1 For Patients	V1.1	16 May 2007
Response to Request for Further information		13 June 2007
GP Database Information List		
Certificate of Insurance		24 May 2007
SDO Funding Letter		30 November 2006

R&D approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for R&D approval from the relevant care organisation, if they have not yet done so. R&D approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly.

Guidance on applying for R&D approval is available from <http://www.rdforum.nhs.uk/rdform.htm>.

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.

Feedback on the application process

Now that you have completed the application process you are invited to give your view of the service you received from the National Research Ethics Service. If you wish to make your views known please use the feedback form available on the NRES website at:

<https://www.nresform.org.uk/AppForm/Modules/Feedback/EthicalReview.aspx>

We value your views and comments and will use them to inform the operational process and further improve our service.

07/Q1205/54	Please quote this number on all correspondence
-------------	--

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

Yours sincerely



Miss Anna Fawc
On behalf of
Dr John Puntis
Chair

Email: anna.fawc@leedsth.nhs.uk

Enclosures:

List of names and professions of members who were present at the meeting

Standard approval conditions

Copy to:

Mrs Greta Pearman, The University of Sheffield

R&D, The University of Sheffield

Leeds (West) Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 02 July 2007

Also in attendance:

Name	Position (or reason for attending)
Dr John Puntis	Consultant Paediatrician
Dr Michael Rivlin	Lay Member, Medical Ethics Lecturer
Dr Ken Shenderoy	General Practitioner

Appendix 5: Approval for Amendment to Recruitment to Interviews



National Research Ethics Service Leeds (West) Research Ethics Committee

A/B Floor, Old Site
Leeds General Infirmary
Great George Street
Leeds
LS1 3EX

Tel: 0113 3923181
Fax: 0113 3922663

25 November 2008

Professor Glenys Parry
University of Sheffield
School of Health & Related Research
Regent Court,
30 Regent Street
Sheffield
S1 4DA

Dear Professor Parry

Study title: Evaluation of new models improving access to psychological therapies
REC reference: 07/Q1205/54
Amendment number: 3.1
Amendment date: 28 October 2008

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 26 November 2008.

Ethical opinion

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

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	1.3	27 October 2008
Participant Information Sheet: An exploration of people's experiences using 'beating the blues'	1b	23 October 2008
Participant Information Sheet: Understanding expectations and experiences of using 'beating the blues'	1b	24 October 2008
Participant Information Sheet	1a	23 October 2008
Participant Consent Form: An exploration of people's experiences using 'beating the blues'	1b	23 October 2008
Participant Consent Form: Understanding expectations and experiences of using 'beating the blues'	1b	24 October 2008
Participant Consent Form: An exploration of people's experiences using 'beating the blues' in a community based clinic	1a	23 October 2008

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The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England

Recruitment Letter - Understanding expectations and experiences of using 'beating the blues'	1b	24 October 2008
Recruitment Flyer - An exploration of people's experiences using 'beating the blues'	1b	23 October 2008
Topic Guide	1b	24 October 2008
Recruitment Flyer - Understanding expectations and experiences of using 'beating the blues'	1b	24 October 2008
Recruitment Flyer - An exploration of people's experiences using 'beating the blues' in a community based clinic	1a	
Notice of Substantial Amendment (non-CTIMPs)	3.1	28 October 2008
Letter of invitation to participant	1b	23 October 2008
Recruitment Letter - An exploration of people's experiences using 'beating the blues' in a community based clinic delivered by a user led third sector organisation	1a	23 October 2008
Recruitment Flyer - Improving access to psychological therapies - Understanding your experience of the service	3.1	21 October 2008
Recruitment Letter	3.1	21 October 2008
Summary of Changes to NRES application	1	21 October 2008

Membership of the Committee

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

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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.

07/Q1206/54:	Please quote this number on all correspondence
--------------	--

Yours sincerely



Laura Milnes
Assistant Committee Co-ordinator

E-mail: Laura.Milnes@luedsth.nhs.uk

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

Copy to: Mrs Greta Pearman, The University of Sheffield

This Research Ethics Committee is an advisory committee to Yorkshire and The Humber Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England

Leeds (West) Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 26 November 2008

Michael Rivlin - Lay Member/Vice Chair
Sheila Fisher - Consultant Maxillofacial Surgeon
Elaine Hazell - Committee Coordinator
Laura Milnes - Assistant Committee Coordinator

*This Research Ethics Committee is an advisory committee to Yorkshire and The Humber Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England*

Appendix 6: PHQ-9

These questions are about depression and how it might affect you

Over the <u>last 2 weeks</u> how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day			
1. Little interest or pleasure in doing things	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3			
2. Feeling down, depressed, or hopeless	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3			
3. Trouble falling or staying asleep, or sleeping too much	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3			
4. Feeling tired or having little energy	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3			
5. Poor appetite or overeating	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3			
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3			
7. Trouble concentrating on things, such as reading the newspaper or watching television	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3			
8. Moving or speaking so slowly that other people could have noticed. Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3			
9. Thoughts that you would be better off dead, or of hurting yourself in some way	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3			
10. If you checked off any problems, how <i>difficult</i> have these problems made it for you to do your work, take care of things at home, or get along with other people?							
Not difficult at all	<input type="checkbox"/>	Somewhat difficult	<input type="checkbox"/>	Very difficult	<input type="checkbox"/>	Extremely difficult	<input type="checkbox"/>

PHQ-9 is adapted from PRIME MD TODAY, developed by Drs Robert L Spitzer, Janet B.W. Williams, Kurt Kroenke, and colleagues, with an educational grant from Pfizer Inc. For research information, contact Dr Spitzer at rls8@columbia.edu. Use of PHQ-9 may only be made in accordance with the Terms of Use available at <http://www.pfizer.com>. Copyright (c) 1999 Pfizer Inc. All rights reserved. PRIME MD TODAY is a trademark of Pfizer Inc.

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Appendix 7: GAD-7

These questions are about anxiety and stress and how it might be affecting you

Over the <u>last 2 weeks</u> how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
2. Not being able to stop or control worrying	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
3. Worrying too much about different things	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
4. Trouble relaxing	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
5. Being so restless that it is hard to sit still	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
6. Becoming easily annoyed or irritable	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
7. Feeling afraid as if something awful might happen	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

8. If you checked off any problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult

For office use only

PHQ-9/GAD VERSION:

ID NUMBER:

STAGE:

DATE:

The GAD-7 was developed by Drs Robert L Spitzer, Kurt Kroenke, Janet B.W. Williams, and Bernd Lowe. For research information, contact Dr. Spitzer at ris@columbia.edu. Copyright (c) 2005 Pfizer Inc. All rights reserved. Reproduced with permission.

SDO IAPT Evaluation - Not for Reproduction



Appendix 8: Example of Stepped Care Model

This is the diagram featured in the NICE guidelines for depression (NICE, 2004b). It illustrates the actions/treatments at each step and who is should be treated at these steps.

Step 5: Inpatient care, crisis teams	Risk to life, severe self-neglect	Medication, combined treatments, ECT
Step 4: Mental health specialists including crisis teams	Treatment-resistant, recurrent, atypical and psychotic depression, and those at significant risk	Medication, complex psychological interventions, combined treatments
Step 3: Primary care team, primary care mental health worker	Moderate or severe depression	Medication, psychological interventions, social support
Step 2: Primary care team, primary care mental health worker	Mild depression	Watchful waiting, guided self-help, computerised CBT, exercise, brief psychological interventions
Step 1: GP, practice nurse	Recognition	Assessment

Appendix 9: Explanation of Outcome Measurement Used

This appendix details the definitions and calculations used to determine outcomes from the PHQ-9 and GAD-7 in this study in addition to computing mean change on these measures from assessment to last session.

Method 1: Reliable and Clinically Significant Improvement

Evans et al. (1998) state that reliable and clinically significant improvement is a way of describing the change in the individual in relation to the change seen in the whole sample (p.70). It is a particularly useful measure of change because it is comparable across measures. It looks at whether the person has changed beyond that which could be attributed to measurement error (Reliable Change) and then does the outcome for the individual compare to scores observed in clinically meaningful comparison groups (Clinical Change). Improvement is considered Reliable if the change between pre- and post-treatment measures are greater than 1.96 x Standard Error of the difference. Likewise if the change is more than -1.96 x Standard Error then a Reliable Deterioration has occurred. Standard Error is calculated using the following formula;

$$SE_{\text{difference}} = SD_1 \sqrt{2} \sqrt{1-r}$$

$SE_{\text{difference}}$ = Standard Error of the difference

SD_1 = Standard Deviation of baseline observations in the sample of interest

r = coefficient α for the scale

Clinically Significant Improvement can be calculated using three different formulae. The most common and useful utilises the mean and standard deviation of a scale found in the normal population. For the PHQ-9 and GAD-7 however, there are no UK norms. Löwe et al., (2008) have produced norms for the GAD-7 in a German Population in a good quality

study however, a UK population would be far superior for the current study. The only norms that have been located for the PHQ-9 are based on an American all female gynaecological sample which is unlikely to be representative of the general UK population (Kroenke et al., 2001). This means that to calculate clinically significant change the only calculation which does not rely upon a normative sample is looking at whether pre to post-treatment change is more than 2 standard deviations from the original mean i.e.

$$\text{Mean}_{\text{pre-treatment}} - 2 \times \text{SD}_{\text{pre-treatment}} = A$$

Change > A is clinically significant.

The mean and standard deviation values were calculated from the whole sample used in the analysis i.e. N = 256 (LIPI only + Stepped-up + CBT only). The calculations are as follows;

For the PHQ-9;

- Pre-treatment SD in sample (N=256) = 5.99
- $r = 0.89$ (Kroenke et al., 2001)
- Therefore $\text{SE}_{\text{difference}} = 2.809$
- **Reliable Change cutoff = $1.96 \times 2.809 = \underline{5.51}$**
- Pre-treatment Mean in sample = 17.20
- **Clinically Significant Change = $17.20 - 2 \times 5.99 = \underline{5.22}$**

For the GAD-7;

- Pre-treatment SD in sample (N=256) = 5.30
- GAD7 $r = 0.92$ (Spitzer et al., 2006)
- Therefore $\text{SE}_{\text{difference}} = 2.12$
- **Reliable Change cutoff = $1.96 \times 2.12 = \underline{4.16}$**
- Pre-treatment Mean in sample = 14.48
- **Clinically Significant Change = $14.48 - 2 \times 5.30 = \underline{3.88}$**

Method 2: Recovery, Remission and Improvement.

Given that calculating RCSC in this way has its limitations, outcomes have also been calculated using the methods employed on an earlier data set from the Doncaster IAPT pilot side (Richards & Suckling, 2009). That is calculating the percentage of people who; have improved (i.e. achieved a moderate or large effect size, pre- to post treatment), recovered (i.e. the number of people who reduce their symptoms by half) and remission which by these authors is defined as the number of people who are classed as non clinical on the PHQ-9 (a score greater than or equal to 10) and GAD-7 (a score greater than or equal to 8) at their last recorded score.

Improvement is calculated using:

$$(\text{First Score} - \text{Last Score}) / \text{SD}_{\text{post treatment}}$$

For the PHQ-9 the Post Treatment SD for the whole sample (N=256) used was 7.05, for the GAD-7 it was 6.52.

Appendix 10: Descriptive data and comparison between whole sample of LIPI cases (with full data) and the random sample used in this study.

This table illustrates that the sample of LIPI used in the analyses in study 1 did not differ from the overall sample of people who had full data and received LIPI only.

Table 15: Comparing Random Sample with Whole Sample of LIPI Cases Only.

	All LIPI N= 1562	Sample N= 130	
Mean PHQ-9 at assessment (SD)	16.2 (6.0)	16.7 (6.0)	t(1690) = -1.032, p = 0.302
Mean GAD-7 at assessment (SD)	14.0 (5.0)	13.5 (5.3)	t (1690) = 1.143, p = 0.253
Mean Age in years (SD)	39.6 (13.2)	38.9 (13.0)	t (1690) = 0.521, p=0.603
Median Duration of illness (months)	9.25	10.33	
Mean Duration of illness (SD)	31.3(59.8)	31.8(55.4)	
Mean Transformed* Duration of illness (SD)	1.06 (0.6)	1.08 (0.6)	t(1690) = -0.236, p = 0.813
Gender N (%)			$\chi^2 (1) = 0.328, p = 0.567$
Male	519 (33%)	40 (31%)	
Female	1043 (67%)	90 (69%)	
Primary problem N (%)			$\chi^2 (2) = 0.534, p = 0.766$
Depression	114 (91%)	9 (7%)	
Anxiety	128 (8%)	120 (92%)	
Other	20 (1%)	1 (1%)	
Ethnicity			Statistical assumption of expected count >5 violated
White	158 (99.6%)	129 (100%)	
Non-white	6 (0.4%)	0 (0)	
Employment			$\chi^2 (4) = 0.729, p = 0.948$
Full/part-time work	864 (55%)	68 (52%)	
Student	40 (3%)	4 (3%)	
Retired	87 (6%)	7 (5%)	
Homemaker	175 (11%)	17 (13%)	
Unemployed	396 (25%)	34 (26%)	
Mean No. Sessions (SD)	4.0 (3.1)	3.8 (4.0)	t(1690)= 0.681, p = 0.496

*Log (Duration + 1) transformation due to positively skewed distribution

Appendix 11: Reliable and Clinically Significant Improvement Calculation for Stepped-up group only.

These calculations demonstrate the figures that were used to determine RCSC in the total number of people stepped-up in this service.

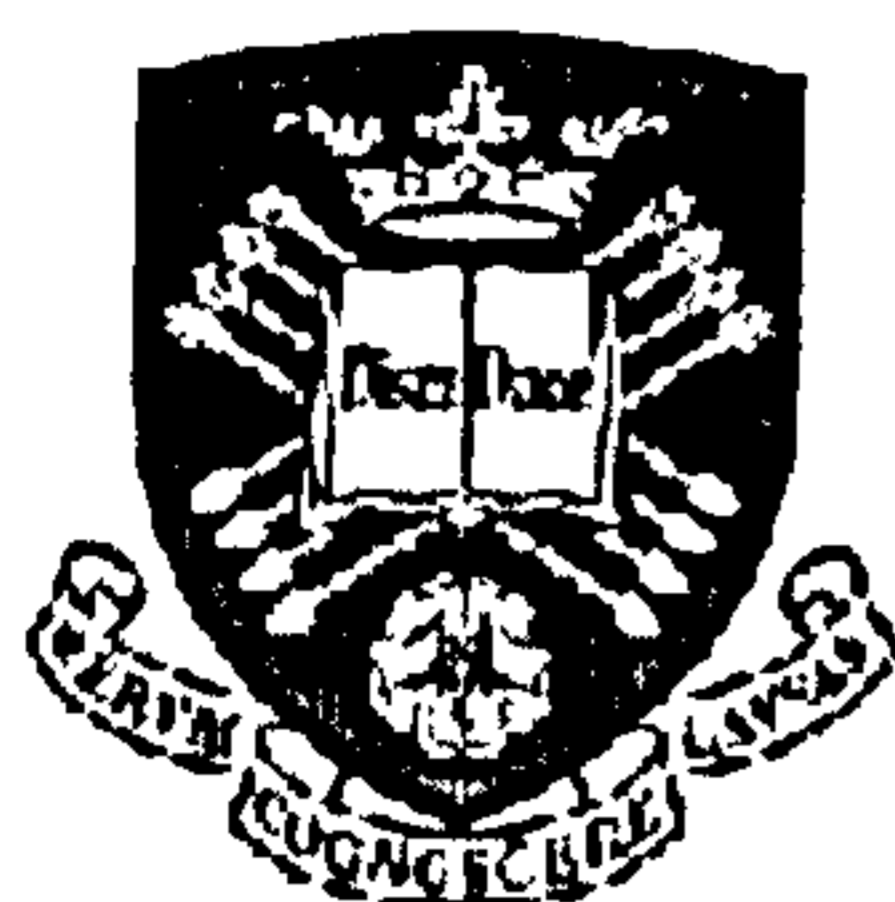
For the PHQ-9;

- Pre-treatment SD in sample (N=98) = 5.93
- $r = 0.89$ (Kroenke et al., 2001)
- Therefore $SE_{\text{difference}} = 2.78$
- **Reliable Change cutoff = $1.96 \times 2.78 = \underline{5.45}$**
- Pre-treatment Mean in sample = 17.17
- **Clinically Significant Change = $17.17 - 2 \times 5.93 = \underline{5.31}$**

For the GAD-7;

- Pre-treatment SD in sample (N=98) = 5.01
- GAD7 $r = 0.92$ (Spitzer et al. 2006)
- Therefore $SE_{\text{difference}} = 2.004$
- **Reliable Change cutoff = $1.96 \times 2.004 = \underline{3.92}$**
- Pre-treatment Mean in sample = 15.09
- **Clinically Significant Change = $15.09 - 2 \times 5.01 = \underline{5.07}$**

Appendix 12: Initial Flyer (sent to 100 people who had been stepped-up and completed or almost completed CBT).



**The
University
Of
Sheffield.**

**Improving Access to Psychological Therapies (IAPT) -
understanding your experience of the service**

Could you help with this research?

We are a group of researchers at the University of Sheffield. We want to understand your experiences of the IAPT service, to help develop better services for people with anxiety or depression. We would like to meet you for about an hour of your time to ask you questions about it. You can say where and when to meet (or we can talk over the telephone if you prefer) and we will give you a £10 gift voucher to say thank you for your time.

If you think you might like to do this, and would like to find out more about it then please complete the tear-off slip at the bottom of this piece of paper, and return it to us at the University of Sheffield in the envelope provided. You don't need a stamp. Until you do this nobody at Sheffield University knows who you are.

You can also give us your contact details over the telephone, by contacting our administrator, Abby Constantine on Tel. 0114 222 0753 or email a.constantine@sheffield.ac.uk.

When we have heard from you, we will send you some further details about what is involved and one of our researchers will contact you to answer any questions you may have and make further arrangements. Any information you give will be treated in confidence.

We look forward to hearing from you!

I am interested in finding out more about this research project and give permission for one of the University of Sheffield researchers to contact me about it.

Name:

Address:

Telephone: Email:

Best times to telephone me:

Please tear off and return this slip in the freepost envelope provided.
You do not need a stamp.

Strand 3.1 Flyer
Version 2D: 13/1/09

Appendix 13: Initial Letter (sent with flyer to 100 potential participants)

[Trust Headed Paper]

(Patient Name and Address)

DATE

Dear [Patient Name]

I am writing to ask if you would be willing to take part in a research project, and to introduce the researchers. A team from the University of Sheffield is trying to understand patients' experiences of the IAPT service. They would like to contact people who have been through the service, such as you, to ask if they would be willing to talk about their experience of and their views on what they have received.

If you think you might be interested in taking part, the enclosed flyer asks for your contact details. We won't pass on any information about you to the University of Sheffield, so they won't know who you are unless you decide you want to be contacted.

If you do decide to take part, it would involve you meeting with one of the researchers and talking with them about what has been helpful and unhelpful in the care you have received. Anything you say to them would remain entirely confidential, and you would not be personally identifiable in the results of the research or any publications.

To find out more you need to fill out the tear-off section of the flyer and return it to the University of Sheffield in the envelope provided. There is a small possibility that you may have received this letter more than once. If this is the case we sincerely apologise.

While you will not benefit yourself from taking part, the information obtained through this research should help the NHS to develop better services for anxiety and depression. However, you do not have to take part. The decision is entirely yours, and if you decide not to take part this will not affect any current care you are receiving or any future care.

Yours sincerely

[CBT therapist signature)

(CB Therapist Name and title)

Appendix 14: Information Pack and Consent Forms (Sent to all those who expressed interest in the project)



The
University
Of
Sheffield.

School of
Health &
Related
Research.

Professor Glorys Parry
Principal Investigator
Improving Access to Psychological Therapies project

Mental Health Section
Regent Court, 30 Regent Street
SHEFFIELD

Telephone: 0114 222 0617
Email: iaptenquiries@sheffield.ac.uk

16th May 2007
Version 3.1

Improving access to psychological therapies

This letter explains more about the research we have asked if you are willing to take part in. Please take time to read the following information carefully. Talk to others about the study if you wish.

What is the purpose of the interview?

We are researching the kinds of services people receive for anxiety and depression. The purpose of the interview is to hear about your experiences of the services you have received.

Why have I been invited and do I have to take part?

We have selected people to represent the range of people who have used the IAPT service. You do not have to take part in the interview, and if you do not wish to do so simply ignore this letter.

What will happen to me if I take part, and what will I have to do?

We will meet with you for about an hour to ask you about your experience of services (or lack of services) for anxiety and depression. We will ask you about what services you have received (if any) and what was helpful and unhelpful about them. We will make a recording of the interview and transcribe it later so that we can carefully read what you have said. We will ask for your permission to use the information you have provided to the IAPT service.

We will arrange to meet you at one of the IAPT interview rooms that is convenient for you. If this is not possible we may arrange to meet you at your home. As a thank you for taking the time to take part in the interview, we will send you a £10 voucher after the interview.

What are the possible benefits, disadvantages and risks of taking part?

It is possible that some people might find talking about their experiences distressing. If this happens to you, please tell the interviewer who will stop the interview until you can carry on.

It is unlikely that the study will help you directly, though some people may find it helpful to talk about their experiences. We certainly hope that the overall results will help improve services for anxiety and depression.

What if there is a problem?

If you have any problem then please contact the research project manager who is Dr Kim Dent-Brown, phone 0114 222 0867. His address is: University of Sheffield, Regent Court, 30 Regent Street, SHEFFIELD S1 4DA.
Email:

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Your name will not appear in any published material from this research, and you will not be identifiable in any way. The only exception to this would be if the interview led you to disclose information which you then decided to make the subject of a formal complaint.

What will happen if I don't want to carry on with the study?

If you decide that you do not want to continue, you can withdraw at any time. Unless you tell us otherwise, we will keep and use any information you have given us up to that point.

What will happen to the information I give?

Information from the interviews will be typed up at the University of Sheffield. Your name and any identifying details such as address or date of birth will NOT be kept with these files. The files we gather will be analysed at the University to try to understand what is most helpful in dealing with anxiety and depression. The person responsible for safe storage of recordings and transcripts (the Data Custodian) is Dave Saxon, University of Sheffield, Regent Court, 30 Regent Street, SHEFFIELD S1 4DA. We will keep the information from the interviews for ten years, after which time it will be destroyed. We may consult them for future studies or allow access to other researchers, but if we do this you will remain anonymous.

The only people who will be able to link your information with your identity will be authorised persons such as the researchers and regulatory authorities at the University or NHS audit departments (for monitoring of the quality of the research). All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

What will happen to the results of the research study?

We will publish some written results and present these at public meetings. Details of these will be available at the website at www.sheffield.ac.uk/iapt and from Dr Kim Dent Brown if you require a paper copy. We will also publish outline results from the research on our website which we encourage you to visit at any time.

Who is organising and funding the research?

The research is sponsored by the University of Sheffield who are responsible for seeing that it is carried out according to the regulations for NHS research. The research is funded by the NHS Service Delivery and Organisation (SDO) Research and Development Programme.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the Leeds (West) Research Ethics Committee, reference number 07/Q1205/54.

What do I do next?

If you would be willing to take part, please sign the enclosed consent forms and the contact information form and return these to us in the addressed envelope provided (no stamp needed).

If you would like further information please contact me at the address at the head of this letter, or email me at g.d.parry@sheffield.ac.uk.

Yours sincerely,

**PROFESSOR GLENYS PARRY
PRINCIPAL INVESTIGATOR**



The
University
Of
Sheffield.

School of
Health &
Related
Research.

CONTACT DETAILS		
Please let us have your contact details so that we can get in touch with you to arrange a suitable place and time to meet with you.		
Name		
Postal Address		
		Postcode
Telephone (Landline)	Mobile Phone	
Preferred Contact		
Hours for Telephone		
Email Address		
Which method would you prefer us to try first to contact you? (Please circle one)	Letter Landline phone call	Text message Mobile phone call
	Email	



The
University
Of
Sheffield.

School of
Health &
Related
Research.

Professor Glensys Parry, Improving Access to Psychological Therapies project
Mental Health Section, Regent Court, 30 Regent Street, SHEFFIELD S1 4DA

Participant Identification Number for this research: _____

CONSENT FORM

Title of Project: Improving access to psychological therapies
Name of Researcher: Professor Glensys Parry

Please initial box

1. I confirm that I have read and understand the information sheet dated 16 th May 2007 (version 3.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	
3. I understand that the researchers will be looking at my medical notes (written and electronic) and I give my permission for this.	
4. I understand that relevant sections of the data collected during the study, may be looked at by individuals from regulatory authorities at the University. I give permission for these individuals to have access to my interview data.	
5. I understand that the interview I undertake will be audio recorded and transcribed, and that portions of the interview may be published in a manner that will not identify me in any way.	
6. I agree to take part in the above study.	

Name of Participant Date Signature

Name of Person Date Signature
taking consent

When completed, 1 for participant, 1 for researcher site file: 1 (original) to be kept in medical notes

Strand 3 Consent form, version 3.1, dated 16th May 2007

Appendix 15: Interview Template

Initial impressions of the IAPT service

- How did your journey through the IAPT service begin?
- Could you remember what you understood about this process at the time?
(prompts: what were your original thoughts about this, how did this feel at the time, what do you think and feel about it now)

Case management

- Could you tell me about your experience of case management?
- Could you tell me about the relationship you had with your case manager?
(prompts: can you give me an example? What were your thoughts/feelings/ideas about this at the time what are they now?)
- Could you explain to me any changes you noticed in yourself/your roles and responsibilities?
(prompts: can you give me an example? what were your ideas about why these changes were/were not happening? What are your thoughts/feelings/ideas about this now?)

Stepping-up

- Would you be able to tell me about the part of your journey where you were stepped up to CBT?
(prompts: how did this come about?)
- What did this mean to you at the time?
(prompts: What do you remember think/feel about this?)
- How do you think about it now
(prompts: What do you think/feel about this now?)
- If there has been a changes, what are your ideas about why this has changed?

CBT

- Could you tell me about your experience of CBT?

○ Could you tell me about the relationship you had/have with your CBT therapist?
(prompts: can you give me an example? What were your thoughts/feelings/ideas about this at the time what are they now?)

○ Could you explain to me any changes you noticed in yourself/your roles and responsibilities?

(prompts: can you give me an example? what were your ideas about why these changes were/were not happening? What are your thoughts/feelings/ideas about this now?)

Other issues

○ Are there any concerns that you had about work or other aspects of your life that the service has/has not been able to help you with?

○ Is there anything that you think is important to tell me that you haven't told me/topics I have not covered?

Appendix 16: Worked Example of IPA Process

The following Table 16 is an extract from one transcript analysed in this study which has been analysed using the steps outlined by the founders of IPA Smith et al. (2009). It illustrates, in the left hand column, the initial comments and reactions to the text during several readings of the text. On the right hand column is the emergent themes. The next stage of the analysis was to list the emergent themes from this transcript in chronological order and engage in a creative process whereby the themes are linked and clustered in a way that provides some explanation of the text. Table 17 that follows illustrates the emergent themes from this transcript.

Table 16: Extract from one transcript (Duncan) with illustration of initial noting and emergent themes

Researcher's initial reactions and comments	Interview text (I: Interviewer, P: Participant [CBT], [LIW] s/he added to uphold anonymity of workers)	Emerging Themes
<p>Preference for face-to-face</p> <p>Assumes CBT has more training. Giving/telling you</p> <p>Only trained indicates less training?</p> <p>Changes. What does the person want? Sharing information, transparency</p>	<p>I: So what's different about [CBT] then, to what you do with the [LIW]?</p> <p>P: Well it's <u>face to face</u> for a start and I do believe [CBT]'s <u>more trained</u>, because they're[LIW] <u>only trained</u> to deal, to <u>give you treatment</u>, tell you what to do, [CBT], presumably s/he's trained to put things into your mind, you know. I know [CBT] wanted, because I have a problem, I <u>used to have more of a problem than I have now</u>, erm sitting still or, I know <u>s/he wanted to do a therapy</u> where s/he made me go into a panic so I would calm down, but it didn't work [laughs]. S/he tried it here but I didn't have the panic attack that s/he tried to create, erm but erm I presume it was all in the mind as well, if you know you're going to see somebody it can be in the mind, like that, what I was saying before when I went to the erm, when I did that, I had the agoraphobia thing in the hotel, that was in my mind,</p>	<p>Worker Competence</p> <p>Change Collaboration</p>

<p>Techniques, behavioural experiments. Encouraged? Is he presuming competence? Should patients be more aware of competence? Having contact with a person important</p> <p>Not using a specific pronoun indicates impersonal relationship?</p> <p>Not appropriate to this person's needs – didn't ask or check whether he could get it?</p> <p>Specific examples of intervention that has been useful. Even though he's been discharged this is still with him.</p> <p>Much richer description of CBT</p>	<p>telling me that I'd already done it. <u>It wasn't a case of can't do it, it was a case of well you've done it, do it again.</u> So presumably it's a thing of [CBT] or whoever, I can't remember the other person's name, <u>knows what they're talking about.</u> So it's like I used to, whenever I used to go to the doctors when I had agoraphobia you always felt better for about the day after, for a day because you'd been to the doctors and they'd said this but then it's come back into your mind again, and you'd be back to square one. So it's just a <u>reassurance thing</u>, I think</p> <p>I: So with [CBT] there was something about seeing her/him face to face, there was something about the way s/he helped you, you changed your mindset?</p> <p>P: Mmm. S/he gave me leaflets and booklets and things.</p> <p>I: Did you get that when you had the LIW or not?</p> <p>P: Erm, <u>they</u> would send you things through the post, but there was one, s/he wanted me to go and get a book, and the only library they had it in were [Place] and I just didn't live near [Place] at the time, erm so I never actually went and got it. But erm I presume when IAPT develops a bit that they might have more internet things.</p> <p>I: Yeah sure. But [CBT] gave you more leaflets and booklets?</p> <p>P: Yeah, s/he put things into my mind. Erm, there was what s/he called the bus scenario and the train scenario. The bus scenario where you are the driver and your anxiety is the passengers, and the anxieties would be driving the bus and telling you were to go but you're the bus driver and you know what route to go, so you go where you want to go, not where the anxiety wants to go. And the train system where you stand on a bridge and the street lighting, and you want to get into the middle train and stay away from the other two trains, so things like that.</p>	<p>Internal Change Worker Competence Support</p> <p>Shared understanding</p> <p>Internal changes</p>
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From the preceding creative process a Table of master themes was created which illustrates the clustered themes, examples of key words and quotes along with line numbers providing evidence for the themes.

Table 17: Table of emergent themes from the whole of Duncan's transcript.

Theme clusters	Key words	Line numbers
Therapist factors/alliance		
Caring	LIW "didn't seem to be a lot of caring" "rather than a caring thing it's more a clerical thing" same if F2F? "no caring part to it" CBT "good communication" "warm"	22, 158, 198, 200
Shared understanding	"why you 're doing it" vs. "just give you the options" "he could see.."	114, 176, 180
Perceived competence	"more trained" (CBT) "only trained to tell you what to do. Presumably he's trained to put things into your head" "knows what they're talking about" "knew what he was doing"	106, 176
Telephone as a barrier to relationship - Perceived shared understanding - Perceived attentiveness	"you can say anything over the phone" "could've pretended" vs "you can't lie to him" "looking anywhere" "were they really listening" "going through the motions"	36 38, 162, 164, 166, 178 50, 40, 158, 159
Client Centeredness/collaboration		
Client awareness of service aims and constraints	"you have to.." (LIW) "they wouldn't be able to fit everybody in" "hadn't got enough time" "it's all about finance" "get people back to work" "targets" "a conveyor belt"	114, 204 38, 66, 168, 182
Preference, choice, power	"not given the choice"	16, 18, 24, 182, 204
Rigidity of intervention	"clip-boardy" "clinical" "clerical"	22, 120
Experience of change		
Internal changes	"putting things in your head" "more relaxed" "more confidence"	50, 106, 132, 148
External changes		134, 136, 148
Pressure for change	"and by a certain amount of time..scores should have come down"	24
Loss	"I can't go back to how I was"	148
Sense of stepping-up		
Service defined/hoop	"only a certain amount of time"	82
Determined by lack of improvement	"weren't getting anywhere" "the scores aren't going down" "not going to be able to deal with you"	24, 84, 96, 186, 190
Non-collaborative decision	"they think" "they discuss you" "they'll send you somewhere else"	84, 186, 188
Emotional Experience of Stepping-up		
Relief, happiness	"relief" "happy"	94, 192
Powerless	"you have to go through these processes" (and see non collaborative)	90

When this process had been conducted for all interviews the analysis moved to looking across the 11 cases. This involved looking at all 11 tables of master themes and drawing out common themes, going back and forth between this stage and the interview transcripts until a final list of themes emerged. These are the themes shown in Figure 5 and discussed in the results section in more detail.