

**INVESTIGATING THE EFFECTIVENESS, ACCEPTABILITY AND IMPACT ON
HEALTHCARE USAGE OF PROVIDING A COGNITIVE BEHAVIOURAL BASED
PSYCHOLOGICAL THERAPY SERVICE FOR PATIENTS WITH PRIMARY ANTIBODY
DEFICIENCY**

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Abstract

Purpose: Patients with primary antibody deficiency report poorer quality of life and higher rates of anxiety and depression than the general population. Cognitive-behavioural therapy has been shown to be a valuable treatment for patients with other long-term physical health conditions, improving wellbeing and enabling them to manage their symptoms more effectively. The aim of this project was to establish the feasibility and effectiveness of providing cognitive-behavioural based therapy to patients with primary antibody deficiency.

Methods: Forty-four patients completed a course of psychological therapy. Participants completed a series of self-report measures examining psychological and physical health, and service usage, prior to starting treatment and following their final session. They also provided feedback on their experience of treatment.

Results: Patients showed improvements in anxiety, depression, insomnia and fatigue. There was a high level of acceptability of the service and the potential for long-term cost savings to the NHS.

Conclusion: Psychological therapy based on the cognitive-behavioural model of treatment appears to be a valuable treatment for patients with primary antibody deficiency and comorbid mental health difficulties.

Key words:

Primary Antibody Deficiency; Mental Health; Cognitive-Behavioural Therapy; Quality of Life; Immunoglobulin Replacement Therapy.

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Introduction

Research and anecdotal evidence suggest a bi-directional relationship between mental and physical health. Individuals with chronic illnesses are more likely to experience mental health problems when compared to the general population¹. The National Institute for Clinical Excellence² found that adults with a chronic physical health problem are around two to three times more likely to experience depression than those with good physical health, and that a physical health problem can be both a predisposing and a maintenance factor for low mood. The Department of Health's Long-term Conditions Positive Practice Guide³ suggests that depression and/or anxiety can increase individual distress, the perceived severity of physical symptoms, use of other healthcare services and overall physical healthcare costs.

There is growing evidence to suggest that treating psychological factors in patients with physical health problems can improve patient quality of life and provide cost savings to the NHS (for example, through better understanding of and concordance in treatment, and appropriate use of medication and resources). The King's Fund reported that in patients with long-term conditions, comorbid mental health problems generate at least a 45% increase in total healthcare costs, and highlighted that better integrated physical and psychological services in the UK will produce cost savings as well as better care¹. The cost benefits, as well as the quality outcomes associated with patient-centred (as opposed to condition-centred) care have been stressed by many leading professionals and professional bodies^{1,3,4,5}.

In terms of the model or type of psychological treatment, the best evidence for effectiveness in physical health settings is for cognitive behaviour therapy (CBT). NICE² therefore recommend that treating depression and other psychological factors in individuals with a physical health problem using CBT, has the potential to improve both quality of life and life expectancy². CBT has been shown to improve psychological well-being within a number of different physical health conditions, including Chronic Fatigue Syndrome⁶⁻⁷, Chronic Pain⁸, Diabetes⁹ and Chronic Obstructive Pulmonary Disease¹⁰.

Primary Antibody Deficiency (PAD) is a chronic physical health condition with a minimal prevalence estimated at 2.1/100,000 of the UK population¹¹. Characterised by recurrent and persistent infections at multiple sites, the initial diagnosis can occur at any point in the lifespan and there is often a delay from first presentation of illness¹². Medically, PAD is managed using a combination of replacement

immunoglobulin therapy and prophylactic antibiotics. Immunoglobulin replacement can be administered by either intravenous or subcutaneous Immunoglobulin Therapy, ranging from weekly to once a month, which has been shown to have beneficial effects for patients' physical health¹³. However, despite appropriate treatment, recent research suggests that PAD can negatively affect a patient's quality of life, with approximately 40% of patients at risk for high levels of physical disability and psychological distress¹⁴.

Although empirical evidence is scarce, the psychological impact of having a chronic health condition can be far reaching and is clearly evident in PAD¹⁴⁻¹⁶. Booker and colleagues examined health-related quality of life and adjustment to illness in PAD and found that 23.7% of patients reported moderate to severe levels of depression and 27% reached 'caseness' for anxiety¹⁴. The researchers suggest that many of the factors (such as fear of breathlessness, negative attitude to diagnostic delay, concerns over the future impact of illness, fatigue, global stress and low levels of palliative coping strategies) which influenced quality of life (defined as poor physical functioning and high levels of depression and somatic symptoms) would be amenable to change through the use of psychological techniques and support, particularly a cognitive-behavioural based treatment. Other research and patient groups have also highlighted the need for the provision of psychological therapy as part of the standard care package for people with PAD¹⁴⁻¹⁷. Therefore, the aim of this project was to establish the feasibility and effectiveness of providing cognitive-behavioural based therapy to patients with PAD. We hypothesised that the CBT would provide similar benefits for patients with PAD as those with other long-term physical health conditions.

Methods

Design

A case series design was used to investigate the impact of psychological therapy for patients with PAD.

Participants

Patients attending the Royal Free Hospital Clinical Immunology Department, prescribed Immunoglobulin Replacement Therapy for PAD and identified through the screening questionnaire as experiencing anxiety, depression, insomnia or fatigue, were invited to attend for an initial assessment with a Clinical Psychologist. In addition, patients who had undergone transition from Paediatric Services were offered an assessment, as transition can be a time of confusion and distress¹⁸ and poor transition can lead to poor outcomes for both physical and mental health¹⁹. Informed consent was obtained from all individual participants in the study.

Measures

We used the *Primary Immunodeficiency Quality of Life Index* (PIQoLI)¹⁴ for the identification of suitable patients for treatment and to evaluate outcome following treatment. The PIQoLI is an aggregate measure that uses abbreviated and/or standardised short versions of the validated measures used in Booker and colleagues quality of life survey¹⁴. Strong correlations between the short form and standard versions of the questionnaire have been shown in patients with PAD²⁰. It asks patients to self-report on different aspects of their life known to influence quality of life. Seven subscale scores (Perceived Illness Severity, Fatigue, Fear of Breathlessness, Worry about Illness, Depression, Anxiety and Insomnia) are gained. Indicators of referral for psychological treatment include a Depression score of 7+, an Anxiety score of 15+, a Fatigue score of 12+, or an Insomnia score of 15+.

The *Functional Assessment of Chronic Illness Scales – Fatigue* (FACIT-F)²¹ is a 13-item questionnaire where patients rate, on a five-point Likert-scale, their fatigue over the last seven days. It has been shown to be a reliable and valid measure of fatigue across a number of different clinical populations, has good test-retest reliability ($r = 0.90$) and internal consistency (Cronbach's alpha range = 0.93-0.95), demonstrates good convergent and discriminant validity, and has been shown to detect clinically significant change over time²¹⁻²².

The *Hospital Anxiety and Depression Scale (HADS)*²³ is a 14-item self-report measure specifically designed for use in outpatient medical settings and often used in health psychology research. Participants indicate how they have felt over the past week on a four-point Likert scale and scores are summed to generate two subscales (Anxiety & Depression). It has been shown to be a valid, reliable and acceptable measure²⁴.

The *Inventory of Health Status Part II V3 (IHS)*²⁵ is a 64-item self-report questionnaire designed to measure somatic symptoms. Participants are asked to indicate the occurrence of a variety of different physical health complaints over the last month or two.

The *Perceived Stress Scale (PSS)*²⁶ is a measure of the degree to which situations in one's life are appraised as stressful. It asks participants to rate, on a five-point Likert scale, their feelings and thoughts during the last month. It has shown adequate test-retest reliability and internal consistency (Cronbach's alphas = 0.84-0.86), and good concurrent, predictive and discriminant validity²⁶.

The *Functional Assessment of Chronic Illness Scales – Treatment Satisfaction – General (FACIT-TS-G)*²⁷ is an eight-item questionnaire where patients rate their satisfaction with treatment. It has been shown to be a reliable and valid measure of satisfaction with treatment across different clinical populations. The two subscales (Treatment Satisfaction and Recommendation) have demonstrated good internal consistency and convergent validity²⁷. Higher scores indicate greater levels of satisfaction.

Self-Designed Cost-effectiveness Questionnaire

Patients were asked about the number of general practitioner (GP), hospital and emergency appointments (including length of stay), contacts with the Immunology Department for advice or information, courses of antibiotics, days off work/education due to ill health and medical appointments, and any inability to fulfil household tasks over the three months prior to starting psychological therapy and the three months preceding the final appointment. They were also asked about the number of hours they spent outside of their home in the week prior to the start and end of treatment as an indicator of general activity.

Procedure

Recruitment was through a convenience sample of patients attending Immunology clinics. Following initial assessment an individualised formulation and treatment plan was developed and, if thought to be beneficial, patients were then offered a short course of Cognitive-Behavioural based therapy to address the difficulties identified.

As part of treatment patients were asked to complete measures of somatic symptoms, global stress, mood, anxiety, insomnia, fatigue, impact on daily life and medical service usage at the start and end of treatment. A measure of patient satisfaction was completed at the end of therapy. Demographic data and information about the number of sessions attended were gathered from clinical notes.

The study was granted ethical approval from Bromley Research Ethics Committee (Ref: 11/LO/1126).

Statistical Analysis

Distribution of data was assessed for normality. For the parametric data, paired sample t-tests were used to examine change following treatment. For the non-parametric data, Wilcoxon signed ranks tests were used. We used an alpha value of 0.004 for all statistical tests. Acceptability was investigated by examining rates of drop-out and mean scores on the FACIT-TS-G. Healthcare usage was investigated by examining patient reports of the total number of GP and hospital appointments, emergency visits and inpatients admissions in the three months prior to the first and last appointment for treatment.

Results

Participant Demographics

Fifty-five patients consented to take part in the project and attended a psychological assessment. The group had a mean age of 47.5 years (SD = 16.6). Thirty-three percent (N = 18) were male and 67% (N = 37) were female. They had a variety of diagnoses: Common variable immunodeficiency (N = 33), IgG subclass deficiency (N = 3), other hypogammaglobulinemia (N = 6), IgA deficiency (N = 2), Specific Antibody Deficiency (N = 3), X-linked agammaglobulinaemia (N = 3), Good Syndrome (N = 1), MBL deficiency (N = 1), Unclassified immunodeficiency (N = 2), and Wiskott-Aldrich Syndrome (N = 1). Forty-five patients classified themselves as White – British, two as White – Other, four as Asian, Asian British Indian or Asian British – Pakistani, three did not state their ethnicity, and one as Other Ethnicity.

Uptake and treatment package

Figure 1 details the participant flow through the study. Following assessment, 48 patients (87%) were offered a package of psychological therapy. Four were discharged after assessment as it was felt by both therapist and patient that they were managing well, and three were referred on for more suitable treatment with their local psychology service. One patient declined treatment without giving a reason. One patient remains in treatment and is therefore excluded from all further analysis. Forty-one patients completed a course of treatment with sessions terminated by mutual agreement between therapist and patient, and 5 terminated treatment early, of their own accord, partially completing the course of therapy (e.g., dropped out of treatment).

INSERT FIGURE 1 ABOUT HERE

Patients who completed therapy attended a median of six sessions (Range = 3-24 sessions), and those who partially completed attended a median of four sessions (Range = 3-6 sessions). There was a higher percentage of men in the partial completers group compared with those who completed a full course of treatment (table 1). Partial completers also appeared to be younger, have lower levels of somatic symptoms and perceived stress at baseline than completers. Baseline scores of anxiety, depression and fatigue were at similar levels.

INSERT TABLE 1 ABOUT HERE

The remit of psychological therapy was broad. Patients were treated with cognitive-behavioural based therapy. CBT is a time limited, systematic, evidence based therapeutic approach, recommended by NICE and delivered by qualified mental health professionals. Taking into account the individual needs of each patient, treatment aims included developing skills to improve mood and sleep, to reduce stress, anxiety or insomnia, teaching individuals how to monitor and respond to symptoms adaptively, and/or providing a space for patients to reflect on the impact the illness had had on their lives and relationships.

Effectiveness

Following treatment patients who completed a course of treatment reported significant improvements in mood, anxiety fatigue and insomnia (table 2). Despite a slight increase in days off work due to ill health, they also reported a greater number of hours spent outside the house per week.

INSERT TABLE 2 ABOUT HERE

Healthcare usage

Figure 2 details the changes in antibiotic medication and medical service usage over the three months prior to the first and last psychology appointment for the whole cohort who completed a full course of treatment. Patients showed an increase in courses of prophylactic antibiotics, GP appointments and hospital emergency (A&E) visits, and a reduction in outpatient (OP) appointments and in-patient (IP) admissions. The number of courses of breakthrough antibiotics remained stable.

INSERT FIGURE 2 ABOUT HERE

Acceptability

Patients reported high satisfaction with the service: Mean FACIT Treatment Satisfaction Scale (N = 40) = 91.7% (SD = 15.6), Mean FACIT Treatment Recommendation Scale (N = 39) = 98.1% (SD = 8.9). Thirty-nine (out of 40) patients said that they would recommend the treatment to someone with their condition (1 maybe) and thirty-seven patients would choose the treatment again (2 maybe, 1 missing data). This acceptability is also supported by the relatively low level of drop-out from the service (only five patients did not complete the course of therapy that was offered to them).

Discussion

Adults with PAD have been shown to have poor quality of life and higher rates of anxiety and depression when compared to the general population. The effectiveness and acceptability of psychological treatments, particularly cognitive-behavioural therapy, is well established for mental health difficulties and some physical health conditions. However to date no-one has examined the utility of using this treatment model to improve the mental health and quality of life for patients with PAD. Therefore, this study examined the effectiveness, potential cost-effectiveness and acceptability of providing cognitive-behavioural based treatment within this population. As hypothesised, and in line with research on the impact of cognitive-behavioural therapy for patients with other long-term medical conditions, improvements in mood, anxiety, sleep and energy levels were found for patients with PAD who completed a full course of psychological therapy. Patients who completed treatment also reported an improvement in their activities of daily living (e.g., greater time spent outside of the house, and a trend towards less time off work and less days unable to fulfil household tasks) and a positive change in their medication and medical service usage.

There was also a high level of acceptability and satisfaction with the model of treatment. All treatment completers were satisfied with their treatment decision, would do it again and recommend to others. Attrition rates were below the average of patients who receive cognitive-behavioural therapy for other conditions. The total attrition rate in this study was 12%, with a within treatment attrition rate of 10.2%, compared with population averages of 36% and 26.2% respectively²⁸.

As with other long-term medical conditions, it is clear that there is a substantial group of patients with PADS who experience associated psychological difficulties, and for whom psychological intervention is very effective. The treatment works by reducing fear and uncertainty about the condition, helping patients to develop strategies to lessen its impact on their life and future, and increasing the ability to self-manage symptoms. Not surprisingly this has an impact on quality of life and lifestyle benefits such as return to work and increased social engagement. There is also evidence of more appropriate use of services (e.g., increase in GP appointments, but a reduction in hospital outpatient appointments and inpatient stays). All these changes have associated cost benefits although some sit outside the health service (e.g., tax income, reduced state benefits after return to work). Further in depth research is

required to fully understand the cost implications of this treatment, in particular whether the costs of providing the therapy are offset by more appropriate use of services.

The study has identified a potentially positive addition to medical treatment in improving quality of life for patients with PADS. However, prudence should be given to the data with regards to the heterogeneity of the population, presenting mental health needs and treatment aims. Further research is needed to better understand the outcomes and factors that impact this for differing patient presentations.

Caution also needs to be taken when interpreting the results due to the relatively small sample size and high level of analysis conducted. Future studies, with more power to conduct median analyses, are needed in order to establish the role that other factors, particularly current health status, play in treatment and outcome. As subjects were not randomised to intervention, a formal intention to treat analysis was not undertaken. When all participants were analysed only the FACIT-fatigue had statistical significance (data not shown, non-parametric statistical methods used due to skewed data distribution). However, given the overall sample size we would expect that failure to complete therapy would alter the likelihood of successful outcome. Further research should consider the use of a control group to ensure that the improvement can be attributed to CBT rather than non-specific treatment benefits. It will also be important to examine the longer-term outcome of the patients in this population to establish whether the effects of therapy continue over time. Finally, as the research took place within a single specialist service, with only one Clinical Psychologist working with the patient group, it will be important to examine the generalisability of these findings to the wider population of patients with Primary and Secondary Immunodeficiencies.

In conclusion, with both patients and professionals noting the importance of integrating medical and psychological treatments^{17, 29} it should be possible to improve Immunology services by providing psychological support alongside medical and nursing interventions.

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This work was supported by the Primary Immunodeficiency Association, the Royal Free Special Trustees and the Royal Free Charity.

Ethical approval:

“All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.”

Conflicts of Interest

The project was funded by the Primary Immunodeficiency Association, the Royal Free Special Trustees and the Royal Free Charity. Mari Campbell has received financial support to attend symposia from CSL, Grifols, BPL and Biotest, an an honorarium from Shire. Andrew Symes has received payments from SCL, Octapharma and Grifols. Sarita Workman has received honorariums from Biotest and LFB, sponsorship from SCL, Octapharma, Grifols, Biotest, BPL and FLB for attendance at Educational Meetings, and an education grant from CSL Behring. Hans Stauss is advisor and shareholder of Cell Medica and recipient of funding from this biotech company. There are no further conflicts of interest.

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Tables

Table 1: Differences between completers and partial-completers

	Completers	Partial-completers
Gender	30 Female (73%) 11 Male (27%)	3 Female (60%) 2 Male (40%)
Age	49.8 (16.3)	38.4 (16.2)
Baseline HADS Anxiety	9.1 (4.5)	8.6 (5.5)
Baseline HADS Depression	6.5 (5.0)	6.0 (5.7)
Baseline FACIT Fatigue	25.4 (13.8)	27.2 (10.8)
Baseline Somatic Symptoms	19.7 (9.1)	13.0 (6.4)
Baseline Perceived Stress	21.2 (7.9)	15.8 (10.5)

Table 2: Changes following treatment for patients who completed a course of psychological therapy

	N	Baseline Mean (Standard Deviation)	End of Treatment Mean (Standard Deviation)	t	p Value
HADS – Anxiety	39	9.1 (4.5)	7.2 (4.7)	3.308	.002
HADS – Depression	39	6.5 (5.0)	4.6 (4.2)	3.117	.003
FACIT Fatigue ^a	36	24.8 (13.6)	29.2 (13.2)	-3.276	.002
PIQoLI – Anxiety	38	13.6 (4.4)	12.3 (4.9)	2.081	.044 n.s.
PIQoLI – Depression	39	4.7 (3.3)	3.4 (3.3)	3.032	.004
PIQoLI – Fatigue	39	9.5 (4.7)	7.2 (5.2)	3.565	.001
PIQoLI – Insomnia	36	13.1 (6.6)	9.3 (7.7)	3.804	.001

^a Higher score = lower fatigue

	N	Baseline Median	End of Treatment Median	Z	p Value
Hours outside home per week	39	25.0	35.3	-2.910	.004
Days off work medical appointments ^b	17 ^c	1.5	1.5	-0.552	.581 n.s.
Days off work ill health ^b	17 ^c	0.0	1.0	-2.346	.019 n.s.
Days unable to complete household tasks ^b	39	2.5	2.0	-1.029	.303 n.s.

^b In the three months prior to appointment. ^c data only available for those in employment at commencement of treatment.

N.B., Data only analysed if participants had completed both the pre- and post-treatment measures.

Missing data accounts for the reduced N in some analysis.

Figures

Figure 1: Participant flow through the study

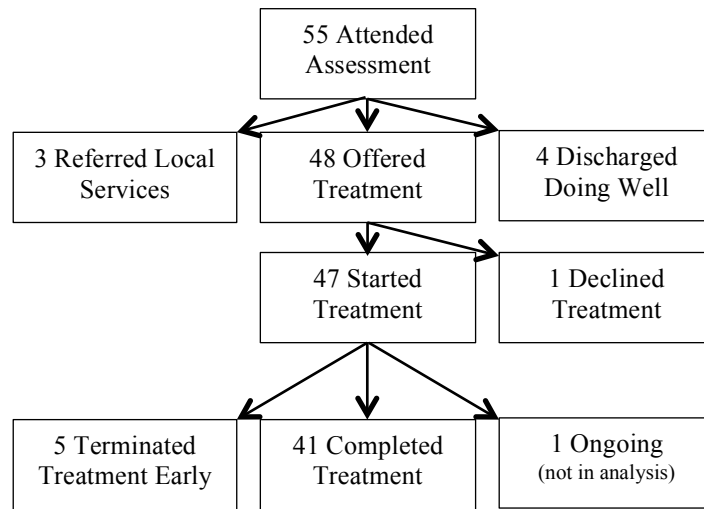


Figure 2: Total medication and medical service usage for patients (N = 40) who completed a course of psychological therapy for the three months prior to first and last psychology session.

