

**Dissertation for Membership of the Faculty
of Occupational Medicine**

**‘Positive Mental Training’ in the
Occupational Health Setting**

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Preface/Acknowledgments

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Abstract

Background

Research suggests that 15-25% of the general population suffer from ‘common mental health problems’ at any time. The costs to employers and society from both direct and indirect costs are vast. Recent evidence suggests that from a workplace perspective interventions using a ‘cognitive behavioural approach’ are most effective.

Methods

It was hypothesised that the self help audio programme, ‘Positive Mental Training’ in the occupational setting would be acceptable to employees, reduce employee ill-health and reduce sickness absence. This study aimed to evaluate; the acceptability of the programme, the study methodology, and to assess response rates and outcomes (sickness absence and self reported clinical status: CORE-OM, HAD, Maslach Burnout Inventory) in order to construct a formally powered sample size.

The study design was an exploratory ‘partially randomised preference trial’ where participants could choose whether they wanted the intervention or not. The study included qualitative and quantitative outcomes.

Results

32 individuals were recruited to the study between April 2009 and August 2009. 28 individuals used the intervention and 4 individuals acted as controls; 25 (88%) females, 7 (22%). Most participants reported depressive symptoms at baseline.

19 (59%) completed 6 month follow-up data. 13 participants were interviewed.

All 3 clinical, validated questionnaires showed statistically significant changes compatible with improved psychological well-being at 4 and 26 weeks. Sickness absence reduced but not significantly. Interview data revealed a range of perceived positive benefits: improved relaxation, sleep, positive impact on work and personal life.

Conclusions

Overall the intervention, and the occupational health setting, were safe and acceptable to employees. The drop out rate was disappointingly high. The lack of a sufficiently sized control group means that the clinical effectiveness of the intervention was not established. Recommendations for future study modifications were made, primarily the inclusion of a randomised element. A formally powered study would require group sample size of 124 to show a 50 % reduction in sickness attributable to mental health.

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Introduction

Mental health problems are common. Figures suggest that 1 in 6 of the general population suffer from a mild to moderate mental health problem at any one time with 1-3 % having a severe mental health condition (1), (2). The overall estimated prevalence of mental health symptoms in the working population is similar (3) however for those with the more severe mental health problems i.e. schizophrenia or bi-polar disorder, research suggests that their prevalence in working populations may be as low as 0.2 % (4) in (5).

Despite a move to view a broader view which considers ‘mental health’ as not simply the absence of ill-health but a continuum from good to poor health (6) there is a need to distinguish the highly prevalent mild to moderate spectrum of disorders from the much less prevalent severe disorders, particularly in the workplace. A definition that has become popular is that used by the British Occupational Health Research Foundation (BOHRF) (5) who described ‘common mental health problems’ as those that;

- occur most frequently and are most prevalent.
- are most successfully treated in primary care rather than secondary care settings.
- are least disabling in terms of stigmatising attitude and discriminatory behaviour.

Anxiety or depression or a combination of both are the most common disorders identified (sometimes referred to as neurotic disorders) (7), (3). Adjustment disorders[†] including symptoms of ‘burnout’ (Appendix 1) may also fall under this descriptor.

[†]Adjustment disorder (can be found in both DSM 1V and ICD-10). Summarised as ‘a maladaptive reaction to an identifiable stressor. Characterised by significant impairment in either social or occupational functioning or by marked excessive subjective stress. Lasts no longer than 6 months’ (8).

'Stress'

'Stress maybe the best modern exemplar of 'Common Mental Health Problems'' (9).

Stress is not included in some commonly used definitions of 'common mental health problems' (5). This reflects the ongoing variation and lack of clarity with the use of the term. The problem is both conceptual and methodological (6): is stress an adverse health outcome (stress response), a characteristic of work (stressor), or a mediating construct i.e. a process of interaction between an individual and their environment? The subjective nature of measurement of both stressors and stress response leaves the possibility that any perceived relationship between the two may also be confounded by the mental state (6)!

An influential theory in the field of stress and health is the transactional theory by Lazarus and Folkman (10) in (8). This states that an individual's reaction to their environment is mediated by the subjective evaluation (appraisal) of the environment and the process of coping with a stress appraised event. The process of coping is in turn influenced by personal characteristics i.e. personality, social skills and problem solving skills. Prolonged exposure to the stressful experience leads to exaggerated affective, cognitive, physiological and behavioural responses. Consequently psychosomatic and psychological distress including anxiety or depression may develop which are less easily reversible, and impaired functioning i.e. sickness absence (10) in (8). Stress complaints have been characterised into 'distress complaints' (anxiety/depression) and burnout (8) (Appendix 1).

The Health and Safety Executive (HSE) defines stress quite simply as the 'adverse reaction a person has to excessive pressure or other types of demands put on them'.

From an employer's perspective it is important to distinguish 'job related stress' since ameliorating work related stressors may alleviate the 'stress'.

Why Should Employers act?

It is widely recognised that being employed can help improve a person's health and wellbeing and help reduce health inequalities; '(Good) work is good for you.' (9). In addition the workplace provides the ideal opportunity to provide facilities and disseminate advice on how to improve and maintain health.

Sickness Absence

Mental health problems and musculoskeletal disorders are the most common cause of sickness absence and worklessness due to ill-health (11). There is a reported strong association between mental health and sickness absence; half of employees reporting psychological disorders are reported to have taken time off work compared to a quarter of those without (4).

We should be aware that sickness absence is particularly likely to be underreported in relation to mental health problems; in part because of the significant scale in which these symptoms go unrecognised and undiagnosed in the workplace, but also because of possible unwillingness of many employees to be labelled as mentally ill (3).

There is also evidence of occupational differences in sickness absence (12); workers in the public sector are most at risk of long term sick leave. Women take more time off than men (5). Sickness absence is a complex behavioural outcome. Decisions to take time off are influenced by factors other than symptoms i.e. social, cultural, economic (i.e. sickness benefit) factors, and job satisfaction (12), (13), (5). Accordingly factors to enhance return to work are likely to be complex.

Mental health symptoms may also manifest as physical symptoms or increase the risk of certain physical conditions i.e. ischemic heart disease (3). Physical conditions have also been associated with increased psychological ill health (1).

When employees do return to work from an absence related to a mental health problem their performance may be affected (presenteeism*). An observational study (14) based in primary care found that even when depressed patients had improved sufficiently in order to return to

work, deficits remained on multiple dimensions of job performance. Presenteeism rather than absenteeism is more common among white collar workers i.e. executive and professional (3).

*Presenteeism ; defined as ‘the loss in productivity that occurs when employees come to work but function at less than full capacity because of ill health’(3).

The costs

It is estimated that 11.4 million working days were lost in 2008-2009 on account of self reported work related stress, anxiety or depression (15) and that 200,000 people with mental health problems will move onto incapacity benefit each year (11). The cost of presenteeism is likely to exceed that of sickness absence; present estimates suggest its cost may be 1.5 times that of sickness absence (3), (16)! Add to this increased turnover, and one can see the costs to employers are vast. This does not include the costs to the tax payer – benefit costs, additional health costs and forgone taxes....

Attempts have been made to estimate the costs of ‘mental health problems’ to the nation;

- 91 million working days lost each year at a cost of 12 billion (17).
- 70 million working days lost each year at a total cost of £26 billion (3).

These economic costs are measurable however beyond that are the human costs which are often hidden and privately borne.

Legal considerations and Mental Health conditions in the workplace

The Health and Safety at Work Act 1974 and the Management of Health and Safety at Work Regulations 1999 provide a framework that supports workplace action on mental health problems. The Health and Safety at Work Act stipulates that employers must create a working environment that is, as far as reasonably practicable, safe and without risks to health. The Management Regulations place a duty of care on employers to assess the nature and scale of risks to health in the workplace: risks to health include risks to mental health.

The Disability Discrimination Act (DDA) 2005 creates a duty on employers that makes discrimination against those disabled with mental health problems illegal. The amendment to the DDA in 2005 means that a specific mental health diagnosis is no longer required in order for a person to meet the legal criteria of ‘a physical or mental impairment which has a substantial long-term adverse effect on his / her ability to carry out normal day to day activities’. The Act may include people with relatively low level but enduring depression.

Recent Governmental Developments

Traditionally government policy has focused on treatment of mental ill health but increasingly there have been moves to press for health and social services promotion of mental health reflected in a succession of more recent policy documents;

- ‘Towards a Safer, Healthier Workplace’ in 2001 (18), the occupational health and safety strategy for NHS in Scotland (NHSiS) led to the development of ‘Peer Audit and Benchmarking Groups’ (PABS); the mental health sub-group recommended NHS staff have access to effective evidence based mental health interventions
- The Government’s Health, Work and Well-being strategy (19) was aimed at making improvements for those of working age by creating healthier workplaces and maximising the opportunity that workplaces provide to help people make healthy lifestyle choices. There followed the publication of the Black Report, ‘Working for a Healthier Tomorrow’ in 2008, a review of the health of the working population (11). This advocated early interventions, especially for mental health problems, and facilitation of increased choice of evidence-based psychological therapies for people with mild to moderate depression and other mental health issues.
- The Government responded with the document ‘Improving Health and Work; Changing Lives’ in 2008, which included the development of the independent cross government steering group; ‘National Strategy for Mental health and Government’. In response the NHS arranged an independent review led by Steve Boorman in 2009 ‘Health and Wellbeing at Work in the United Kingdom’ (16). This summarises the impact of ill health on work and provides some examples of good practice.
- The Scottish Government publication in 2007, ‘Better Health Better Care’ identified mental health as a target area for improvement for NHS Scotland (20). The appended ‘HEAT’ targets have a sickness absence target of 4% for NHS organisations.

Additional benefits

In addition to the financial and legislative incentives a company that is perceived as supporting staff is likely to keep existing staff, attract new ones, and generate goodwill among potential customers (3).

Sickness absence in the host NHS organisation

Staff took a total number of 8087 days off sick in the 6 months preceding the study; this extrapolates to 8 days per employee annually. Although this compares favourably with annual sickness absence rates for NHS employees (in England) estimated at 10.7 days per year (16) mental health accounted for the highest incidence of sickness absence at 26%.

Management of common mental health problems

Robust guidelines exist for the individual clinical management of depression and anxiety (21), (22). Most research focuses on the ‘medical outcomes’ of such interventions although a few have explored the occupational outcomes (23).

‘Positive Mental Training’ is a self help psychological intervention that incorporates many techniques considered effective for the management of common mental health problems. In order to contextualise this study within the literature base this section will explore the present research evidence in relation to these techniques; CBT (cognitive behavioural therapy), relaxation techniques, mindfulness, self help interventions in general and some recent research on workplace interventions. Finally the intervention ‘Positive Mental Training’ will be described in more detail; origin, development, present use and comparisons with CBT.

Cognitive Behavioural Therapy (CBT)

Following consistent and robust scientific evidence it is widely accepted that CBT is effective for the management of common mental health problems, specifically anxiety and depression (22), (21).

Traditionally CBT techniques fall into 2 categories (24);

- Cognitive therapy; This is based on the assumption that prior learning is having maladaptive consequences and that by detecting and undoing these dysfunctional thinking habits, and providing a more realistic or functional way of thinking, mood will be improved (i.e. cognitive restructuring and ‘rational emotional therapy’).
- Behavioural activation; this encompasses imaginal therapy, gradual (or graded) exposure, exposure response prevention; self control desensitisation and self instructional training.

All these components may be included to varying degrees in any CBT intervention which tend to be a pragmatic combination of concepts and techniques (24). Debate continues on the key effective components for any such intervention (24), (25). Recent research suggests that the ability of the cognitive component of therapy to improve mood and reduce relapse in depression is its co-incidental ability to promote distance from negative thoughts rather than logically challenging erroneous beliefs as previously believed. Teasdale (26) describes that cognitive therapy helps depression through an increase in ‘meta-cognitive awareness’; ‘a cognitive set in which negative thoughts and feelings are seen as passing events in the mind rather than as inherent aspects of self or as necessarily valid reflections of reality’ and not as originally perceived by changing the thoughts themselves. This ability to ‘step back’ is central to mindfulness, mindfulness-based stress reduction and mindfulness based cognitive therapy.

Mindfulness

Mindfulness is an ancient form of meditation or ‘mental training practice’ originally derived from the Theravada tradition of Buddhism. The essence of mindfulness involves awareness and acceptance of whatever is occurring in the present moment (27).

Mindfulness-Based Stress Reduction (MBSR) was developed originally as a 10 week group course accompanied by regular self care practice using audio assistance (28). Studies using MBSR with health care professionals have reported reduced ‘stress’ levels and burnout (27) , (29) but these studies are small. Mindfulness Based Cognitive Therapy (MBCT) was subsequently developed, again as a group taught technique combining mindfulness training

with elements of standard CBT (30), (31). The emphasis was on changing awareness of, and the relationship to thoughts, or increasing ‘metacognitive awareness’ (26). Early evidence suggests MBCT may be effective for recurrent depression- a systematic review concluded that MBCT reduced relapse in chronic depression (three or more episodes) by over 50% over a one year follow up (31).

Self help and guided self help; background

Many individuals prefer psychological therapies as opposed to medication (32) however there are significant barriers to accessing effective psychological therapies primarily due to a lack of suitably trained therapists to meet demand (33). This results in long waiting lists and dissatisfaction among clients. Other studies have shown that large numbers of the general public consistently do not seek support for their mental health problems (3).

Suggested solutions include the adoption of a stepped care approach to enhance the effectiveness of service delivery by providing low intensity ‘minimal interventions’ i.e. evidence based self help interventions which may allow more efficient service delivery (33). The workplace may be an ideal entry point for treatment for those recognised in need with beneficial effects for employees and employers.

The advantages of self –help are evident (34), (35), (32):

- Individuals may be reluctant to use medication i.e. concerned about possible side effects or drug interactions, pregnancy or breast feeding.
- Face to face therapy may heighten specific symptoms, at least initially i.e. anxiety, and may lead to avoidance of seeking help.
- May prepare individuals to enter any necessary formal treatment.
- May reduce concern about stigma.
- Allows for personal preference.
- Family members can become more involved.
- May allow increased confidentiality.
- Flexibility-do not need to fit in therapist appointments/ travel time.
- Might reduce therapist time and be cost efficient.
- Might allow therapists to see an increased number of people.

Potential disadvantages:

- In pure self help one is unable to identify those with more complicated problems.
- Internet packages are designed to address one problem at a time and individuals may choose the wrong intervention for their symptoms.
- Internet aided self help may lead to concerns about security.
- Non completion may increase disillusionment.

Although CBT therapists have used self help exercises for many years as ‘homework’ (33) or ‘marginal treatment’ it is only relatively recently that psychological principles have become available in the form of self help and even more recently has there been any attempt to evaluate its use (36). There are many books available commercially but few have been actually been empirically evaluated in trials (36).

Early reviews of self help were predominantly restricted to bibliotherapy using cognitive behavioural strategies and although they often showed large effect sizes they were also often of poor methodology and no clear information given on the intervention used (37).

Subsequently one has seen a rapidly expanding media for self help: CDs, DVD, audio and even interactive voice response technology (38). Recent research supports the effectiveness of Computerised CBT as an alternative treatment for anxiety and depression (22), (35), (39) including for individuals with symptoms of more chronic duration (40).

Despite this many questions do remain unanswered about self-help, including ambiguity about optimal intervention design and delivery i.e. clinical versus non-clinical setting or client characteristics to maximise the effectiveness and acceptability of interventions to individuals (41).

Autogenic training and relaxation

A Cochrane review of ‘depression for relaxation’ (42) reviewed 11 randomised control trials (RCTs) or quasi – RCTs of relaxation techniques, including progressive muscle relaxation (43), autogenic training (the regular practice of simple mental exercises of body awareness which aim to promote relaxation and stress relief) and relaxation imagery. The study concluded that relaxation was more effective than no, or minimal treatment, on (self reported) symptoms but not as effective as psychological treatments.

Workplace evidence; what can employers do?

Recent opinion advocates the biopsychosocial model of health conditions; sickness and incapacity involve biological, psychological and social dimensions, and rehabilitation should address them all focussing on barriers to a return to work rather than identifying individual deficiencies (44).

Workplace ‘risk’ factors

Extensive work has been done in terms of work characteristics related to higher rates of psychological ill health and sickness absence (45), (46). In response the HSE have produced ‘consensus’ Management Standards for ‘stress’ at work which define the characteristics, or culture of an organization where the risks from work-related stress are being effectively managed and controlled. The Management Standards cover six key areas of work design; demands, control, support, relationships, role and change.

It is less clear what specific interventions are effective in reducing perceived work related ‘stress’ and supporting those with common mental health problems to either remain at, or return to work. Research may be hampered by the fact that the range of design features necessary to conduct good quality scientific research can be difficult in the workplace (13), (6):

- Identifying a stable work environment within which the effects of the intervention can be isolated.
- Establishing access to participants and sufficiently large samples in both experimental and control groups.
- Identifying experimental and control groups which are similar in occupational profile and other relevant socio-demographic characteristics but separate to avoid cross-contamination.
- Ethical and practical barriers to implementing an intervention to a restricted group of employees when it is believed to be of benefit.
- Interventions in this area are often unique and non standardised so it is difficult to generalise results of effectiveness or to replicate studies.
- Employees and employers may be concerned about issues such as Data Protection, commercial competition and confidentiality.

Workplace Interventions: definitions

Work place interventions are traditionally classified as primary (prevention and retention) and secondary (rehabilitation) programmes (16), (5), and as organisational (work based), worker based (individual) or a mixture of both (5). Organisational level actions seek to change the characteristics of the work. Individual interventions seek to change the way individuals perceive environmental stressors, or build their ability to cope with or mitigate these stressors (6). They may encourage the development of both active and passive coping skills. Individual interventions tend to be either based on CBT, training in relaxation techniques, or a combination of both (commonly referred to as 'multimodal'). 'Positive Mental Training' may be considered multimodal. Other approaches exist including psycho-education and problem solving skills.

Self help in the workplace

No studies have been performed previously using 'Positive Mental Training' in the workplace setting. Limited studies were identified on Medline, PsycINFO and the Cochrane Library that utilised self help interventions in the workplace, or that explored their impact on employment. This was not a full systematic search.

Grime in 2004 (47) compared a computerised CBT programme with 'CAU' (care as usual) in a group of employees with a recent history of stress related sickness absence. Although he found lower depression and anxiety scores at 1 month this was a short-lived effect and the small sample size made interpretation difficult. The study did not evaluate sickness absence. In (48) and (8) study volunteers received 'take home' tapes with exercises to practice progressive muscle relaxation training as part of multi-modal stress management programmes however it was not possible to evaluate the effect of the self help component separately.

Additional Workplace Evidence

In 2005 BOHRF published a systematic review entitled 'Workplace Interventions for People with Common Mental Health Problems' (5). A key conclusion was that the most effective approach to support employees already experiencing common mental health problems was brief (up to 8 sessions) of individual therapy, especially CBT interventions. The method of delivery (i.e. computer based versus face to face) did not seem relevant.

Limitations of this review should be recognised; the studies identified were often of poor methodological quality- not randomised controlled studies with control groups. Follow up periods were often short in (49) (the mean follow up for individual interventions was 9 weeks). Participants were commonly volunteers or samples selected by the employer (49), studies involved small sample sizes, and outcome measures were very mixed and not always objective or validated. The review did not specifically search for self help interventions and although studies were often aimed at those on sickness absence (202) or at higher risk of sickness absence (47) this was not a consistent outcome variable (50).

Sickness absence and Work interventions

A comprehensive review of workplace ‘counselling*’ (13) reported an overall benefit of workplace counselling on reducing sickness absence although individual studies did not consistently show this outcome.

*Definition of counselling used by McLeod; a form of voluntary intervention (chosen by the employee), responsive to the needs of the client or group, and primarily intended to bring about a change in an area of psychological /behavioural functioning.

Appendix 2 summarises some recent workplace or work related studies identified during a literature search that evaluated sickness absence as a key outcome. The search included Medline, PsycINFO, Cochrane library, ASSIA, Dynamed and CINAHL databases. A recent Cochrane review in 2009 ‘Preventing Occupational Stress in Healthcare Workers’ 2009 (51) did not evaluate sickness absence.

Despite a plethora of research exploring workplace interventions for common mental health problems the evidence for effectiveness is not compelling and a ‘gold standard’ intervention has certainly not been identified. Study factors, including methodological flaws; low study power, variable intervention techniques which are therefore difficult to compare, differing severity of participant’s symptoms, sickness absence data based on self report and therefore subject to recall bias (8), and other more tangible factors such as cultural and economic (i.e. sickness absence benefits) (13) make it difficult to draw any more firm conclusions. Differential effects on psychological symptoms and work resumption do seem evident suggesting that reduction in psychological symptoms may not be an important factor in

promoting return to work and also that return to work does not have an adverse effect on psychological symptoms even if work related (52), (50), (53).

It has been suggested that severity of symptoms maybe a moderator in the effectiveness of interventions but even this is not supported by consistent evidence (8), (52), (54), (55), (56) (57).

On balance, evidence still seems to favour the use of CBT and/or relaxation techniques *but in combination with* either workplace association or modifications. Further research is required to establish groups of workers who may benefit most.

Could access to supported self help interventions based on CBT and relaxation techniques through the workplace sit alongside other workplace supports and provide a cost effective solution?

The Intervention

‘Positive Mental Training’ is based on a Swedish self-hypnosis programme. It consists of 3 compact discs (CDs) each with 4 x 18 minute tracks and an introductory DVD of 13 minutes.

History of ‘Positive Mental Training’

‘Positive Mental Training’ was developed from the concept of ‘Integrated Mental Training’ used by an eminent Swedish researcher, Lars Eric Unestahl in the 1970’s. ‘Integrated Mental Training’ is a systematic long term training of mental processes (thoughts, images, attitudes and emotions) initially developed to help individuals achieve peak performance and wellness in sport (58). Unestahl identified 4 mental dimensions relevant to the ideal performance state: self image, emotion (the right feeling), attitude and goal (image). His programme was developed, applied and tested on national and Olympic teams in the 1970s (58) before being introduced into schools, education and health and clinical areas in the 1980s. He has developed a wide range of ‘self’ hypnosis materials, the core of which is ‘mental training’.

Description of ‘Positive Mental Training’

‘Positive Mental Training’ encompasses recognised techniques i.e. imaginal therapy, exposure response prevention; self control desensitisation and self instructional training found in cognitive behavioural therapy. It has similarities with mindfulness and therefore it is likely to increase ‘metacognitive awareness’. Techniques such as relaxation, self hypnosis* and ‘visualisation’ are used to improve access to positive memories in order to bring about a change in thinking style (59).

The recordings are listened to at home, the same track every day for a week, working through the 12 tracks over 12 weeks.

- Hypnosis- special state of relaxation and focused attention. Study by Alladin (60) used hypnosis in conjunction with CBT and provided preliminary evidence that this may be a beneficial combination.

Appendix 3 compares ‘Positive Mental Training’ techniques with Cognitive Behavioural Therapy.

Table 1 The tracks; Components of ‘Positive Mental Training’

	Track	Programme title	Technique
DVD			Introduction; reassurance and explanation.
CD 1	1	Muscular relaxation 1	Experiential Jacobson relaxation, mindfulness technique.
CD 1	2	Muscular relaxation 2	Experiential Jacobson relaxation, setting of conditioned trigger.
CD 1	3	Mental relaxation 1	Visualisation of safe place- a self hypnosis tool.
CD 1	4	Mental relaxation 2	Reinforcing of visualisation of safe place and ease of access.
CD 2	5	Self Confidence	Suggestion, reframing, associating with past positive memories to increase self confidence.
CD 2	6	Problem Solving	Very deep relaxation with desensitisation techniques; lessening anxiety.
CD 2	7	Mind/body	Demonstrating arm lifting through

	Track	Programme title	Technique
		programming	suggestion to increase self determinism.
CD 2	8	Trigger the future	Association with past positive experiences and bringing those to the present.
CD 3	9	Distance and Meaning	Distancing and reframing of past events from safe place.
CD 3	10	Love Yourself	Suggestion, visualisation and reframing to increase self-esteem.
CD 3	11	Creative Thinking	Suggestion; increasing self belief and problem solving.
CD 3	12	Vision for the future	Association of positive past performance with visualisation of future.

The programme requires no reading skills. It can be effectively delivered in any setting with simple training and can be used at home or work.

Present evidence

A primary care benchmarking ‘Partially Randomised Preference Trial’ (PRPT) of ‘Positive Mental Training’ (59) found that ‘Positive Mental Training’ was the treatment choice of 92% of participants and as effective as anti-depressants in improving depressive symptoms. It is estimated that over 10,000 people have received this intervention in Edinburgh with no reported problems. It has been accepted by the local mental health intervention network as a component of stepped care (61).

In summary; ‘Positive Mental Training’ delivers evidence based effective techniques in an accessible, audio format which could be effectively administered by suitably identified staff with minimal training, including occupational health staff.

Methodology

Hypothesis and aims

It was hypothesised that ‘Positive Mental Training’ in the occupational setting would be acceptable to employees, reduce employee ill-health (as measured by pre-determined validated questionnaires), and reduce the duration of sickness absence.

The study aimed to:

1. Assess the acceptability of the intervention, ‘Positive Mental Training’ to employees.
2. Assess the methodology and identify how an initial study design could be improved or modified.
3. Evaluate response rates and outcomes so that a formally powered sample size could be constructed.

Study design

‘Positive Mental Training’ is likely to meet the criteria for ‘complex intervention’ as defined by the Medical Research Council (MRC): ‘Complex interventions comprise of a number of separate elements that seem essential for effective functioning of the intervention although the ‘active ingredient’ of the intervention that is effective is difficult to specify’ (62).

The Medical Research Council (MRC) (62) provides guidance for the evaluation of ‘complex interventions’. The MRC describes 5 suggested stages in this assessment: Pre-clinical or theoretical phase, Phase 1; Modelling, Phase 2; Exploratory trial, Phase 3; Definitive RCT and Phase 4; Long term surveillance.

Phase 1 modelling involves developing an understanding of the intervention and its components and its possible effects which may include, for example, use of computer modelling package, qualitative interviewing or quantitative surveys (satisfaction questionnaires). Qualitative research can be helpful in identifying which are the active ingredients of a complex intervention and which are not related to treatment effect, which

groups are most likely to respond most positively and whether indeed the intervention should exclude certain groups.

Phase 2 is crucial prior to a main randomised control trial. It includes ‘testing the intervention’ to examine delivery in routine settings, identify an appropriate control group, provide estimates of key trial parameters such as recruitment rates, randomisation, treatment effects and estimates of effectiveness and other requirements for a main trial. Studies at this stage may be adaptive in terms of design, analysis and intervention. Progression through the phases is a continuum of increasing evidence although the progressions may be iterative and not necessary linear (62).

‘Positive Mental Training in the Occupational Health Setting’ was an exploratory study that combined components of both Phase 1 and Phase 2. A mixed methodological approach was adopted to include qualitative and quantitative elements.

A Partially Randomised Preference Trial design (PRPT) was chosen;

This model allows prospective participants to choose one of 3 options:

- Participants can choose to use the intervention in addition to their normal care, ‘Care as Usual’ (CAU).
- They may continue with their CAU alone.
- If they have no preference they can be randomly allocated to each group, CAU or CAU + intervention.

This study design has been used in large studies in primary care (63) including with ‘Positive Mental Training’ (59).

The study received ethical approval from the Lothian Research Ethics Committee (Appendix 4) and approval from the organisation’s senior management team.

Study population

Entrance criteria

Inclusion criteria:

Any employee attending the local National Services Scotland occupational health (OH) department who was identified as suffering from 'common mental health problems' i.e. depression, anxiety, adjustment disorder, (including the descriptors 'stress' or 'burn-out') had the opportunity to participate in the research.

Participation was open to those attending OH as a self-referral, at a review appointment or following a management (HR) referral.

Exclusion criteria:

- Bipolar disorder, psychosis, active alcohol or drug problem, family history of psychosis or bipolar disorder.
- Severe depression with suicidal ideation (a clinical decision based on clinical assessment although questionnaire responses were used to facilitate assessment).
- Impaired hearing.
- Unable or unwilling to give consent.
- Already using the programme.
- Unable to understand English to a sufficient degree to follow the verbal messages on the CDs.

Participants were provided with a CD /DVD player if necessary.

Pre- study audit

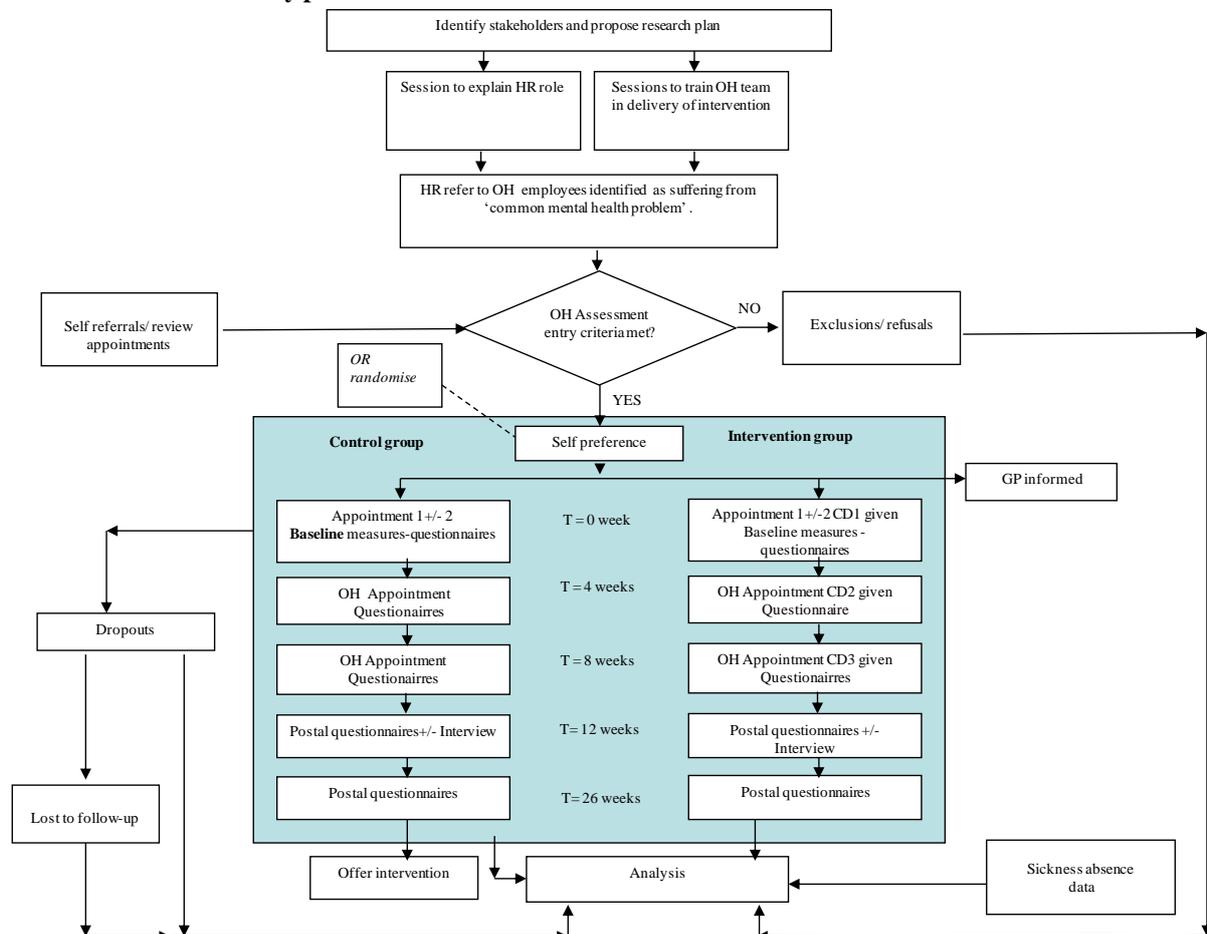
Following discussions with a statistician it was concluded that a sample size of 50 participants allowed estimation of the primary outcomes of the study (percentages of participants choosing to take part and opting for different preferences) to within a standard error of 7%. A short ten week pre-study audit from March to May 2008 considered participation for individuals presenting at the start of a medically certified absence for common mental health conditions. Only 14 eligible people were identified. The initial recruitment period planned was 6 months; this extrapolated to a group of 30-35 eligible

employees. Although this figure was expected to be higher due to anticipated earlier occupational health referrals it was not possible to predict numbers more accurately and the entrance criteria was widened.

Process

Figure 1 (Figures 1 and 2 provide full details of the study process)

Flow chart of full study protocol



Participant recruitment

Management referrals;

- When line managers received a medical or self certificate of ill health where a ‘common mental health problem’ was identified, they were asked to contact occupational health via Human Resources as soon as possible with employee details. (In normal practice this may take up to 28 days).
- Occupational health (OH) referrals were triaged and potential study participants identified. All referrals were invited for an Occupational Health assessment as soon as possible. A patient information sheet and accompanying letter with details of the study was sent to potential participants alongside their OH appointment letter (Appendix 5).
- OH assessment took place. If no exclusion factors were present, consent was requested for study participation and initial paperwork completed (or further appointment booked with the study researcher for paperwork completion depending on time pressure, circumstances etc).

Self-referrals/ reviews;

- Individuals were assessed as usual by clinical OH staff member and, if appropriate, the study was discussed with them. If interest was expressed a follow-up appointment was offered within a week (but longer than 24 hours) to complete study consent and initial paperwork.

Consent was sought to inform employees’ GP of their participation.

Employees that agreed to participate were allocated to their chosen group or randomised.

Study follow-up

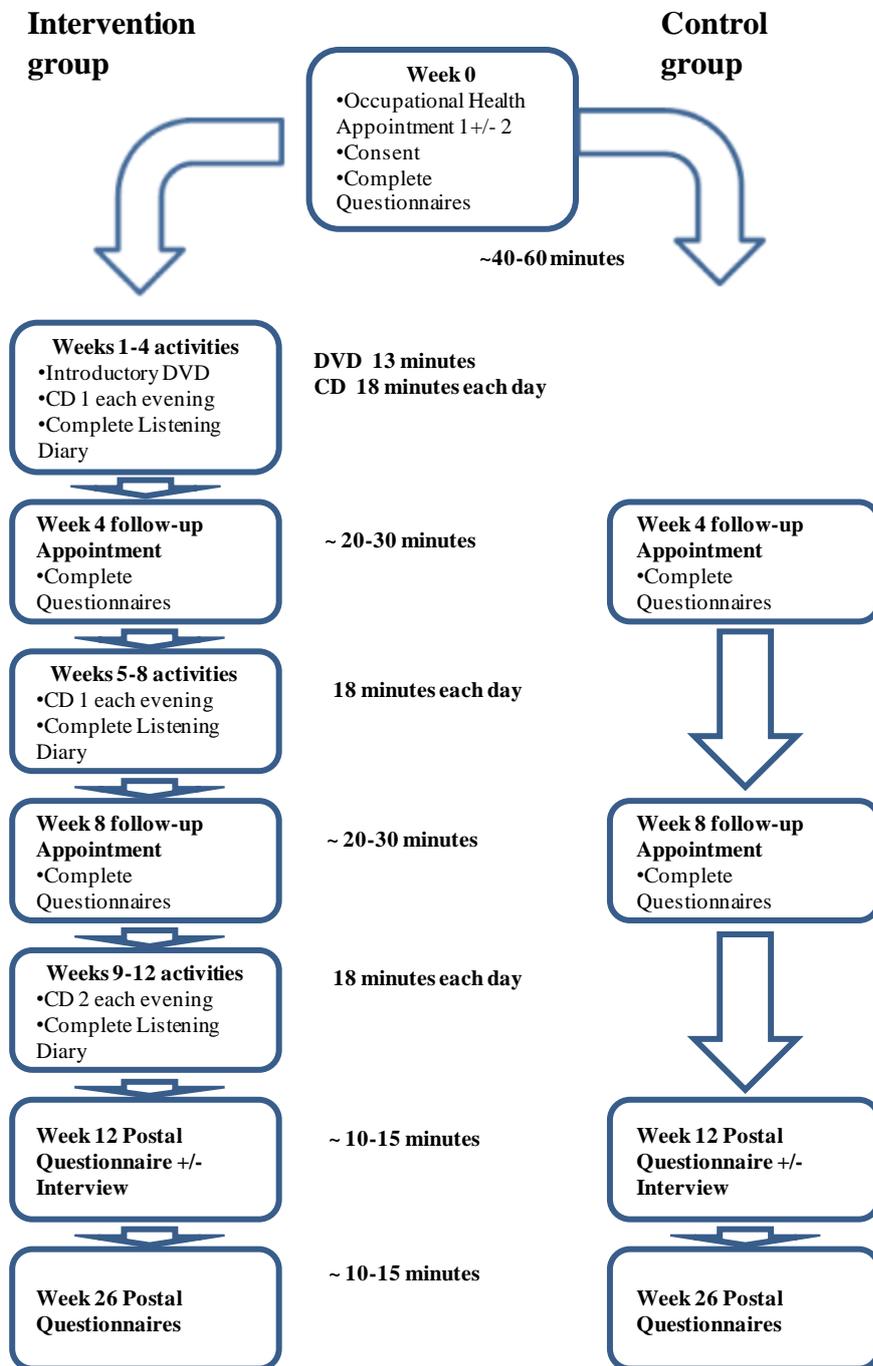
All participants were asked to attend OH review appointments at 1 and 2 months. Study OH review appointments were focused on the use of CDs. Additional occupational health appointments were arranged if required according to clinical need.

All participants were asked to complete a series of validated questionnaires during the 6 month follow-up (Appendix 6, 7, 8, 9).

Non-responders to questionnaires or follow-up visits were contacted on 3 occasions either by mail or telephone. Those that dropped out were asked to complete a 'Post Intervention Satisfaction Questionnaire' (Appendix 10) at the point they dropped out.

Figure 2

Flowchart of study participation – (including approximate times)



Adverse effects

Participants who are feeling depressed may find it upsetting being asked to think about positive thoughts or they may find their emotions are heightened initially, and, for example, become more tearful. Participants were advised of these potential effects and given appropriate advice at the introductory interview. The protocol determined that participants reporting adverse symptoms would be assessed on an individual basis, and managed as considered appropriate by the occupational health professional which may be simply reassurance. Participants were given contact numbers for, and access to, the occupational health department during working hours should they wish advice. They also had access to an Employee Assistance Programme. Participants were made aware that they were free to drop out of the study at any point should they wish to do this.

Scope

Viability in terms of recruitment

Recruitment, preference and drop-out rates for use with planning future studies.

Demographics and relevant clinical information (Appendix 11, 12, 13)

Data was collected at time 0 and time 26.

Sickness absence data;

- Quality and quantity
- Compare pre-study and post-study sickness absence (days and spells).

(Recruitment numbers did not allow for comparison of sickness absence data between the CAU group and Intervention + CAU group).

Clinical Questionnaires (Appendix 6)

These quantitative standardised measures were self-completed at OH appointments (time 0, 4) and sent to the participant's home for completion (time 12, 26).

Clinical Outcomes in Routine Evaluation-Outcome measure (CORE-OM) (Appendix 7).

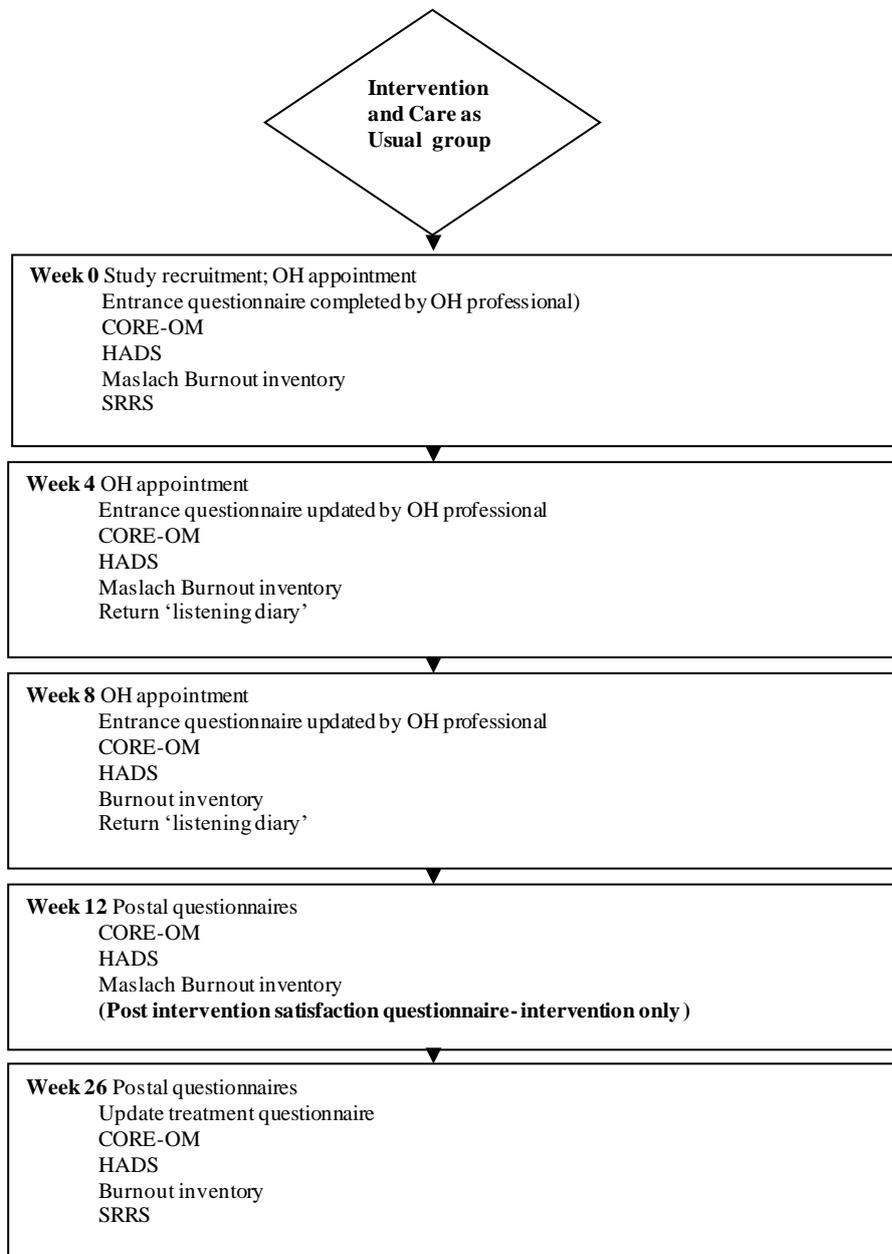
Hospital Anxiety and Depression Scale (Appendix 8).

Maslach Burnout Inventory – General Survey (Appendix 9).

Pre-intervention, during intervention, and post-intervention measures were compared.

Figure 3

Questionnaires-timeline



Work related/ non-work related stressors

Potential confounders (external factors influencing effects seen in the study) were measured using the Social Re-adjustment Rating Scale (SRRS) (Appendix 14). This was administered at time 0 and time 26.

Post Intervention Satisfaction Questionnaire.

This non-validated questionnaire was administered at time 12 or at time of study drop-out (Appendix 10).

Impact on Work Functioning

Extracted from the Core Workplace Counselling ‘Assessment’ and ‘End of Therapy’ form (Appendix 15). This was administered at time 0 and time 26.

Engagement with intervention

Participants were asked to record the number of times that they had listened to the CDs on a self-recorded ‘listening diary’ (Appendix 16) to establish:

- Was this a viable method of collecting this information?
- An indication of patterns of individual’s engagement.

Statistics

- The primary purpose of the study was descriptive, and rates of participation and preference were estimated and confidence limits calculated.
- For secondary analysis of these rates, and of outcomes in relation to presenting characteristics of participants, associations were tested by: chi-squared, t or non-parametric tests, or correlation where appropriate.
- Power: the results of the study were used to calculate a study size that would have the power to show a statistically significant reduction in sickness absence if it existed.

The statistics package SPSS data editor version 17 was used for all analysis.

Benchmarking

Because internal comparison was not possible due to the small control group, CORE-OM data was benchmarked against the CORE National Workplace counselling database (64).

Qualitative measures

Selected participants were invited for individual interview, in work time, and in the workplace. Individual interviews were chosen due to the sensitive nature of mental ill-health. A purposive sampling method was used to identify a group of employees that included females and males, a range of ages, members of the control group and intervention group, those who appeared to have engaged less with the intervention and those who dropped out. The interviews ultimately undertaken were restricted by participant consent.

The semi-structured one-to-one interviews were conducted at, or shortly after, the 12 week time point. The qualitative data aimed to explore:

1. What was the participant's experience of receiving the intervention? (Intervention group only).
2. What was the participant's perceived benefits / limitations of the intervention?
3. What was the participant's perception of the role of occupational health in providing this treatment/ support to employees?

One individual (J Thompson) performed all the interviews. The interviews were based around broad open questions which aimed to allow the participants the flexibility and freedom to express their own views, unhindered by any of the interviewer's pre-conceptions.

The interviews were recorded and transcribed verbatim. The researcher used the transcripts to look for emerging themes and concepts. This process aimed to be iterative: an interactive process that used emerging data to develop theory. During this process the researcher identified an emerging theme and sought ethical consent to explore factors that motivated the use of (self help) interventions/ strategies.

Results Part 1 Quantitative data

The study was run over a 5 month time period April 2009 to August 2009.

Table 2 summarises the organisation's demographics and occupational health activity during this time.

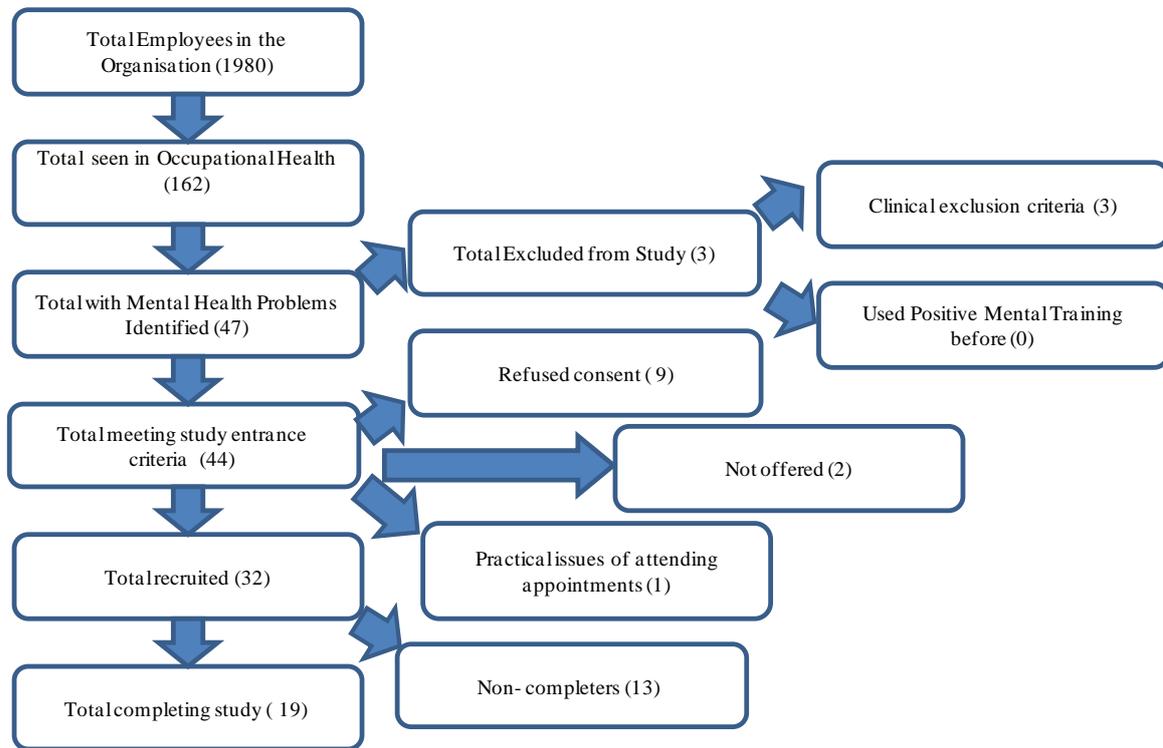
Occupational Health activity

Table 2. 5 month period April 2009 to August 2009

	Organisation Employees	OH appointments
Total	N/A	179
Total Number of individuals	1980	162
Management Referral	/	138 (77%)
Self Referral	/	22 (12%)
Review	/	19 (11%)
Male	1177 (59%)	48 (30%)
Female	802 (41%)	114 (70%)
Full time	1658 (83.7%)	/
Part time	322 (16.3%)	/

Figure 4

Flow chart of Study recruitment process 5 month period 2009



Recruitment rates

47 (29%) individuals attending OH were identified as suffering from mental health problems; 12 (26%) male, 35 female (74%).

Of the 47 with mental health problems (MHPs); 44 (94%) met the study criteria; 3 (6%) were excluded due to clinical exclusions. Nobody was excluded because they had used the programme before.

9 of the 44 (20%) individuals refused consent- this included those who declined participation or simply failed to attend an arranged appointment. 2/44 (5%) individuals were not offered study participation (either considered inappropriate during consultation or time pressure of OH clinician). 1 (2%) individual was willing to take part and met the entrance criteria but due to mobility issues could not attend the required follow up appointments.

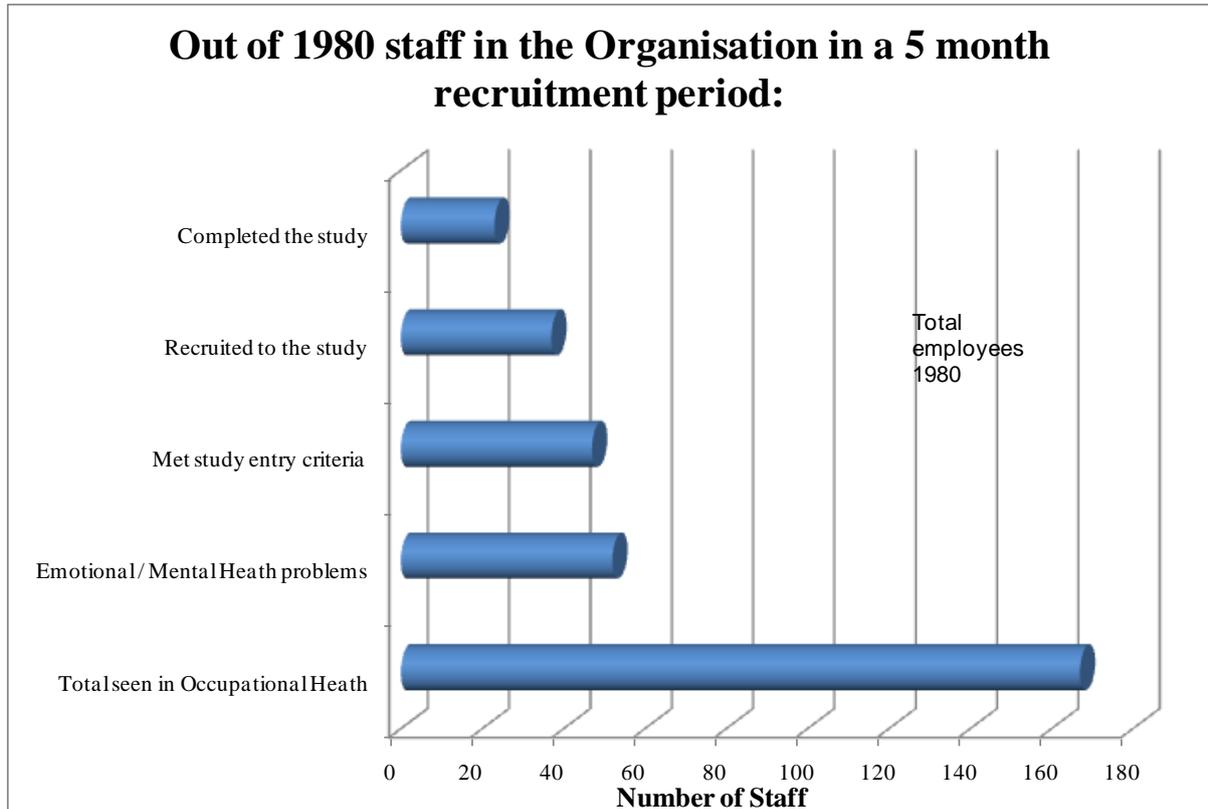
Study uptake rate from total OH appointments; 32/179, 95 % CI 18% +/- 6 (12-24) %.

Uptake rate from those identified with MHPs; 32/47, 95 % CI 68% +/- 14 (54-82) %.

Uptake from those meeting clinical study criteria; 32/44, 95% CI 73% +/- 13 (59-85) %.

Only 4 (12%) individuals wished to participate as ‘controls’ and 28 (88%) therefore as the intervention group. Nobody was willing to be randomised in the context of the self preference study.

Figure5



Reasons for non- Participation

Table 3. Reasons for non participation n=15

Reason	Number	%
Clinical exclusion	3	20%
Used programme before	0	0%
Refused consent	9	60%
Not offered participation	2	13%
Practicalities of appointment	1	7%
Total	15	100%

Comparing participants /non participants

Table 4. Comparing participants /non participants

Route of referral	Individuals with CMHP**	Non Participants	Participants	χ^2	P value
				6.84	0.033
Management Referral	16 (34 %)	9 (60%)	7 (22%)		
Self Referral	23 (49 %)	5 (33%)	18 (56%)		
Review	8 (17%)	1 (7%)	7 (22%)		

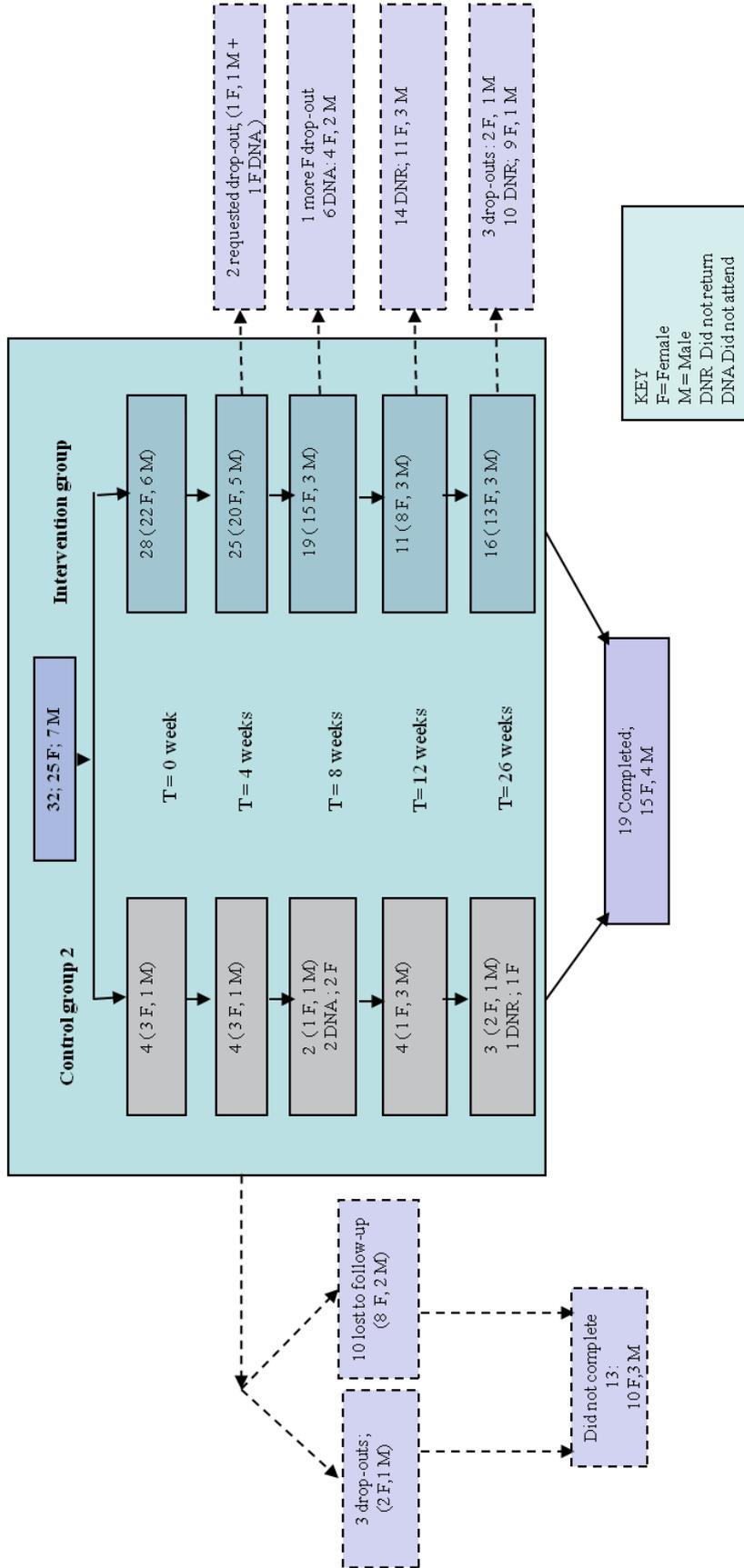
Sex				χ^2	P value
				0.7	0.4
Male	12 (26 %)	5 (33%)	7 (22%)		
Female	35 (74%)	10 (66%)	25 (78%)		
Total	47 (100%)	15 (32%)	32 (68%)		

** ‘common mental health problems’ See main text for definition

- Although more females took part in the study than males there was no statistically significant relationship between the sex of an individual and whether they chose to take part in the study (Pearson χ^2 0.7, p = 0.40).
- There was a statistically significant relationship between the referral route of individuals and whether they took part in the study: self referrals were more likely to participate. (Pearson χ^2 6.84, p = 0.033).

Figure 6

Flow chart of recruitment, retention and drop outs



Demographics of study participants

Table 5 Demographics of study participants

Description	Number	%
Number of Participants	32	100
Age range	23-57	
Mean age	40 (SD 8.6)	
Ethnic- Caucasian	32	100
Part-time	8	25
Time with organisation (range)	1-30 years	
Mean time with organisation	14 years (SD 8.8)	
Grade range	3-senior manager	
Co-existing physical problems	14	44
Social history; Partner	23	72
Parents	5	16
Alone	4	12
Children / dependants at home;		
age < 5	2	6
age >5	7	22
<5 and >5	1	3
No children at home	22	69

Formal help-seeking behaviour prior to study participation

Table 6. Formal Help-seeking Behaviour prior to Study Participation n=30

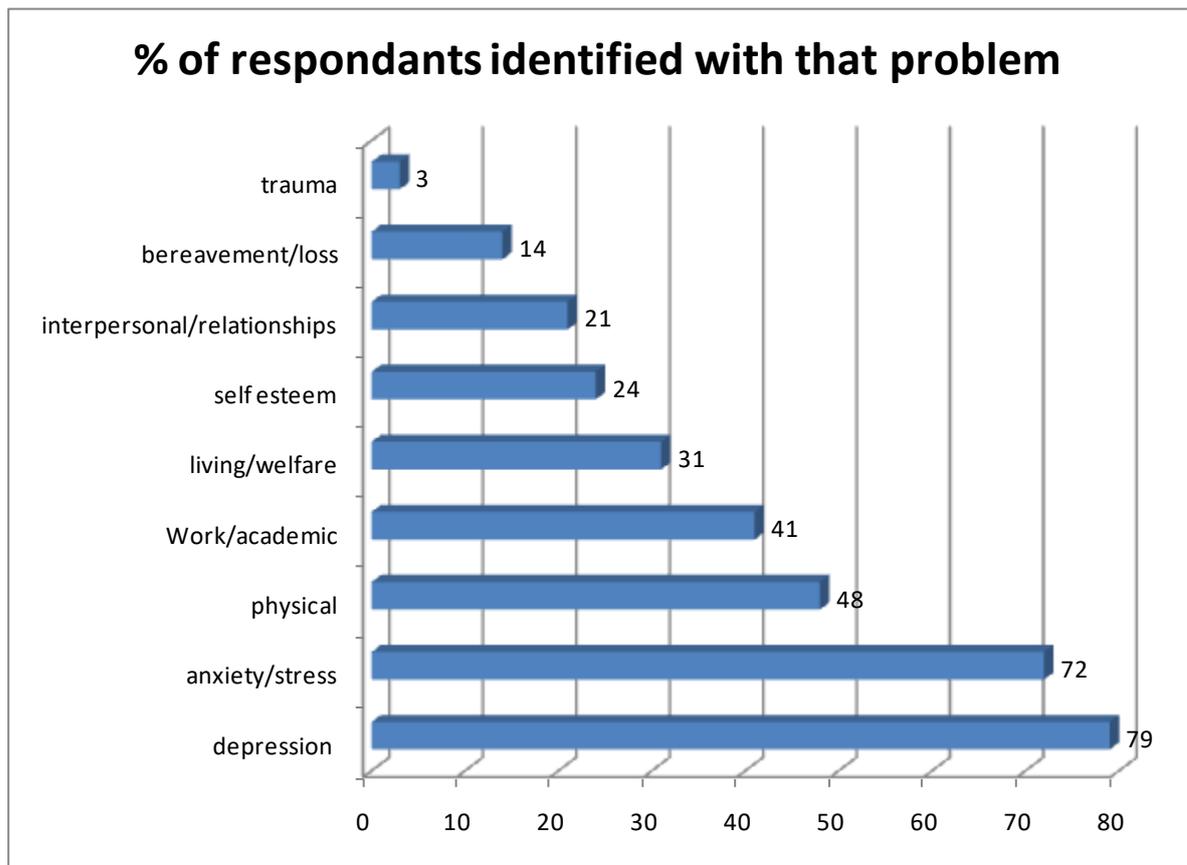
Treatment incidence	Concurrent	%	<12 months	%	>12 months	%
GP (primary care team)	17	57	6	20	6	20
Psychology/ Psychotherapy specialist team	4	13	0	0	2	7
Counsellor/ voluntary sector	4	13	1	<1	1	0
None	5	17	0	0	N/A	N/A
Medication at recruitment	14 (13 anti-depressant/ 1 anxiolytic)	47	N/A	N/A	N/A	N/A

Reported problems

Length of time individuals reported their problems

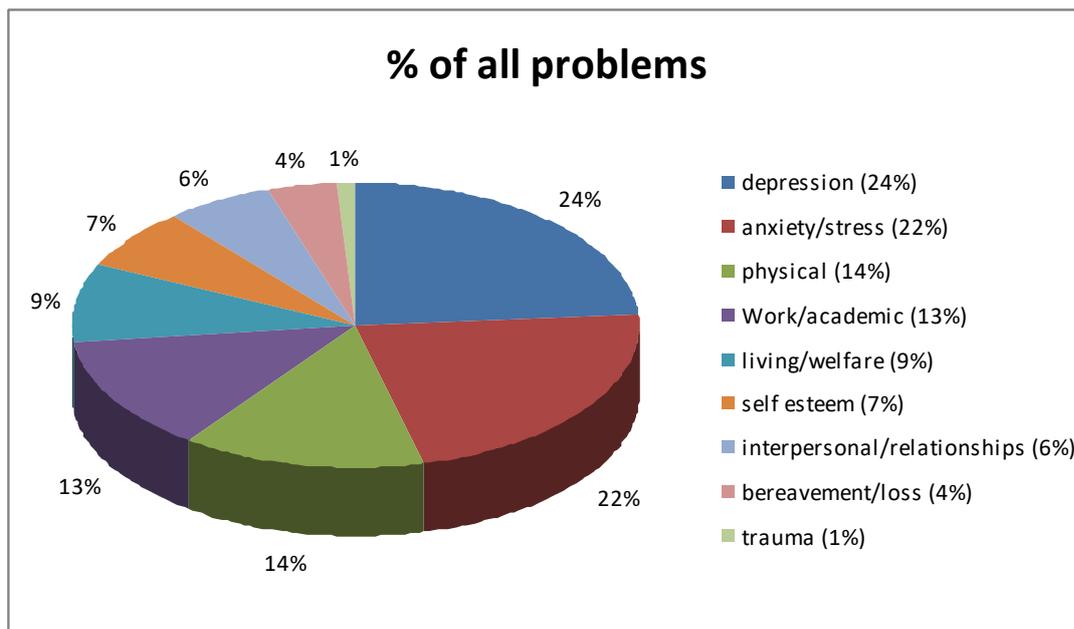
Less than 6 months; 7 (24 %), 6-12 months; 8 (28%), > 12 months; 4 (14 %) and recurrent/continuous; 10 (34%).

Figure 7



(>100 because respondents frequently identified more than one problem) *Core categories 'depressive symptoms,' and therefore not restricted to those with a formal diagnosis of 'clinical depression'.

Figure 8



Control demographics

Table 7 Control Demographics

Characteristic	
Age range (years)	35-50
Mean age (years)	42
Sex	3 female, 1 male
Route of referral	2 S/R, 1 HR, 1 review
Core 'caseness' at recruitment?	2 yes, 2 no
Treatment to date	All attending GP as a minimum
Medication	3 medication, 1 no medication
Completed study?	3 yes, 1 dropped out at time 12
Main Problem identified	3 anxiety, 1 depression
Length of problems	<6 months to recurring continuous

The Social Re-adjustment Rating scale (SRRS)

(Results from all participants)

SRRS scores

Time 0; Mean 155, SD 86 Range 50-455.

Time 26; Mean 129, SD 41 Range 77-21.

Comparing:

SRRS at time 0 and Sex

Mean female SRRS score 166 (SD 86), Mean male SRRS score 119 (SD 83).

- There was no statistically significant difference between SRRS at time 0 and male and female participants; $t = 1.28$, $p = 0.21$ (Independent t-test).

Age and SRRS score

- There was evidence of some correlation between a participant's age and SRRS score; Pearson correlation 0.412, $p = 0.019$. (Correlation)

SRRS and Core score

- There was no evidence of correlation between the SRRS at time 0 and core score; Pearson correlation 0.14, $p = 0.45$.

Time 0 SRRS and Time 26 SRRS

- There was no statistically significant difference identified between time 0 SRRS and time 26 SRRS; $t = 1.58$, $p = 0.14$ (Paired samples t-test).

Change in treatment time 0-time 26

n=17 (Intervention group)

1 individual started antidepressants during study.

2 individuals STOPPED antidepressants during study.

1 individual had commenced counselling. No other additional formal treatment reported.

2 individuals reported attending face to face hypnotherapy at end of study.

Clinical status at recruitment

Table 8

Score at Time 0	N	Range	Minimum	Maximum	Mean	Std. Deviation
Total Core score	31	2.64	0.15	2.79	1.4	0.8
HAD A	32	18	1	19	11.3	5.2
HAD D	32	19	0	19	7.7	4.7
Maslach Ex	29	5.8	0.2	6	3.5	1.7
Maslach Cy	29	6	0	6	2.5	1.8
Maslach Pe	29	4.5	1.5	6	3.9	1.2

* Core score is often x 10 in research literature.

- 61% participants met the CORE criteria for clinical 'caseness'. 2 scores were within the 'severe range' (core total score >2.5).
- The mean HAD A score lay within the accepted 'moderate caseness' range (HAD 11-14).
- Mean HAD D approached the 'mild caseness' range (8-10).
- Maslach scores compared to the established 'categories' for 'experience of burnout'; Maslach Ex; High, Maslach Cy; High, Maslach Pe; Low.
- In the intervention group alone, 63% met the Core criteria for 'clinical caseness'. The HAD A, HAD D, and Maslach scores remained within the above categories.

Comparing route of referral with clinical score

There was no significant relationship between route of referral and likelihood of having a clinical score (Pearson χ^2 4.06, p value 0.131) (Chi square).

Use of the Intervention

Only 10 individuals used the diary.

The average number of times individuals reported listening to the CDs in the preceding 4 weeks was 14 times at 4 weeks, and 11 times at week 8. This data was primarily based on direct questioning at appointments. Data for 12 weeks was only available from interviews. Some individuals (from interview data) reported that they listened to the CDs more in days preceding an OH review appointment. 9/17 (53%) reported that they were still using the CDS at week 26.

Clinical outcomes; Changes over time (Intervention group)

Time 0 to time 4

- There were statistically significant changes between time 0 and time 4 Core total, Core Functioning, HAD A, HAD D and Maslach Pe scores.
- There was no statistically significant difference between time 0 and time 4 Maslach Ex or Maslach Cy.

Table 9 Time 0 to time 4 Paired samples t- test

Score	Mean (SD of each mean)		
	Time 0	Time 4	P value from paired sample
Total Core score	1.46 (0.75)	0.94 (0.67)	<0.000
Core F	1.5 (0.9)	0.95 (0.82)	<0.000
HAD A	11.4 (4.55)	8.56 (4.59)	0.001
HAD D	7.64 (4.53)	4.72 (3.43)	0.001
Maslach Ex	3.43 (1.9)	2.84 (1.35)	0.126
Maslach Cy	2.51 (1.89)	1.93 (1.6)	0.132
Maslach Pe	3.91(1.37)	4.61 (1.1)	0.045

Time 0 to time 26

- There were statistically significant changes between time 0 and time 26 total Core, Core functioning HAD A scores, HAD D and the 3 Maslach scores (Paired samples T test).

Table 10 Time 0 to time 26

Score	Mean (SD of each mean)		
	Time 0	Time 26	P value from paired sample
Total Core score	1.5 (0.75)	0.7 (0.5)	<0.000
Core F	1.5 (0.9)	0.7 (0.5)	<0.000
HAD A	11.4 (4.6)	7.3 (3.7)	<0.000
HAD D	7.6 (4.5)	3.6 (2.9)	0.013
Maslach Ex	3.46 (1.9)	2.32(1.68)	0.024
Maslach Cy	2.52 (1.9)	1.8 (1.5)	0.039
Maslach Pe	3.92 (1.37)	5.18 (0.73)	0.013

Time 4 to Time 26

- Only core functioning showed a statistically significant change between time 4 and time 26 (Paired samples t- test).

Table 11 Time 4 to Time 26

Score	Mean (SD of each mean)		
	Time 4	Time 26	P value from paired sample
Total Core score	0.9 (0.7)	0.7 (0.5)	0.228
Core F	0.9 (0.87)	0.7 (0.54)	0.033
HAD A	8.3 (4.87)	7 (3.65)	0.227
HAD D	4.3 (3.19)	3.6 (2.94)	0.409
Maslach Ex	2.7(1.23)	2.42 (1.58)	0.500
Maslach Cy	1.74 (1.67)	1.74 (1.54)	1.000
Maslach Pe	4.6(1.23)	5.13(0.84)	0.073

Summary of scores at Time 26

- 17% participants met the CORE criteria for clinical ‘caseness’ (based on 18 scores).
- The HAD A and HAD D mean scores now lay within the non-clinical category.
- Maslach scores:
Maslach Ex; Moderate
Maslach Cy; Moderate
Maslach Pe; High

Clinical outcomes; associations (Intervention group)

Male and females Time 0-Time 26

- There was no statistically significant difference between male and female outcomes however this may be due to the very small sample size; only 3 men completed the intervention (Independent t- test).

Table 12 Male /females Time 0-Time 26

Score	Mean difference (SD of each mean diff.) female	Mean difference (SD of each mean diff.) Male	
	Time 0	Time 26	P value from independent t-test
Core total	0.86 (0.56)	0.57 (0.28)	0.141
Had A	4 (3.7)	5.67 (3.05)	0.7
Had D	3.38 (4.78)	2.67 (4.61)	0.96

Chronicity of symptoms; Time 0 - Time 26

- There was no significant difference between outcomes of participants with chronic symptoms and those with symptoms of shorter duration (Independent t –test).

Table 13 Chronicity of symptoms; Time 0 - Time 26

Score time 0-26	Mean difference (SD of each mean diff.) Chronic	Mean difference (SD of each mean diff.) Non chronic	P value from independent t-test
Core total	0.5 (0.56)	1 (0.42)	0.071
Had a	4.17 (2.31)	4.4 (4.25)	0.9
Had d	2.17 (2.4)	3.9 (5.55)	0.48

Completion characteristics (Intervention group)

Route of referral

- There was no significant relationship between the likelihood of completing the study and referral route; Pearson χ^2 5.35, p=2.5) (Chi square).

Sex

- There was no significant relationship between completion rates and either sex; Pearson χ^2 0.039, p value 0.843) (Chi square).

Age

- Individuals completing the study were significantly older (mean completer=44, non completer 36), t value 2.5, p value 0.02 (Independent t- test).

Clinical status at recruitment

- There was no significant relationship between the clinical status of participants at recruitment and likelihood of completing the study (Pearson χ^2 0.76, p=0.38) (Chi square).

Control group clinical outcomes

Table 14

Score	Mean scores		
	Time 0	Time 4 (n=4)	Time 26 (n=3)
Total Core score	1.1 (non case)	0.9 (non case)	1 (non case)
HAD A	10 (mild)	8 (mild)	8.5 (mild)
HAD D	6.5 (non case)	6.5 (non case)	6.5 (non case)
Maslach Ex	4.16 (high)	4.4 (high)	3.8 (high)
Maslach Cy	2.67 (high)	3.2 (high)	3.1 (high)
Maslach Pe	3.83 (low)	3.67 (low)	4.42 (average)

Statistical tests were not been applied due to the small sample size

Impact of symptoms on work time 0 / time 26 (Intervention group)

- There was a statistically significant reduction in participant's perception of the impact of their symptoms on their work at time 0 and time 26, $z = -2.805$, $p = 0.005$ (Wilcoxon signed rank test).

Table 15 Perception of impact on work time 0 /time 26

Time 0	Time 0	%	Time 26	%
No effect	1	4	10	62
Minimal difficulty	11	46	4	25
Moderate difficulty	4	17	1	6.5
Severe difficulty	2	8	1	6.5
Sickness absence	6	25	0	0
Total	24	100%	16	100%

Sickness absence data

Appendix 18 shows detailed breakdowns of organisational and study participant sickness absence data

- In both the pre study period October 2008 - March 2009 and post study period April 2009 - September 2009 mental health accounted for the highest sickness absence in days, seconded by 'other' (even when back pain and other musculoskeletal causes were added together)

Comparing pre study and post study sickness absence data

(Intervention group)

- There was no statistically significant reduction in the number of days absence post study compared to pre study for all absences, mental health absences and those absences attributable to 'other causes'.
- There was no statistically significant reduction in the number of spells of sickness absence post study compared to pre-study for all absences, mental health absences and 'other causes'.

(The spell data analysis was based on total small numbers.)

Table 16 Sickness absence data pre/post comparison Days only (Wilcoxon signed rank test)

	Z	P value
All absence	-1.5	0.13
Mental health absence	<0.00	1
Other absence	-8.41	0.4

Table 17 Sickness absence data pre/post comparison Spells only (Wilcoxon signed rank test)

	Z	P value
All absence	-0.46	0.64
Mental health absence	-4.47	0.66
Other absence	-1	0.32

Sample size for future studies?

(See Appendix 19 for details of calculation)

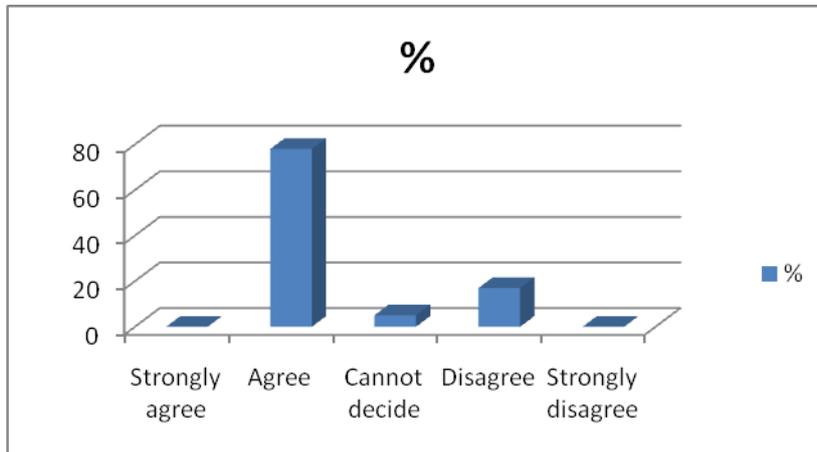
- The size of study required that would have a 80 % power at 5 % significance level to detect a 50 % reduction in the number of days sickness absence between control group and intervention group FOR all sickness absence in the follow up study period (6 months) i.e. 26.06 to 13.03, is **46 subjects per group**.
- The size of study required that would have a 80 % power at 5 % significance level to detect a 50% reduction in number of days sickness absence between control group and intervention group FOR mental health absences i.e. 11.34 to 5.67, is **124 subjects per group**.

Satisfaction Questionnaire results

Total number questionnaires completed =19

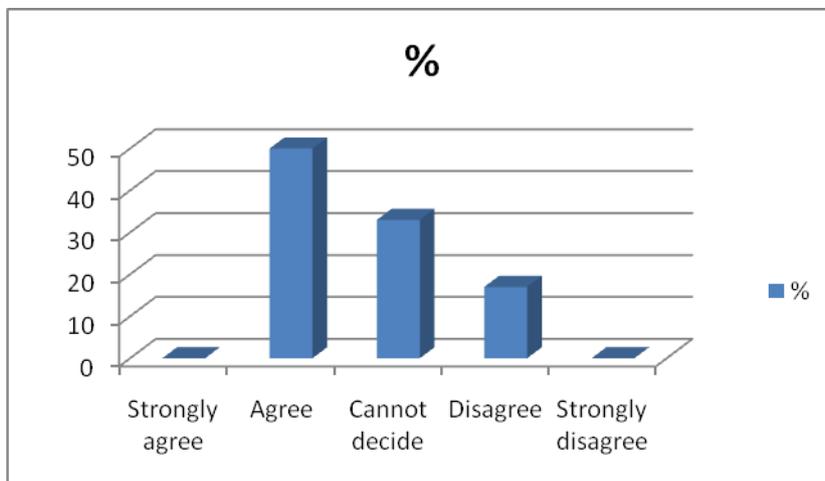
Question 1. Overall, the programme 'Positive Mental Training' has helped the way I feel.

Figure 10 a



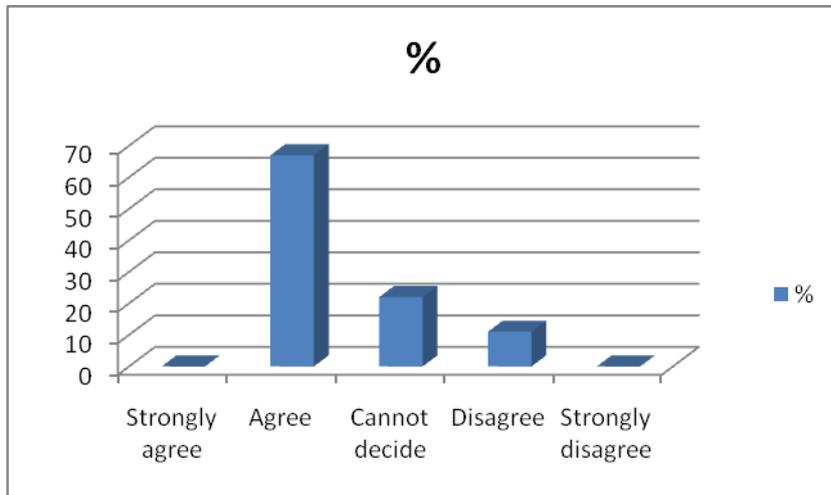
Question 2 The programme has had a positive effect on my working life.

Figure 10 b



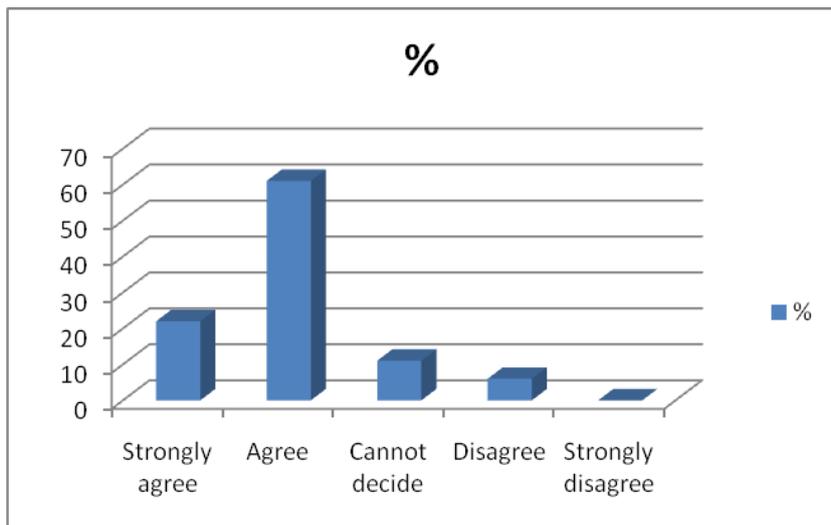
Question c. The programme has had a positive effect on my home / personal life, including relationships

Figure 10 c



Question 4. I plan to keep listening to the programme after the study is complete

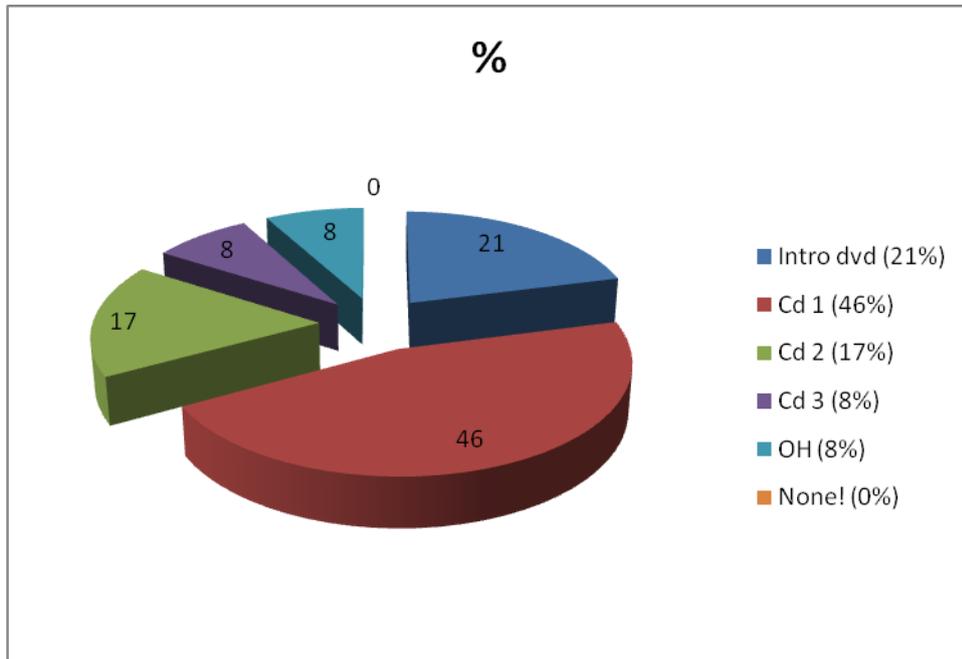
Figure 10 d



Question 5. Please tick the box relating to the component in the programme that you found;
a. most helpful. b. least helpful. (The scores for question 5 are greater than 18 because several individuals identified more than one component as being most helpful.)

Question 5a “most helpful”.

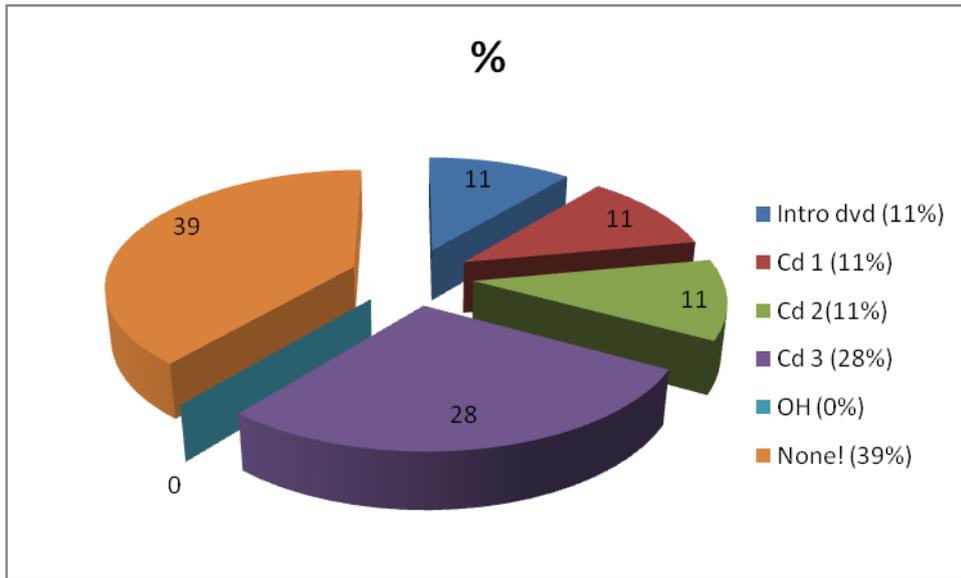
Figure 10 g



Most individuals found CD1 was most helpful; n =12, followed by the introductory DVD, n = 5 and CD 2 n = 4

Question 5b “least helpful”.

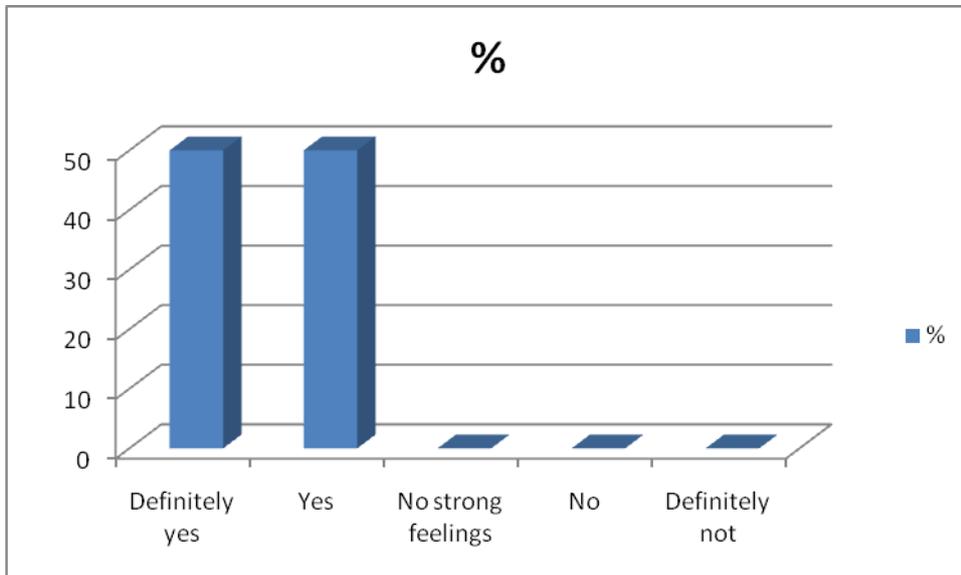
Figure 10 h



The component that most individuals found least helpful was CDs 3 n= 5.

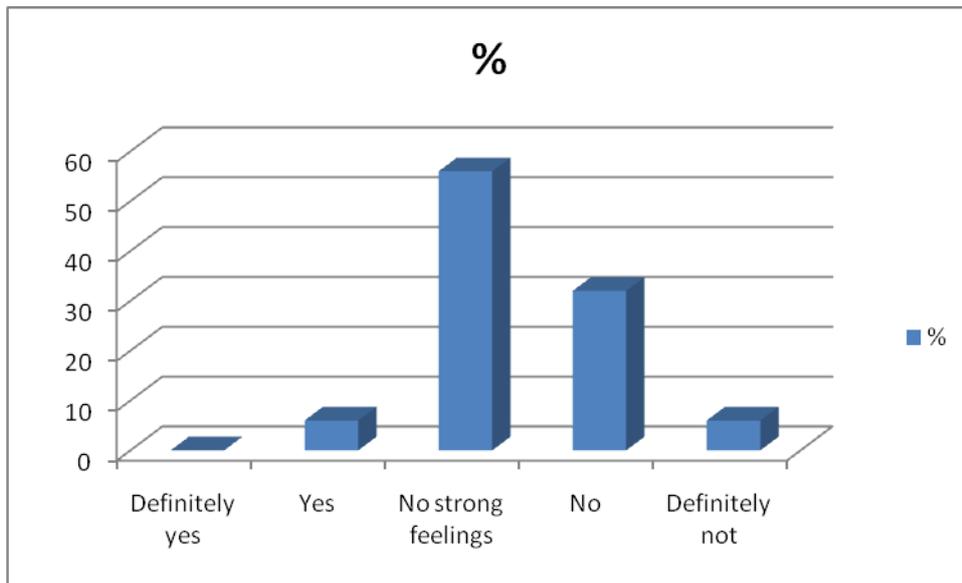
Question 6. Would you recommend the programme to a colleague?

Figure 10 e



Question 7. Would you prefer to have received the programme from your GP?

Figure 10 f

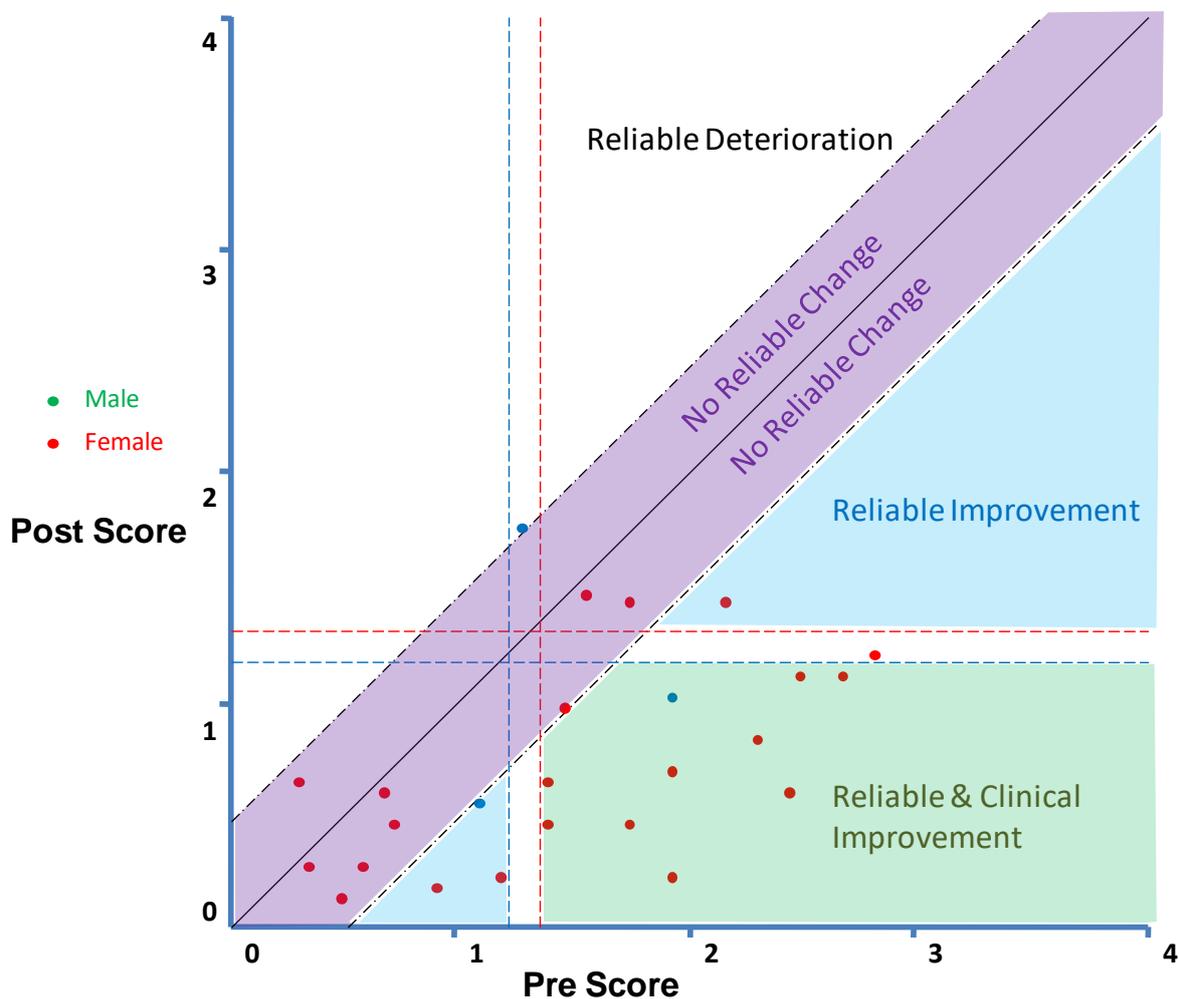


Core data

(Appendix 17 for details).

The scatter plot shows how many participants (intervention group only) met each combination of Clinical change criteria and Reliable change criteria. All Pre intervention Core measures (time 0) and Final Core Outcome Measures were included. 25 individuals are included (2 individuals dropped out before completing time 4 paperwork and one individual did not complete the time 0 questionnaire due to an administrative error). The timing of the final outcome measures varies between time 4, 8, 12 or 26 weeks. Table 22 summarises the timing and core clinical category of participant's final core score.

Figure 11



Summary; 60 % participants showed a reliable change
 44% a clinical and reliable change
 36% showed no reliable change.

Table 18 Timing of Final Core questionnaires

Stage	End Clinical status	End non clinical status	Total number
Time 4	1	2	3
Time 8	1	4	5
Time 12	1	3	4
Time 26	1	12	13
Total	4	21	25

Core National Benchmark Data

Individual data (Appendix 20)

This data was provided by 'CORE' from their National Database for Workplace Counselling. The outcomes are based on 4318 clients who completed valid pre and post therapy measures. Appendix 19 gives a detailed description of the benchmark population; 75 % showed a reliable (+/- clinical) improvement post therapy. The average pre therapy score was 1.75 and post score 0.87. This compares to the study population where 60 % showed a reliable (+/- clinical improvement) and the average pre score was 1.46 and post score 0.72 and

Organisational data (Appendix 21)

In the lowest 25th centile of organisations in the Core data base, 67<73% individuals showed a reliable (+/- clinical improvement). The results of this study ((60% reliable (+/- clinical improvement)) therefore fall below the lowest centile rate for organisational improvement however this includes 9 individuals who showed NO reliable change and 6 of these were BELOW the clinical cut off at recruitment.

Results Part 2 Qualitative methods

A detailed interview analysis and description of interviewees can be found in Appendix 22.
(*n*= participant study number)

13 employees were interviewed. Interviews ranged in length from 18 minutes to 42 minutes. Interviewees described the prior use of a wide range of self help and formal help seeking behaviours including simple activities such as ‘lavender’ baths and listening to music, to the specialist ‘Gestalt’ psychotherapy.

A variety of factors were identified that motivated help seeking behaviour including: open mindedness, convenience of interventions, desperation, validation, the impact of symptoms on their life, the realisation that present strategies were not working and for several participants trying to remain at work. Although recommendations from others were a recognised influence on behaviour, others felt afraid and avoided seeking advice from their GP because they thought that they would be signed off work:

‘Because the first time, I think, when someone suggested I go to see the GP and maybe take some time off work I could not face that. I could not face to be in the house’ (13).

Barriers to help seeking behaviour included stigma, feelings of shame, state of mind, perception of efficacy and adverse effects of the intervention, lack of motivation, trust, lack of information and conflicting advice.

The interviews elicited a wide range of perceived benefits of the intervention, including improved relaxation, sleep, an increased ability to ‘step back’ which was put to use in potential conflict situations, and perceived benefits on working and home life:

‘And people in the office, they say they have seen a difference in me in performance issues at work – I was able to think a wee bit more outside the box’ (04).

Some individuals did report difficulties with certain tracks and skills, predominantly ‘visualisation’:

‘If I could think of one (happy place) I would not need to be listening to the CD’ (06).

A few who remained sceptical about the benefits of the CDs were also willing to continue in the hope that with practice then skills might improve. Most valued the ability to alter the listening order of tracks and some had developed a routine for the use of the CDs.

The occupational health setting was in general well received.

‘I have found the whole thing very helpful actually the halo you know that shining wee light you know and it certainly has made me think more of self help and not just reiki’ (520).

Discussion

This section combines both qualitative and quantitative data to gain a greater understanding of, and ‘triangulate’ results.

Practical study difficulties

Data Recording

Practical difficulties were encountered with the anonymous recording of non- participant’s data. It is not clear if all of these individuals were identified; this would impact on the percentage uptake figures recorded. However, the incidence of individuals attending OH with mental health problems is close to the figure of 1/3 quoted in (65).

Organisational consent

Despite early involvement with the development of the study protocol the organisation requested an additional consent form before releasing individual sickness absence data at a late stage in the study follow up process. At this point a number of individuals had already dropped out, and therefore consent was only obtained for 21 participants.

Competing health promotion

Competing health promotion activities available to all employees may have reduced the number of HR and self referrals to OH with common mental health problems during the study period.

Occupational Health staff

During the study there were changes to Occupational Health and administrative staff which may have adversely influenced staff commitment to the study. Errors with follow up plans for 3 participants may have affected their motivation to complete the study.

Demographics

General

Job grades, length of time with organisation and social status varied widely between participants. There was a wide age range of participants however the mean age was consistent

with that of other workplace studies (47), and that of the Core workplace database (64). Although more females took part in this study this was a non significant result and probably simply reflects the fact that more females were identified as meeting the study criteria. Research has reported that women are more likely to report common mental health problems and work related illnesses than men (1, 16).

Clinical Problems

To maximise recruitment no criteria for ‘caseness’ severity was applied for participation. There was wide variety in the type, severity, number and length of problems reported by participants. Research does suggest that self help interventions may be most helpful for those with less severe health problems (41), (35) but not exclusively (40). We have also seen how ‘Positive Mental Training’ has similarities to ‘mindfulness’ (or MBCT) which is showing potential as a treatment for recurrent depression (66).

41% participants reported a work related problem, comparable with the Core National Workplace database figure of 38% (Appendix 21).

Referral route

Employees self referring to OH were significantly more likely to take part in the study (χ^2 6.84, $p = 0.033$) with 78% of possible self referrals taking part! This suggests that those self referring to OH are highly motivated to identify and engage with potential supportive strategies. This is relevant since (68), a comprehensive review of self help interventions for anxiety disorders, reported that increased motivation was associated with increased response to treatment.

‘Self referrals’ were also just as likely to have ‘clinical’ core scores at recruitment and were therefore not just the ‘worried well’ (67).

Acceptability

Identifying acceptability of an intervention is a critical precursor to a definitive trial and is helpful in predicting to what extent interventions may ultimately become embedded in routine clinical practice i.e. sustainability of the intervention (62).

Uptake

The uptake rate of 72% is high and compares favourably with other workplace studies utilising self help interventions; (47) reported a 34 % uptake of eligible employees to a guided self help Computerised CBT programme.

Self preference

The fact that only 13% (n=4) of participants agreed to act as controls, and no one volunteered to be randomised, was consistent with previous research (59). Some individuals did state that if no choice had been available they would have agreed to 'randomisation only'. Only one 'control' stated that she did not wish the intervention. One wished to concentrate on an imminent course of CBT, and the remaining 2 felt they had used very similar techniques previously, including hypnosis and neurolinguistic programming.

Satisfaction questionnaire data

The satisfaction questionnaire data was predominantly positive (only one individual definitely did not plan to use the CDs going forward). This data however represented only 68% of the intervention group (due to drop outs and non-responders) and may represent those that engaged more with the intervention.

Qualitative interview data

Participants reported a range of perceived benefits from the intervention. Some individuals who continued to listen to the CDs described feeling motivated not only by perceived immediate benefits, but also the hope that with 'practice' they might 'get better' at the techniques and gain even more in the longer term.

Again the sample interviewed may not be representative of the wider group of participants; patients who fail to engage with the intervention may also be those that are more difficult to recruit to further research such as qualitative interviews (69). The presence of the researcher as interviewer also requires consideration; participants may have felt an obligation to report positively about the study. The interviewer's perception was that participants were honest when describing difficulties with the programme and quite forthcoming in their criticism of certain elements i.e. the voice, music.

Occupational Health setting

Both interviews and questionnaire responses reflected that participants were satisfied with the OH setting- only one individual would have preferred to receive the CDs from their GP. This also contrasts with the findings of Grime (47) where ‘association with the employer’ was a common reason for employees declining study participation. Factors such as employee morale, work satisfaction and work relationships are likely to influence an employee’s perspective of OH and therefore variation may be expected between workplaces.

Completion /drop out rates

The dropout rate was disappointingly high (41%) but is not dissimilar to other research using self-help interventions; recent studies of internet guided interventions reveal dropout rates ranging from 3% to 34 % (70) with the highest attrition rates related to the longest follow ups. Grime (47) reported a dropout rate of 31% over a 6 month follow-up. A recent study of MBSR also suffered from high dropout rates (27) while a meta-analysis of ‘stress interventions’ (49) reported dropout rates ranging from 0-40% with a mean of 11%.

The only significant finding was that those who completed the study were slightly older than those who dropped out (mean age 44 versus 36) although small sample sizes may account for these negative findings.

We do not know if individuals dropped out because they had recovered, because they were not motivated or if they did not engage with the intervention. Client variables have been considered the most potent factor influencing the impact of self help psychological interventions and motivation, resourcefulness and conscienciousness likely to be critical (36). Some participants who dropped out were approached for interview but declined. Interview data did suggest that for some individuals, as they improved, they felt less need for the CDs.

Overall, qualitative and qualitative evidence suggested that this intervention was very acceptable to employees however future research should explore client and external factors that might affect engagement with the intervention and retention in the study.

Clinical Status outcomes

Core/HAD and Maslach scores

Participants presented with a wide range of symptom severity at recruitment, as measured by the validated questionnaires. Of particular interest were the low (i.e. non clinical) baseline HAD and Core scores of one individual on sickness absence due to ‘work related stress’. This seems consistent with a complex relationship between psychological well-being and sickness absence and the position of ‘stress’ as a mediating construct (6).

Statistically significant changes in scores, and subsequent moves from clinical populations of ‘higher’ severity to ‘lower severity’ were observed with all of the validated questionnaires over the 6 month period. We cannot exclude, however, that this was not simply an effect of ‘regression to the mean: ‘natural remission,’ (71) or even a non-specific or placebo effect for example, an expectation of relief or suggestibility.

The Maslach scores Ex and Cy showed no change between time 0 and time 4 or time 4 and time 26 but a significant change overall from time 0-26. This may be due to the fact that changes between the 0-4 time point and 4-26 time points were intermediate and there was not enough power to pick up these smaller differences. This latter argument fits well with literature that reports the Maslach Burnout Inventory as a stable score over time (72). The completion of the Maslach Burnout Inventory was complicated by sickness absence.

We cannot exclude a ‘multiple testing’ effect accounting for some results (when testing for statistical significance there is still a 1 in 20 chance of a significant result occurring by chance alone, and the higher the number of tests performed the more likely this outcome is) however the congruency of results makes this seem an unlikely explanation for results.

No relationships were found between participant characteristics and clinical improvement i.e. route of referral, sex, age or chronicity of symptoms. Small samples sizes may have accounted for these non significant results.

Core benchmarking data

We have seen that when benchmarked the Core outcomes (60 % of participants with a reliable +/- clinical change and 40 % a 'reliable + clinical' change) fell below the improvement rates seen for lowest 25% workplace counselling service performers (73) (Appendix 21). There was a degree of congruence between the populations in terms of prevalence of anxiety and depressive symptoms (the most commonly reported problems consistent with population studies) and work related problems. The study population did have a higher percentage of females, fewer younger individuals and also a higher percentage of individuals with physical conditions. Physical problems have been associated with decreased mental health (1) .

Also 50 % of the study's outcome data is based on 6 month follow up- data. We do not know the average timescale for the Core database follow-up measure. If we consider a typical course of counselling or CBT to be 8-12 weeks then post treatment scores may have been taken at much earlier time points. We also do not have data on severity of symptoms and the varying lengths that individuals may have experienced problems in the Core database although this information can be obtained. This was therefore a 'top line' benchmark and the differences between the populations may make the validity of this comparison questionable. As a low labour intensive 'guided self help' intervention the improvement rate achieved by 'Positive Mental Training' may be considered acceptable and ultimately cost effective.

Perceived Benefits

Qualitative data reflected that interviewees felt 'Positive Mental Training' had had a range of positive effects. The reported increased 'ability to step back' from situations was similar to changes reported in a qualitative study of MBCT (74). For the researcher the most vivid and specific effect that one individual attributes to 'Positive Mental Training' was 520's description of listening to the CDs in a taxi before a colonoscopy (Appendix 22). Interestingly in (74) an individual using MBCT also reported their positive experience of using 'the body scan', a 'mindfulness' technique, during an endoscopy procedure.

A few interviewees described increased motivation to restart old activities, and /or explore new avenues of support. This effect has been noticed previously of self help interventions; Christensen (75) observed that help seeking behaviour for standard CBT seemed to increase

following the use of CCBT (76). Participants using MBSR in Cohen Katz's study (29) reported doing more exercise and taking more time for themselves.

Perception of Impact of Symptoms on Work- Presenteeism

By assessing the impact of interventions on work functioning alongside the knowledge of effect on sickness absence a more comprehensive view of effects of interventions on work disability can be established (23).

Presenteeism is difficult to measure and would ideally be based on an objective assessment of work performance however there are obvious practical issues in this regard. The study population reported a significant perceived reduction of the impact of symptoms on work performance, $z -2.805$, $p = 0.005$. Recommendations for future research include the use of a validated self report instrument specifically developed i.e. 'Work Limitations Questionnaire' (77).

Negative Effects

- **Deterioration rate;**

One study participant showed a reliable deterioration using the Core criteria, remaining within the 'clinical' group pre and post treatment. He had ongoing concerns relating to the health of a family member.

It had been suggested that high deterioration rates may be seen with self directed treatments (78) in (79), although the subsequent review (now old) on self administered bibliotherapy in depression by (79) found lower rates of 9% more in keeping with this study's results.

- **Initial heightened emotion;** 2 individuals interviewed reported increased tearfulness in the initial stages of the programme; one described this as the realisation that she had found something that might help her (see qualitative interview results section). These heightened emotions did not persist. In (29) participants using MBSR reported difficulties with apparent unresolved emotional issues resurfacing. This effect was not reported by participants in this study.

The primary care study using 'Positive Mental Training' (59) reported no adverse effects.

Perceived Difficulties

Participants reported difficulties finding time to listen to the CDs and /or lack of motivation to do so.

Qualitative data reflected that although participants often reported irritation with the music and voice there was no evidence to conclude that this had an influence on their actual use of the CDs.

It was common for participants to engage with certain tracks more than others.

Visualisation was a technique interviewees frequently found difficult but equally for others one that was very effective, an outcome also reflected in the satisfaction questionnaire results.

Sickness absence

76% of participants consenting to access to their sickness absence data had sustained some absence in the six month prior to study recruitment. Although study participants had a higher rate of sickness absence than the wider organisation employee population, this was influenced by a few individuals with longer term absences.

Only 29% of participants had actually sustained any recorded absence on account of ‘mental health’). Days off sick were more likely to be attributed to ‘other causes’ than mental health, consistent with the organisation’s overall sickness absence pattern. It is postulated that a proportion of these ‘other’ days off were attributable to mental health symptoms. Future studies should evaluate total sickness absence in addition to mental health absences.

Assuming that consent to obtain sickness absence data is obtained at the outset of a future study, unless participants subsequently withdraw consent, dropout rates should not need to be accounted for when calculating the population required to evaluate sickness absence effects.

Study Design Reflections and Suggestions for Improvement

The Partially Randomised Self Preference Trial (SPRT)

Randomised controlled trials are widely accepted as the most reliable method of determining the effectiveness of an intervention but are expensive and notoriously challenging to complete to a robust level when investigating mental health interventions (80). The MRC also acknowledges that there are circumstances where they are simply not possible (62) .

The design chosen reflected the absence of published data on the acceptability and viability of using the intervention ‘Positive Mental Training’ in the workplace. The study design chosen was also in the context of an exploratory study with view to providing evidence to justify, develop and optimise future research design (62).

The self preference design meant an adequately sized control group was NOT successfully recruited to allow comparison of clinical outcomes or retention rates. The ethical committee was approached to request to change the study to a ‘randomisation only’ process after recruitment of 20 individuals. Due to practicalities, necessary changes to study documentation, organisational concerns and clear limitation of recruitment numbers, the study continued as a self preference design. The self preference route satisfied the main aims to test the acceptability of the intervention, allow some calculation of potential clinical benefit and to calculate future study sizes.

These are arguments for the use of the self preference randomised trial particularly in the setting of psychological (and / or participative) evaluation (82). The strong preference for the intervention when compared to ‘Care as usual’ was not unexpected and a common problem in randomised controlled trials is that patients (or clinicians) have strong treatment preferences and therefore refuse randomisation (80). Although the use of non-randomised groups is considered unreliable because of the presence of unknown or uncontrolled confounders (81) the absence of the above patients means that results from trials may not be generalisable. Patient motivation is also a factor that may influence the outcome of a treatment (82) and this may be particularly relevant when we are considering self-help interventions. If patients find themselves allocated to a treatment they do not wish or control, they may feel demotivated or even resentful. Interpretation of such trials may thus be difficult; was the treatment

unsuccessful because it does not work or was it unsuccessful because the person did not engage with a resulting underestimation of effectiveness (83)?

Analysis of a SPRT is complex and some account needs to be taken of the two kinds of evidence, some randomised and some observational, with potential confounders also adjusted for. In this study the control group did have lower baseline clinical scores (mean Core and HAD score). Due to the small sample size statistical significance was not calculated and while this may have simply been a chance finding, it may also have influenced their choice on study participation.

Future study designs should consider a pilot of the acceptability of randomisation, or compare ‘Positive Mental Training’ to an alternative self help intervention or even placebo (84).

Pure self help and guided self help

Self help may be ‘pure’ or ‘guided’. Research has consistently suggested that guided self help is more effective than pure self help and that the level of therapist contact may be relevant (41), (70), (68). Despite this there remain no strict agreed principles about the levels of supervision and research tends to refer to the aforementioned categories only. NICE refers to guided self help as a ‘self administered intervention’ where ‘a healthcare or para professional would facilitate the use of the material by introducing, monitoring and reviewing the outcome of such treatment- this intervention would have no other therapeutic goal and would be limited in nature’ (22).

Although this study offered ‘Positive Mental Training’ as a ‘guided’ self help intervention it can equally be used as a pure self help intervention. Qualitative interview data explicated that participants considered the follow-up appointments important and they encouraged motivation, and avoided disillusionment. (35) reported concerns that ‘‘patients’ may be particularly susceptible to not completing a self help programme and a feeling of failure and disappointment may result in helplessness and amplify mental health symptoms’.

Future studies may wish to consider if an additional follow up appointment at time 12 would fuel ongoing motivation, and increase study completion rates.

Questionnaire timing

Research suggests that the setting in which individuals complete questionnaires or surveys may influence their responses (85). Participants completing questionnaires in the presence of a researcher may feel inclined to report less severe symptoms and this needs to be considered when interpreting results.

In this study individuals completed questionnaires either in the presence of the researcher or at home over the different time points. Consideration was given to sending all questionnaires by post for completion. The final process chosen aimed to maximise response rates. If the aforementioned phenomenon was present it is likely that this would have reduced any apparent impact of the intervention over time. Data does not reflect this effect; there is no deterioration of clinical scores over time.

Confounders (SRRS)

Adverse life events have been associated with increased risk of mental health problems (1). The SRRS is a rating scale with which individuals are commonly familiar (Appendix 13). However participants described difficulty interpreting the statements. It should be also be pointed out that the validations of this scale are when it has been used to assess stressful events over a 12 month period: in the study it was used to reflect a 6 month period only due to time constraints of the study.

The absence of correlation between the SRRS score and Core score at recruitment, and the non significant change between the SRRS at time 0 and time 26, suggest that the improvement in clinical status observed were not due to the confounding effect of perceived stressors or life events but this is clearly not conclusive.

Consideration should be given to identifying an alternative scale for future studies i.e. Life Event Inventory (86).

Confounders (Additional treatment)

It is important to consider the impact that additional treatment may contribute to observed changes seen in an intervention study. Data obtained at week 26 do not suggest that this would have had a significant effect in this study. An adequately powered randomised trial could compensate for, or address this.

Fidelity

As a pre-recorded DVD and CD these components of the intervention are standardised. Initially discussions took place to evaluate the standardisation of the initial recruitment interview by videotaping or direct observation. Ethical approval was declined to allow one of the programme developers to assist with this process. For practical reasons, the practitioners simply attended standard training and had a list of key points to discuss at the initial interview. It is recognised that a therapeutic relationship between practitioner and participant may have developed and influenced outcomes. Future studies should consider the impact that differing OH personnel, including grades, may have on recruitment, retention and clinical outcomes.

Dose response

There has been some work suggesting a dose response relationship between the frequency of use of self help packages and eventual outcomes (87).

Most interviewees were flexible with their use of CDs and frequently varied the listening order. Although encouraging such 'flexibility' might increase engagement with the programme and retention in a study, it would exacerbate the difficulty in evaluating the impact of any 'dose response'.

Future studies must weigh-up the benefits of encouraging familiarity with techniques by repetitive listening, but also the impact on engagement of encouraging flexibility. A pragmatic balance will allow further evaluation of 'effectiveness' in a naturalistic way.

The relaxation CD was popular; further research may want to explore the effect of this CD alone.

Motivating factors

Belief in the effectiveness of interventions was frequently not the key factor that motivated ACTUAL help seeking behaviour. This is in keeping with other research exploring a related theme (88).

Conclusions

Although practical difficulties were experienced when undertaking this study, it achieved its aims. The mixed exploratory approach allowed for greater insight and for triangulation of data. The results of quantitative and qualitative data suggest that as a guided self help intervention, 'Positive Mental Training' offered in a workplace setting was acceptable and safe for employees suffering from 'common mental health problems' who completed follow up data but dropout rates were disappointingly high. Quantitative data was limited due to sample size, lack of recruitment of a control group, and limited access to participant's sickness absence data. Conclusions cannot therefore be made about the effectiveness of the intervention. Analysis, including benchmarking, justifies further research and estimations for an adequately powered study sample size were made.

Most participants felt 'Positive Mental Training' had had some positive effect on their general well being, home life or work. Individuals frequently planned to continue using the programme, alongside other interventions or activities. Benefits of 'Positive Mental Training' may continue to develop overtime.

Recommendations for future research

- Ensure inclusion of a relevant comparison group i.e. randomisation to either 'Positive Mental Training' or control (Care as usual), another (self help) intervention and / or placebo (84). The SPRT might be considered for further studies.
- Further exploration, by qualitative and/ or quantitative means, individual characteristics that might influence engagement with the intervention thus targeting the intervention to those who might benefit most.
- Evaluate the impact of potential confounders including severity of problems and changes to treatment overtime.
- Consider evaluating the relaxation CD alone.
- Include a validated assessment of work performance.
- Replace the SRRS scale with an alternative scale to measure life events.
- Follow up sickness absence data over at last 12 months.

Finally;

- Occupational Health Professionals should reflect on the motivating factors and barriers that influence individuals' use of psychological (including self help) interventions and strategies, and the potential influence on this behaviour that they may have in their role.

Word count of main document; 13,822

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