Development, implementation and evaluation of a pilot educational group intervention for lower limb amputees

AND CLINICAL RESEARCH PORTFOLIO

PART I

(Part II bound separately)

Kim Barry, M.A. (Soc.Sci)

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology (D Clin Psy)

Section of Psychological Medicine
(Division of Community Based Sciences)

August 2008

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Abstract

Objective: To carry out a systematic review of the literature examining the efficacy of group, individual, or combined individual and group cognitive behavioural interventions (CBI) at reducing depression in individuals with rheumatoid arthritis (RA).

Methods: Electronic databases including MEDLINE, EMBASE, PsycINFO and all EMB reviews were searched. Studies that met the following criteria were included: published journal articles from 1980 onwards; published in English; include participants over 18 years old with a clinically confirmed diagnosis of RA; provision of group, individual, or combined CBI; included measure of depression or negative mood. Data was extracted on study design, sample size and characteristics, type of intervention, control group, and direction and nature of outcomes. The methodological quality of each study was rated.

Results: Eleven trials met inclusion criteria. Four included an individual CBI, five a group CBI, and two a combined CBI. Eight studies reported a reduction in depression scores immediately post intervention in the intervention group. There did not appear to be any significant difference in post intervention depression outcome dependent on the type of CBI received. However, gains were only maintained at follow up when participants received an individual CBI. Methodological quality scores ranged from 100 – 48%; highlighting the variance in methodological rigour and reporting.

Conclusions: CBIs in any format do appear to have some beneficial effect on depression in patients with RA. Longer-term benefits were only evident for participants who received an individual CBI. No firm conclusions can be drawn from the current review due to the methodological limitations and small number of identified studies.

Introduction

Rheumatoid arthritis (RA) is a chronic autoimmune disease which is thought to affect around 0.8% of the UK adult population (1) and between 1-3% of the population in Western countries (2). It is a progressive disease with an unpredictable course of remissions and exacerbations that can lead to significant physical disability, reduced quality of life, and increased psychological difficulties (3). RA has an acute onset which can occur at any age but incidence normally occurs between the ages of forty and sixty. Symptoms include pain, joint swelling, morning joint stiffness, poor sleep, fatigue, and weight loss (1). Due to the changeable nature of the disease symptoms can alter from day to day or even hour to hour thus making them difficult to cope with and detrimental to daily functioning (4). At present very little is known about the causes of RA and there is no known cure for the disease. Current medication aims to maximise joint function and pain control however prolonged use can give rise to a variety of problematic side effects. In some instances these side effects can force the patient into non-compliance or use of less effective medications (5). In spite of medical treatment persons with RA continue to report high levels of pain, disability, and poorer quality of life.

Given the unpredictable nature of RA and negative impact it can have on physical functioning, sense of independence, working ability, and social relationships, it is understandable that psychological functioning may also be effected. Both anxiety and depression are thought to be highly prevalent in people with RA; in particular major depressive disorder has been reported at rates between 13% and 17% (6,7) and up to 20% (8). This is a higher prevalence rate for depression than is found in the general population (9). A systematic review and meta-analysis carried out by Dickens et al. (10) which reviewed studies comparing depression in RA with control subjects found it is more

common in persons with RA. In addition to the significant prevalence rates of depression preliminary results indicate an overall mood deterioration for RA patients in the first two years after diagnosis (11).

When considering the relatively high prevalence rates of depression in RA populations it is especially important to take into account the effect depression has on the overall functioning of the individual. Katz and Yelin (12) reported an association between depression and an increase in the clinical characteristics of the disease such as greater number of painful joints; reduced functioning (i.e. spending more days in bed), and an increased number of RA related GP and hospital visits. The interaction between depression and disease impact is unclear but it may be that experiencing depression contributes to reduction in functioning and increases levels of disability or vice versa. It is also possible that the relationship is reciprocal however the importance of the association cannot be ignored and other studies have highlighted that measures of RA related disability are positively associated with depression (11).

In conjunction with prevalence rates of depression it is also important to acknowledge that some symptoms of depression i.e. fatigue, difficulty with everyday activities, listlessness, loss of appetite, and sleep disturbances are similar to the physical symptoms of RA. These similarities may lead the patient and healthcare professionals to assume the disease is progressing which in turn may further lower mood and lead to unnecessary increases in medication (13). The overlap in presentation of symptoms may also make detection and subsequent treatment of depression in persons with RA more difficult for health professionals.

A number of studies have examined factors associated with increased levels of depression in RA patients. In common with other painful chronic conditions depression in RA populations has shown links with the experience of pain (10). As pain is such a prominent feature of RA, it is difficult to determine whether it acts as a causal factor of depression or alternatively if depression increases vulnerability to pain. It may not be inappropriate to assume this is a bi-directional relationship. Somewhat surprisingly disease activity (as measured by clinical indices e.g. joint function, erythrocyte sedimentation rate, C-reactive protein) does not show an association with mood (11, 14). Research indicates factors such as a person's beliefs about their illness and their coping strategies are associated with psychological and functional status (15). In comparison to non-depressed persons with RA, depressed RA patients perceive their illness as more serious and feel hopeless about a cure even when the severity of the condition is adjusted for (16).

As the presence of depression in persons with RA can have such a significant impact on their functioning and ability to cope with the disease it would appear that psychological and psychosocial therapies addressing mood should be of benefit. There has been a considerable amount of research carried out in the past twenty-five years that examines the efficacy of a number of psychological and psychosocial interventions in people with RA. These have included self-management and self-help programmes, cognitive behaviour therapy interventions, educational programmes, psychotherapy, support programmes, and total rehabilitation programmes (17).

A number of recent reviews have examined and compared these numerous interventions for adult RA populations. Riemsma et al. (4) assessed the effectiveness of patient education interventions on health status in individuals with RA. Patient education

compromised of 'information only', 'counselling', and 'behavioural treatment' interventions. The authors reported significant effects of patient education at first follow-up for measures of disability, affected joint counts, patient global assessment, psychological status and depression, and a positive trend for pain but no effects for anxiety or disease activity. However at final follow-up no significant effects of patient education were found. The authors concluded that patient education had small short-term effects but there were no longer-term benefits.

Astin et al. (5) conducted a meta-analysis of randomised controlled trials of psychological interventions for RA. These included cognitive behavioural interventions (a number including bio-feedback), traditional psychotherapeutic interventions, and interventions where individuals wrote or spoke about difficult emotional and stressful experiences. Significant post intervention effects were found for pain, functional disability, psychological status (depression), coping and self-efficacy. Follow-up effects were retained for tender joints, psychological status and coping. The review did not identify any clear differences in effects by treatment type although findings did suggest all interventions might be more effective for patients with shorter disease duration. The authors identified many methodological flaws within this literature but posited that psychological interventions may be an important adjunctive therapy to medical management in RA.

One potential limitation of the reviews discussed are the grouping of different interventions under generic terms rather than evaluating the efficacy of individual treatments. In contrast one paper specifically evaluated cognitive behavioural interventions for RA populations utilising case studies and controlled group treatment outcome studies (18). Cognitive behavioural treatments were described as a coping skills training based approach utilising

biofeedback techniques, relaxation training, problem solving, and cognitive pain-coping skills training. The review reported that subjective ratings of pain are generally improved as an effect of the intervention. Additional outcomes such as sleep, functional impact, pain behaviour and joint involvement may show improvement but findings were inconsistent.

All of the above reviews (4, 5, 18) included both group and individually administered interventions. Research indicates that patients prefer education about RA to be delivered on an individual basis by health professionals, emotional issues were best addressed on an individual basis (with health professional or fellow patients) and group interventions were preferred for self-management, exercise and relationship issues (3). These findings may highlight that in addition to the type of intervention provided the format (group vs. individual) may impact on its efficacy.

Rationale

It was felt that although there is a considerable amount of research in the field of patient education and psychological interventions for RA only one review (18) conducted seventeen years ago evaluated cognitive behavioural interventions (CBI) specifically. Therefore it was felt that the literature would benefit from an updated review of CBIs for RA. Additionally as greater emphasis has been placed on the prevalence of depression in this clinical population and the association it has on functional outcomes it is appropriate to evaluate the impact of CBIs on depression. From a clinical perspective if the evidence suggested participating in a CBI could reduce depression in RA this may have implications for increased use in this population in an attempt to lessen the negative impact of RA on the individual.

The aims of the current review are:

1. To examine the effectiveness of CBIs in reducing depression in patients with RA.
2. To compare the effectiveness of group format CBIs with individual format CBIs in reducing depression in patients with RA.

Method

Selection process and data extraction:

Initially a computerised search was conducted using the databases MEDLINE [1950 – March week 1 2008], CINAHL [1982 – March week 1 2008], EMBASE [1980 – week 11 2008], PsycINFO [1985 – March week 2 2008], British Nursing Index [1985 – February 2008], British Nursing Index Archive [1985 – February 2008] and all EMB Reviews [1st Quarter 2008]: ACP Journal Club; Cochrane Central Register of Controlled Trials; Cochrane Database of Systematic Reviews; Cochrane Methodology Register; Database of Abstracts of Reviews and Effects; Health Technology Assessment; NHS Economic Evaluation Database.

Using the advanced OVID search function "map term to subject headings", the following search terms were generated and the following search format conducted:

1. Arthritis, rheumatoid
2. Cognitive therapy/ or Psychotherapy/ or psychosocial interventions
3. Psychotherapy, Group/ or Health Education/ or Psychoeducation
4. Cognitive therapy/ or behaviour therapy/ or Psychotherapy
5. Self-management or self-care
6. Depression/ or depression
7. Adaptation, Psychological

8. Anxiety
9. 2 or 3 or 4
10. 6 or 7 or 8
11. 1 and 9 and 10

To check the sensitivity of these search criteria the 'find citing articles' function in OVID was used when the full text article was available electronically. An electronic search of Internet search engines Web of Science and Google Scholar was conducted using a combination of the terms outlined above. Key journals (Journal of Rheumatology, Pain, Arthritis Care and Research, Arthritis and Rheumatism) were electronically searched from 2000 to present. In addition reference sections of included papers and relevant review articles were examined in order to identify any further relevant publications.

Studies were selected for entry into the review according to the inclusion and exclusion criteria (see Table 1). CBIs were defined as structured interventions that included additional components (e.g. cognitive and behavioural strategies) to patient education on RA. Thermal bio-feedback training was also considered as part of a CBI when combined with other strategies.

The first author reviewed the title and abstract of each identified article. The article was retrieved if it included an RA population and a patient CBI. If it was unclear from the title or abstract whether a study met inclusion criteria the full article was retrieved.

Methodological assessment

Demographic, clinical, and methodological data were extracted from each included article (see Table 2). The quality of each article was assessed using quality criteria generated by the author using SIGN 50 guidelines (19) and the CONSORT checklist (20). This generated a 21-item scale (See Appendix 1.2). For each individual quality criteria a score of 2, 1, or 0 was awarded. A score of 2 represented a well covered/ adequately addressed point, a score of 1 represented a poorly addressed point, and a score of 0 represented a quality criteria that was either not addressed, not reported, or not applicable to the study. Each criteria item was of equal weighting. The total points accrued were divided by the maximum possible points (forty-two) and multiplied by 100 to produce a percentage. This allowed for the quality of the studies to be compared. A second independent reviewer reviewed three of the eleven included studies and correlation between quality ratings was high. Any disagreements between reviewers were resolved through discussion. Due to the heterogeneity of sample sizes, study design, intervention types and follow-up periods it was deemed inappropriate to conduct a meta-analysis as it would have little practical meaning.

Calculation of effect sizes for included studies

If effect sizes for included studies were not reported, where possible the review author calculated these. Effect sizes are reported in Table 3. Note that where the two sample sizes differ markedly then, when computing the mean standard deviation, it is appropriate to follow procedures for computing a pooled variance estimate. A worked example using the mean and standard deviation for immediate post intervention data from Sharpe et al. (24) is presented. Effect size calculation taken from Dancey and Reidy (41).

$$d = \frac{\text{Mean of condition 1} - \text{Mean of condition 2}}{\text{Mean Standard Deviation}}$$

$$\text{Mean SD} = \frac{\text{SD of condition 1} + \text{SD of condition 2}}{2} = \frac{2.53 + 4.42}{2} = 3.475$$

$$d = \frac{3.83 - 5.9}{3.475} = -0.6 \text{ (rounded to one decimal places)}$$

Results

The electronic search of databases revealed 127 studies. Ninety-one were discarded on the basis of title or title and abstract alone. The full article was retrieved for the remaining 36 studies, 27 of which were excluded. Reasons for exclusion included a non-CBI; no intervention provided; no measures of depression or negative mood; combined pharmacological and CBI; depression scores not reported (see Figure 1). A further 2 articles were identified from reference list searches. No further studies were identified from any other search strategy detailed. In total eleven studies were identified as suitable for inclusion in the present systematic review and rated as previously outlined (see Appendix 1).

Quality of studies

Ten out of the eleven included studies were randomised controlled trials; one study (21) was "quasi-experimental"; this was a within subjects design where participants completed a baseline period prior to commencing the intervention. Two sets of studies (22-25) used the same participant sample. Both of these are longitudinal follow-up studies and are discussed individually as they address the longer-term efficacy of CBIs. Included studies varied in methodological quality producing quality scores between 48–100%. Quality scores are reported for each study (see Table 3). Quality criteria were divided into discrete areas reflecting key methodological issues (aims, sampling procedure, demographics,

assignment to groups/randomisation, intervention, measures of assessment, analysis and interpretation) which will be discussed in turn.

Aims:

All included studies except two (23,26) had a clearly focussed research question and clearly stated aims and hypotheses.

Sampling Procedure:

Sample size and origin of participants was reported in all included studies. Generally participant numbers were relatively small and ranged from 33 (22, 27) to 141 (26). Inclusion and exclusion criteria were addressed in all but two studies (22,23) however clarity of reporting was variable. Bradley et al. (22) did not report participant baseline demographics or whether treatment and control groups were comparable at baseline. Baseline demographics were reported in the second Bradley et al. (23) study but group comparability was difficult to assess. There was no comparison group in the Sinclair et al. (21) study. Drop out rates were reported (score of 1 or 2) in all studies apart from Kraaimatt et al. (28). A higher proportion of females participated in all studies except Parker et al. (26), however this is not surprising as RA is more prevalent in women (29). One study (21) utilised an entirely female sample population and reported large variability in participant age range (24-80 years). Mean disease duration for participants varied between 12.63 months (23,24) and 15.6 years (28); two studies explicitly included participants with a maximum duration of two years (23,24).

Assignment to treatment groups:

This was one of the least well-reported quality items. All studies (apart from Sinclair et al. (21), who did not include a control group) reported random allocation to treatment groups; only four (24-26, 30) received the full 2 points for a clear description of the randomisation process.

Intervention:

In general cognitive behavioural interventions were clearly described. Four studies (22, 23, 26, 31) did not report whether interventions were standardised or a manual was used for administration.

Measures of assessment:

All studies included a published measure of depression or negative mood (see Table 3). The mean and standard deviation score of the depression scores for each participant group at baseline are presented. When possible the classification of severity of the depression score, according to the relevant depression measure scoring criteria, has also been included (Table 3). It was not possible to classify severity of depression scores for all included studies; specifically where it was not possible to readily access the interpretive data for a measure (e.g. The Impact of Rheumatic Diseases on General Health and Lifestyle, IRGL). All depression or negative mood measures were self-report and none of the studies corroborated outcome with a clinician-based assessment. The Impact of Rheumatic Diseases on General Health and Lifestyle (IRGL) (32) is not a familiar measure within the UK but it has been validated for Dutch populations and is derived from the more commonly used Arthritis Impact Measurement Scales (AIMS) (33).

Regarding all outcome measures (including depression or low mood) utilised only five studies (21, 24, 25, 26, 34) received a score of 2 for measuring outcomes in a standard, valid and reliable manner. Studies did not receive the maximum score if they adapted measures or measures were not validated or published. Over half the studies did not give a clear description of outcome measures (22, 23, 26, 27, 30, 34). Details of all outcome measures are presented in Table 2.

Analysis and interpretation:

Only two studies included *a priori* calculations of power and sample size (24,25). P values were reported in all studies but effect sizes were not. Descriptive statistics (means and standard deviations) were reported in all studies. Only four studies received a score of 2 for using an intention to treat analysis (24,25, 30,34). Results were generally found to be poorly reported and did not clearly refer back to aims; seven studies (21-23, 25, 26, 28, 31) received a score of 1 (poorly addressed). It was difficult to extract results of between group comparisons and Bradley et al. (22) did not report any results for between group comparisons on change in depression scores. When possible effect sizes were calculated by the author and are displayed (see Table 3). According to Cohen (35) a small effect size can be interpreted as ≤ 0.2, medium effect as 0.3 – 0.5, and large effect as ≥ 6.

Description of cognitive behavioural interventions (CBIs)

Cognitive behavioural interventions were administered in a range of formats across the studies (see Table 2): individual thermal bio-feedback sessions followed by group CBI (22, 23); individual CBI (24, 25, 26, 30); and group CBI (21, 27, 28, 31 34). Number of CBI sessions ranged from 3 (21) to 12 (32) and duration of sessions lasted between one to two hours. Additionally two studies included between 1 (30) and 3 (26) follow-up sessions.

CBIs were diverse across the included studies and encompassed an eclectic array of cognitive and behavioural strategies (see Table 2). Relaxation (progressive muscular relaxation, visual imagery or both) was the only behavioural strategy included within every CBI. All studies except Bradley et al. (22, 23) explicitly report the use of cognitive strategies (e.g. cognitive restructuring) although the focus of cognitive interventions differed between studies. Cognitive intervention strategies focussed on pain management (21, 27, 34); disease related cognitions (31); and cognitive restructuring as a general coping strategy (24, 25, 26, 28, 30). Other common components included education about RA (24, 25, 28, 31, 34) and goal setting (22-25, 30).

One study (30) offered a participant tailored CBI with four possible treatment modules (see Table 2). The authors report that the 'fatigue' and 'negative mood' modules were the most popular choices. Two studies included an additional home-based multimedia component as part of the CBI (21, 26). When comparing CBIs, although they were varied, there did not appear to be any distinct differences in content between individual or group interventions.

Description of control groups

As previously discussed only one study (21) did not include a control group. Control groups were varied (see Table 2), comprising of 'standard care' control groups (24, 25, 30, 34), 'standard care' and 'alternative intervention' control groups (22, 23 26, 28), and 'patient information' (27). In the Van Lankveld et al. study (31) all participants received the CBI but partners also participated in the CBI in the experimental group. In every study all participants continued to receive routine medical treatment throughout the duration of the study period.

Effect of CBI on depression outcomes

The main findings and reported or calculated effect sizes of studies are presented (see Table 3). In total eight studies found a positive significant effect (reduced scores) of the CBI on depression outcome in the intervention group (21, 23-25, 27, 30, 31, 34). Of these however three studies (22, 27, 31) did not analyse or report any significant between group differences for change in depression scores across time. Three studies did not find any reduction in depression scores (22, 26, 28). All studies carried out a differing number of outcome measure completions: baseline, post intervention and follow-up (see Table 2).

In order to address the aims of the review the effect of the CBI on depression outcomes will be discussed in terms of combination, individual, and group CBI formats.

Combined individual and group CBIs:

Bradley et al. (22, 23) compared a combined individual thermal bio-feedback and group CBI with a social support therapy control group (SS) and a no adjunctive therapy (NAT) control group. Bradley et al. (22) reported a significant difference in pre and post depression scores in both the CBI and SS groups. Scores in the NAT group did not change. Bradley et al. (23) did not find any significant change in depression scores for any of the groups from post intervention to 6 month follow-up although during this time period depression scores increased.

Individual CBIs:

Two studies reported a significant decrease in depression/negative affect scores immediately post intervention in the CBI group and a significant difference in scores when

the intervention and control groups were compared (24, 30). These reductions were maintained at follow-up (25, 30). Sharpe et al. (24) reported a reduction in the number of participants meeting clinical caseness for depression from baseline to post intervention and 6 month follow-up in the CBI group.

Parker et al. (26) did not find any significant effect of the intervention on depression/negative affect scores across any assessment time points.

Group CBIs:

Four studies (21, 27, 31, 34) reported a significant change in depression/negative affect scores in the CBI group immediately post intervention. When comparing reduction of depression scores by group only one study (34) reported significantly greater decreases in the CBI group compared with the control group. The reduction in depression scores in both the intervention and control group in the Van Lankveld et al. study (31) is a positive finding overall as participants in the experimental and control groups received the CBI, the only difference was partner participation. Reduction in depression scores were most evident immediately post intervention. Sinclair et al. (21) did not have a control group to make a comparison with.

One study (28) reported a significant time effect across all groups indicating an increase in depression scores from post intervention to follow-up.

Discussion

The present review aimed to identify, assess, and describe the effectiveness of trials of CBIs on depression/negative affect outcomes in people with RA. The general findings, methodological limitations, conclusions and future directions will be discussed.

Overall summary of results

When examining all studies included in this review eight out of eleven (21, 22, 24, 25, 30, 27, 31, 34) did report a significant effect of the CBI in reducing depression scores. Excluding one study (31) where all participants received the CBI and one that did not include a control group (21), four studies (24, 25, 30, 34) found the CBI was more effective at reducing depression scores than standard care. In addition to this effect sizes of the CBI fell within the medium effect range 0.3 to 0.5 immediately post intervention. This indicates that a significant proportion of the reduction in depression scores can be attributed to participation in the CBI.

It could be argued that a benefit of participating in a group intervention is the support received from others with the same condition and it is in fact this social support, not the CBI, that contributes to reduction in depression scores. Only one study by Bradley et al. (22) had a structured social support group as a control condition but as this was a poor methodological quality study no conclusions can be drawn from it. This concept of social support leading to improvement in depression is an area that would warrant attention in future research.

When examining reduction in depression scores post intervention there does not appear to be any observable differences in effectiveness of CBIs delivered via an individual, group,

or combined therapy format. One study from each format did not report any significant change (reduction) in depression scores (23, 26, 28). Conversely differences were found in the effectiveness of formats at follow-up. Only individual CBI studies (24, 25, 30) which received high methodological quality ratings report maintained reductions in depression scores at follow-up. Group format (31) and combined CBI (23) reported an observable but non-statistically significant increase in depression scores from post intervention to follow up.

A tentative interpretation of this finding may be that although individual and group format CBIs appear to have an initially comparable effect on depression scores post intervention, group CBI effects may not be maintained in the longer term. One explanation for this may be that despite similarities in the cognitive and behavioural interventions utilised by both formats within individual CBIs the strategies discussed during therapy become more tailored to the persons' needs. Individual therapy may provide participants with the opportunity to discuss strategies in more depth than in a group setting. This more concentrated and personalised input received may enable employment of the strategies more effectively over a longer duration even after the intervention itself has ceased. This comparison between formats must be viewed as a very preliminary finding however due to the small number of studies using either CBI format identified by the search process.

One further question of interest that has arisen after reviewing the included studies is whether the duration of RA impacts on the effectiveness of the CBI in reducing depression. As an arbitrary cut-off for the purposes of this review mean duration of disease was divided into three categories (< 5 years, $5 \geq 10$ years, > 10 years). The three studies whose participants had a lower mean length (<5 years) of disease duration (24, 25, 30) reported

similar outcomes to studies that whose mean participant disease duration fell within the 5 to 10 year range (21, 27, 31 34). Of interest, the three studies with mean disease duration greater than 10 years were those that did not find any significant effect of the CBI (26) and an increase in depression over time (23, 28).

Although 10 years has not been identified within RA literature as a point when the disease becomes progressively worse, more disabling, or can lead to increased levels of depression, this result may suggest otherwise. Some research has suggested that psychological therapies should be provided in combination with medical management early in the disease in order to encourage active coping strategies and potentially reduce levels of disability (36). Again the preliminary suggestions from this review may add to this argument although the interpretation of 'early' warrants further attention before conclusions or recommendations could be made. Ten years may not normally be considered 'early' after a diagnosis.

In general the findings of the present review would suggest that participating in a CBI, group or individual, is beneficial for reducing depression at least in the short term in an RA population. However caution should be taken in interpreting these findings due to the limited evidence base and the variable quality of design adopted in the majority of the reviewed studies.

Methodological Limitations

In interpreting the findings from this review it is important to consider methodological concerns that may influence results. Only four studies (24, 25, 30, 34) received a quality rating above 75%. Many of the reviewed trials failed to attempt to avoid biases in the

design and implementation of their research. Firstly, when evaluating the effectiveness of treatment interventions good quality experimental studies would aim to randomly and preferably blindly allocate participants to treatment groups. All but one (21) of the included studies described themselves as a randomised controlled trial however only four gave an adequately clear description of the randomisation process (24-26, 30). Poor descriptions of randomisation make it difficult to interpret how well confounding variables were controlled for within the comparison groups and therefore limit the interpretation of the findings. Secondly, the included study samples were generally small and likely to be statistically underpowered. This is even more probable as only two studies (24, 25) had conducted an *a priori* power calculation. In addition although most studies did report drop out rates it was difficult to determine how the authors dealt with missing data at post intervention and follow-up as only four explicitly reported using an intention-to-treat analysis (24, 25, 30, 31). Failure to include all participants who commence in an intervention group may exaggerate the treatment effect. Participants who continue with the entire course of a CBI may be more motivated to make changes to their coping strategies in relation to their RA and may therefore benefit from greater treatment effects.

A further methodological consideration lies in the actual CBIs utilised. Although a comparative strength of the included studies was that they provided a clear description of the CBI and administered the intervention in a standardised way utilising a manual, the actual intervention components across studies could be viewed as quite diverse and varied in their focus. For example in some studies pain management played more of a central role (21, 27, 31, 34) whereas others adopted a wider disease management approach (22-25, 28). This diversity was also evident in the number of CBI sessions offered and follow-up support received. Additionally as included studies covered a twenty-year time span it is

appropriate to assume CBIs have developed substantially over this period and may not be comparable. Combined these concerns may limit the interpretation of the findings as it may not be wholly appropriate to analyse the CBIs collectively or make comparisons between them.

In interpreting the findings of the current review it is also of value to take into account the variability in control groups in the included studies. Control groups received alternative interventions ranging from self-help information (27) to patient education (26). Perhaps until the efficacy of CBI's at reducing depression is more clearly established a beneficial design may have been to compare only CBI and standard care as this allows for the effect of the intervention to be judged more clearly and may have yielded a bigger participant sample. However this is an extremely simplistic design and would only allow for the effectiveness of a CBI to be evaluated independently and does not allow for CBIs to be compared with other potentially beneficial interventions for this population e.g. self-management approaches. By conducting research that offers an alternative treatment intervention to a CBI this would enable clinicians to decide whether or not CBIs are actually more effective than other forms of treatment for depression in individuals with RA. Comparison of differing interventions adds to the wider literature base providing the best evidence based practice and most effective treatment package for the patient. In addition having a standard care control group can also be difficult to monitor as this may vary quite considerable between individuals and this would be better controlled for by having a standardised second intervention comparison group.

When discussing variance between studies the use of a number of different outcome measures for depression/negative mood increase the difficulty in comparing results across

trials. The appropriateness of the depression measures utilised must also be considered when interpreting results. For example depression measures such as the Beck Depression Inventory (BDI-II) (37) and Centre for Epidemiological Studies –Depression (CES-D) (38) include questions about loss of energy, tiredness and fatigue, required effort, and changes in sleep pattern and appetite. All of these are common somatic symptoms present in depression but could also be physical symptoms of RA or side effects of medication. Lindsey and Powell (39) highlight assessment of mood in the chronic pain patient as difficult because physical variables associated with depression may also be related to physical aspects of the condition itself. They argue that these difficulties are better but not perfectly addressed by measures such as the Hospital Anxiety and Depression Scale (HADS) (40) as it does not include somatic symptoms and is therefore more likely to eliminate confounding physical symptoms. A final limitation of outcome assessment in the literature is the lack of attention paid to the clinical significance in reduction of depression. Statistical changes in outcome measures are not always representative of changes in the emotional functioning and well being of an individual. Only two studies (24, 25) discussed how depression measures related to clinical indicators of depression. Future research would benefit greatly from further exploration of this question as an additional outcome measure.

A number of limitations regarding the methodological quality of the current review must also be taken into account. Firstly inclusion of papers was limited to English language and published articles. This search strategy may be perceived as too narrow, nevertheless this approach was chosen in order to maintain some control over the methodological quality of the reviewed articles. Secondly depression or negative mood was taken as the core measure for psychological adjustment in RA patients. Depression is only one element in a

constellation of factors such as anxiety that contribute to psychological adjustment and future reviews would benefit from taking a wider ranging perspective. It may also be questioned why this review focuses on depression when this was not the central concept in the CBIs utilised. However as previously discussed depression was chosen as the focal outcome measure due to the suggestion that it can be associated with greater levels of disability in patients with RA (12) and as it is also known to negatively impact on adherence to advice regarding management of chronic conditions.

Conclusions and future directions:

The evidence summarised in this review indicates that CBIs do show efficacy at reducing depression in patients with RA but this is to a varying degree. Findings were generally consistent across all studies, irrespective of format, in highlighting a decrease in depression scores immediately post intervention but results were contradictory in terms of maintenance of gains. These findings are in keeping with previous reviews on general patient education and psychological interventions for RA populations (4, 5). It was found that CBIs themselves showed variation in their format (group versus individual programmes, use of manuals, presence of family/friend support) and organisation (number and length of sessions). They were also varied in terms of content (e.g. relaxation, biofeedback, social communication, cognitive and/or behavioural strategies) therefore it may be beneficial for future research to further investigate which separate components are more efficacious in order to provide a more tailored intervention.

One interesting finding relating to longer term effects of CBIs is that three high quality individual studies reported reduced depression scores were maintained at 6 month (24, 30) and 18 month follow-up (25). This was not the case for group CBI studies with similar

follow-up durations. As highlighted by the literature, depression is thought to have a significant impact on level of disability experienced (12). Throughout the current review the author did attempt to note any reported associations between these two factors in the included studies, however this was not addressed at all. This is an area that would warrant attention in future research, adding to the evidence base for implementing CBIs as an adjunct to medical treatment in individuals with RA. The suggestion that individual CBIs maintain benefits over a longer time period could have noteworthy clinical implications. It is not unreasonable to assume that group format interventions are a more cost effective way of reaching a greater number of people but as the current review may indicate individual CBIs may prove more cost effective in the longer term. Additionally the current review highlighted the possibility that duration of disease may impact on intervention effectiveness. This could potentially lead to recommendations for more targeted interventions perhaps specifically aimed at individuals with a shorter disease duration or tailoring CBIs dependent on stage or duration of disease.

Despite indications that CBIs do show benefits in reducing depression in patients with RA these must be viewed with caution. There is not enough evidence to draw any firm conclusions due to the limited availability and variable quality of the current research. Further methodologically rigorous studies would help to ascertain the true effectiveness of these interventions. In addition it would be of benefit for future research to address the question of clinical significant change in addition to statistical significance.

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Table 1: Inclusion and exclusion criteria for review studies.

Inclusion Criteria	Exclusion Criteria
Studies published from 1980 onwards	Studies including a mixed population of arthritis or chronic disease patients (i.e. not RA alone)
Studies published in the English Language	
Studies include adult participants (18 or over)	Studies that do not report depression or negative mood scores (both pre and post intervention)
Studies include participants with a clinical confirmation of a diagnosis of rheumatoid arthritis (RA)	Qualitative studies, Case studies, Dissertation abstracts, Poster presentations, Expert opinions or Reviews.
Studies include provision of group, individual or combined cognitive behavioural intervention	
Studies include a measure of depression or negative mood	Studies including combined pharmacological and cognitive behavioural interventions.
Published journal articles	

Table 2: Methodological characteristics and participant demographics of the included studies.

Study	Type of study	Participant demographics	Intervention	Assessment points	Outcome measures (not depression/mood)	Study Limitations
Bradley et al. 1985	**RCT**	**N:** 33 **DO:** 15 **M:F:** NR **MA:** NR **DD:** NR **C of O:** USA	**EG:** Individual & group CBI 5 Individual sessions: thermal bio-feedback training. 10 Group sessions: education on CBT; skills acquisition (relaxation training, behavioural goal setting); self instructional training (use of self rewards, cognitive coping strategies); application phase (subjects practised skills and feedback to group). Family member or friend attended group sessions. Duration of sessions not reported. **CG1:** Structured social support therapy 15 group sessions: education; discussion of present coping strategies; development of improved coping methods. Family member or friend attended sessions. Duration of sessions not reported. **CG2:** Standard Care	1. Baseline: pre intervention (not specified) 2. Post intervention (not specified)	Trait subscale of State Trait Anxiety Inventory. Visual Analogue pain scale. Health Locus of Control Scale Arthritis Helplessness Index Rheumatoid Activity Index	Participant demographics not reported for each group. Combination of individual and group treatment. Randomisation process poorly described. Use of unpublished visual analogue scales.
Bradley et al. 1987	**RCT**	**N:** 53 **DO:** 13 **M:F:** 10:43 **MA:** 50.09 (12.44 s.d.) **DD:**11.49 (11.41s.d.) **C of O:** USA	**EG:** Individual & group CBI 5 Individual sessions: thermal bio-feedback training. 10 Group sessions: education on CBT; skills acquisition (relaxation training, behavioural goal setting); self instructional training (use of self rewards, cognitive coping strategies); application phase (subjects practised skills and feedback to group). Family member or friend attended group sessions. Duration of sessions not reported. **CG1:** Structured social support therapy 15 group sessions: education; discussion of present coping strategies; development of improved coping methods. Family member or friend attended sessions. Duration of sessions not reported. **CG2:** Standard Care.	1. Baseline: immediately pre intervention 2. Immediately post intervention 3. Follow-up: 6 months	Trait subscale of State Trait Anxiety Inventory. Visual Analogue pain scale. Health Locus of Control Scale Arthritis Helplessness Index Rheumatoid Activity Index	Randomisation process poorly described. Use of non standardised visual analogue scale. Difficult to analyse whether participant groups were comparable at baseline due to poor reporting of demographics.

Study	Type of study	Participant demographics	Intervention	Assessment points	Outcome measures (not depression/mood)	Study Limitations
Evers et al. 2002	**RCT**	**N:** 64 **DO:** 5 **M:F:** 29:71 % **MA:** 54.13 (11.17 s.d.) **DD:** 3.45 (2.08 s.d.) **C of O:** Netherlands	**EG:** Individual participant tailored CBI Participants choose two out of possible four modules: 'Pain and functioning'; 'fatigue'; 'negative mood'; 'social'. All treatment modules consisted on cognitive and behavioural interventions. Homework assignments given. 10 bi-weekly 1-hour sessions. Relapse prevention booster session 4 weeks after completion of CBI. **CG:** Standard Care	1. Baseline: pre intervention. 4 -8 weeks post screening for study. 2. Post intervention: 6 months after CBI completion. 3. Follow-up: 12 months after CBI completion.	Disease Activity Score. Impact of Rheumatic Diseases on General Health and Lifestyle (IRGL). Pain Coping Inventory. Checklist of Individual Strength. Illness Cognitions Questionnaire. Utrechse Coping Lijst (Stress).	No description of researcher concealment re allocation to groups. Some outcome measures not administered in full.
Kraaimaat et al. 1995	**RCT**	**N:** 58 **DO:** 6 **M:F:** 32:68 % **MA:** 57 (15.3 s.d.) **DD:** 15.6 (12.4 s.d.) **C of O:** Netherlands	**EG:** Group CBI Medical management of RA; progressive relaxation; rational thinking; active coping behaviours; goal setting. 10 weekly 2-hour sessions. **CG1:** Occupational therapy Biomedical information; energy conservation; joint protection; use of devices for daily activities; physical exercise. 10 weekly 2-hr sessions. **GC2:** Wait list	1. Baseline: pre intervention (not specified). 2. Immediately post intervention. 3. Follow-up: 6 months after completion of CBI.	Rheumatoid Arthritis Knowledge Test. Pain Coping Strategies. Pain Coping Inventory. Clinical indicators of disease activity.	Randomisation process poorly described. Difficult to analyse whether participant groups were comparable at baseline due to poor reporting of demographics. Results poorly reported.

Study	Type of study	Participant demographics	Intervention	Assessment points	Outcome measures (not depression/mood)	Study Limitations
Leibing et al. 1999	**RCT**	**N:** 55 **DO:** 8 **M:F:** 14:41 **MA:** 52.7 (11.9 s.d.) **DD:** 9.4 (9.3 s.d.) **C of O:** Germany	**EG:** Group CBI Information & education about RA; relaxation & imagery; CBT interventions & pain management strategies; pleasant activity scheduling. 12 weekly 90-minute sessions. **CG:** Standard Care.	1.Baseline: immediately pre intervention. 2. Immediately post intervention 3. Follow up – 9 months after completion of CBI.	Hanover Functional Ability Questionnaire. Pain Visual Analogue Scale & Pain Diary. State Trait Anxiety Inventory. Arthritis Helplessness Index. Bernese Coping Modes. Clinical indicators of disease activity.	Randomisation process poorly described. Outcome measures poorly described and use of non validated visual analogue scales.
O'Leary et al. 1988	**RCT**	**N:** 33 **DO:** 3 **M:F:** 0:100 **MA:** 49.3 **DD:** 8.0 **C of O:** USA	**EG:** Group CBI Education on bio-psychosocial model of pain; cognitive and behavioural pain management strategies; goal setting; self-reward; pleasurable activities; relaxation; attention refocusing; dissociation; re-labelling emotions; communication techniques. 5 weekly 2-hour sessions. **CG:** Received copies of 'The Arthritis Helpbook'; given information sheet to encourage increased activity.	1. Baseline: pre intervention (not specified). 2. Post intervention (not specified).	Health Assessment Questionnaire. Arthritis self efficacy scale. UCLA loneliness scale. Perceived stress scale. Sleep diary. Clinical indicators of disease activity.	Randomisation process poorly described. Results difficult to interpret due to missing data. Large number of statistical tests performed without correction of significance level.

Study	Type of study	Participant demographics	Intervention	Assessment points	Outcome measures (not depression/mood)	Study Limitations
Parker et al. 1995	**RCT**	**N:** 141 **DO:** 0 **M:F:** 81:60 **MA:** 60.0 **DD:**12.2 (9.8 s.d.) **C of O:** USA	**EG:** Individual CBI stress management. Relaxation training; instruction in CBT strategies for managing stressors associated with RA. Additional home based multimedia computer program component. 10 weekly 90 minutes sessions. 15-month maintenance programme consisting of one session per 3 months. **CG1:** Attention-control group Individual patient education. 10 weekly 90-minute sessions. 15-month maintenance programme consisting of one session per 3 months. **CG2:** Standard care.	1. Baseline: pre intervention (not specified). 2. Post intervention (not specified). 3. Follow-up: 3 months after completion of CBI. 4. Follow-up: 15 months after completion of CBI.	Hassles Scale Daily Stress Inventory. Arthritis Helplessness Index State Trait Anxiety Inventory. Arthritis Self-Efficacy Scale. Coping Strategies Questionnaire. McGill Pain Questionnaire & Pain Visual Analogue Scale. Arthritis Impact Measurement Scales. Clinical indicators of disease activity.	Use of non-validated visual analogue scales as outcome measures. Randomisation process poorly described. Results not clearly reported.
Sharpe et al. 2001	**RCT**	**N:** 53 **DO:** 8 **M:F:** 30:70 % **MA:**55.06 (14.07 s.d.) **DD:**12.63mths (8.22 s.d.) **Cof O:** UK	EG: Individual CBI Education on RA; relaxation training; attention diversion; goal setting; pacing; problem solving; cognitive restructuring; assertiveness & communication; management of flare-ups and high risk situations. 8 weekly 1-hr sessions. CG: Standard care.	1. Baseline: immediately pre intervention. 2. Immediately post intervention. 3. Follow up: 6 months after completion of CBI.	Coping Strategy Questionnaire. Health Assessment Questionnaire. Hospital Anxiety and Depression Scale (HASD). Ritchie Articular Index.	Paper of a very high methodological standard.

Study	Type of study	Participant demographics	Intervention	Assessment points	Outcome measures (not depression/mood)	Study Limitations
Sharpe et al. 2003	**RCT**	**N:** 53 **DO:** 9 **M:F:** 30:70 % **MA:** 55.06 (14.07 s.d.) **DD:**12.63mths (8.22 s.d.) **Cof O:** UK	**EG:** Individual CBI Education on RA; relaxation training; attention diversion; goal setting; pacing; problem solving; cognitive restructuring; assertiveness & communication; management of flare ups and high risk situations. 8 weekly 1-hr sessions. **CG:** Standard care	1. Immediately post intervention. 2. Follow-up: 6 months after completion of CBI. 3. Follow-up: 18 months after completion of CBI.	Coping Strategy Questionnaire. Health Assessment Questionnaire. Hospital Anxiety and Depression Scale (HASD). Ritchie Articular Index.	Difficult to analyse whether participant groups were comparable at baseline due to non-reporting of demographics.
Sinclair et al. 1998	**Within subject design**	**N:** 90 **DO:** 2 **M:F:** 0:90 **MA:** 46 (11.8 s.d.) **DD:** 10.3 (8.8 s.d.) **C of O:** USA	**EG:** Group CBI Boundaries and expectations of others; attributions about stressful events; addressed cognitive distortions; cognitive methods of pain management; anger management; social support issues. Additional home based multimedia video component. 3 bi-weekly 2 hour sessions. **CG:** Standard Care.	1. Baseline: 6 weeks pre intervention. 2. Pre intervention: 1 week. 3. Immediately post intervention. 4. Follow-up: 3 months after completion of CBI.	The Perceived Health Competence Scale. Arthritis Self-Efficacy Scales. Arthritis Helplessness Index. Health Locus of Control Scale. Vanderbilt Multidimensional pain coping Inventory Pain Visual Analogue Scale Arthritis Impact Measurement Scales	No direct measure of depression. Authors report negative affect scores correlate strongly with measures of depression. Adaptation of some outcome measures. No control group. Results poorly reported.

Study	Type of study	Participant demographics	Intervention	Assessment points	Outcome measures (not depression/mood)	Study Limitations
Van Lankveld et al. 2004	**RCT**	**N:** 59 couples **DO:** 1 couple **M:F:** 35:65 **MA:** 50 **DD:** 7.2 **C of O:** Netherlands	**EG:** Group CBI Education on RA; restructuring of disease related cognitions; active coping styles; prevent activity reduction in response to pain; consequences of disease on partner-patient relationship. Partner participated in CBI sessions. 8 90-minute sessions over a 4-week period **CG:** Group CBI Education on RA; restructuring of disease related cognitions; active coping styles; prevent activity reduction in response to pain. Partner did not participatee in CBI sessions. 8 90-minute sessions over a 4-week period	1. Baseline: 2 weeks prior to commencing CBI. 2. Post intervention: 2 weeks after completion of CBI 3. Follow-up: 6 months after completion of treatment.	IRGL Perceived Limitations: 10 Item Scale Perceived dependence: 9 item Scale Coping with Rheumatoid Stressors Scale Maudsley Marital Questionnaire Spouse Reaction Questionnaire Communication Improvement measure.	Randomisation process poorly described. Use of non-validated or published scales.

Key
RA: Rheumatoid Arthritis; **N:** Total number of participants; **DO:** Drop out (at end of study); **M:F**: Male to Female ratio; **MA:** Mean Age (Years; Standard deviation in parenthesis if reported); **DD**: Duration of disease (Years unless otherwise specified); **C of O**: Country of origin; **NR**: Not reported.

EG: Experimental group; **CG**: Control Group; **CBI**: Cognitive behavioural intervention.

Table 3: Main findings in relation to depression and calculated review quality rating for included studies.

Authors	Type of CBI	Depression/ mood outcome measures	Mean depression score at baseline (SD) and severity of depression score	Main findings for depression	Immediate post intervention (ES)	Follow-up (ES)	Clinical significance of change in depression	Quality rating (%)
Sharpe et al. 2001	**Individual**	Hospital Anxiety and Depression Scale (HADS). Published.	EG = 4.87 (4.01) Normal depression range CG = 4.68 (4.68) Normal depression range	CBI group became less depressed and the standard care control group became more depressed (p=0.018). This difference was maintained at 6-month follow-up (p=0.05). Significant difference between group scores at follow-up (p<0.001).	CBI compared with control group: **ES= 0.60**	CBI compared with control group: **ES= 0.49**	'Possible' depression scores reduced from 17% pre treatment to 9% immediate post intervention and 4% at 6 month follow-up. Within standard care control group 'possible' depression scores increased from 14% of participants pre intervention to 31% at post intervention and 6 month follow-up.	**100**
Sharpe et al. 2003	**Individual**	Hospital Anxiety and Depression Scale (HADS). Published.	Not reported but assumed to be as above	Significant group by time interaction across three assessment points (p=0.012; ES=0.5). CBI group became less depressed as control condition became more depressed from post intervention to 18- month follow-up.	Not applicable.	CBI compared with control group: Reported **ES = 0.5**	'Possible' depression scores in CBI group reduced from 17% (post intervention) to 4% (6-month follow-up) of participants. At 18-month follow-up 13% of participants scores fell within the 'possible' depression range in CBI group. 'Possible' depression in control group increased from 14% to 31% of participants in same time period. Stable at 18-month follow-up.	**88**

Authors	Type of CBI	Depression/ mood outcome measures	Mean depression score at baseline (SD) and severity of depression score	Main findings for depression	Immediate post intervention (ES)	Follow-up (ES)	Clinical significance of change in depression	Quality rating (%)
Evers et al. 2002	**Individual**	Beck Depression Inventory (BDI, Dutch version). Depression subscale in Impact of Rheumatic Diseases on General Health and Lifestyle (IRGL). Published.	EG (BDI) = 12.79 (6.46) Minimal depression range CG (BDI) = 12.18 (6.70) Minimal depression range	Significant time x group interaction effect for depression ($p<0.01$) (BDI) Significant difference (improvement) in depression and negative mood scores (respectively) in CBI group post intervention ($p<0.01$) ($p<0.05$) and 6-month follow-up ($p<0.01$) ($p<0.05$). No improvement in standard care control group.	CBI compared with control group on BDI: **ES= 0.51** CBI compared with control group on IRGL: **ES = 0.44**	CBI compared with control group on BDI: **ES= 0.55** CBI compared with control group on IRGL: **ES = 0.43**	Not addressed.	**81**
Leibing et al. 1999	**Group**	Depression Scale (DS). Published.	EG = 59.8 (7.8) Mild/moderate depression range CG = 57.2 (9.6) Mild depression range	Significant difference (improvement) in depression scores in CBI condition ($p=0.0047$) pre to post intervention. Significantly greater decreases in depression scores in CBI condition compared with control group ($p=0.049$) pre to post intervention.	Intragroup changes in CBI: Reported **ES = 0.59** CBI compared with control group: Reported **ES = 0.48**	Not applicable.	Not addressed.	**76**

Authors	Type of CBI	Depression/ mood outcome measures	Mean depression score at baseline (SD) and severity of depression score	Main findings for depression	Immediate post intervention (ES)	Follow-up (ES)	Clinical significance of change in depression	Quality rating (%)
Van Lankveld et al. 2004	**Group**	Depression subscale in Impact of Rheumatic Diseases (IRGL). Published.	EG = 4.2 (3.7) No severity classification available CG = 5.4 (4.6) No severity classification available	Significant difference (improvement) in depression scores in both groups ($p<0.05$) from pre intervention to follow-up. No significant difference in change in depression scores between group. Non-significant but present increase in depression scores post intervention to follow-up.	CBI compared with control group: **ES = 0.32**	CBI compared with control group: **ES = 0.15**	Not addressed.	**74**
Parker et al. 1995	**Individual**	Centre for Epidemiological Studies – Depression (CES-D). Published and standardised.	EG = 9.5 Greater 16=depression CG = Not reported	Report no significant difference in depression scores between groups at post intervention, 3 or 15-month follow-up. No significant difference in depression scores in CBI group at any assessment point.	Cannot calculate ES.	Not applicable.	Not addressed.	**69**

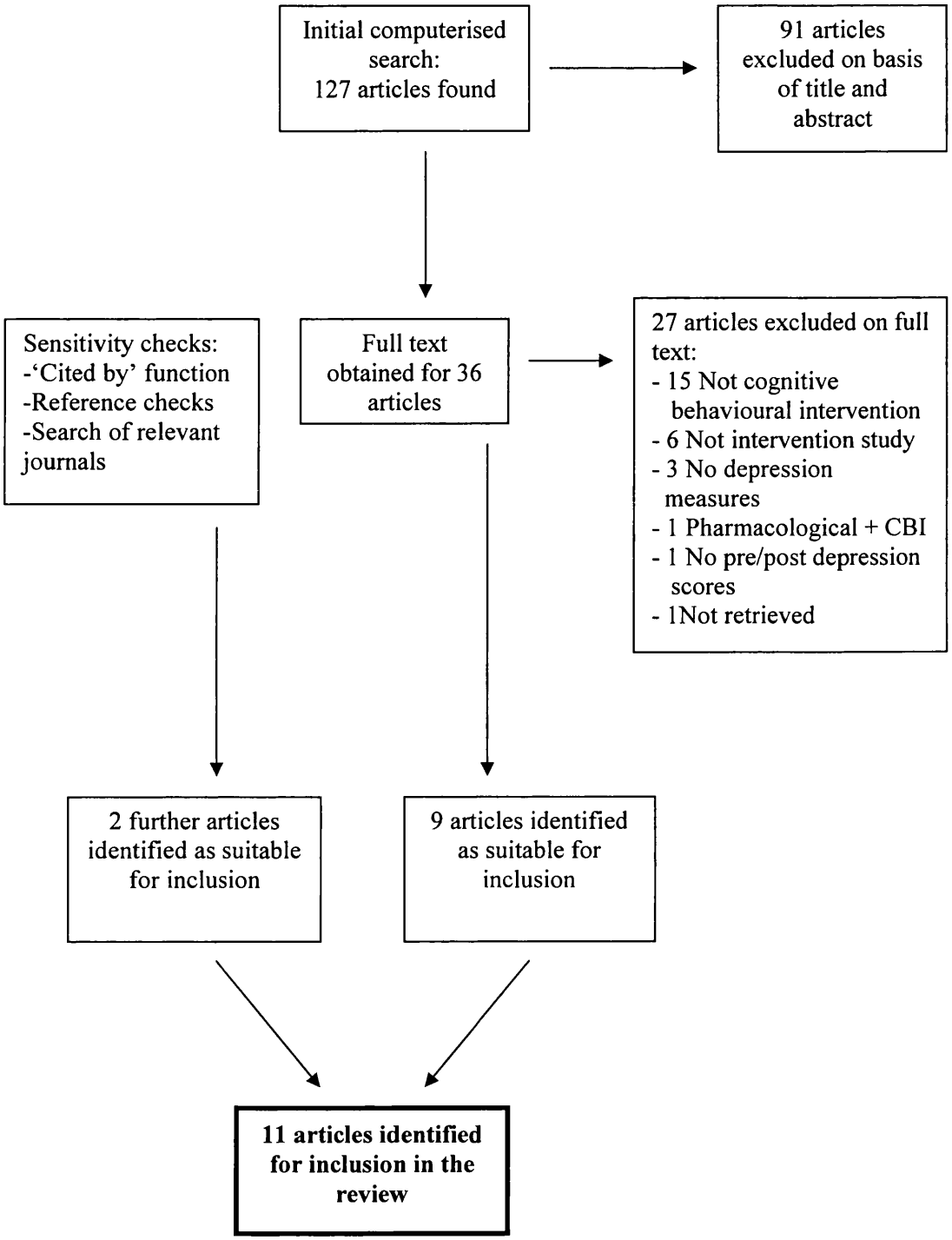
Authors	Type of CBI	Depression/ mood outcome measures	Mean depression score at baseline (SD) and severity of depression score	Main findings for depression	Immediate post intervention (ES)	Follow-up (ES)	Clinical significance of change in depression	Quality rating (%)
Kraaimaat et al. 1995	**Group**	Depression Scale in IRGL. Published.	EG = 2.00 (2.2) No severity classification available CG 1 = 3.4 (4.7) No severity classification available CG 2 = 3.2 (3.2) No severity classification available	Report an increase in depression scores from pre to post intervention and post intervention to 6-month follow-up in all groups. Significant time main effect for depression ($p<0.01$) across all study groups. No group effect.	CBI compared with control group 1: **ES = 0.28** CBI compared with control group 2: **ES = 0.20**	CBI compared with control group 1: **ES = 0.18** CBI compared with control group 2: **ES= 0.28**	Not addressed.	**64**
O'Leary et al. 1988	**Group**	Zung Depression Scale. Published.	EG = 36.22 Below 50=normal CG = 34.69 Below 50=normal	Significant difference (improvement) in depression scores in the CBI condition ($p<0.05$) from pre to post intervention. No significant differences in change in depression scores between groups. Higher post treatment arthritis efficacy was associated with less depression ($r(26)=-0.67$; $p<0.001$).	Cannot calculate ES.	Not applicable.	Not addressed.	**62**

Authors	Type of CBI	Depression/ mood outcome measures	Mean depression score at baseline (SD) and severity of depression score	Main findings for depression	Immediate post intervention (ES)	Follow-up (ES)	Clinical significance of change in depression	Quality rating (%)
Sinclair et al. 1998	**Group**	Positive and Negative Affect Schedule (PANAS). Published.	EG = 2.11 for negative affect. Normal range for negative affect. Greater scores out of total score of 50 indicate higher levels of distress.	Significant change ($p<0.05$) in negative affect scores from pre to post intervention. Positive affect increased and negative affect decreased.	Cannot calculate ES.	Not applicable.	Not addressed.	**60**
Bradley et al. 1987	**Individual and Group**	Depression Adjective Checklist (DAC). Published.	Not reported	No significant difference ($p=0.07$) in depression scores post intervention to six-month follow-up No significant difference between groups. Depression scores increased in all groups post intervention to follow-up, particularly in no adjunctive therapy condition.	Not applicable.	CBI compared with control group 1: **ES = 0.48** CBI compared with control group 2: **ES = 0.24**	Not addressed.	**59**

Authors	Type of CBI	Depression/ mood outcome measures	Mean depression score at baseline (SD) and severity of depression score	Main findings for depression	Immediate post intervention (ES)	Follow-up (ES)	Clinical significance of change in depression	Quality rating (%)
Bradley et al. 1985	**Individual and Group**	Depression Adjective Checklist (DAC). Published.	Not reported	Significant difference (improvement) in depression scores in the CBI group ($p<0.005$) but also in the social support condition ($p<0.01$) from pre to post intervention. No comparison between groups on depression scores. Reduction in depression scores in all groups ($p<0.001$).	CBI compared with control group 1: **ES = 0.50** CBI compared with control group 2: **ES = 0.52**	Not applicable.	Not addressed.	**48**

Key: CBI: Cognitive behavioural intervention; EG: Experimental group; CG; Control group; SD: Standard deviation; ES: Effect size (Calculated by review author if not reported in study).

Figure 1: Article selection process



CHAPTER 2

MAJOR RESEARCH PROJECT PAPER

Development, implementation and evaluation of a pilot group educational intervention for lower limb amputees.

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Prepared in accordance with requirements for submission to Disability and Rehabilitation (Appendix 2.1)

Abstract

Purpose: To develop and evaluate the effectiveness of a pilot group educational intervention programme, based on self-management and psychoeducational approaches, for individuals with a recently acquired lower limb amputation.

Method: Thirty-four participants were quasi-experimentally allocated to an intervention or usual care control condition, dependent on the day they attended for their physiotherapy rehabilitation appointment. Intervention participants received a six-week educational group programme covering a range of practical and psychological topics. Participants completed pre and post self-report measures.

Results: Within condition analyses showed improvements on measures of depression, generalised self-efficacy, self-efficacy specific to amputation related behaviours, and quality of life. However, when compared, there were no significant differences between the two conditions on any outcome measures and calculated effect sizes were small. Clinical indicators did suggest more reductions in the intervention condition for participants meeting criteria for anxiety and depression. Participant feedback on the group intervention was generally positive.

Conclusions: From the current results, the group educational intervention does not appear to be any more effective at reducing depression or anxiety, or improving self-efficacy or quality of life, than usual care for lower limb amputees. This was a small pilot study and may contribute to future research in identifying areas such as social support and coping styles that could be addressed through psychoeducational interventions.

Introduction

Psychological impact of lower limb amputation

Amputation of a lower limb poses a range of physical, emotional, psychological and social challenges to individuals. Amputation has been associated with a number of psychological difficulties including post-traumatic stress disorder [1], nxiety and depression [2]. Desmond & MacLachlan [3] reported prevalence rates of 32% for significant depressive symptoms and 34% for clinical anxiety in a sample of older males with upper and lower limb amputations acquired an average of 639 months previously. Similarly high levels of anxiety and depression have been found in other amputee studies [4-6]. In a review of the literature on psychosocial adjustment to amputation, Horgan and MacLachlan [7] concluded that depression and anxiety are higher up to two years post amputation but subsequently decline to normal population levels. They also reported increased levels of social discomfort and body image anxiety.

Frequency and cause of lower limb amputation

Amputation of a lower limb, either above or below the knee, can be carried out for a variety of reasons including vascular disease, diabetes, trauma, tumour, or as a secondary measure due to infection. An epidemiological study carried out in 2000 [8] using data from 4 UK cities reported amputation prevalence rates of 5.0 – 26.2 per 100,000 per year. Frequency of amputation increases with age and around two thirds occur in patients over sixty years old [9]. This may have significant implications for the current ageing population and increasing incidence of Type 2 diabetes and vascular diseases.

Adaptation to amputation

Disability literature proposes that understanding a persons' adjustment should focus on their perception of their disability rather than the disability itself. It is the appraisal process that is argued to have considerable influence on subsequent adjustment [10] and more recent research has focused on the impact of psychological and psychosocial factors on this. These may be more predictive of adjustment than the medical or physical aspects of the amputation or ensuing disability [4]. Research highlights body image concerns [11], perceived social stigma [12], restrictions to everyday activities (i.e. self-care, visiting friends, household tasks, less satisfaction with social contacts) [13], and feelings of vulnerability [14] as predictors of psychological adjustment following amputation.

Coping style and coping strategies have also been found to be important predictors of adaptation. Avoidance [15], 'cognitive disengagement' and 'emotion focussed' strategies [16], have been associated with increased psychological distress and poorer adjustment in lower limb amputees. Conversely, problem solving, support seeking, humour, and cognitive acceptance are linked with positive adjustment and reduced anxiety and depression [15,17-18].

Approaches to rehabilitation

Despite recent research focusing on the impact of psychological and psychosocial variables on adjustment to amputation the functional/physical adaptation of patients (e.g. learning to use prostheses) continues to receive most attention. Rehabilitation and recovery from limb amputation requires a comprehensive multidisciplinary service that attends not only to medical needs but common concerns such as post-amputation psychological distress and potential psychosocial vulnerabilities [4].

Wegner et al. [19] posit that psychological care of amputees should be undertaken by all members of the rehabilitation team. They proposed the Permission, Limited Information, Specific Suggestions, Intensive Therapy (PLISSIT) model to facilitate this. Permission allows the clinician to introduce and integrate psychological care and discussion of psychosocial issues within the clinic setting. Limited information encourages the provision and use of self-management and patient education materials. Specific suggestions provide the patient with psychological and behavioural strategies (i.e. relaxation, reducing avoidance, increasing positive coping). Intensive therapy, for example motivational interviewing or cognitive behavioural therapy,is kept for treatment of severe difficulties that are not alleviated by previous levels.

Self-management and Psychoeducation

Evidence for the inclusion of psychological and psychosocial issues in rehabilitation and ongoing care comes from the treatment of chronic disease conditions utilising self-management and psychoeducational programmes. Self-management complements traditional patient education in supporting individuals to achieve the best possible quality of life and encourages a greater sense of personal responsibility for health and well-being. It is based on the development of five core skills: problem solving skills, ability to make day to day decisions about their condition on the basis of sound knowledge, ability to find and utilise appropriate resources and support, capacity to make informed choices about one's own healthcare in conjunction with health professionals, and taking action to change behaviour and master new skills [20].

Effectiveness of self-management approaches has been reported for a range of chronic conditions including arthritis [21], stroke [22], diabetes [23-24], and back pain in the

elderly [25]. In addition, psychoeducational group interventions incorporating medical information with psychological and psychosocial approaches were found to improve quality of life in adolescents with epilepsy [26].

One of the most central elements of self-management and psychoeducational approaches relates to its effectiveness in enhancing individuals' self-efficacy. Self-efficacy is a concept first developed by Bandura [27] and has been described as how confident a person is in their own ability to carry out the behaviour necessary to achieve a desired goal; confidence (self-efficacy) will increase with each successful behaviour [28]. When applied to chronic health conditions it is hoped that as patients learn to successfully manage their disease their self-efficacy will increase. This concept of self-management can be viewed as doubly appropriate for many amputees who have to cope and adjust to not only their amputation but will often have a co-morbid chronic condition such as Type 2 diabetes or vascular difficulties, which requires self-management.

At present there is little research looking at the use of self-management or educational group approaches within the amputee population. Delehanty and Trachsel [29] evaluated the effectiveness of a brief group intervention for people with a lower limb amputation. The intervention group received three weekly two-hour sessions utilising a cognitive behavioural approach. Topics included understanding the effects of amputation, patient education around related diseases, prostheses fitting, physical and occupational therapy, and self-care. At eight months post discharge significant differences were found between the intervention and control groups in terms of levels of distress.

Another similar study was conducted in the USA by the Promoting Amputee Life Skills research group (PALS) [30]. This was a group intervention for individuals who had acquired a lower limb amputation at least six months previously although many were several years post amputation. Participants were already attending an amputee support group before being recruited into the study. Preliminary findings reported that 77% of participants found the intervention group more helpful than a support (control) group; at six months follow-up control group participants were 2.5 times more likely to be depressed. Overall participants in the treatment group showed a significant increase in self-efficacy and positive mood and were less likely to experience limitations in functioning [30].

Aims and Hypotheses

The current study aimed to add to the limited research base that highlights the need for psychological and psychosocial factors to be considered in tandem with physical rehabilitation needs in amputees. This was done through the design, implementation and evaluation of a pilot educational group, based on self-management and psychoeducational approaches for people with lower limb amputations early in their rehabilitation. It was set within an NHS clinic. The study aimed to address the following hypotheses:

Hypothesis 1: Change scores on all outcome measures will be significantly greater and indicate more improvement for the intervention condition compared to the control condition.

Hypothesis 2: Anxiety and depression scores will reduce in the intervention condition from baseline to post intervention. Quality of life and self-efficacy scores will improve in the intervention condition from baseline to post intervention.

Hypothesis 3: There will be no change or an increase in anxiety and depression scores in the control condition from baseline to post intervention. There will be no change or a decrease in the quality of life and self-efficacy scores within the control condition from baseline to post intervention.

Methods

The current study received ethical approval from the South Glasgow Local Research and Ethics Committee. It was conducted between November 2007 and May 2008 in the West Of Scotland Mobility and Rehabilitation Centre (WestMARC), Southern General Hospital, Glasgow, UK.

Design

The current study adopted a quasi-experimental between groups design. Participants were allocated to study conditions depending on which day they attended the limb fitting centre in WestMARC for their physiotherapy appointment; intervention condition participants attended on Tuesdays and control condition participants attended on any other weekday. Physiotherapy appointments are offered to patients depending on when the referral is received and staff availability, therefore allocation to study conditions was determined by physiotherapy appointment allocation and not by the researcher. Due to the practical limitations of the study neither the researcher, participants or group facilitators were blind

to condition allocation. It was felt by physiotherapy staff that patients would find it difficult to attend the educational group if they had to travel independently therefore truly random allocation to conditions was not deemed appropriate.

Participants

All participants were current inpatients or outpatients attending for physiotherapy rehabilitation at the WestMARC gymnasium. Inclusion criteria for the study were: uni-lateral or bi-lateral amputation of a lower limb, aged eighteen or above, and fluent English speaker. Participants were excluded if they displayed severe cognitive impairments (determined by the clinical judgement of the health professionals involved), were receiving any additional psychotherapeutic treatment, or had an upper limb amputation.

In total 34 people consented to take part in the study, 17 in each experimental condition. Participant demographics are presented in the results section (see table 2). A diagram displaying the flow of participants through the study can be seen in figure 1.

No comparison is made between those who agreed to participate and those who did not, as ethical permission was not sought to collect demographic data for non-consenters.

[Insert figure 1 about here]

Sample Size

Due to the paucity of research examining effectiveness of group interventions with lower limb amputees, the sample size could not be determined *a priori*. It was considered whether power calculations could be determined from studies evaluating group

interventions in chronic health conditions utilising the Hospital Anxiety and Depression Scale (HADS) [31] as an outcome measure. However this was not considered to be a viable option as the potential studies identified were deemed to be of poor methodological quality. Additionally it was felt that it would be inappropriate to make judgements about the current study amputee population based on other chronic conditions as the difficulties faced and experiences due to the disease may not be comparable.

As the present research is a pilot investigation run over a short duration with access to a relatively limited sample population, it was felt the focus should be on identifying the potential benefits of the intervention as a precursor to future research that could be carried out with a larger sample. From discussion with WestMARC staff a minimum number of 12 participants were expected to participate in the intervention condition.

Measures

Participant characteristics:

Participant demographic information, in/out patient status, amputation related information, and mental health information was collected.

1. Psychological Distress:

Psychological distress was measured using the fourteen item self-report HADS [31]. The HADS omits somatic items making it appropriate for use with people experiencing physical health problems. It rates patient's experience and severity of anxiety and depression related symptoms within the past week (seven items for each subscale, score range 0-21). The four score ranges are 'normal' (0-7), 'mild' (8-10), 'moderate' (11-14) and 'severe' (15-21).

The HADS is a standardised measure with established psychometric properties and has been previously utilised with amputees [5, 32-34]. Internal consistency of the two scales as assessed by Cronbach's alpha was 0.93 for anxiety and 0.90 for depression [35].

2. Quality of life:

A new quality of life (QoL) questionnaire (see Appendix 2.2) was developed, as current measures were deemed insensitive to QoL factors specific to an amputee population. The measure was developed in conjunction with consultation from WestMARC staff and available literature [36-37]. It contains four broad areas related to quality of life: activities of daily living, physical health and energy levels, psychological well-being, and relationships and social activities. Participants completed ten self-report questions with responses made on a 10-point visual analogue scale. The response scales were rotated for each question in an attempt to avoid marking bias. Answers were summed to provide a total score (maximum 100). Higher scores indicate greater QoL.

3. Self-efficacy:

Self-efficacy was evaluated using two self-report measures. The Generalised Self Efficacy Scale (GSES; see Appendix 2.3) is a ten-item scale aiming to assess the strength of an individual's belief in one's ability to respond to and cope with new or difficult situations, and deal with associated obstacles or setbacks [38]. Responses were made on a four-point scale ("Not at all true" = 1, "Exactly true" = 4) and the total is all responses summed together. The GSES has not been previously utilised with an amputee population. High internal consistency for the scale has been found in a number of studies, with Cronbach's alpha scores ranging from 0.82 to 0.93 [39].

In addition, a specific self-efficacy measure (see Appendix 2.4) was developed by the lead researcher in consultation with WestMARC staff and utilising available literature [36]. This measure assessed self-efficacy/confidence relevant to each of the topic areas covered by the educational group intervention. Participants completed ten self-report questions with responses made on a 10-point visual analogue scale. Answers were summed to provide a total score (maximum 100). Higher scores indicate greater specific self-efficacy.

Group Evaluation:

In order to collect participant feedback on the group intervention, a brief self-report questionnaire was developed (see Appendix 2.5). This covered overall satisfaction, most and least beneficial topics, value of group resources, and suggestions for improvement. In addition, a sub sample of 3 participants who attended the educational group, were invited to participate in a focus group.

Recruitment and Research Procedures

All consecutive patients who met study inclusion criteria were approached by the researcher and provided with verbal and written information about the study (see Appendix 2.6). Research procedures for each condition can be seen in figure 2. Participants completed baseline measures immediately when they were recruited into the study and post intervention (or time matched period for control participants) measures six to eight weeks later.

[Insert figure 2 about here]

Assistance was provided to complete questionnaires if required. If participants could not be contacted via WestMARC post intervention questionnaires were posted to their home for completion and the researcher made a follow up telephone call.

Educational Group Intervention

The educational group comprised of six one-hour sessions held over a consecutive six-week period. Four cycles of the educational group were completed over the duration of the study. Participants could join the group at any point as each session was delivered as an independent component. The group programme and manual were developed by the author and encompassed core self-management principles, educational information, and amputee specific issues (i.e. phantom pain) as highlighted by the research literature [40]. Information about session themes and facilitator is presented in table 1.

[Insert table 1 about here]

At the first educational group session attended, each participant received a resource pack containing session handouts and a progressive muscular relaxation CD. The resource pack was forty-two pages long in total. Control participants received the resource pack on completion of the study.

Data Analysis

An intention-to-treat analysis was conducted whereby participants were included in their assigned group no matter how many sessions they attended. In order to deal with attrition rates baseline data was carried forward and included in the analysis.

Prior to carrying out statistical analyses data were explored to check for normality. As none of the data were normally distributed non-parametric statistical analyses were utilised. Mann Whitney tests were used to determine differences between the intervention and control conditions on duration of amputation, years of education completed, and outcome measures at baseline. Pearson's Chi-squared analysis tested for significant differences in the categorical variables between groups (i.e. gender, in/out patient, type and cause of amputation, relationship and living situation, mental health history).

In order to address hypothesis 1 change in each score from baseline to post intervention was calculated for all outcome measures for each participant. The Mann Whitney test was used on change scores to determine any significant difference between conditions. The Wilcoxon test was used to determine any significant differences from baseline to post intervention on all outcome measures within conditions (Hypotheses 2 and 3). P-values $<.05$ were considered statistically significant. The use of multiple tests does increase the probability of a type 1 error. There was no adjustment to compensate for this increased error rate. The present study represented a pilot investigation of a newly developed intervention therefore an inflated type 1 error rate was deemed acceptable in order to identify important outcomes for future research.

Ancillary analysis was conducted using a Mann Whitney test to determine any significant difference in change scores in the intervention condition due to the number of group sessions attended (<3 versus >3). A post hoc power calculation was also conducted. In addition the clinical indicators for depression and anxiety according to the HADS are commented on in each condition. Evaluation feedback about the group intervention is also discussed.

In an attempt to consider the use of more robust parametric statistical analyses (independent t-test or ANOVA) the use of log transformations was considered for the change scores of the current data set. However it was decided that due to the pilot nature of the research it would be of greater benefit to analyse the data without transformations to identify patterns or trends for this particular sample population.

Results

Baseline Data

A total of 34 participants took part in the current study: 17 in each condition. Participant demographics are reported in table 2. The median and range are reported as they are considered more appropriate measures of central tendency for non- normally distributed data.

[Insert table 2 about here]

Statistical analyses revealed no significant difference between the two conditions on participant demographics. There were no statistically significant differences found between conditions on outcome measures at baseline assessment.

Within Condition Analyses

The Wilcoxon test detected a significant difference between baseline and post intervention scores in the intervention condition for the HADS depression subscale ($z = -1.921$, N-ties = 13, $p=0.026$, one-tailed), GSES ($z = -1.859$, N–ties = 14, $p=0.033$, one-tailed), specific self-efficacy ($z = -2.133$, N-ties =17, $p=0.016$, one-tailed) and QoL ($z = -2.070$, N-ties = 16, $p=0.019$, one-tailed) but not anxiety ($z = -0.208$, N-ties = 16, $p=0.426$, one-tailed). The

rank values indicate a reduction in depression scores and an increase in scores on the GSES, specific self-efficacy and QoL.

In the control condition, the anxiety subscale score on the HADS increased significantly from baseline to post intervention (z = -1.843, N-ties = 12, p=0.047, one-tailed). Specific self-efficacy (z = -2.656, N-ties = 13, p=0.002, one-tailed) was the only variable that increased significantly in a positive direction between baseline and post intervention in this condition. There was no significant difference on the depression subscale of the HADS (z = -0.241, N-ties = 11, p=0.432, one-tailed), GSES (z = -1.843, N-ties = 12, p=0.233, one-tailed), or QoL (z = -0.665, N-ties = 13, p=0.266, one-tailed).

Between Condition Analyses

The Mann Whitney test showed no significant differences in the change scores between the intervention and control conditions on any of the outcome measures: HADS depression subscale (U=120.00, N_1=17, N_2=17, p=0.398, two-tailed); HADS anxiety subscale (U=135.00, N_1=17, N_2=17, p=0.762, two-tailed); GSES (U=106.50, N_1=17, N_2=17, p=0.192, two-tailed); specific self-efficacy (U=130.00, N_1=17, N_2=17, p=0.627, two-tailed); quality of life (U=99.00, N_1=17, N_2=17, p=0.119, two-tailed).

Effect sizes were also calculated for each of the outcome measures. Effect sizes for depression (0.15), anxiety (0.05), and specific self-efficacy (0.09) fell into the small effect range $\leq$0.2 [41]. The effect sizes for the GSES (0.23) and QoL (0.27) measures indicate a small to medium effect ($\geq$0.3) of the educational group intervention. Using the effect size for the depression subscale it is possible to carry out a post hoc power calculation. Power for the current study using the depression measure was 0.07. This is significantly smaller

than the recommended level of 0.8 [41] to detect any significant effects that may have existed. Using these values, 699 participants in each group would have been required to detect a significantly well-powered small effect [42].

The median and range scores for each outcome measure at baseline and post intervention. Levels of probability are reported for within and between condition comparisons.

[Insert table 3 about here]

Ancillary Analyses

Session attendance:

Frequencies for the total number of participants and sessions attended are displayed in graph 1.

[Insert graph 1 about here]

From graph 1, it is clear to see that the majority of participants in the intervention condition attended at least 50% of the six group sessions. The Mann Whitney test revealed no significant difference in change scores on any measure between participants who had attended more than three or less than three group sessions; anxiety subscale ($U=25.00$, $N_1=7$, $N_2=10$, $p=0.364$, two-tailed), depression subscale ($U=30.00$, $N_1=7$, $N_2=10$, $p=0.648$, two-tailed), GSES ($U=30.50$, $N_1=7$, $N_2=10$, $p=0.685$, two-tailed), specific self-efficacy ($U=31.00$, $N_1=7$, $N_2=10$, $p=0.739$, two-tailed), and QoL ($U=19.00$, $N_1=7$, $N_2=10$, $p=0.126$, two-tailed). Reasons for non-attendance at the group were reported as ambulance transport

problems, illness, attendance for physiotherapy on a day other than Tuesday, required return to ward for medication, and other appointments.

Clinical Indicators:

According to the HADS [38] scoring criteria, individuals' scores indicate 'normal' (0-7), 'mild' (8-10), 'moderate' (11-14) or 'severe' (15-21) levels of anxiety or depression. The number of participants whose scores fell into each category at baseline and post intervention can be seen in graphs 2 and 3.

[Insert graph 2 about here]

[Insert graph 3 about here]

Out of a possible thirty-four participants at the beginning of the study, ten met criteria for some level of probable depression (29%) and thirteen for probable anxiety (38%). The majority of participants in both experimental conditions fell within the 'normal' range for anxiety and depression. The number of participants in the depressed range (mild, moderate, severe) declined in both conditions from baseline to post intervention. In the intervention condition, number of participants increased in the 'mild' anxiety category but fell in the 'moderate' and 'severe' categories. The total number of participants in the 'mild' and 'severe' categories increased post intervention in the control condition.

Group Evaluation:

Of the nine participants who completed the group evaluation questionnaire, eight reported that the group was useful and one found it 'slightly' useful. The most helpful topics were preventing falls (3 participants), prosthesis use (2 participants), care of the residual limb

and massage (2 participants), all topics (2 participants). The least helpful topics were mood management (4 participants), relaxation (1 participants), accessing community resources (1 participants), and all helpful (3 participants).

On the whole, comments made by the participants on the evaluation questionnaire and during the focus group were positive. The main benefit was discussing difficulties with other amputees as this normalised their own experiences. A few quotes from the focus group and questionnaire are outlined below:

"I found the group very helpful, there was nothing like this when I had my first amputation years ago." (Participant 7).

"I thought the group was exceptional and the people who did the talks were able to make it understandable. I particularly liked the talk when the lady brought along the titanium leg [prosthesis issues] and the talk on healthy eating, I learnt a lot from those." (Participant 4).

"I enjoyed the group, even though I don't normally go in for groups. I think it should just be expected for people to attend." (Participant 34).

Suggestions for improvement focussed on the presence of a longer-term amputee at sessions, increased discussion between patients, more regular sessions, and not overloading sessions with information.

Discussion

The goal of the current study was to evaluate whether providing an educational group intervention to individuals with a recent lower limb amputation would impact on measures of depression, anxiety, general self-efficacy, self-efficacy specific to adjusting to an amputation, and quality of life. Within the intervention condition statistical results indicated a reduction in depression and a positive improvement in generalised self-efficacy, specific self-efficacy, and quality of life from baseline to post intervention. There was no change in anxiety scores during the study in the intervention condition. Conversely, in the control condition only specific self-efficacy improvement and anxiety scores increased. Despite these initially promising findings, there was no statistically significant difference in change in scores on outcome measures when the two conditions were compared. This suggests that although the educational group may have led to some improvements in the intervention condition over the study period when compared to the control condition who received only routine care, it was not more effective at creating change in the outcome measures.

This result may be partly explained by the small participant sample in that a significant effect was less likely to be detected. Additionally there was some effect of the intervention on outcome measures, as highlighted by the effect size calculations, however as these all fell within the small (≤ 2) to moderate range (≥ 3) [41] this adds weight to the argument that the intervention itself was not greatly effective.

The findings of the current study are not in keeping with previous literature on self-management interventions in other chronic conditions which found beneficial effects on a range of factors related to psychological distress and quality of life [21-24]. Furthermore,

specific to amputation it does not support limited previous research that reported reduced levels of distress [29] and increased positive mood and self-efficacy [30] in intervention conditions when compared with controls. However when the intervention group is examined independently the reduction in depression scores and increased general self-efficacy is comparable results reported in the PALS study [30]. It is worth acknowledging that the PALS study [30] had large participant numbers in comparison to the current research and this may explain why they found a large effect of the intervention.

An improvement in specific self-efficacy was found in both experimental conditions. This perhaps is not a surprising result in that this measure attempted to address more definitive behaviours and activities that would be affected or need to be learned after amputation. The principles of self-efficacy posit that when individuals successfully complete a task self-efficacy increases [27], therefore it would be expected that as individuals have more opportunity to experience activities and successfully learn new behaviours after amputation, self-efficacy would be enhanced.

Two major differences between the previous amputee group intervention studies and the present one relate to timing issues in the studies. Delehanty and Traschel [29] participants received the intervention shortly after amputation with follow-up eight months post discharge. In the current study intervention participants ranged from inpatient to three years amputation duration, and measures were completed immediately post intervention. These differences may limit comparability of the studies in terms of the sample population and design. In the PALS study [30] duration of amputation was at least six months. Median scores were 9 and 29 weeks for the intervention and control conditions respectively. This indicates that duration of amputation was actually considerably shorter for the present

study sample, especially in the intervention condition, and this may impact on current level of adaptation. It is possible that more recent amputees may not yet be fully aware of the impact it will have on their lives, functionally and psychologically. In contrast, PALS participants, who had been amputees for a longer period may have greater consciousness of the impact of amputation and experienced accompanying higher levels of psychological distress. These higher levels of distress may have provided greater potential for increases in positive mood and improved adaptation compared with participants in the current study.

One further point to consider in relation to the difference in findings between the current study and previous research is in origin. Both the Delehanty and Traschel [29] and PALS studies [30] were carried out in Canada and the USA respectively which operate on a different healthcare system to the NHS. It is possible that as participants in the previous studies may pay for their healthcare they take greater responsibility for utilising services and see greater benefits.

Prevalence of depression (29%) and anxiety (38%) in the current study is similar to that previously reported [3-6], however as the majority of these studies have included both upper and lower limb amputees they must be compared with caution. Singh et al. [43] administered the HADS [31] on admission to a rehabilitation ward after a lower limb amputation. They reported that 27% and 25% of patients had symptoms of depression and anxiety respectively. However only 4% and 9% met criteria at discharge after a mean duration of 54.3 days. Singh et al. [43] posits that this rapid resolution may be attributed to the rehabilitation period where new skills and improving patient independence and mobility are the focus. This finding could provide evidence that depression scores reduced in the intervention condition due to routine care and not attendance at the educational

group. On the other hand as reduction in depression was not replicated in the control condition, and anxiety was not reduced in either condition, improvements in the intervention condition cannot be wholly accounted for by usual care.

Clinical Significance

As research within the field has identified that psychological and psychosocial factors may be more predictive of subsequent adjustment than the medical or physical aspects of the amputation [4], it is important to consider the clinical implications of this study in addition to statistical analyses. It is beneficial to examine any differences in the number of participants meeting criteria for depression and anxiety between conditions as this clinical outcome may be more representative of participants' psychological status and subsequent impact on functioning. Post intervention no participants in the intervention condition met criteria for symptoms of 'moderate' or 'severe' depression and the number of participants meeting criteria for 'moderate' and 'severe' anxiety decreased. Participants who met 'moderate' or 'severe' criteria at baseline may have reduced scores to the 'mild' range post intervention indicating improvement. In comparison the control conditions only reduction was in the number of participants meeting criteria for 'mild' depression. There was no change or an increase in the number meeting criteria for anxiety and depression for all other categories. A tentative explanation for this may be that despite the lack of statistically significant difference between conditions, in clinical terms more improvements in anxiety and depression were observed in the intervention condition.

It is worth noting that although the percentage of the sample that met criteria for depression or anxiety (mild, moderate or severe) was akin to rates reported in the literature, the majority of participants fell within the normal range and then the mild and moderate

categories. Some literature suggests more severe levels of anxiety and depression [3] than was evident in the current sample. Similar to the current findings, Fisher and Hanspal [32] also reported lower prevalence rates of depression in their elderly amputee sample. They determined depression to be an uncommon reaction to amputation whereas increased anxiety was more common.

Although the majority of the literature focuses on the negative impact of amputation a number of recent qualitative and quantitative research papers have explored the possibility that amputation can provide some positive experiences. This may partly explain the lower than expected rates of severe psychological distress in the present sample. Positive themes that have arisen out of the research relate to elimination of pain, restoring mobility through use of prosthesis, reappraising or changing attitude to life, and making social or downward comparisons to individuals in a worse position [44-45, 18, 4]. Finding positive aspects to your amputation may act as a protective factor against psychological distress. The lower levels of psychological distress may also be impacted on by the age of the current sample (median age 67 years). One study found that older amputees are less subject to depressive symptomatology, than younger counterparts [13].

From a service user point of view it is also important to highlight the positive feedback about the group intervention. Participants received benefit from attending the group in terms of learning new information and strategies to aid adaptation to their amputation and having the opportunity to normalise their experiences through discussion with other amputees. This is encouraging qualitative information which suggests the educational group was valuable to participants even though this was not indicated by the statistical analyses.

Methodological Limitations

There are a number of methodological limitations that must be taken into account when evaluating the outcomes of the current research. Ideally recruitment into the study would have been open to all current physiotherapy attendees with subsequent random allocation to experimental conditions. This was not deemed feasible due to practical difficulties with independent patient transport. Although there were no statistically significant differences between conditions on participant demographics, visual inspection of the data did highlight some variation on factors such as type and cause of amputation. These differences in amputation demographics are important to consider as it is not unreasonable to expect they would impact greatly on psychological and physical adaptation. This issue would be better addressed by full randomisation, perhaps even stratification of participants in order to achieve an even distribution of amputation types and causes across conditions. In connection with this an interesting area for future research may be in the development of tailored groups that address the differing needs associated with type or cause of amputation and duration of amputation.

A further limitation lies in the small sample size, although it is worthwhile noting that WestMARC physiotherapy staff felt participant numbers were representative of the numbers of patients attending the department during the study period. Additionally the current sample does appear to be comparable with other amputee research populations [8], but again the generalisability of the findings should be viewed with caution due to the small sample. Due to the low number of participants the study was underpowered which limits the probability of identifying a significant effect of the intervention. In addition non-parametric statistical analyses were carried out on the data which can sometimes be viewed as more conservative than parametric equivalents.

If similar research were to be conducted in future it was calculated that 699 participants per condition would be required to detect a significantly powered effect. Such a large scale study would not be practically feasible and the findings and small effect sizes generated by the current research would suggest that an intervention such as the educational group may not actually be required by the majority of lower limb amputees. Taken together these arguments suggest that replicating this study as its stands would not be beneficial. However positive qualitative feedback and the results of the within condition analyses do suggest that there was some benefit to attending the group so it may be appropriate to carry this research further in a different way. Perhaps one way of doing this rather than attempting to run a large scale randomised controlled trial would be by attempting to identify individuals at risk of developing psychological difficulties post amputation, by monitoring factors such as social support, type and cause of amputation and prior psychiatric history that we know have an impact, and providing a more targeted and specific group or individual intervention for them. This would hopefully provide a more effective and valuable way of utilising resources.

Two further potential limitations in the design of the study relate to the lack of researcher blinding and use of unpublished and unstandardised measures. Owing to practical difficulties in recruitment and administration of questionnaires it was not possible for the researcher or to be blind to condition allocation which may have led to bias in data collection. The specific self-efficacy and QofL measures were developed in an attempt to address issues specific to an amputee population however no evaluation was conducted to see if they achieve this.

Another point to consider when interpreting results is the variable attendance rates at group sessions; only one participant attended the full six. This increases the difficulty in fully evaluating the effectiveness of the group intervention. Non-attendance was often due to extraneous circumstances out with individual participants' control and is a feature of conducting research in an actual clinical environment. One potential way to address this would be by offering more educational groups, possibly at various locations if feasible and perhaps paying travel expenses to allow patients to travel independently to groups.

Suggestions for future research

There are a number of directions future research in the amputee field could take associated with introducing self-management and psychoeducational interventions as an adjunct to current care. One area that was not assessed by the present study relates to the idea of social support. Social support and seeking social support has been acknowledged in the literature as a key element of adapting to and coping with amputation [13, 15, 18, 47, 48). A qualitative study by Gallagher and MacLachlan [17] reported that amputee participants strongly advocated the importance of meeting and talking with other people who had gone through the process of amputation and rehabilitation. Future research may benefit from investigating social support more explicitly, perhaps through the inclusion of a social support control condition, which could then be compared with the intervention. Of note in the present research participants identified social support as a valuable asset of the educational group. Also, although it was not statistically significant, the number of participants who were married and lived with either their spouse or family was greater in the intervention condition and this may have impacted on outcome.

Due to time restrictions it was not possible to carry out a longitudinal follow-up assessment with participants in order to gauge any further changes over time in the two experimental conditions. This would be a valuable addition to similar studies in future, particularly as some research indicates that psychological distress reduces to normal population levels two years post amputation [7].

In keeping with the already existing literature future research into group interventions may wish to focus on coping styles which have been shown to impact on adaptation to amputation. In general, self-management, educational, and psychoeducational interventions attempt to promote the use of more adaptive coping strategies and this was hoped to be the case for the current group intervention. Active problem solving has been negatively associated with depression [15, 16] and positively associated with adjustment [16]. There may be opportunity to develop interventions focussing on enhancing these strategies and evaluating them directly as an outcome measure.

This study and the query it raises regarding the benefit of reproducing similar research in future highlights the discrepancy between statistical and clinical significance. Despite the outcome that the educational group intervention was not more effective than a usual care control the clinical indicators appeared to imply that the number of participants meeting criteria for depression and anxiety was reduced in the intervention condition. Added to this was the positive service user evaluation. Clinical evaluation in the present study was very limited but this may be an area that warrants more attention and development of more clinically and personally relevant measures such as the individualised patient generated index (PGI) [46] quality of life measure.

One of the major questions raised by the current research relates to when is the most appropriate time for a psychological or psychosocial intervention such as the current educational group to be provided. In the current study the majority of participants were quite recent amputees and were not experiencing the levels of depression and anxiety expected. It is possible that the current non significant findings are mainly due to the small sample size however, an alternative hypothesis may be that more recent amputees do not require any further intervention than that provided by physiotherapy and usual care at the earlier stages of their rehabilitation. At this point they are focussed on the physical aspects and it is only at a later stage when the psychological and psychosocial difficulties come into play. It would be of interest to consider delivering similar psychoeducational interventions to individuals with a longer duration of amputation as perhaps this may lead to differing outcome in efficacy. Longer duration amputates might also provide a valuable resource in terms of enlightening researchers about their own experiences of amputation and the potential value of additional psychological or educational interventions.

Conclusions

The results of this pilot study indicate that there was a reduction in depression scores and improvement in self-efficacy and quality of life scores in the intervention condition over the six weeks of the intervention however these changes were not statistically significantly different when compared to the control condition. If the study were to be replicated in future a larger sample size would be required and the benefit of doing so could be queried as the effect size of the intervention on outcomes was small. Future studies may benefit from more longitudinal follow up and exploration of group impact on social support and coping strategies. It would also be advantageous to evaluate the effect of increased

attendance at group sessions and when in the rehabilitation process is an intervention such as this most valuable.

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Table 1: Educational group intervention programme outline

Session	Session Title	Session outline	Led by
1	Group Introduction	Introduction to group, self-management principles & goal setting.	Psychologist
2	Prosthesis Issues	Discussion about prosthesis use, potential difficulties, queries about own prosthesis.	Prosthetist
3	Phantom pain, residual pain & residual limb massage	Discussion of phantom limb pain, strategies for managing pain and how to carry out residual limb massage	Physiotherapist & Physiotherapy technician
4	Healthy Eating & relaxation	Information provided on healthy eating, discussion of relaxation strategies and in vivo progressive muscular relaxation conducted within session	Dietician & Psychologist
5	How to prevent falls & care of the residual limb	Discussion of strategies on how to try and prevent falls and taking care of your residual limb	Nurse & Physiotherapist
6	Mood Management, Accessing community resources & maintaining contacts with family and friends.	Discussion of mood management strategies, how to interact with family and friends and a list of community resources and contact numbers provided.	Psychologist & Occupational Therapist

Table 2: Participant demographics by intervention conditions. Data presented are number of participants (%) for categorical data; median and range (in parentheses) for continuous data.

Participant demographics	All participants	Intervention condition	Control condition
Number in group	34	17	17
Gender (Male:Female)	22:12 (65:35%)	11:6 (65:35%)	11:6 (65:35%)
Median Age (Years)	67 (43)	67 (41)	68 (39)
Median duration of amputation (Weeks)	19.5 (172)	9 (172)	29 (124)
Median Education Completed (Years)	11 (10)	10 (9)	12 (10)
Type of amputation			
- Unilateral TT	14 (41%)	10 (59%)	4 (24%)
- Unilateral TF	13 (38%)	3 (18%)	10 (59%)
- Bilateral TT	6 (18%)	3 (18%)	3 (18%)
- Bilateral TF	1 (3%)	1 (6%)	0 (0%)
Cause of amputation			
- Diabetes	15 (44%)	11 (65%)	4 (24%)
- Vascular	10 (29%)	5 (30%)	5 (29%)
- Tumor	3 (9%)	0 (0%)	3 (18%)
- Trauma	1 (3%)	0 (0%)	1 (6%)
- Other	5 (15%)	1 (5%)	4 (24%)
Inpatient: Outpatient	12:22 (35:65%)	6:11 (35:65%)	6:11 (35:65%)
Relationship status			
- Married	15 (44%)	10 (59%)	5 (29%)
- Widowed	7 (21%)	3 (18%)	4 (24%)
- Divorced	4 (12%)	1 (6%)	3 (18%)
- Single	8 (24%)	3 (18%)	5 (29%)
Living Status			
- Alone	12 (35%)	4 (24%)	8 (47%)
- With spouse	14 (41%)	9 (53%)	5 (29%)
- With family	7 (21%)	4 (22%)	3 (18%)
- Sheltered accommodation	0 (0%)	0 (0%)	0 (0%)
- Residential home	1 (3%)	0 (0%)	1 (6%)
Previous mental health problems			
- Yes	5 (15%)	2 (12%)	3 (18%)
- No	29 (85%)	15 (88%)	14 (82%)

Key:
TT = Transtibial amputation; TF = Transfemoral amputation. All percentages in the tables and text have been rounded by two decimal places unless otherwise specified.

Table 3: Comparison of outcome measures between baseline and post intervention assessment periods and level of significance for within and between condition comparisons. Data presented are median and range (in parentheses); p value for level of significance.

Outcome measure	Intervention Condition (Baseline)	Intervention Condition (Post)	Within condition comparison: Intervention condition (one tailed) (p value)	Control Condition (Baseline)	Control Condition (Post)	Within condition comparison: control condition (one tailed) (p value)	Between condition comparison: two-tailed (p value)
HADS – depression	4 (10)	3 (8)	0.026*	5 (16)	6 (16)	0.432	0.398
HADS – anxiety	5 (15)	5 (11)	0.426	7 (15)	9 (15)	0.047*	0.762
GSES	31 (17)	35 (16)	0.033*	30 (22)	32 (21)	0.233	0.192
Self-Efficacy	70 (64)	80 (61)	0.016*	65 (55)	70 (59)	0.002*	0.627
QoL	50 (57)	59 (55)	0.019*	47 (70)	44 (65)	0.266	0.119

*Indicates a significant result at the .05 probability level.

Figure 1: Progression of participants through the study.

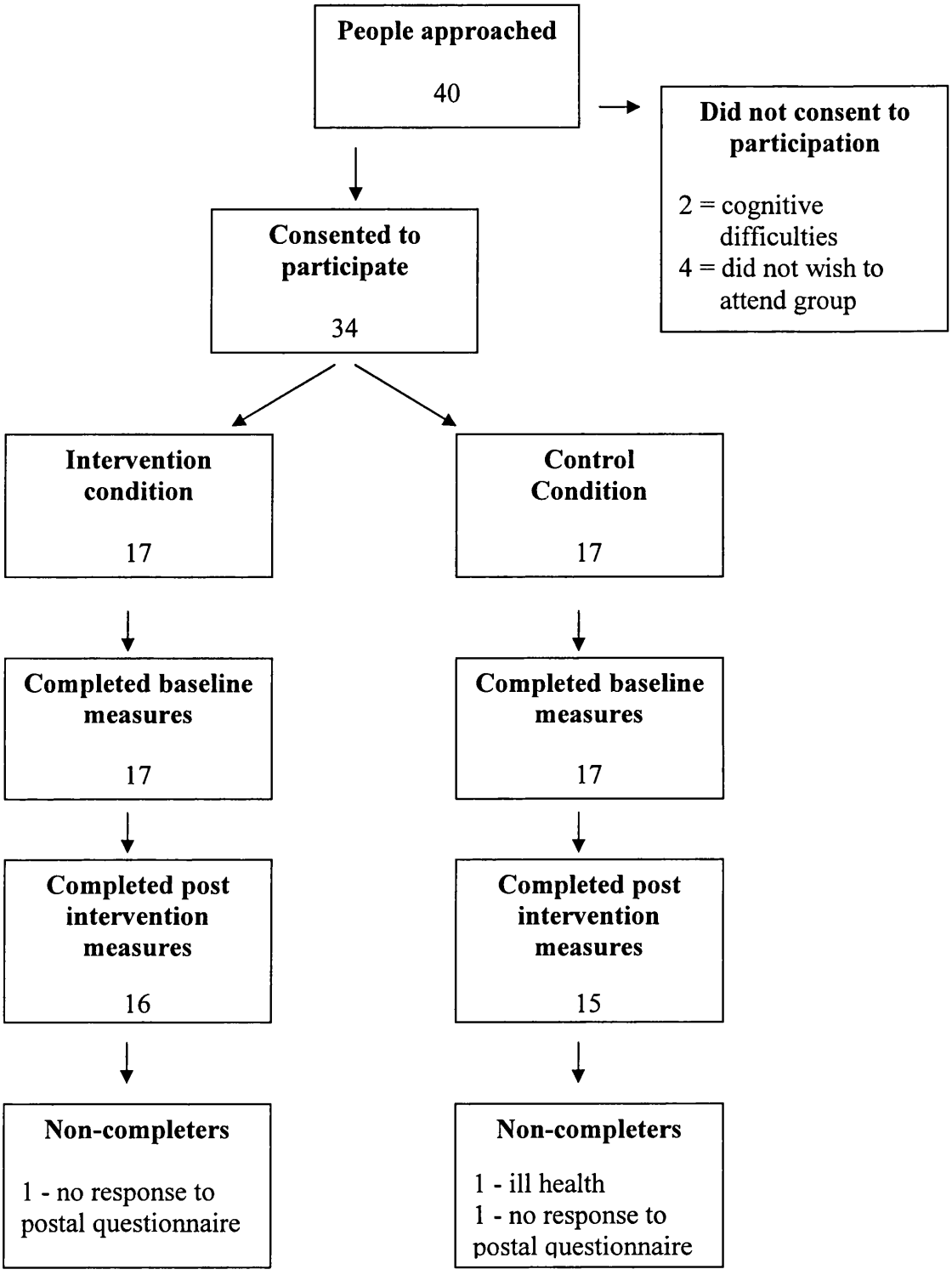
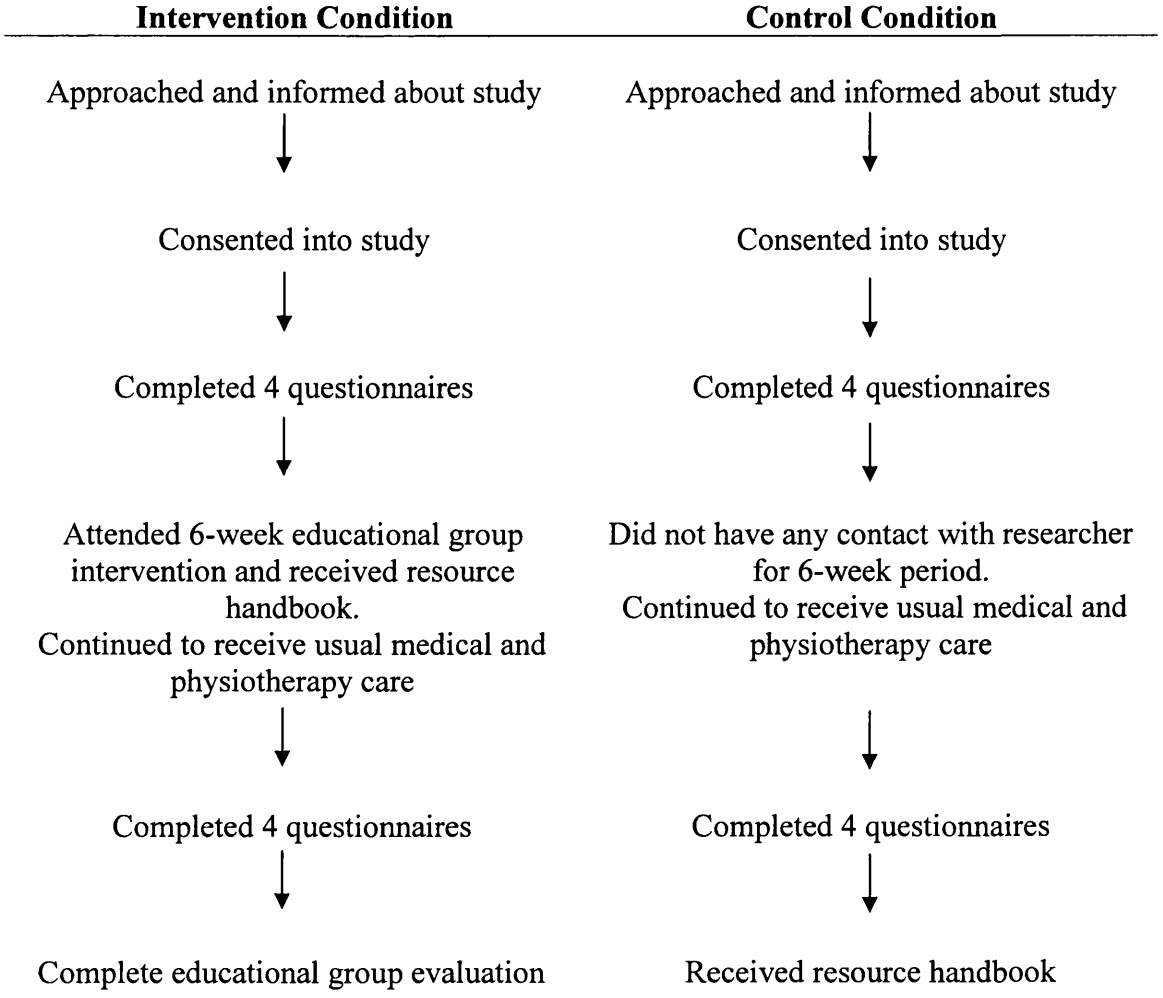
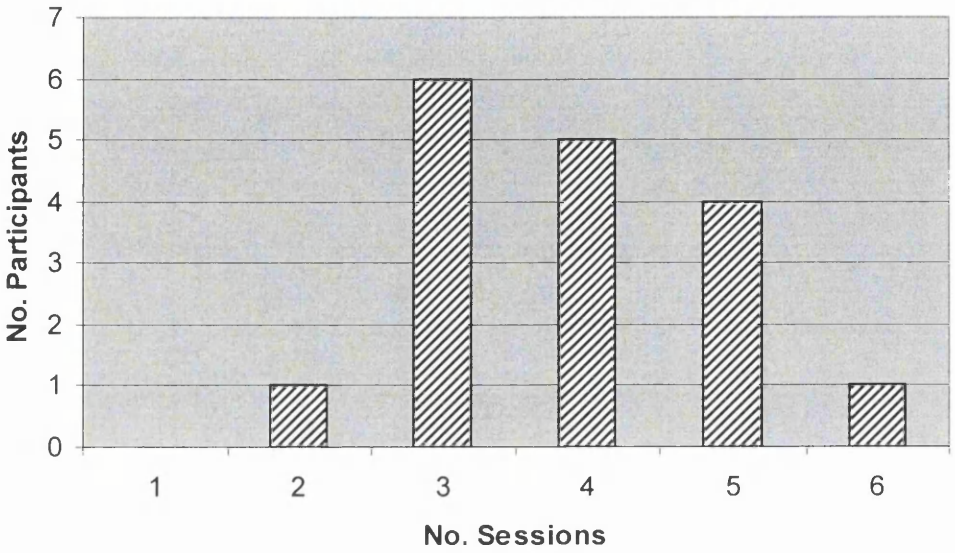


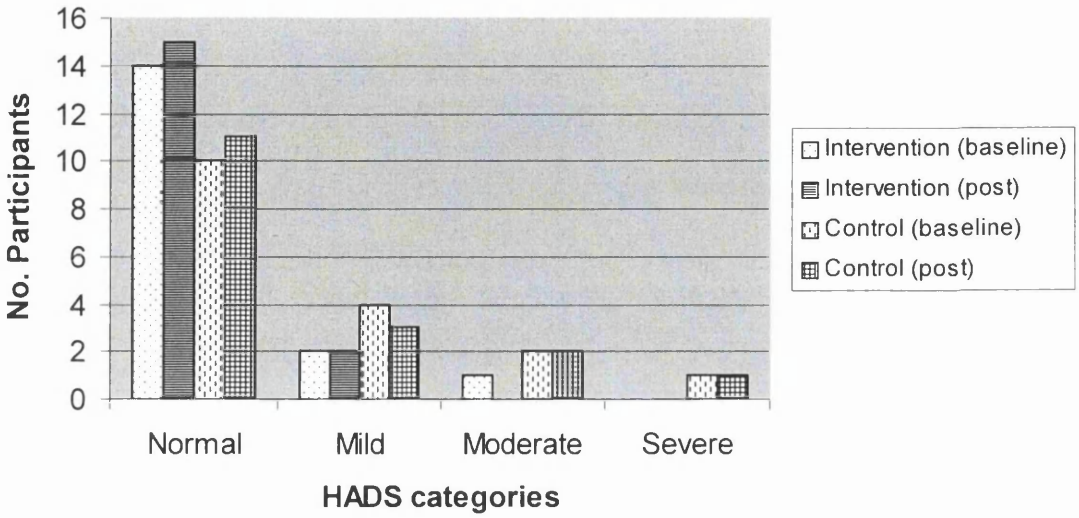
Figure 2: Recruitment and research procedures for the intervention and control conditions.



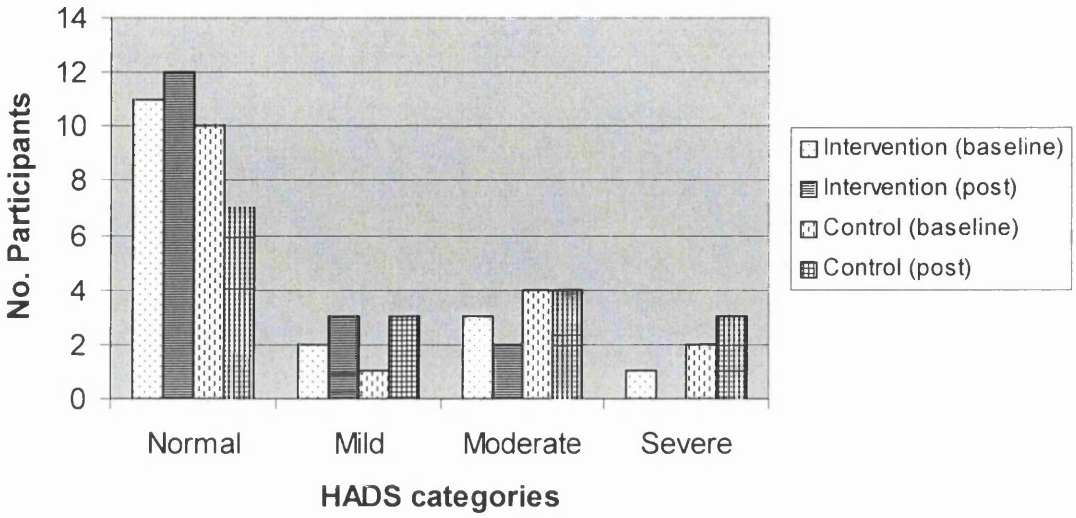
Graph 1: Number and frequency of session attendance



Graph 2: Participants meeting depression criteria at baseline and post intervention



Graph 3: Participants meeting anxiety criteria at baseline and post intervention



CHAPTER 3

ADVANCED CLINCAL PRACTIVE I: REFLECTIVE CRITICAL ACCOUNT ABSTRACT

A reflective account on the process of therapy with a young person and his family.
(Full account bound separately in Volume 2)

KIM BARRY
MA (Soc.Sci)

Section of Psychological Medicine
Division of Community Based Sciences
University of Glasgow

Abstract

Reflective practice can be defined as 'an active process whereby the professional can gain an understanding of how historical, social, cultural, cognitive and personal experiences have contributed to professional knowledge acquisition and practice. An examination of such factors yields an opportunity to identify new potentials within practice, thus challenging the constraints of habituated thoughts and practices' (Wilkinson, 1998). It is a skill which has latterly been encouraged in the clinical psychology profession as a means to critique ones own clinical practice, in the hope of leading to further development and improvement of skills and knowledge.

For this reflective account, I have chosen to discuss the process of therapy with a young person and his family, using Gibbs' (1988) model to provide a framework from which to explore my feelings and evaluation of the case. I feel working with this particular client provided me with a number of learning opportunities to develop my communication skills, ensure ethical practice, and improve my knowledge of psychological models and theories. The ongoing progression of these core competencies is in keeping with the National Occupational Standards for Psychology (BPS, 2006c) and was achieved by utilising a number of learning resources.

CHAPTER 4

ADVANCED CLINCAL PRACTIVE II: REFLECTIVE CRITICAL ACCOUNT ABSTRACT

A reflective account on the experience of team working and management of psychology resources.
(Full account bound separately in Volume 2)

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MA (Soc.Sci)

Section of Psychological Medicine
Division of Community Based Sciences
University of Glasgow

Abstract

Reflective practice is a critical element of learning and should be viewed very much as an ongoing process throughout a person's professional career (Kolb, 1984). The main aim of reflection is to contribute to the development of autonomous, qualified and self-directed individuals, and improved care.

In the present account I have chosen to reflect on my experience of working within two community addiction teams as part of a Clinical Psychology Addiction Service. At times I found this way of working difficult, due to differing reactions to my presence by staff and also working at a greater distance from my clinical psychology colleagues. However during the course of the placement I feel I have developed confidence as an autonomous practitioner and been able to promote the use of psychology as a valuable resource.

Having this experience allowed me to develop opinions about how to utilise and organise psychology resources from a personal perspective and wider service level. The placement offered me a number of valuable opportunities that I can use as I progress onto the next level of my career as a qualified Clinical Psychologist. I now feel I would be more able and would welcome opportunities to work in multidisciplinary teams and actively seek out chances to become involved in service delivery developments.

CONTENT OF APPENDICES

Appendix 1: Systematic Review

Appendix 2: Major Research Project Paper

Appendix 3: Major Research Project Proposal

APPENDIX 1.1: Arthritis and Rheumatism: authors instructions

The following document has been edited to include only relevant information for the preparation of the systematic review presented in chapter 1. A full version of the document is available on the website www.rheumatology.org/publications/ar/index.asp.

In relation to the presentation of tables, the author ignored the request that they be double-spaced as this was felt to have a detrimental effect on clarity and readability.

Arthritis & Rheumatism
Instructions To Authors

Format and organization

Corresponding author should include address, telephone number, fax number, and E-mail address if applicable.
Type all pages of the manuscript, including those containing references, tables, and figure legends, double space in 12-point type, with 1- to1½-inch margins. Number all sheets in succession, including references, tables, and figure legends. Title page is page 1. On the first page, type the title, name(s) of the author(s) and their major degrees, grant supporter(s), address for reprint requests, and corresponding author's telephone and fax numbers and E-mail address.

Full-Length Articles, Reviews, and Brief Reports

Definition: Full-Length Articles are descriptions of original research that adds to the body of knowledge in arthritis and the rheumatic diseases. Reviews critically and analytically discuss new and rapidly evolving fields.
Full-Length Articles and Reviews should not exceed 4,200 words from introduction through discussion (not including references, tables, and figure legends). The total number of tables and figures combined may not exceed 6, and the number of references may not exceed 50. Captions of tables and figures should be brief but allow the reader to understand the purpose of the table or figure at a glance. Captions do not include descriptions of methods or other material more appropriately presented in the text.

Content

Do not use new technical words, laboratory slang, words not defined in dictionaries, or abbreviations or terminology not consistent with internationally accepted guidelines.
Define any abbreviations the first time they are used.
In order to make the description of patients as clear as possible and to facilitate comparisons with other studies, the Methods section should include, whenever possible, a short paragraph detailing the proportion of patients who satisfy the ACR classification criteria for the particular disease described.

Illustrations

Each figure legend should be no more than 200 words; lengthy descriptions of methods should appear in the Methods section of the article and not in figure legends.

Tables

Type tables entirely in double space. Do not include any vertical lines in tables. Include horizontal lines below the title and headings and above the table footnotes only; there should be no horizontal lines separating the individual lines of data in the table body. Refer to current issues of the journal for further guidance regarding table style.

Provide each table with an explanatory title so that it is intelligible without specific reference to the text.
Provide each table column with an appropriate heading. Indicate clearly any units of measure on a table.
Lengthy descriptions of methods should appear in the Methods section of the article and not in table footnotes.

References

Compile references numerically according to the order of the citation. Use abbreviations for titles of medical periodicals that conform to those in Index Medicus.
In 1997, the journal changed its reference style to conform to the style suggested in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. All references should be in this style, which can be found in the article "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (N Engl Med, January 23, 1997, pp 309-15). For a standard journal reference, the Uniform Requirements style is as follows: Mattey DL, Hutchinson D, Dawes PT, Nixon NB, Clarke S, Fisher J, et al. Smoking and disease severity in rheumatoid arthritis: association with polymorphism at the glutathione S-transferase M1 locus. Arthritis Rheum 2002;46:640-7.

APPENDIX 1.2: Methodological quality checklist

Study	
Author	
Year	

Quality Criteria	Score
INTERNAL VALIDITY	
1. Aims and Objectives	
Clearly focussed aims and research question?	
Hypotheses clearly stated?	
2. Sampling Procedure	
Sample size reported?	
States where recruited from?	
Inclusion/exclusion criteria described?	
Treatment and control groups similar at start of the trial?	
Baseline demographics for each group reported (age, gender, disease duration)?	
Drop out rates reported?	
3. Assignment to treatment groups	
Are participants randomised?	
Is method of randomisation clearly described?	
Is randomisation allocation concealed?	
4. Intervention	
Well described?	
Standardised or Manualised?	
4. Assessment	
Outcomes measured in standard, valid and reliable way?	
Are measures well described?	
5. Analysis/ Interpretation	
Power analysis conducted?	
Effect sizes identified/ reported? (includes p values)	
Descriptive statistics provided?	
Subjects analysed in groups to which they were randomly allocated (intention to treat)?	
Results clearly stated and refer back to aims?	
Generalisability discussed?	
Total Score (Max 42)	
Total %	

Score Key:
2 = Well covered/ adequately addressed
1 = Poorly addressed
0 = Not addressed/ Not reported
NA = Not Applicable

APPENDIX 2.1: Disability and Rehabilitation: authors instructions

The following document has been edited to include only relevant information for the preparation of the major research project presented in chapter 2. A full version of the document is available on the website hppt://www.tandf.co.uk/journals/authors/tidsauth.asp.

In relation to the text that should be italicised in print (point 12 in notes on style section), the author ignored the request it be underlined and has just included the text in italics for ease of reading.

Disability and Rehabilitation: Instructions for Authors

Submissions
Submissions should be in English presented in double line spacing.
The submission should include a separate title page with the name(s) and affiliation(s) of the author(s) and the name and address for offprint requests with a telephone, fax number (including country and area codes), and electronic mail address.

Writing a paper for *Disability and Rehabilitation*
For all manuscripts, non-discriminatory language is mandatory. Sexist or racist terms should not be used. Structured abstracts of around 200 words are required for all papers submitted and should precede the text of a paper.
In writing your paper, you are encouraged to review articles in the area you are addressing which have been previously published in the journal, and where you feel appropriate, to reference them. This will enhance context, coherence, and continuity for our readers.

Structure of Paper
An introductory section should state the purpose of the paper and give a brief account of previous work. New techniques and modifications should be described concisely but in sufficient detail to permit their evaluation; standard methods should simply be referenced. Experimental results should be presented in the most appropriate form, with sufficient explanation to assist their interpretation; their discussion should form a distinct section. Extensive tabulations will not be accepted unless their inclusion is essential.

Abstracts
Structured abstracts are required for all papers, and should be submitted as detailed below, following the title and author's name and address, preceding the main text.
All papers submitted to the Journal of Disability and Rehabilitation should have a 'structured abstract' of no more than 200 words. The following headings should be used, following the title, author's name and address, and preceding the main text:

Purpose State the main aims and objectives of the paper.
Method Describe the design, and methodological procedures adopted.
Results Present the main results.
Conclusions State the conclusions that have been drawn and their relevance to the study of disability and rehabilitation.

Notes on Style
All authors are asked to take account of the diverse audience of the journal. Clearly explain -- or avoid the use of -- terms that might be meaningful only to a local or national audience. However, note also that we do not aspire to be international in the ways that McDonald's restaurants or Hilton Hotels are international; we much prefer papers that, where appropriate, reflect the particularities of each social and cultural system.
Some specific points of style for the text of articles, research reports, case studies, reports, essay reviews, and reviews follow:
1. We prefer US to 'American', USA to 'United States', and UK to 'United Kingdom'.

2. We use conservative (British, not US, spelling, i.e. colour not color; behaviour (behavioural) not behavior; [school] programme not program; [he] practises not practices; centre not center; organization not organisation; analyse not analyze, etc.
3. Single 'quotes' are used for quotations rather than double "quotes", unless the 'quote is "within" another quote'.
4. Punctuation should follow the British style, e.g. 'quotes precede punctuation'.
5. Punctuation of common abbreviations should follow the following conventions: e.g. i.e. cf. Note that such abbreviations are not followed by a comma or a (double) point/period.
6. Dashes (M-dash) should be clearly indicated in manuscripts by way of either a clear dash (-) or a double hyphen (- -).
7. We are sparing in our use of the upper case in headings and references, e.g. only the first word in paper titles and all subheads is in upper case; titles of papers from journals in the references and other places are not in upper case.
8. Apostrophes should be used sparingly. Thus, decades should be referred to as follows: 'The 1980s [not the 1980's] saw ...'. Possessives associated with acronyms (e.g. PA), should be written as follows: 'The APU's findings that ...', but, NB, the plural is APUs.
9. All acronyms for national agencies, examinations, etc., should be spelled out the first time they are introduced in text or references. Thereafter the acronym can be used if appropriate, e.g. 'The work of the Assessment of Performance Unit (APU) in the early 1980s ...'. Subsequently, 'The APU studies of achievement ...', in a reference ... (Department of Education and Science [DES] 1989a).
10. Brief biographical details of significant national figures should be outlined in the text unless it is quite clear that the person concerned would be known internationally. Some suggested editorial emendations to a 'typical' text are indicated in the following with square brackets: 'From the time of H. E. Armstrong [in the 19th century] to the curriculum development work associated with the Nuffield Foundation [in the 1960s], there has been a shift from heurism to constructivism in the design of [British] science courses'.
11. The preferred local (national) usage for ethnic and other minorities should be used in all papers. For the USA, 'African-American', 'Hispanic' and 'Native American' are used, e.g. 'The African American presidential candidate, Jesse Jackson...'; for the UK, 'Afro-Caribbean' (not 'West Indian'), etc.
12. Material to be emphasized (italicized in the printed version) should be underlined in the typescript rather than italicized. Please use such emphasis sparingly.

Citations in Text
We prefer that references are cited using the numerical system (e.g. [3], [5-9]). They should be listed separately at the end of the paper in the order in which they appear in the text.

Notes on Tables and Figures
1. Tables and figures should be valuable, relevant, and visually attractive. Tables and figures must be referred to in the text and numbered in order of their appearance. Each table and figure should have a complete, descriptive title; and each table column an appropriate heading.
Tables and figures should be referred to in text as follows: figure 1, table 1, i.e. lower case. 'As seen in table [or figure] 1 ...' (not Tab., fig. or Fig).
2. The place at which a table or figure is to be inserted in the printed text should be indicated clearly on a manuscript:

[Insert table 2 about here]

3. Each table and/or figure must have a title that explains its purpose without reference to the text.
4. All figures and tables must be on separate sheets and not embedded in the text.

References
References should follow the CBE Citation & Sequence format. Only works actually cited in the text should be included in the references. Indicate in the text with Arabic numbers inside square brackets. Spelling in the reference list should follow the original. References should then be listed in numerical order at the end of the article. Examples are provided as follows:
Journalarticle:
[1] Steiner U, Klein J, Eiser E, Budkowski A, Fetters LJ. Complete wetting from polymer mixtures. Science 1992;258:1122-9.
Bookchapter:
[2] Kuret JA, Murad F. Adenohypophyseal hormones and related substances. In: Gilman AG, Rall

TW, Nies AS, Taylor P, editors. The pharmacological basis of therapeutics. 8th ed. New York: Pergamon; 1990. p 1334-60.

Conferenceproceedings:

[3] Irvin AD, Cunningham MP, Young AS, editors. Advances in the control of Theileriosis. International Conference held at the International Laboratory for Research on Animal Diseases; 1981 Feb 9-13; Nairobi. Boston: Martinus Nijhoff Publishers; 1981. 427 p.

Dissertationsor Thesis:

[4] Mangie ED. A comparative study of the perceptions of illness in New Kingdom Egypt and Mesopotamia of the early first millennium [dissertation]. Akron (OH): University of Akron; 1991. 160 p. Available from: University Microfilms, Ann Arbor MI; AAG9203425.

Journalarticle on internet:

[5] Loker WM. "Campesinos" and the crisis of modernization in Latin America. Jour of Pol Ecol [serial online] 1996; 3(1). Available: http://www.library.arizona.edu/ej/jpe/volume_3/ascii-lokeriso.txt via the INTERNET. Accessed 1996 Aug 11.

Webpage:[6] British Medical Journal [Internet]. Stanford, CA: Stanford Univ; 2004 July 10 - [cited 2004 Aug 12]; Available from: http://bmj.bmjjournals.com/

Internetdatabases:

[7] Prevention News Update Database [Internet]. Rockville (MD): Centers for Disease Control and Prevention (US), National Prevention Information Network. 1988 Jun - [cited 2001 Apr 12]. Available from: http://www.cdcnpin.org/db/public/dnmain.htm

Further examples and information can be found in the CBE style manual Scientific Style and Format, sixth edition.

APPENDIX 2.1: Participant quality of life questionnaire

Thinking about the how you have felt over the last two weeks, please mark with an X on the scale how much you agree with each of the statements below

1. **How much difficulty do you have attending to your personal care (Toileting, washing, dressing) since your amputation?**

|----------|----------|----------|
0 5 10
No difficulties at all Same as before A lot more difficulty

2. **I feel able to carry out normal household tasks (cleaning, going shopping, preparing drinks and meals, gardening) since my amputation?**

|----------|----------|----------|
0 5 10
Completely agree Neither agree nor disagree Do not agree

3. **How much difficulty do you have taking part in social activities compared to be fore your amputation?**

|----------|----------|----------|
0 5 10
A lot more Difficulty Same as before No difficulties at all

4. **I feel able to have close relationships with and speak to my family and friends since my amputation?**

|----------|----------|----------|
0 5 10
Do not agree Neither agree nor disagree Completely agree

5. **I have less energy to take part in social activities or carry out household tasks since my amputation?**

|----------|----------|
0 5 10
Completely agree Neither agree nor disagree Do not agree

6. **I feel more self-conscious and unhappy with my body since my amputation?**

|----------|----------|
0 5 10
Not True Neither true or not true True

7. **My mood since my amputation has been**

|----------|----------|
0 5 10
Much worse Same as before Much better

8. **I have felt anxious or nervous since my amputation**

|----------|----------|
0 5 10
More often Same as before Less often

9. **My satisfaction with my life since my amputation is**

|----------|----------|
0 5 10
Much worse Same as before Much better

10. **My physical health since my amputation is**

|----------|----------|
0 5 10
Much better Same as before Much worse

GENERALIZED SELF-EFFICACY SCALE

Name:.....

Date:..... Record Number:.....

	Not at all true	Barely true	Moderately true	Exactly true
1. I can always manage to solve difficult problems if I try hard enough.	1	2	3	4
2. If someone opposes me, I can find means and ways to get what I want.	1	2	3	4
3. It is easy for me to stick to my aims and accomplish my goals.	1	2	3	4
4. I am confident that I could deal efficiently with unexpected events.	1	2	3	4
5. Thanks to my resourcefulness, I know how to handle unforeseen situations.	1	2	3	4
6. I can solve most problems if I invest the necessary effort.	1	2	3	4
7. I can remain calm when facing difficulties because I can rely on my coping abilities.	1	2	3	4
8. When I am confronted with a problem, I can usually find several solutions.	1	2	3	4
9. If I am in a bind, I can usually think of something to do.	1	2	3	4
10. No matter what comes my way, I'm usually able to handle it.	1	2	3	4

APPENDIX 2.4: Participant self-efficacy questionnaire

Please read through the questions below and place an X on the scale between 0 and 10.

1. **Do you feel able to use your prosthesis satisfactorily?**

|----------|----------|----------|
0 5 10
Not able at all Quite able Completely able

2. **Do you feel able to deal with any difficulties you may have when using your prosthesis? e.g. infection?**

|----------|----------|----------|
0 5 10
Completely able Quite able Not able at all

3. **Do you feel able to take care of your stump properly?**

|----------|----------|----------|
0 5 10
Not able at all Quite able Completely able

4. **Do you feel you are able to do things to stop you from falling?**

|----------|----------|----------|
0 5 10
Completely able Quite able Not able at all

5. **Do you feel you are able to cope with any pain or discomfort you may have in your stump?**

|----------|----------|----------|
0 5 10
Not able at all Quite able Completely able

6. Do you feel you are able to stick to a healthy diet?

|----------|----------|----------|
0 5 10
Completely able Quite able Not able at all

7. Do you think you are able to help yourself relax when you are feeling uptight?

|----------|----------|----------|
0 5 10
Not able at all Quite able Completely able

8. Do you feel able to access and approach useful community resources for people with amputations?

|----------|----------|----------|
0 5 10
Completely able Quite able Not able at all

9. Do you feel you are able to maintain good relationships with your family and friends?

|----------|----------|----------|
0 5 10
Not able at all Quite able Completely able

10. Do you feel that you are able to do things that help improve your mood when you are feeling low or anxious?

|----------|----------|----------|
0 5 10
Completely able Quite able Not able at all

APPENDIX 2.5: Group Evaluation Questionnaire

Please answer the questions below about your views on the group

1. **Did you find the group useful?**
   (Please circle one answer)

   Yes No Slightly

2. **Which group topic did you find most helpful**
   (Please circle one answer)

   Prosthesis use
   Managing aches and pains
   Stump care
   Stump massage
   Healthy eating
   Relaxation
   Falls prevention
   Accessing community resources
   Mood management strategies

3. **Which group topic did you find least helpful?**
   (Please circle one answer)

   Prosthesis use
   Managing aches and pains
   Stump care
   Stump massage
   Healthy body
   Relaxation
   Falls prevention
   Accessing community resources
   Mood management strategies

4. **Did the group meet your expectations?**
   (Please circle one answer)

   Yes No Slightly

5. **How do you think we could improve the group if we run it in future?**

6. **Did you find having the resource pack/ folder helpful?**
   (Please circle one answer)

   Yes No Slightly

7. **What section did you find most helpful in the resource pack/ folder?**

Any other comments:

Thank you for filling in this questionnaire

APPENDIX 2.6: Participant information sheet.

WESTMARC
Southern General Hospital
1345 Govan Road
Glasgow
G51 4TF

Evaluation of an Educational Group for People who have had Amputations

You are invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what is involved. Please take time to read the following information. Talk to others about the study if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

The purpose of this study is to evaluate how effective an educational group is at reducing low mood and anxiety and improving quality of life for people who have undergone an amputation. The educational group will be six sessions long and cover practical and social issues important to individuals who have had a leg amputated.
In order to evaluate this group, we plan to compare questionnaire scores of people who attend the psycho-educational group, with scores of people who do not attend the group but continue with their usual treatment at WestMARC.

Why have I been chosen?

You have been chosen to take part as you have recently had an amputation of one or both legs, and are currently attending for physiotherapy appointments at the physiotherapy gym in WestMARC on a regular basis.
It is hoped that by getting people like you to take part in the study, we will be able to evaluate if a group is helpful for people who have had a lower limb amputated. If people find the group helpful, it may be introduced as a permanent part of the rehabilitation service offered by WestMARC.

Do I have to take part?

No, it is up to you to decide whether or not to take part. You will be given this information sheet to keep and given one week to decide if you would like to take part in the study. You can ask the researcher any questions you have about taking part, when they give you this information or they can be contacted by telephone. If you decide you would like to take part you will be asked to sign a consent form. You are still free to withdraw at any time during the study without giving a reason. A decision to not to take part or withdraw at any time, will not affect the care you receive.

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

If you decided to take part you would be asked to complete five questionnaires, which should take between 20 and 30 minutes. After you have completed the questionnaires, some people will go on to attend six group sessions, other people will not attend the group sessions. All Participants will continue to receive their usual treatment provided at WestMARC. All the resources used in the group will be put into a folder that everyone who chooses to take part in the study will receive.

Six weeks after completing the questionnaires for the first time, all individuals who have chosen to take part in the study will be asked to complete the five questionnaires again. You will be asked to fill out the questionnaires a third and final time, three months after you have filled in the questionnaires for the second time. At this time the questionnaires would be posted out to your home and you would be asked to return them in an enclosed envelope. If the researcher has not received the questionnaires from you within two weeks of posting them, they will contact you via telephone to complete the questionnaires. It is important that you give consent for the researcher to have access to your personal details (address and telephone number), and this is included on the consent form. Your details will not be used for any other purpose than contact by the researcher. If you are unhappy with the researcher having your personal details please discuss this with them.

What are the possible benefits of taking part?

Education similar to that which has been shown to be of benefit in dealing with an amputation will be provided. It is hoped that in taking part in the current study it will help to evaluate whether offering an educational group is helpful to people who have recently experienced a lower limb amputation. Everyone who takes part in the study will receive the group resource pack. This contains useful information that may help you during your recovery.

What if there is a problem?

If you have any concerns about this study, you should ask to speak with the researcher, Kim Barry, who will do their best to answer your questions. She can be contacted on 0141 232 1100. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital. If you would like the opportunity to discuss this study with an independent body you can also contact the local research and development department on 0141 2105.

Will my taking part in the study be kept confidential?

Yes, all the information about your taking part in the study will be kept confidential. Once you have agreed to take part in the study you will be allocated a participant number, which will be used throughout the rest of the study rather then your name.

What will happen to the results of the research study?

The results of the study will be used by the researcher to write up a report for an educational project. Results may also be published in peer reviewed scientific journals. It is hoped that results from the current study will be used by WestMARC staff to further develop the educational group so that it can be made available to all patients at WestMARC in the future.

When the study is completed a participant leaflet, containing the main outcomes of the study, will be available through staff at the WestMARC gym.

Contact Details

If you have any further questions about this study please feel free to contact Kim Barry (Trainee Clinical Psychologist) on 0141 232 1100 or email 0511362b@student.gla.ac.uk.

Thank you very much for taking the time to read this information leaflet and considering taking part in the study

APPENDIX 2.7: Participant consent form

Evaluation of a group intervention for lower limb amputees.
Participant Consent Form. Version 1 (4/09/07)

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Title of Project: **Evaluation of a psycho-educational group intervention for lower limb amputees**

Name of Researcher: Kim Barry

Please initial box

1. I confirm that I have read and understand the information sheet dated 4/9/07 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

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

3. I agree to the researcher having access to my personal address and telephone number. ☐

4. I agree to the researcher contacting me by telephone ☐

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

Name of Patient	Signature	Date
Name of Person taking consent	Signature	Date

APPENDIX 3.1: Major research project proposal

'Evaluation of an educational group intervention for lower limb amputees'.

Abstract:

A Review of current literature indicates there is an association for some individuals between amputation and the development of a range of psychological difficulties, including depression and anxiety (Desmond & MacLachlan 2006a). These psychological difficulties can impact on recovery and rehabilitation and as a result, it would seem important to incorporate elements that address psychological and psychosocial well-being into a rehabilitation service. In chronic disease conditions, self-management programmes that encompass psychological issues faced by patients, have demonstrated significant beneficial effects on quality of life (Snead et al., 2004).

The aim of the proposed study is to evaluate the effectiveness of an educational group intervention for lower limb amputees attending West MARC for physical therapy rehabilitation. Participants in the intervention and control groups will complete pre and post treatment measures assessing depression, anxiety, quality of life and self-efficacy. It is hypothesised that participation in the intervention group will reduce depression and anxiety scores and improve quality of life and self–efficacy measures, relative to the control group. If possible a three-month follow up will be conducted to monitor the maintenance of change over time.

Introduction:

Amputation of a lower or upper limb through planned amputation or trauma can pose a range of physical, emotional and social challenges to individuals and cause significant psychological reactions. Research has shown that amputation has been associated with a number of psychological difficulties including Post Traumatic Stress Disorder, anxiety, depression, and insomnia (Cavanagh et al., 2006). A study carried out by Desmond & MacLachlan (2006a) with a sample of older males, who had lower or upper limbs amputated on average 639 months previously, reported prevalence of 32% for significant depressive symptoms and 34% for clinical anxiety, as measured using the Hospital Anxiety and Depression Scale (HADS). Similar findings were found in patients with upper limb

deficiency acquired through either congenital birth defects or amputation. A number of other studies examining lower and upper limb amputations have also documented high levels of anxiety and depression in individuals following amputation (Rybarczyk et al., 2004).

A growing body of evidence suggests that not only is amputation strongly associated with decreased psychological well-being, but psychological and psychosocial factors may be more predictive of subsequent adjustment than the medical or physical aspects of the amputation or ensuing disability (Ryberczyk et al., 2004). In general disability literature it has been proposed that the emphasis should be focused on the individuals' perception of their disability rather than the disability itself. This appraisal process is argued to have considerable influence on subsequent adjustment (Elliot et al., 2002). The psychosocial factors that may predict psychological adjustment following amputation are body image concerns (Rybarczyk et al., 2000), perceived social stigma (Rybarczyk et al., 1995), restrictions to everyday activities (Williamson et al., 1994), and feelings of vulnerability (Rybarczyk et al., 2004).

Coping style and coping strategies have also been found to be important predictors of psychosocial adaptation. Desmond & MacLachlan (2006b) found avoidance to be strongly associated with psychological distress and poor adjustment in lower limb amputees. In contrast, problem solving was negatively related to depressive and anxious symptoms. Social support seeking was negatively related to symptoms of depression, and positively associated with social adaptation. In keeping with these findings, Oaksford et al. (2005) conducted a qualitative study with lower limb amputees, which found the use of positive coping strategies such as support seeking, humour and cognitive acceptance, were important factors in positive adjustment to amputation. Ferguson et al. (2004) reported that psychological recovery in landmine survivors, who had undergone subsequent traumatic amputation of lower and upper limbs, was influenced by the individual's resilience characteristics, social support, medical care, economic situation and societal attitudes towards people with disabilities.

To date, research in the amputation field has focused mainly on the functional adaptation of patients, such as learning to use prostheses and little research has addressed the psychosocial aspects that may impact on rehabilitation. Therefore research about the

psychological impact of amputation and the impact of an individual's psychological well-being on rehabilitation are important issues in this area which warrant attention. Evidence suggests rehabilitation from limb amputation requires a comprehensive, multidisciplinary service that not only attends to the medical needs of the patient but also common issues such as post-amputation depression and anxiety, negative body image, feelings of vulnerability, social support changes, grief, pre-amputation psychological issues, and phantom limb pain (Rybarczyk et al., 2004).

In the present healthcare climate, self-management of chronic disease and patient psychoeducation, are becoming established methods of encouraging individuals to take greater responsibility for their own health. Self-management complements traditional patient education in supporting patients to achieve the best quality of life with their chronic condition. It adds problem-solving skills to the traditional patient education methods, which offer information and technical skills. A central concept to all self-management programmes is self-efficacy; this is how confident a person feels to carry out the behaviour necessary to achieve a desired goal (Bodenheimer, 2002). An individual's self-efficacy increases as they successfully carry out behaviours and achieve their self-directed goals.

The effectiveness of chronic disease self-management groups has been reported for arthritis (Lorig et al., 2005), stroke (Kendall et al., 2006) and diabetes (Warsi et al., 1995; Deakin et al., 2005). Psychoeducational group interventions, incorporating medical information, healthy lifestyle behaviours, family and peer relationships, understanding self-image and self-esteem, and stress management techniques, have produced beneficial effects on quality of life in adolescents with epilepsy (Snead et al., 2004).

There has been little research conducted regarding the usefulness of self-management and psychoeducational rehabilitation groups with individuals who have undergone an amputation. One study conducted by Delehanty and Trachsel (1995) compared a three-session intervention group with a control group. The treatment intervention included sessions normalising stress reactions, preparation for future stressors, and expansion of coping strategies. At eight months post discharge, the treatment group displayed lower distress levels and greater activity levels than the control group.

A similar study to the proposed research has been conducted in the United States by the PALS research group (Promoting Amputee Life Skills), with individuals with at least a six month amputation duration. Preliminary findings from the study report that 77% of participants found the intervention group more helpful than a support (control) group, and at six months follow up control participants were 2.5 times more likely to be depressed than those in the intervention group. Overall, participants in the treatment group showed a significant increase in self-efficacy and positive mood and were less likely to experience limitations in function (Amputee Coalition of America Annual Report, 2006, Pg 8)

Currently within the West Of Scotland Mobility and Rehabilitation Centre (WestMARC), an informal group has been developed for both inpatient and outpatient clients attending the gymnasium for physiotherapy. At present, this programme is based on educational and self-management principles. It encompasses sessions on practical issues facing amputees, relaxation, healthy eating, and mood difficulties. A formal scientific evaluation of the group is now proposed by the current study.

Aims and Hypotheses:

The proposed study aims to evaluate the effectiveness of an educational group intervention for patients who have a lower limb amputation.

Hypothesis 1: There will be a significant difference in change in scores between the intervention and control group.

Hypothesis 2: Anxiety and depression scores will reduce in the intervention group.

Hypothesis 3: Quality of life and self-efficacy scores will improve in the intervention group.

Hypothesis 4: Anxiety and depression scores will increase in the control group.

Hypothesis 5: Quality of life and self-efficacy scores will decrease in the control group.

Plan of investigation:

Participants:

All participants will be current inpatient or outpatient clients, attending for physical therapy rehabilitation at the West of Scotland Mobility and Rehabilitation Centre (WestMARC), Southern General Hospital. All participants will have experienced a uni or bi lateral amputation of a lower limb at least two weeks, prior to attendance at the group.

After discussion with WestMARC staff it was determined that the greatest number of patients attend for physiotherapy appointments on Tuesdays. Therefore, it was felt that holding the group intervention on a Tuesday would maximise the amount of potential participants available for recruitment. Inlividuals attending for physiotherapy appointments on Tuesdays will be recruited into the intervention arm of the study. Control group participants will be recruited on any otherweekday.

Inclusion/Exclusion criteria:

Participants must be aged eighteen or above, have a uni or bi lateral lower limb amputation, be fluent English speakers. Participants will not be eligible for recruitment if they display severe cognitive impairments (as determined by the clinical judgement of the health professionals involved in their care), are receiving any additional psychotherapeutic treatment from another source, or have an upper limb amputation.

Recruitment Procedures:

The researcher will attend the WestMARC gymnasium during a Tuesday clinic to provide potential participants with verbal and written information about the study. Potential participants will be given one week to consider participation and will complete a consent form. Recruitment procedures follow the same format for patients recruited into the control group.

Due to the homogeneity of the patient population, it is not anticipated that there will be any significant differences in demographics or individual features such as type of amputation, length since amputation, or causes of amputation in intervention participants compared to control participants. If possible, attempts will be made to match participants in the two groups for gender matched and age plus or minus four years.

Measures:

Participants will be asked to complete a battery of five assessment measures prior to commencing the group, upon completion of the group, and if possible three months post-intervention. Post intervention participants will also be asked to complete a brief group evaluation questionnaire. Control group participants will complete outcome measures at the same time points as intervention group participants.

Participant demographics (i.e. age, gender, years of education, marital status, living situation) will be collected prior to commencement of the study. Information about their amputation (duration, cause, type) will also be collected.

Psychosocial Functioning:

Emotional functioning will be measured using the Hospital Anxiety and Depression Scales (HADS) (Zigmond & Snaith, 1983). Many existing scales measuring depression and anxiety place emphasis on somatic indicators. The HADS is a fourteen item self-report questionnaire that omits somatic items and measures the patient's experience of anxiety and depression related symptoms within the past week. The four score ranges can be classified as 'normal' (0-7), 'mild' (8-10), 'moderate' (11-14) and 'severe' (15-21).
It is a standardised measure with established psychometric properties.

Impact of amputation and prosthesis use:

The physical and psychosocial functioning and prosthesis use will be measured through the use of the Trinity Amputation and Prosthetic Experience Scales (TAPES) (Gallagher & MacLachlan, 2004). The TAPES is a specifically designed quality of life questionnaire for an amputee population. The TAPES has nine subscales; general adjustment, social adjustment, adjustment to limitation, functional activity restriction, social activity restriction, athletic activity restriction, functional satisfaction with prosthesis, aesthetic satisfaction with prosthesis, weight satisfaction with prosthesis.

Quality of life:

Quality of life is a complex concept including both objective and subjective factors and in general terms, quality of life can be defined as a grade of 'goodness'. It was felt that the current general quality of life measures are not sensitive or precise enough to assess quality of life factors specific to an amputee population. Therefore, the lead researcher has developed a quality of life measure with consultation from WestMARC staff. The self-report measure comprises of ten questions with responses made on a visual analogue scale. Scores will be summed together to provide a total score (see Appendix 2.2). The scale was designed using guidance on development of quality of life measures (Johnston et al., 1995; Bowling, 2005).

Self-efficacy:

Two measures of self-efficacy will be administered, a generalised self-efficacy measure and a specific self-efficacy questionnaire. The Generalised Self Efficacy Scale (GSES) aims to assess the strength of an individual's belief in one's ability to respond to and cope with new or difficult situations and to deal with any associated obstacles or setbacks (Jerusalem & Schwarzer, 1992). The GSES is a ten-item, self-report scale. Responses are made on a four-point scale ("Not at all true" – 1, "Exactly true" – 4) and the total is all responses summed together. A higher score indicates a greater sense of generalised self-efficacy.

A specific self-efficacy scale with questions relevant to the topics covered by the intervention group has been developed by the lead researcher with consultation from WestMARC staff (see Appendix 2.4). This measure will consist of ten questions and responses will be made on a visual analogue scale. Scores will be summed together to provide a total score.

Group Evaluation:

A brief self-report questionnaire, including questions on how satisfied participants were with the group and what they found most beneficial has been developed (see Appendix 2.5).

Design:

The proposed study will adopt a quasi-experimental between groups design. Participants will not be randomly allocated to groups as allocation will be determined by when they attend their physiotherapy appointment at WestMARC.

Research Procedures:

Recruitment into the study will be carried out as outlined above. Each participant will be allocated a participant number to ensure anonymity. Participants will complete outcome measures prior to commencing the group. The educational group will consist of six, sixty-minute sessions held over a consecutive six-week period. A total of three to four groups will be conducted and it is expected that between four to eight participants (maximum) will attend each group. The group intervention will be administered as a rolling programme; therefore participants can join at any point. The group will be led by a number of health

professionals. An outline of the intervention protocol, and session lead is provided in Table 1 below.

Upon completion of the group, participants will immediately re-complete the outcome measures and group evaluation questionnaire. If possible, at three months post group completion, participants will be asked to complete all assessment measures again via post. Control group participants will complete assessment points at a time-matched interval and will receive the group resource pack upon completion of the study.

Table 1: Group intervention protocol

Session no	Session Title	Session outline	Led by
1	Fish & Chips	Introduction to group, outline of sessions, practical issues	Psychologist
2	Prosthesis issues	Discussion about prosthesis use,	Prosthesist
3	Aches & pains & stump massage	Discussion of phantom limb pain, stump massage	Physiotherapist & Physiotherapy technicia
4	Healthy body & mind Relaxation	Diet information, In vivo relaxation	Dietician Physiotherapist
5	Stump care & falls prevention	How to care for your stump How to prevent falls	Nurse& Occupatio Therapist
6	Accessing community resources & maintaining contacts with family and friends. Mood management	Discussion of resources available in the community, and how to interact with friends and family members Mood management strategies	Occupational therapist Psychologist

Justification of sample size:

This study is the first piece of research to look at the effects of a psychoeducation group intervention on symptoms of anxiety and depression in an amputee population. There is little appropriate previous research that could be used to estimate the number of participants required for the current study.

Chronic disease literature that examines the impact of group intervention programmes on participant's anxiety and depression (evaluated using the HADS) was researched in an attempt to calculate appropriate power and sample size for the proposed study. A significant number of these studies did not report the necessary data characteristics (means and standard deviations) to conduct power calculations. Additionally it was felt that it would be inappropriate to make judgements about the current study amputee population based on other chronic conditions as the difficulties faced and experiences due to the disease may not be comparable.

As the proposed study is intended to be of an exploratory nature using a convenience sample, and is being conducted to contribute to the limited research base it is deemed to be of value without *a priori* power calculations. Post hoc effect size and power calculations will be carried out when a reasonable sample of data has been collected.

Settings and equipment:

The current research project will be conducted on a single site, West of Scotland Mobility And Rehabilitation Centre (WestMARC), Southern General Hospital. Access to a photocopier will be required.

Data Analysis:

Data will be inputted into, and analysed using the SPSS for Windows statistical package. Descriptive statistics will be calculated and presented. If the data is normally distributed, t-tests will be used to determine any between group variance in assessment measure scores and demographic information. ANOVAs will be used to assess the change in scores from baseline to post treatment in the two groups and also to test for significant change in scores on outcome measures between the groups. A bonferroni correction will be carried out due to multiple testing. If parametric tests are unsuitable non-parametric equivalents Mann Whitney U and Wilcoxon analyses will be used. It is anticipated that an intention to treat approach will be used in order to address participant drop-out.

Health and Safety:

There are no foreseeable issues regarding researcher or participant safety. All elements of the study will occur in WestMarc which is a health and safety approved NHS site.

Ethical Issues:

As previously reported, participants will give written informed consent to take part in the proposed study and will have the right to withdraw at any stage.

It may be possible that by completing the HADS, participants may be identified as suffering from significant levels of depression or anxiety. This will be monitored throughout the group process by the lead researcher and referrals will be made to the Clinical Psychologist working within the service if required.The researcher will make

every attempt to ensure that participation in the current study does not interfere with patients rehabilitation or medical care.

A potential issue may relate to withholding the intervention from the control group. Control group participants will receive the resource pack on completion of the study. Should participants wish to discuss any of the resource information they will be able to contact the lead researcher via WestMarc.

Financial Issues:

Costs for this study will be minimal.

Paper costs: 1 ream (500 sheets) white paper	£1.40
Headed paper x 50	£5.00
Photocopying costs: 720 photocopies @ £0.015	£10.80
Envelope costs: 100 envelopes (A5)	£0.53
Postage costs: 60 freeposts @ £0.255	£14.10
Recordable CDs: 40	£9.00

Total Cost: £40.83

Timetable:

It is proposed that an application for ethical approval will be completed for submission to the meeting held in September 2007. If approved, it is proposed the study will be in a position to commence recruitment by October/November 2007. It is anticipated that group intervention will be completed by March/April 2008. If it is possible to repeat assessments at the three-month follow-up stage, final data will be collected by June/July 2008

Practical Applications:

The proposed study represents an important step towards the design and implementation of a potentially effective group intervention to reduce depression and anxiety and improve quality of life for recent lower limb amputees. If the results from the current study are found to be significant, this may indicate the benefit of introducing a group intervention as part of routine care received during the rehabilitation process, and may justify provision of a rolling programme that can be continued and further developed by the staff team at WestMARC.

Ethical and management approval submissions:

Ethical approval will be sought from South Glasgow and Clyde Local Research Ethics Committee. Research and development approval will be sought from the South Glasgow NHS Research and Development Department.

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